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Treatment of Facial Deformities Using 3D Planning and Printing of Patient-Specific Implants

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RAMBAM
Health Care Campus

Dr. Dekel Shilo DMD, Ph.D
Department of Oral and Maxillofacial Surgery

October 22, 2019

Dear Dr. Aaron Berard**,**
Science Editor of the Journal of Visualized Experiments

Enclosed please find our manuscript entitled "**Treatment of facial deformities using 3D planning and printing of patient specific implants**"

This is an exciting time in the history of surgery as technology is developing faster than ever. 3D virtual planning and 3D printing is proving itself and is a new tool in our profession's toolbox. We can now virtually plan our operation, creating surgical guides to help with accuracy and create 3D printed patient specific implants which fit perfectly to the planned reconstructed/re-positioned bone based on our planning. Clinicians do not understand the full potential of the field and use external companies, thus slowing the implementation of the technology to the everyday surgical procedure. Planning your own surgical procedures and patient specific implants entitles great advantages. The surgeon enters the operating room with the implant he developed following movements and reconstruction procedures he planned and thus he is aware of each step, and knows how to deal with unexpected developments during surgery.
This protocol is intendent for this exact purpose, allowing the surgeon to plan his own surgeries and create his own patient specific implants. In-house planning of the implant also reduces costs dramatically allowing for implementation of the method.
There are two major fields in Maxillofacial surgery in which this technology can be used on the daily basis; Bony reconstruction following avulsion injuries such as trauma or oncologic resections and in orthognathic surgeries to correct facial deformities.
The first indication is detailed in an article submitted with the title: "3D planning and printing of patient specific implants for reconstruction of bony defects". The second is detailed in this report. The two indication use different softwares and techniques and are thus separated.

We hope you would find it suitable for publication in the Journal of Visualized Experiments.
We have no conflict of interests to report.
Sincerely Yours,

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TITLE:
Treatment of Facial Deformities Using 3D Planning and Printing of Patient-Specific Implants

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KEYWORDS:
3D planning, 3D printing, titanium plates, patient-specific implants, cutting guides, deformities, orthognathic surgery, waferless surgery, maxillofacial

SUMMARY:
As technology develops and becomes more user-friendly, planning of operations and patient-specific surgical guides and fixation plates should be performed by the surgeon. We present a protocol for 3D planning of orthognathic skeletal movements and 3D planning and printing of patient-specific fixation plates and surgical guides.

ABSTRACT:
Technological advancements in surgical planning and patient-specific implants are constantly evolving. One can either adopt the technology to achieve better results, even in the less experienced hand, or continue without it. As technology develops and becomes more user-friendly, we believe it is time to allow the surgeon the option to plan his/her operations and create his/her own patient-specific surgical guides and fixation plates allowing him full control over the process. We present here a protocol for 3D planning of the operation followed by 3D planning and printing of surgical guides and patient-specific fixation implants. During this process we use two commercial computer-assisted design (CAD) software. We also use a fused

deposition modeling printer for the surgical guides and a selective laser sintering printer for the titanium patient-specific fixation implants. The process includes computed tomography (CT) imaging acquisition, 3D segmentation of the skull and facial bones from the CT, 3D planning of the operations, 3D planning of patient-specific fixation implant according to the final position of the bones, 3D planning of surgical guides for performing an accurate osteotomy and preparing the bone for the fixation plates, and 3D printing of the surgical guides and the patient-specific fixation plates. The advantages of the method include full control over the surgery, planned osteotomies and fixation plates, significant reduction in price, reduction in operation duration, superior performance and highly accurate results. Limitations include the need to master the CAD programs.

INTRODUCTION:

3D printing is an additive method based on gradual placement of layers from different materials, thus creating 3D objects. It was originally developed for rapid prototyping and was introduced in 1984 by Charles Hull, who is considered the inventor of the stereolithography method based on solidifying layers of photopolymer resin[1]. Technological advancements in virtual planning of surgeries and planning and printing of patient-specific implants are constantly evolving. Innovations arise both in the field of computer assisted design (CAD) software and in 3D printing technologies[2]. Simultaneous to developments in technology, the software and printers become more user-friendly. This shortens the time required for planning and printing and allows the surgeon the option to plan his/her operations and create his/her own patient-specific surgical guides and fixation plates in a field that was exclusively an engineer's "playground". These developments also allow for surgeons and engineers to introduce new applications and designs of patient-specific implants[3-5].

One of these applications is 3D planning of orthognathic surgeries followed by 3D planning and printing of surgical guides and patient-specific fixation plates. Historically, orthognathic surgeries were planned using articulators. A facebow was used to register the relationship of the upper jaw to the temporomandibular joint thus positioning the patient's casts in the articulator. Later, the surgical movements were performed on the casts and an acrylic wafer was prepared to help with proper positioning of the jaws during surgery. This method was used for many years and is still used nowadays by most, but the utilization of cone beam computed tomography (CT) together with intra-oral scanners and CAD software allowed for accurate planning, sparing the need for facebows or casts and moving towards creation of digitally planned wafers[6]. This method reduced the inaccuracy of manual manipulation and measurements but still had flaws including using the instable lower jaw as a reference point for positioning the upper jaw and lack of control over the vertical positioning of the upper jaw[7]. Thus, a new method was introduced. This method is called the "waferless" surgery and is based on repositioning of the jaws anatomically using surgical cutting guides and patient-specific fixation titanium plates[8]. This method resolves the disadvantages of the digital wafer method described before. We will describe this method, which allows the surgeon complete freedom in planning these surgeries in a patient-specific manner, with minimal possible errors and inaccuracies. This method allows for a "waferless" surgery, which means there is no need for using the opposed jaw as reference for repositioning the bones, thus decreasing the inaccuracies derived from this reliance[9].

PROTOCOL:

1. Repositioning of the jaws

NOTE: This section is performed using the imaging software (i.e., Dolphin).

1.1. Load the facial bones CT image DICOM files of the patient (**Figure 1A**) into the software by selecting the **3D** button on the left and clicking **Import New DICOM** (**Supplemental Figure 1**). Enter the 3D editing mode by clicking **3D** | **Edit**.

1.2. Orient the 3D image using the orientation button on the left. Create a panoramic image using the build X-rays button on the left (**Supplemental Figure 2**).

1.3. Go to **Tools** | **Orthognathic Surgical Planning** | **Start New Workup**.

1.4. Position the segments in the panoramic image. Crop each segment to contain the area of the corresponding bone.

NOTE: The cleaning stage is useful when, for accuracy, a scanned dental arch and a CT scan are superimposed to create a wafer. This is not indicated in a "waferless" surgery as presented here and thus at this stage one can clean CT imperfections if they exist.

1.5. Choose the appropriate osteotomy for the patient on the left pan under osteotomies (such as LeFort I, sagittal split, etc.). Mark the exact location of the osteotomy lines by moving the yellow circles (**Supplemental Figure 3**).

NOTE: It is extremely important to note the root apexes of the teeth as the location of the osteotomy decided here will be the one performed later based on the surgical guides. Always avoid the roots and maintain a 5 mm distance.

1.6. Mark different landmarks by left clicking on the right location for each suggested landmark.

NOTE: This is important for measurements and movement purposes in the next stages.

1.7. Perform movements of bone segments. Drag the bone to the right location, or for accuracy, right click and choose **Input Movements Using Keyboard**.

1.8. In order to track the movement of key landmarks, press **Treat Options Button** on the left and choose **Show Landmark Offset and Measurement Tables**.

NOTE: In the next tab the pre and post virtually planned operation can be observed (**Supplemental Figure 4**).

1.9. Export the stl files of the two different positions of bone segments, one in the pre-operative stage and one in the post-operative stage, using the slide bar on the left and the **Export Segments in stl** button on the left.

2. Preparation of patient-specific fixation plates and surgical guides

NOTE: This section is performed using the 3D design software (i.e., Geomagic Freeform).

2.1. Click **File | Import Model** (**Supplemental Figure 5A**) to import the stl files obtained from step 1.9 showing the position of the upper jaw and midface following the osteotomy but prior to the repositioning in the final position.

2.2. Start with planning the patient-specific fixation plates in the final position of the upper jaw. In the tool palette on the left under the **Planes** category, select **Create Plane** (**Supplemental Figure 6A**). Here the initial design of the plates will be performed. Manually move the plane parallel to the bone where the plate will be placed.

2.3. Under the **Sketch** category (**Supplemental Figure 6B**), choose a circle shape and create circles with a size appropriate for the screws to be used later. Create a second circle around the previous one 3 mm larger in diameter to outline the fixation plate.

NOTE: The size of the circles is determined based on the fixation sets used in each institute. The circles are placed above and below the planned surgical osteotomy (decided already in section 1).

2.4. Project the design from the plane to the bone. Under the **Curves** category (**Supplemental Figure 7**), use the project sketch tool and choose the circles that will be transferred from the plane to the bone.

2.5. To connect the outer circles for the outer border plate design, choose under the **Curves** category the split tool and define the part of the circle that will be removed to allow for a connection to the adjacent circles. Using the select option, choose the defined part of the circle and delete it. Under the **Curves** category, use the draw curve tool and connect the outer circles to create a continuous outer shape of the patient-specific plate.

2.6. Before creating the fixation plate, duplicate the upper jaw by right clicking and selecting **Duplicate** from the object list (**Supplemental Figure 7A**). This will allow the use of the Boolean tool in the next stages to create the fixation plate.

2.7. Under the **Detail Clay** category, use the emboss with curve tool. This creates the volume of the fixation plate based on the curves previously projected. Choose the outer shape curve and then place the circle-shaped cursor inside and on the surface of the shaped plate (note that the cursor should be placed on the side to be embossed). At the bottom, choose the parameters of the function, mainly the **Distance** option that controls the thickness of the future fixation plate.

2.8. Separate the plate from the upper jaw. At this stage the Boolean option is performed. Choose the original upper jaw, right click from the object list and click **Boolean** | **Remove from** | **Upper Jaw with Plate**.

2.9. To create the holes for the screws, either draw the screws/scan them and then use the Boolean option or use the SubD tool. Under the **SubD Surfaces** category (**Supplemental Figure 8**), use the wire cut SubD tool to create rods perpendicular to the plate in the size of desired holes, which is performed based on the circles created in step 2.3 originating from the perpendicular plane.

2.10. Next, subtract the rods from the plate using the **Boolean** | **Remove from** technique.

NOTE: At this stage the final fixation plate is ready (**Supplemental Figure 9**). Appropriate surgical guides need to be planned for the osteotomy in order for the plates to fit perfectly.

2.11. To create the guides, reposition the upper jaw to its original location but with the screw holes marked in the bone according to the fixation plate created in the final position of the jaw (note the holes in the midface do not change position as the midface stays in the same position).

2.11.1. To perform this, reposition the jaw with the curves for the holes used for the final fixation plate to the original location of the jaw prior to the movement. Under the **Select/Move Clay** category, use the **Register Pieces** option. choose the **Source** (upper jaw post movement) and the **Target** (upper jaw and midface prior to the movement). Use a large number of fixed points on both objects for accuracy in the repositioning.

2.12. Based on newly positioned holes create the surgical guides in a similar way as described for the fixation plates (steps 2.3−2.10).

REPRESENTATIVE RESULTS:

To observe the clinical use of the method, we present a case of a 23 year old female. She suffered from condylar hyperplasia at a younger age in the right condyle resulting in asymmetry of both jaws. **Figure 1A** shows the retrognathic upper jaw and prognathic lower jaw exhibiting the discrepancies between the jaws. In the frontal view, the severe asymmetry can be observed as detailed using the yellow and red lines. Using the imaging software (**Supplemental Figure 1**), a surgical treatment plan was performed (**Supplemental Figure 2**, **Supplemental Figure 3**, and **Supplemental Figure 4**). The surgical plan was based on lateral cephalometric analysis. The location of the planned bony osteotomy is important in order to preserve the healthy dentition and also to allow for proper placement of the fixation screws in intact bone. The 3D stl files were exported from the imaging software and imported to the 3D design software in both pre- and post-planned bony movement setups (**Supplemental Figure 5**). The patient-specific fixation plate was planned (**Supplemental Figure 6**, **Supplemental Figure 7**, **Supplemental Figure 8**, and **Supplemental Figure 9**) followed by the surgical guide planning (**Supplemental Figure 10** and **Supplemental Figure 11**). The fixation plate was planned on the post-operative planned location and the surgical guide on the current status of the patient, based on the planned osteotomy. In the presented patient, a bimaxillary operation was performed. The upper jaw was repositioned in the first stage following by repositioning of the lower jaw according to the final dental occlusion. A vestibular incision above the mucogingival line in the upper jaw was performed to expose the bone. The nasal floor was elevated, the surgical guides were anatomically positioned followed by drilling holes in the bone through the holes in the guides (these holes would later match the patient-specific fixation plate following reposition of the jaw). An osteotomy at the LeFort I level based on the surgical guide was performed using a reciprocal saw. The septum, lateral walls of the nasal cavity and the pterygomaxillary junction were separated using appropriate osteotomes. The upper jaw was mobilized and repositioned symmetrically in the appropriate location based on the holes in the final patient-specific fixation plate which matched the previously drilled holes in the upper jaw and midface (using the surgical guides). The plate was fixated using titanium screws and the surgical wound was sutured. An osteotomy of the lower jaw was then performed using a sagittal split osteotomy and repositioned based on the dental occlusion. The final result is shown in **Figure 1B**; note the correction of the discrepancies of the jaws and the severe asymmetry.

FIGURE LEGENDS:

Figure 1: Pre- and Post-operative imaging of a 23-year-old patient with asymmetry in the facial bones. (**A**) Pre-operation imaging. Left: a cephalometric image; Right: a frontal 3D reconstruction view of CT showing the severe asymmetry. (**B**) Post-operative imaging. Left: a lateral cephalometric image; Right: a posterior-anterior cephalometric image showing the perfect correction of the asymmetry.

Supplemental Figure 1: A view of the workspace and the 3D button for importing and editing in the 3D mode.

Supplemental Figure 2: Building an X-ray image. When planning a surgical plan, building a panoramic X-ray image from the CT image is mandatory.

Supplemental Figure 3: Osteotomy in the imaging software. A Le-Fort I osteotomy is observed separating the upper jaw from the midface. The location of the osteotomy is crucial as it will be used in the next stages for surgical guides construction and fixation plate positioning. Avoid the dental roots.

Supplemental Figure 4: Surgical treatment plan in the imaging software. The pre and post operation 3D planning can be observed. Pre-operative is shown on the left and post-operative is shown on the right.

Supplemental Figure 5: Importing into the 3D design software. The 3D stl files were exported from the imaging software and imported to the 3D design software. (**A**) Pre-operative midface, upper jaw and lower jaw. (**B**) Post-operative upper jaw and lower jaw (notice that the midface does not change its location).

Supplemental Figure 6: Planning the fixation plate. (**A**) A parallel plane is created. (**B**) The holes for the screws and the outer shape of the plate are planned on the plane.

Supplemental Figure 7: Fixation plate construction. (**A**) Following projection from the plane and finalizing the outer form of the plate. (**B**) Creating the thickness of the plate.

Supplemental Figure 8: Fixation plate hole preparation. (**A**) Using the Boolean function for separating the fixation plate. (**B**) Marking the holes in the plate using the SubD option.

Supplemental Figure 9: Finalized patient-specific fixation plate. (**A**) The finalized plate. (**B**) The plate on the bone following the planned bony movement. Notice the perfect fit.

Supplemental Figure 10: Surgical guide planning. The planning is performed using the holes planned on the upper jaw in the final position (to receive a perfect fit with the holes in the fixation plate) but after moving the jaw to the pre-operative position, as the guides are the first to be used during the operation for bone osteotomy preparation.

Supplemental Figure 11: Finalized surgical guides. (**A**) The finalized surgical guides on the pre-operative bony facial bones. (**B**) Both the surgical guides and the final fixation plates.

DISCUSSION:

3D planning and printing is one of the most rapidly evolving methods in the surgical field. It is not only a promising tool for the future, but a practical tool used nowadays for highly accurate surgical results and patient-specific solutions. It allows for highly accurate results and reduces the dependency on the surgeon's experience[10]. It solves many of the disadvantages of previous old fashion surgical methods, but the costs delay the full implementation of the method[10]. In-house planning and printing of the surgical guides reduce the costs to a neglectable expanse and reduces dramatically the cost of the patient-specific fixation plate. In this report we describe a method for 3D planning of orthognathic surgery followed by 3D planning and printing of surgical guides and patient-specific fixation plates as a basis for the surgeon to perform the whole process in-house. This protocol can be used for any orthognathic surgery, implementing all the above advantages.

This protocol is based on two CAD software. The first is the imaging software, which allows for segmentation and surgical planning including osteotomy location and bony movements. The second is the 3D design software, which allows for the planning of the surgical guides and the patient-specific fixation implants.

When using the imaging software, it is crucial to acquire a proper CT image, to properly plan the osteotomy location, avoiding damage to dental roots and to always keep in mind where the future fixation plates will be placed thus leaving enough room for the planned plates and screws. Keep in mind the holes prepared in the surgical guides need to match the holes of the final fixation plate. Be sure to export the proper stages of the surgical planning, the position of the upper jaw after the osteotomy but before the movement, and another stl file with the final position of the upper jaw.

When using the 3D design software, it is important to first plan the final patient-specific fixation plates. Following the hole preparation for the screws, the upper jaw with the holes needs to be repositioned according to the location before the surgical movement for preparation of the surgical cutting guide with the holes in the right position. Thus, the order of the steps is crucial for accurate positioning and proper surgical guide preparation. Always remember that if there is a doubt regarding discrepancies in bone continuity due to artifacts or improper bone segmentation it is preferred to add bone in the missing part because a slight space between the fixation plate and the bone in a specific area is preferred over bony interfere with the placement of the plate. It is important to remember that at times orthodontic preparation can result in bony deficiencies and exposed dental roots, so one should not assume this is due to artifacts.

This method describes basic principals in surgical planning of orthognathic cases including the planning of surgical guides and patient-specific fixation plates. It solves the inaccuracies existing in previous non-computed and semi-computed methods such as digital wafers and allows full control over the vertical dimension that did not receive a definite solution in those methods. Other advantages of the method include complete control over the surgery by performing a virtual plan of the operation, including the planned osteotomies and fixation plates, significant reduction in price (compared to outsourcing the planning), and reduction in operation duration. Limitations include the need to master the CAD programs and the price of the 3D printed titanium plates which is significantly higher than using wafers and stock titanium plates. The methods described here, especially the planning of surgical guides and plates can be further modified for many surgical purposes. We describe the use of this method for the surgical planning of bony resection and reconstruction in facial bones. This method can be used to innovate in the field of surgical planning and reconstruction[3,5] and can also be applied in research, for example in planning of sophisticated scaffold designs for bone regeneration.

ACKNOWLEDGMENTS:
No funding was received for this work.

DISCLOSURES:
The authors have nothing to disclose.

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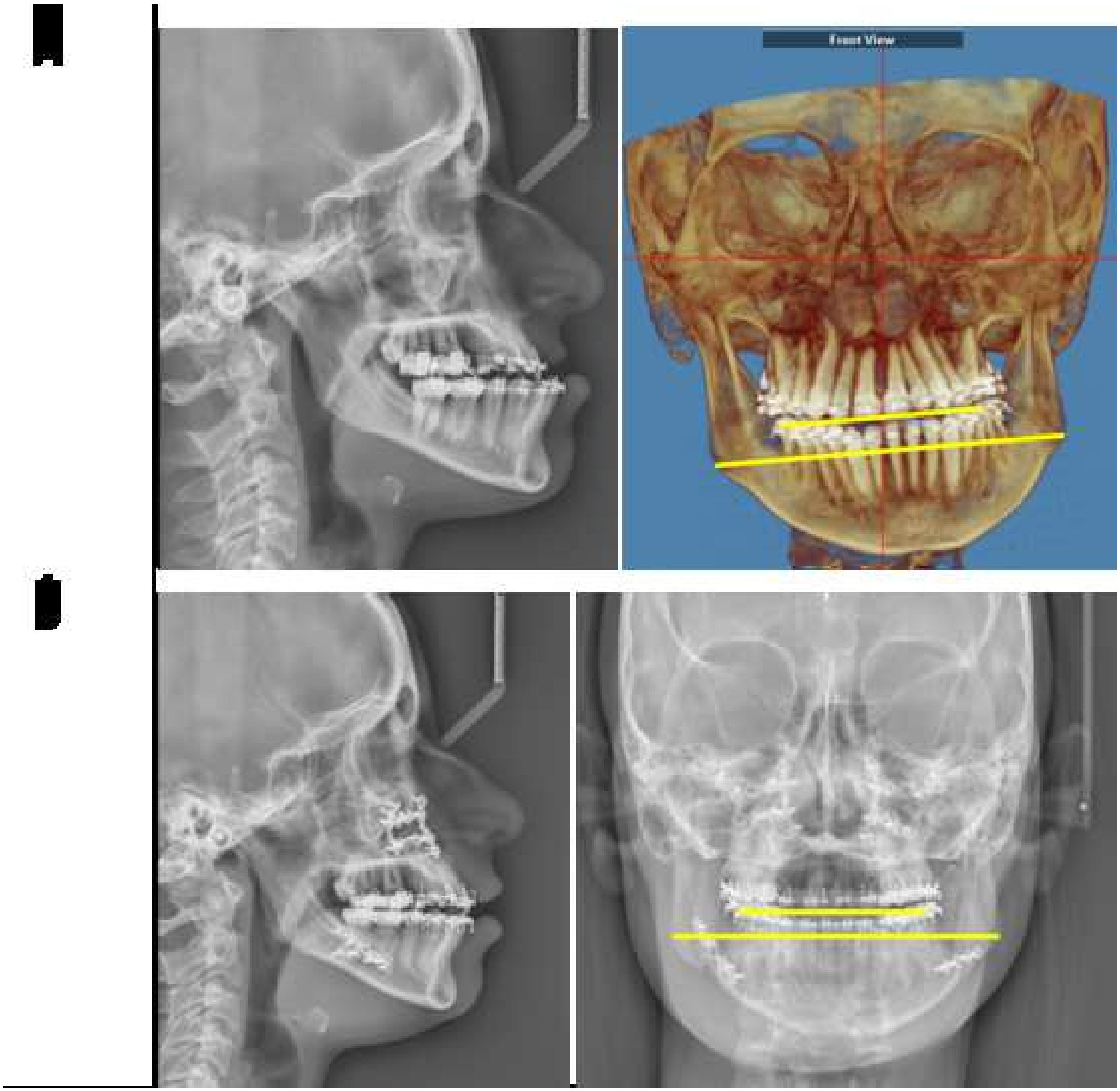
Figure 1

Click here to access/download;Figure;13.psd



Name of Material/Equipment	Company	Catalog Number	Comments/Description
Dolphin imaging software	Dolphin Imaging Systems LLC (Patterson Dental Supply, Inc)		3D analysis and virtual planning of ort
Geomagic Freeform	3D systems		Sculpted Engineering Design

hognathic surgeries

RAMBAM
Health Care Campus

Dr. Dekel Shilo DMD, Ph.D
Department of Oral and Maxillofacial Surgery

December 31, 2019

Dear Dr. Xiaoyan Cao,
Editor in the Journal of Visualized Experiments

Enclosed please find our revision letter for the manuscript entitled "**Treatment of facial deformities using 3D planning and printing of patient specific implants**".

First, we would like to thank the reviewers for their valuable comments, we feel taking them into account greatly improves our article.
Below are the comments and our response.

Editorial Comments:

1. *Please take this opportunity to thoroughly proofread the manuscript to ensure that there are no spelling or grammar issues. The JoVE editor will not copy-edit your manuscript and any errors in the submitted revision may be present in the published version.*

Revised

2. *Please adjust the numbering of the Protocol to follow the JoVE Instructions for Authors. Step 1 followed by 1.1, followed by 1.1.1, etc. Each step should include 1−2 actions and contain 2−3 sentences. Use subheadings and substeps for clarity if there are discrete stages in the protocol. Please refrain from using bullets, dashes, or indentations.*

Adjusted

3. Protocol: Please use the active/imperative voice and complete sentences throughout the protocol. Any text that cannot be written in the imperative tense may be added as a "NOTE."

Changed

4. Please revise the Protocol text to avoid the use of personal pronouns (e.g., I, you, your, we, our) or colloquial phrases.

Revised

5. For actions involving software usage, please provide all specific details (e.g., button clicks, software commands, any user inputs, etc.) needed to execute the actions. Please be as specific as you can with respect to your experiment providing all necessary details.

Rechecked

6. Line 98: CT image of what? Please specify.

Changed to: "facial bones CT image DICOM files of the patient"

7. Line 109: Please specify the location of the osteotomy decided here.

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Department of Oral and Maxillofacial Surgery

Changed to: “Choose the appropriate osteotomy for the patient on the left pan under osteotomies (such as Le Fort I, Sagittal Split, etc.). Mark the exact location of the osteotomy lines by moving the yellow circles.”

8. Line 113: How to mark different landmarks?

Changed to: “Mark the different landmarks by using the left mouse-click button in the right location for each suggested landmark. Note: this is important for measurements and movement purposes in the next stages.”

9. Line 133: Please specify the size of the circles.

The size is decided by the surgeon according to the fixation system he will use in the operating room.

Changed to “Under “Sketch” category choose a circle shape and create circles in a size appropriate for the future screws intended to be used (the size of the circles is determined based on the fixation sets used in each institute).”

10. *Please combine some of the shorter Protocol steps so that individual steps contain 2-3 actions and maximum of 4 sentences per step.*

Shorter steps in the first part of the protocol were combined.

11. Please include single line spacing between each numbered step or note in the protocol.

Performed

12. *After you have made all the recommended changes to your protocol section (listed above), please highlight in yellow up to 2.75 pages (no less than 1 page) of protocol text (including headers and spacing) to be featured in the video. Bear in mind the goal of the protocol and highlight the critical steps to be filmed. Our scriptwriters will derive the video script directly from the highlighted text.*

The protocol is just over two pages, thus all of it can be used.

13. Please include an Acknowledgements section, containing any acknowledgments and all funding sources for this work.

Performed

14. Please include a Disclosures section, providing information regarding the authors’ competing financial interests or other conflicts of interest. If authors have no competing financial interests, then a statement indicating no competing financial interests must be included.

Performed

Reviewer 1:

I have no objections and recommend the manuscript be accepted as is.
Major Concerns:
None

Dr. Dekel Shilo DMD, Ph.D
Department of Oral and Maxillofacial Surgery

Minor Concerns:
None

Reviewer 2:

The article focused on the 3D print technic which is very popular now. The topic is relatively new and quite interesting, and the research method is relatively routine.

Major Concerns:
1.*One typical case was selected in the paper, and the indications of 3D printed titanium plate should be explained.*

All surgeries use titanium plates for fixation of the newly positioned jaw (moved based on acrylic wafers performed on cast models) by bending plates in the operating room. Yet with this method, personalized 3D patient specific plates are used thus allowing for superior accuracy and minimal errors serving both as a “bony wafer” and a perfect fixation plate. This method is appropriate for all cases in the orthognathic field.

The following was added to the first paragraph of the discussion: “This protocol can be used for any orthognathic surgery, implementing all the above advantages.”

2.*This paper describes how to use software technology to make 3D printed titanium plate, but there is no description of the actual intraoperative use, and whether the postoperative effect is consistent with the preoperative design expectation. It is suggested to add relevant content.*

The following was added: “In the presented patient, a bimaxillary operation was performed. The upper jaw was repositioned in the first stage following by repositioning of the lower jaw according to the final dental occlusion. A vestibular incision above the mucogingival line in the upper jaw was performed for exposure of the bone. The nasal floor was elevated, the surgical guides were anatomically positioned followed by drilling holes in the bone through the holes in the guides (these holes will later match the patient specific fixation plate following reposition of the jaw). An osteotomy at the Le Fort I level based on the surgical guide was performed using a reciprocal saw. The septum, lateral walls of the nasal cavity and the pterygomaxillary junction were separated using appropriate osteotomes. The upper jaw was mobilized and repositioned symmetrically in the appropriate location based on the holes in the final patient specific fixation plate which matched the previously drilled holes in the maxilla and midface (using the surgical guides). The plate was fixated using titanium screws and the surgical wound was sutured. An osteotomy of the lower jaw was then performed using a sagittal split osteotomy and repositioned based on the dental occlusion. “

Minor Concerns:
In this paper, the traditional orthognathic surgery design from model surgery to 3D printed digitally planned wafers was evaluated, and a new design of orthognathic surgery without digitally planned wafers was proposed. The method called the "waferless" surgery and is based on repositioning of the jaws anatomically using surgical cutting guides and patient specific fixation titanium plates

Reviewer 3:

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Major Concerns:
i) *The authors do not describe existing techniques or protocols or software that are currently used.*

The common practice nowadays is still manual preparation of acrylic wafers based on casts or digitally prepared wafers.
In cases where a waferless operation is performed (with all the detailed advantages of this technology) the whole case is prepared using external companies and engineers. We wanted to demonstrate (and prepare a protocol for surgeons to use) that current technology allows for the surgeon to plan his own surgeries resulting in better acquaintance of the patient, "virtually perform the operation" thus enter the operation well prepared observing all possible pitfalls and reducing costs of this technology.

The current technologies are detailed in the introduction:
"Historically, orthognathic surgeries were planned using articulators. A facebow was used to register the relationship of the maxilla to the temporomandibular joint thus positioning the patient's casts in the articulator. Later, the surgical movements were performed on the casts and an acrylic wafer was prepared to help with proper positioning of the jaws during surgery. This method was used for many years and is still used nowadays by most, but the utilization of cone beam computed tomography together with intra-oral scanners and computer assisted design softwares allowed for accurate planning, abandon the need for facebows and casts and creation of digitally planned wafers. This method reduced the inaccuracy of manual manipulation and measurements but still had flaws including using the instable lower jaw as a reference point for positioning the maxilla and lack of control over the vertical positioning of the maxilla. Thus, a new method was introduced. This method is called the "waferless" surgery and is based on repositioning of the jaws anatomically using surgical cutting guides and patient specific fixation titanium plates. This method resolves the disadvantages of the digital wafer method described before. We will describe this method"

If you this this should be further elaborated or better explained we will rephrase.

ii*) Though novelty is not a requirement for the journal but, how this protocol is different or similar needs to be clearly described*.

Please refer to the previous answer. To our knowledge although technology exists, this protocol is not detailed elsewhere and to date is in use almost exclusively by engineers.

"This shortens the time required for planning and printing and allows the surgeon the option to plan his operations and create his own patient specific surgical guides and fixation plates in a field that was exclusively an engineer's "playground". These developments also allow for surgeons and engineers to introduce new applications and designs of patient specific implants"

iii) *Also, the disadvantages of this protocol and suitability of the protocol should be discussed.*

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Advantages and disadvantages were modified and some new ones were added to the discussion section:

“This method describes basic principals in surgical planning of orthognathic cases including the planning of surgical guides and patient specific fixation plates. It solves the inaccuracies existing in the previous non-computed methods and the semi-computed methods such as digital wafers and allows full control over the vertical dimension which did not receive a definite solution in those methods. Other advantages of the method include complete control over the surgery by performing a virtual plan of the operation, including the planned osteotomies and fixation plates, significant reduction in price (compared to outsourcing the planning) and reduction in operation duration. Limitations include the need to master the CAD programs and the price of the 3D printed titanium plates which is significantly higher than using wafers and stock titanium plates.”

As to the suitability the following was added to the first paragraph of the discussion: “This protocol can be used for any orthognathic surgery, implementing all the above advantages.”

iv) *How the software used in the protocol differs than other software must be included.*

There are many different softwares out there, each work a bit differently, yet the principles are similar and this software (Geomagic) is used by the largest companies and is considered the best in the market for the surgical filed and thus it was chosen for this protocol.

Sincerely Yours,

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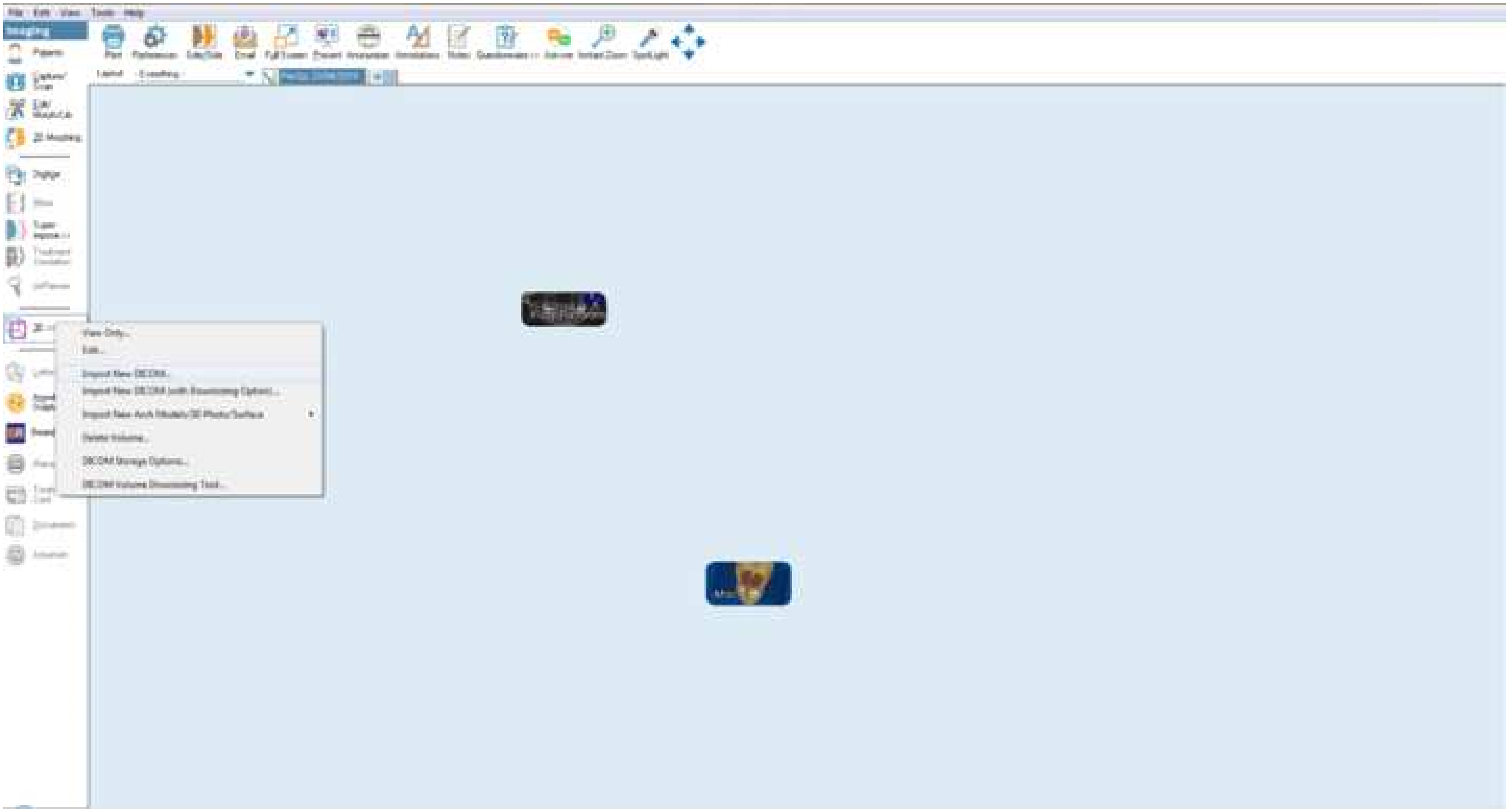
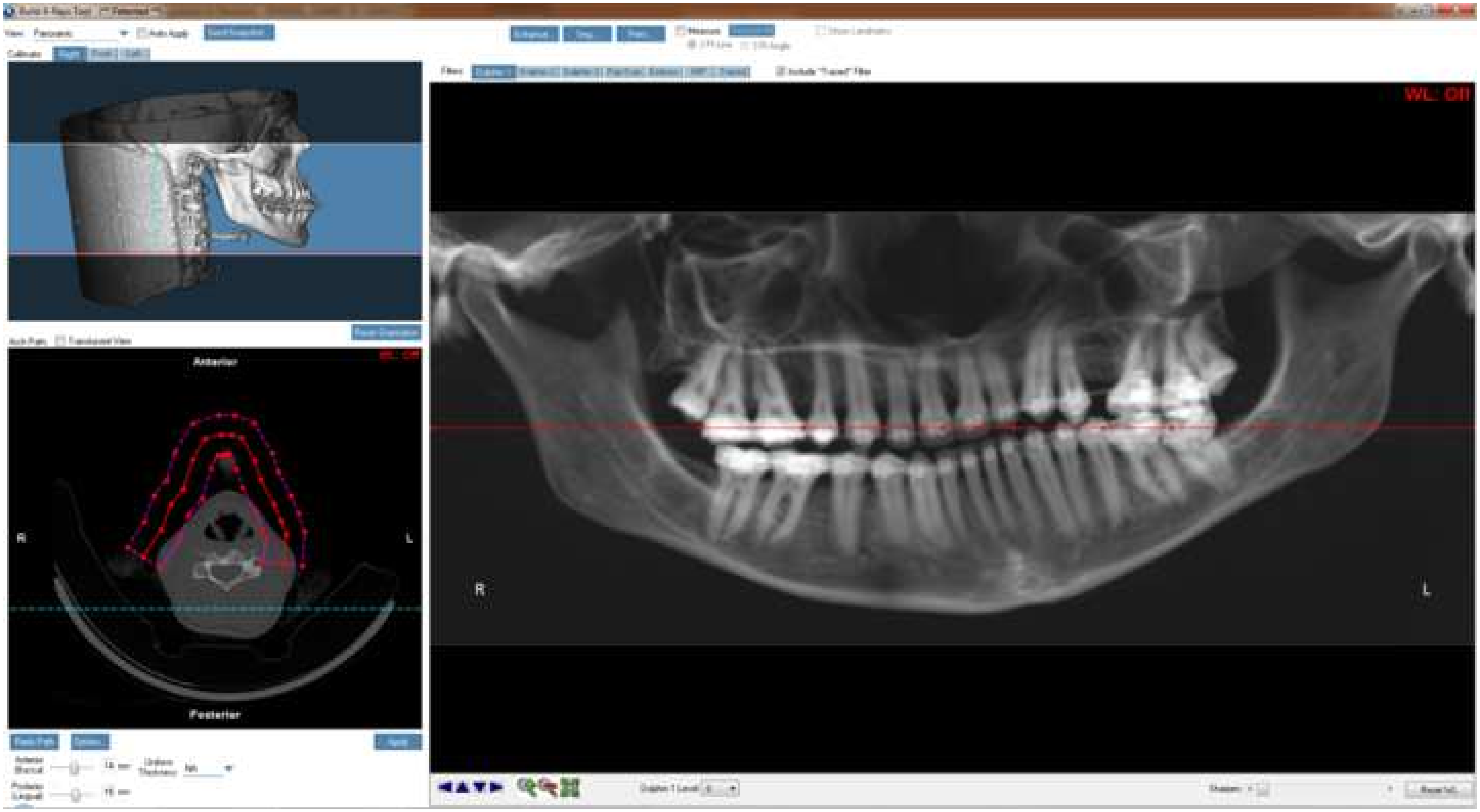
Supplemental Figure 1



Supplemental Figure 2 Click here to access/download;Supplemental File (Figures, Permissions, etc.);3.psd



Supplemental Figure 3

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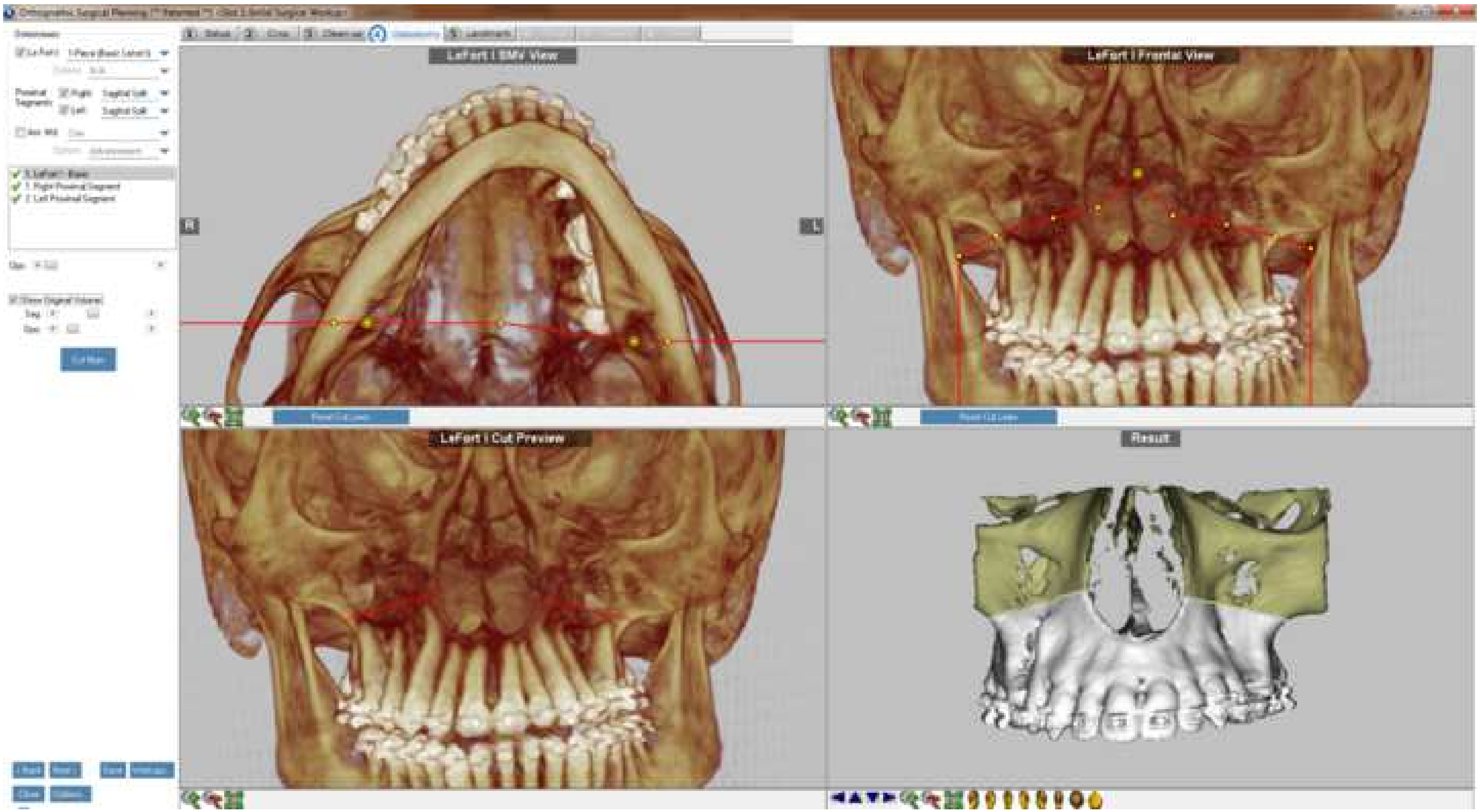
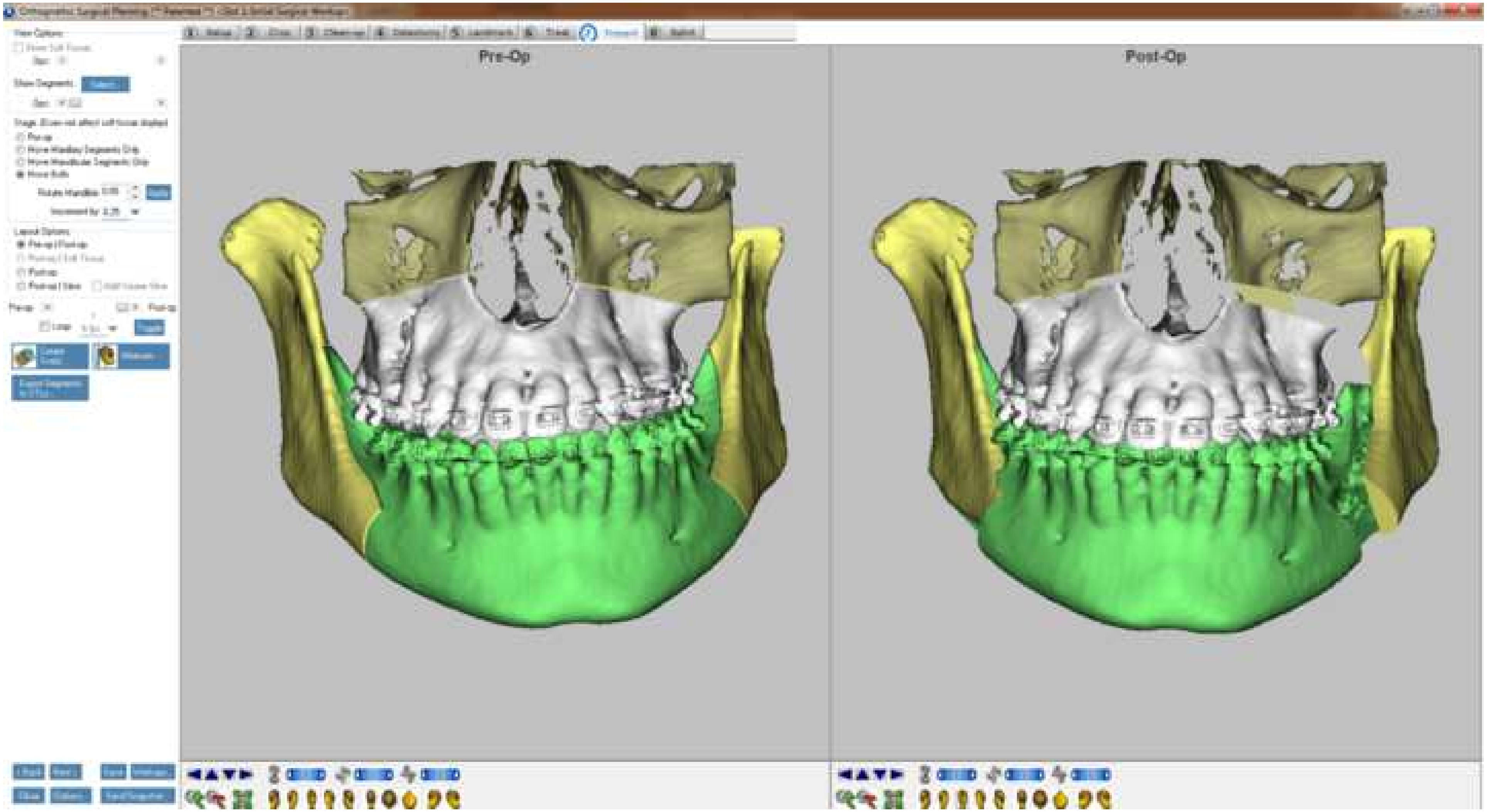


Supplemental Figure 4



Supplemental Figure 5

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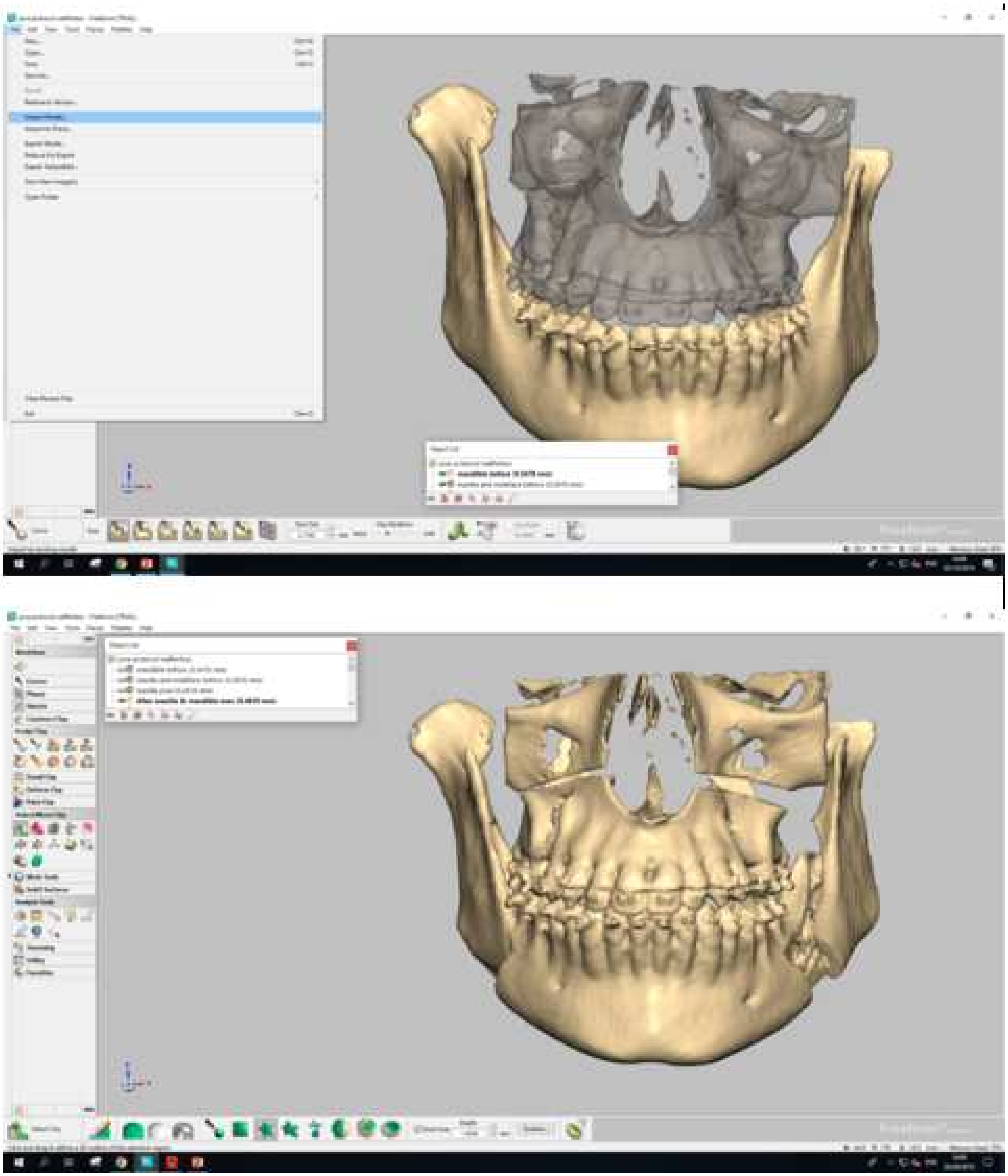

Supplemental Figure 6

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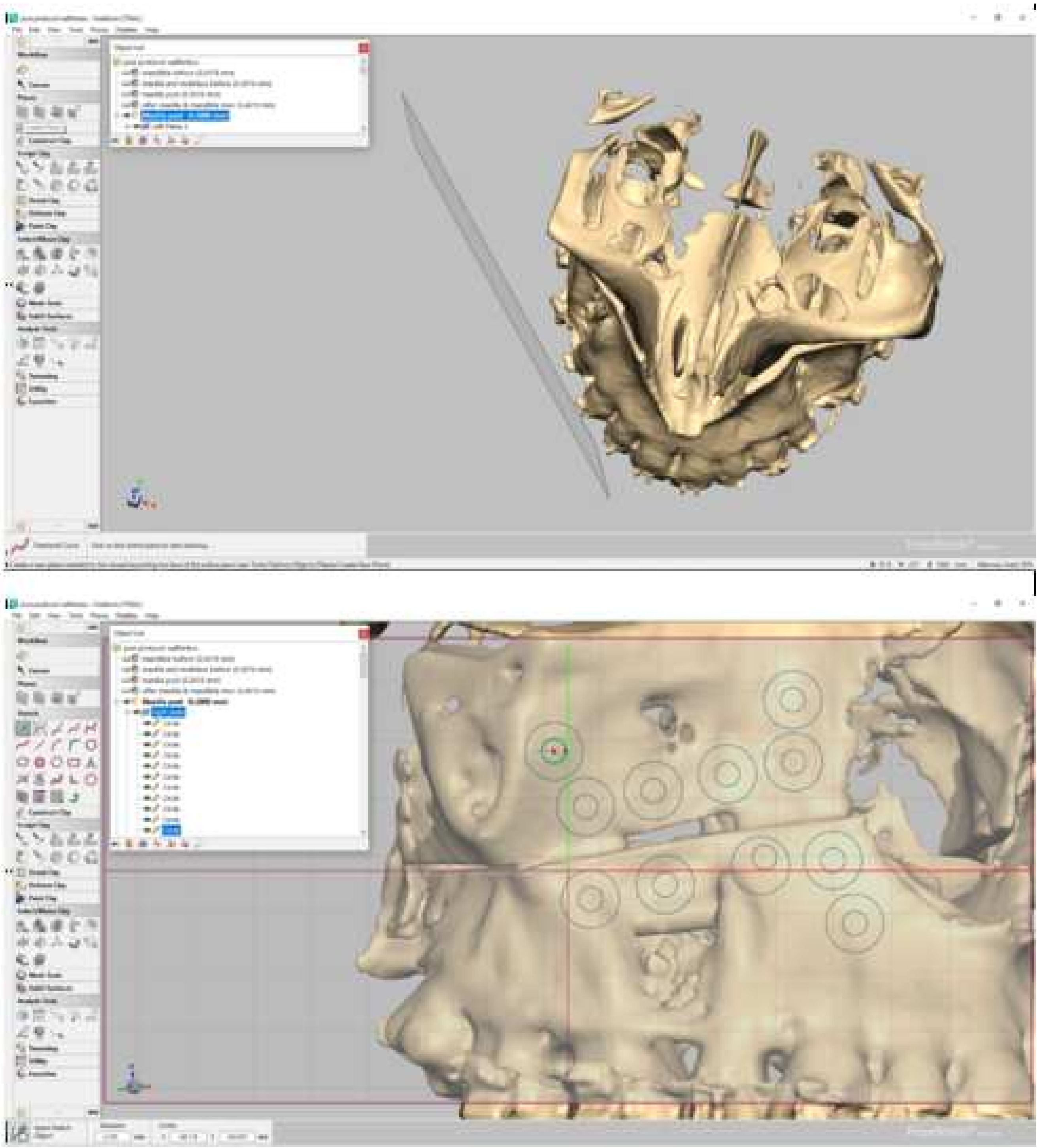

Supplemental Figure 7

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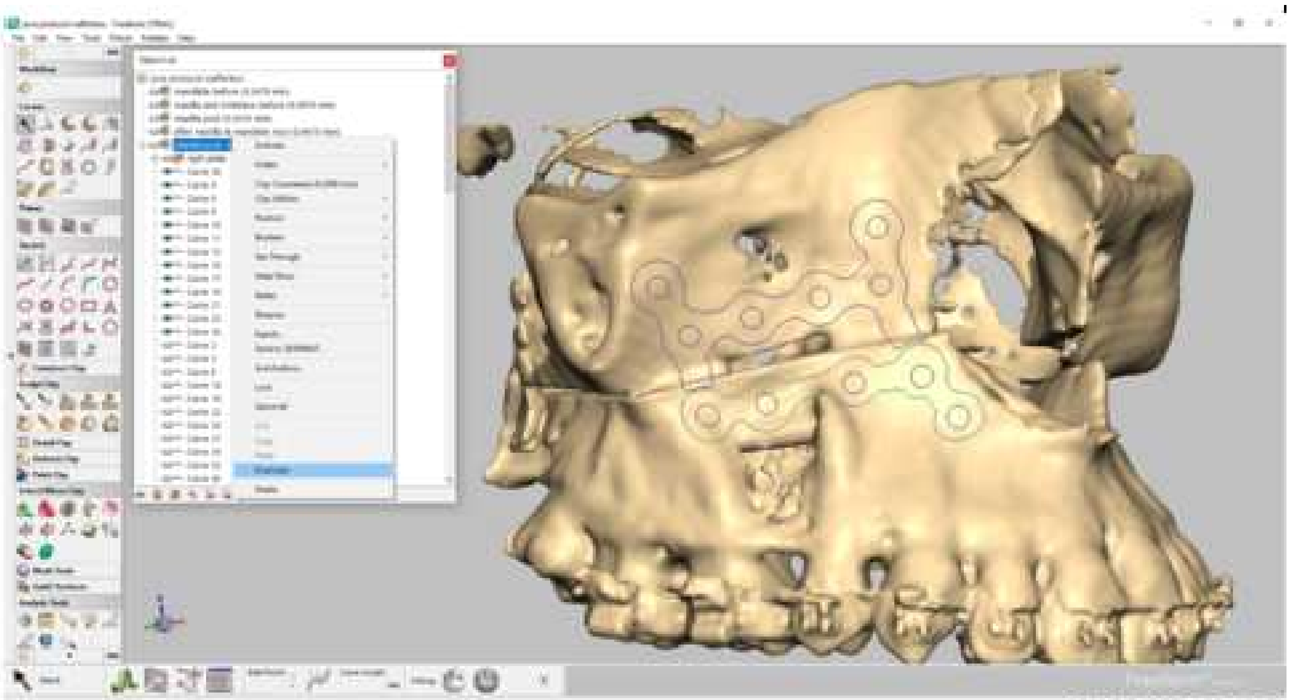

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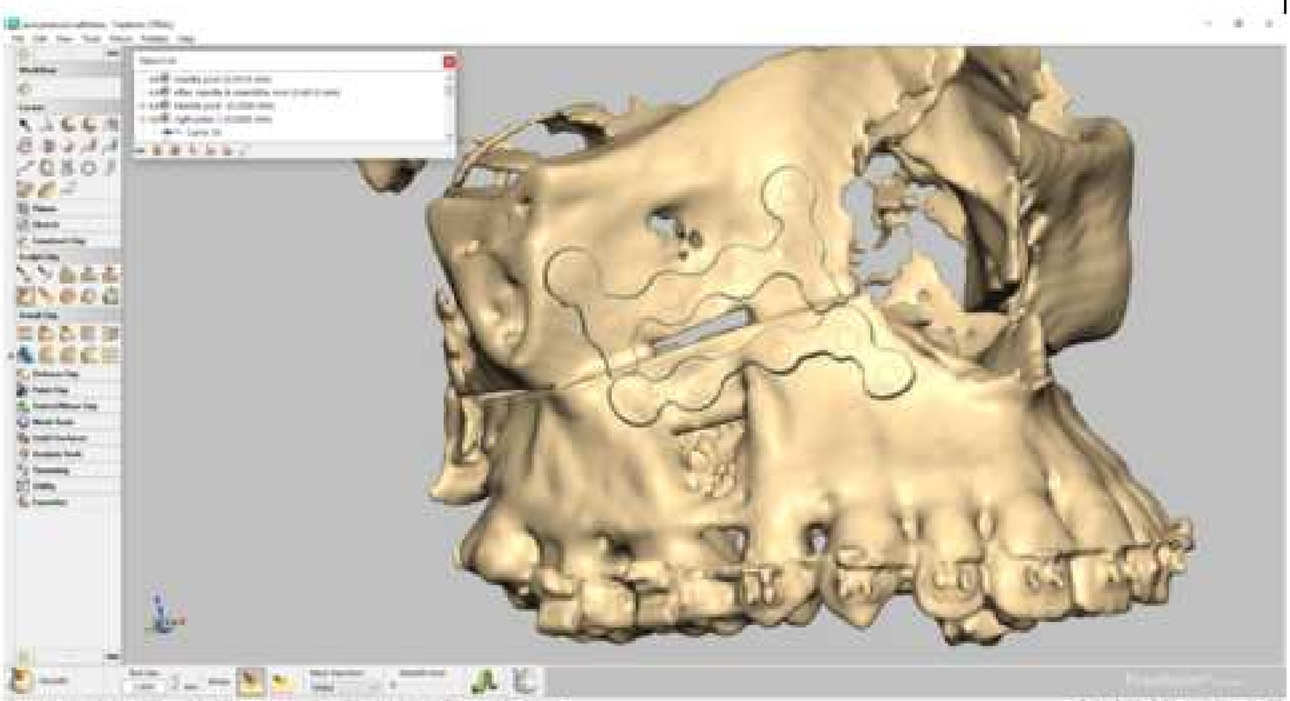

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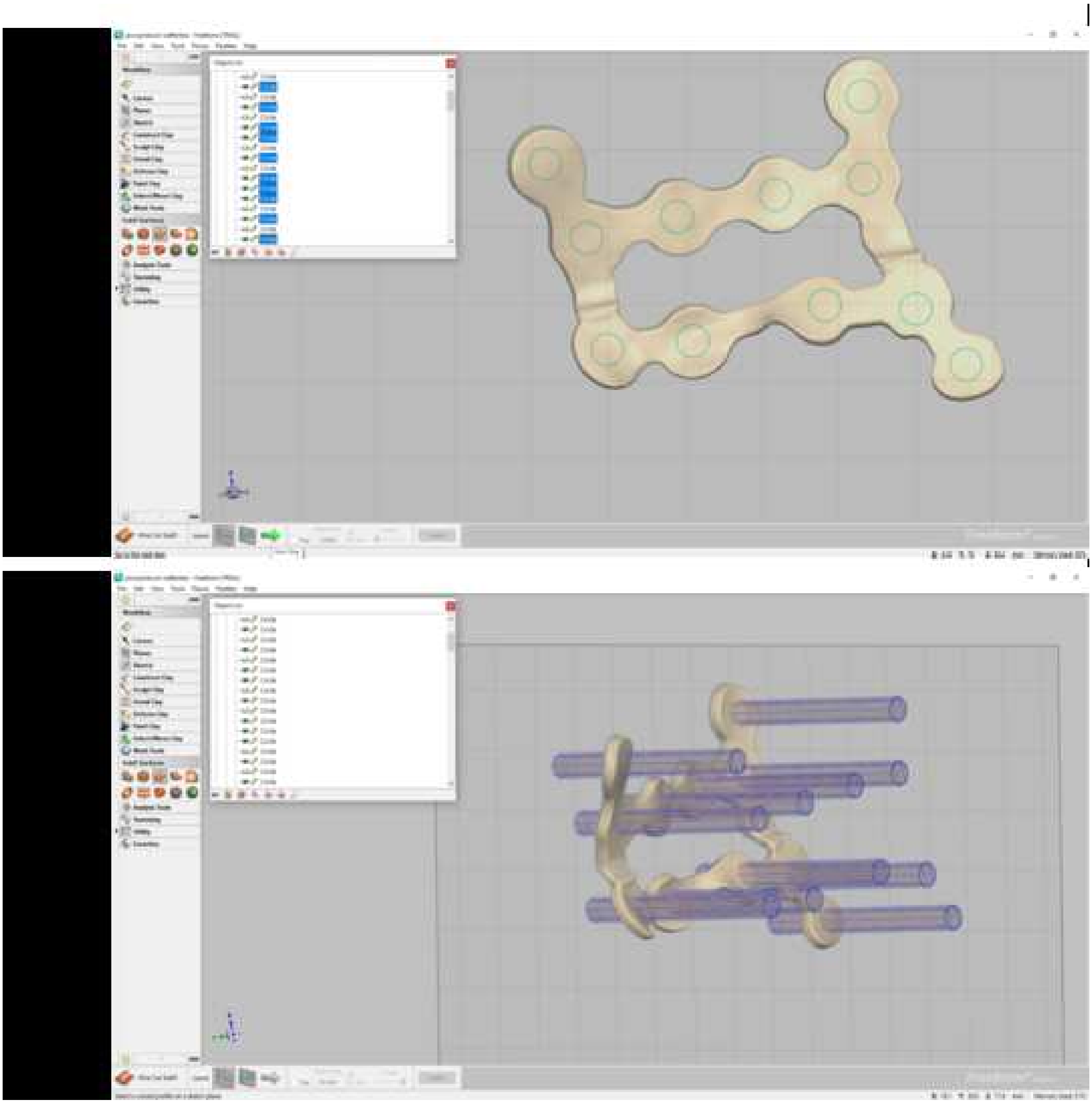

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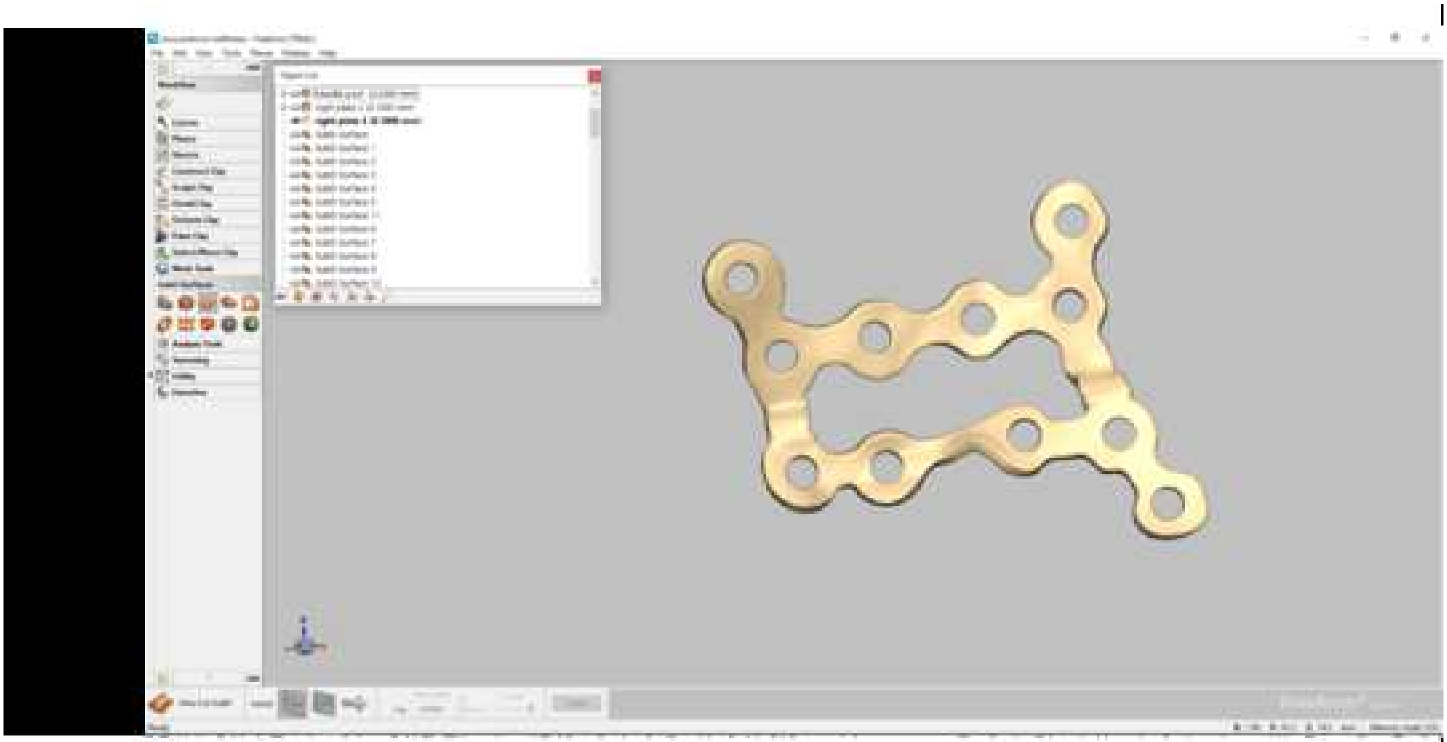

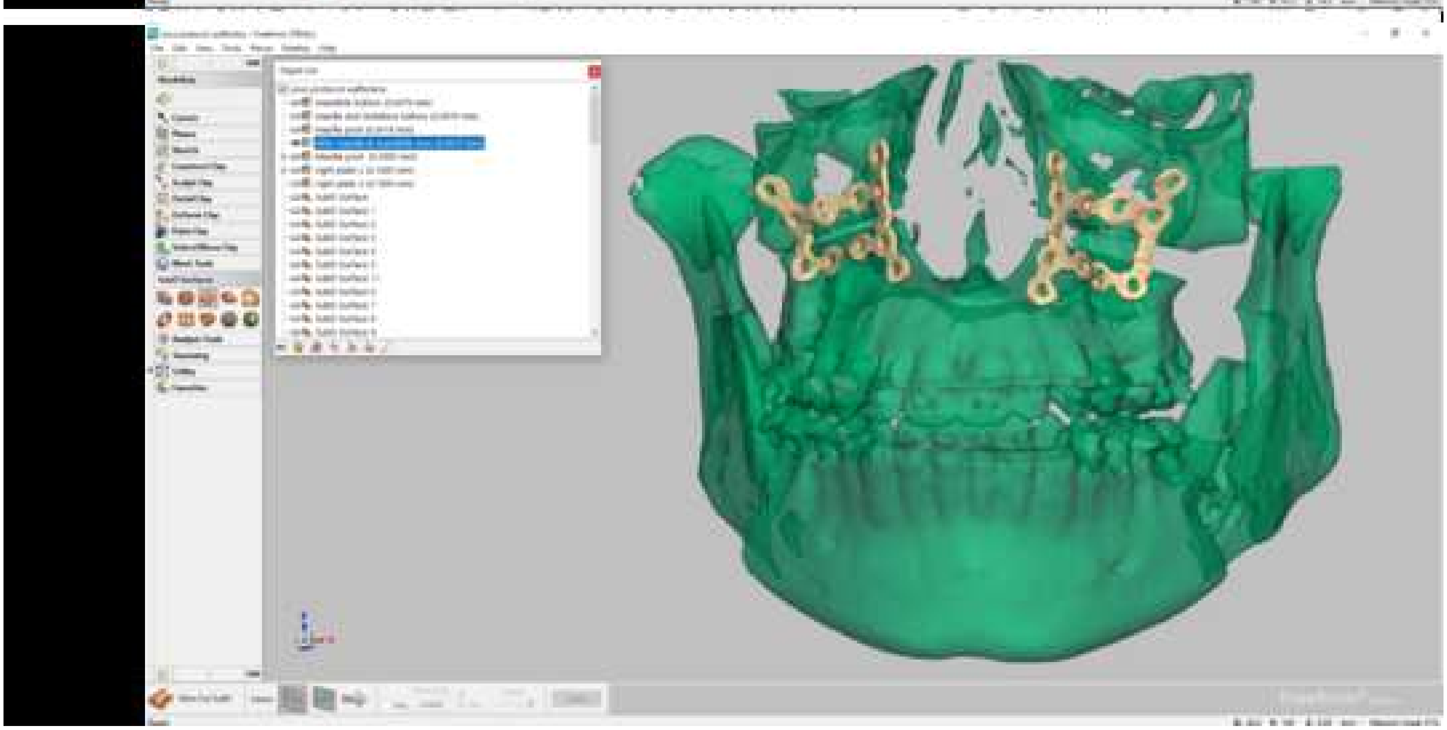

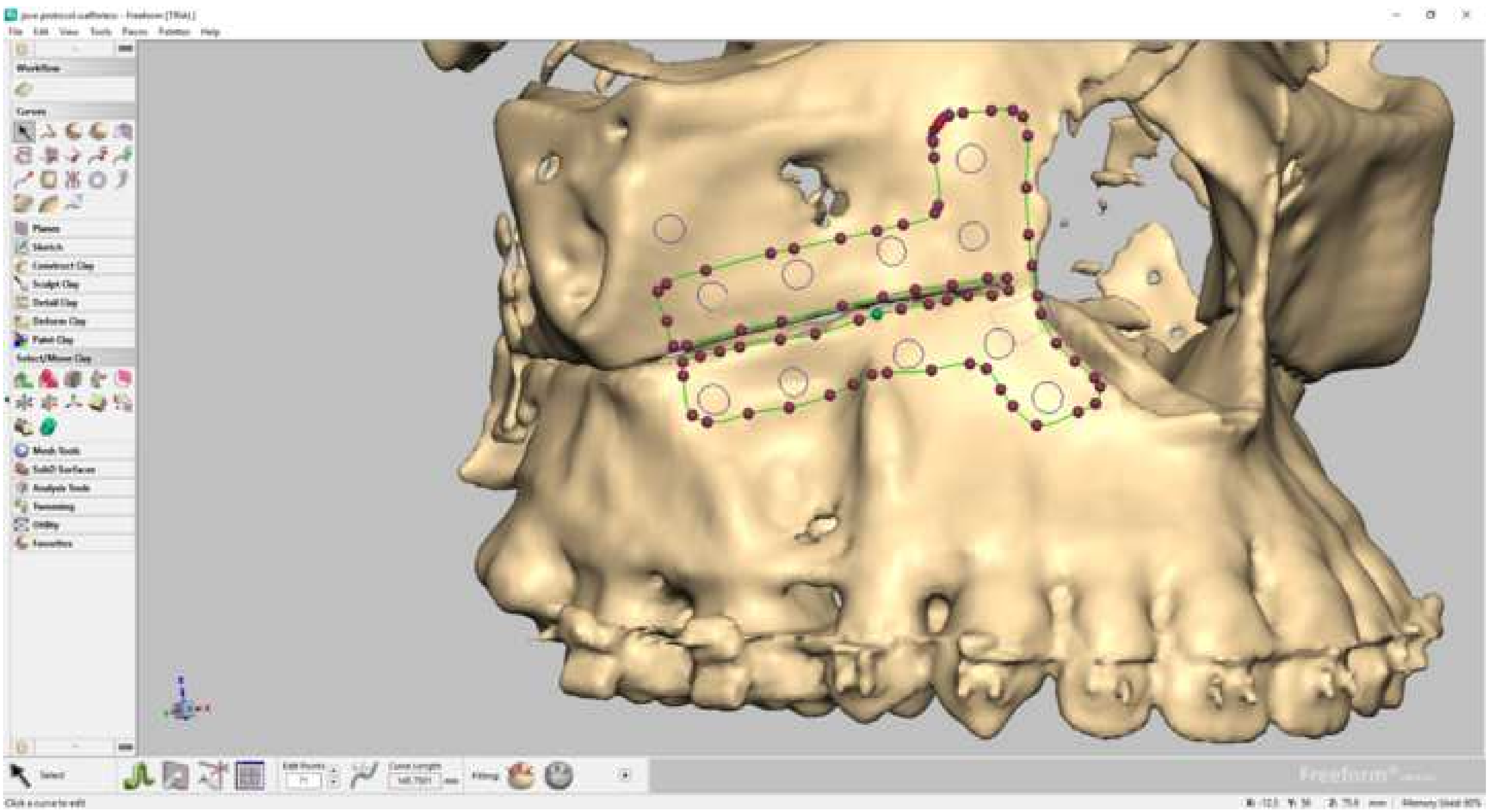

Supplemental Figure 11

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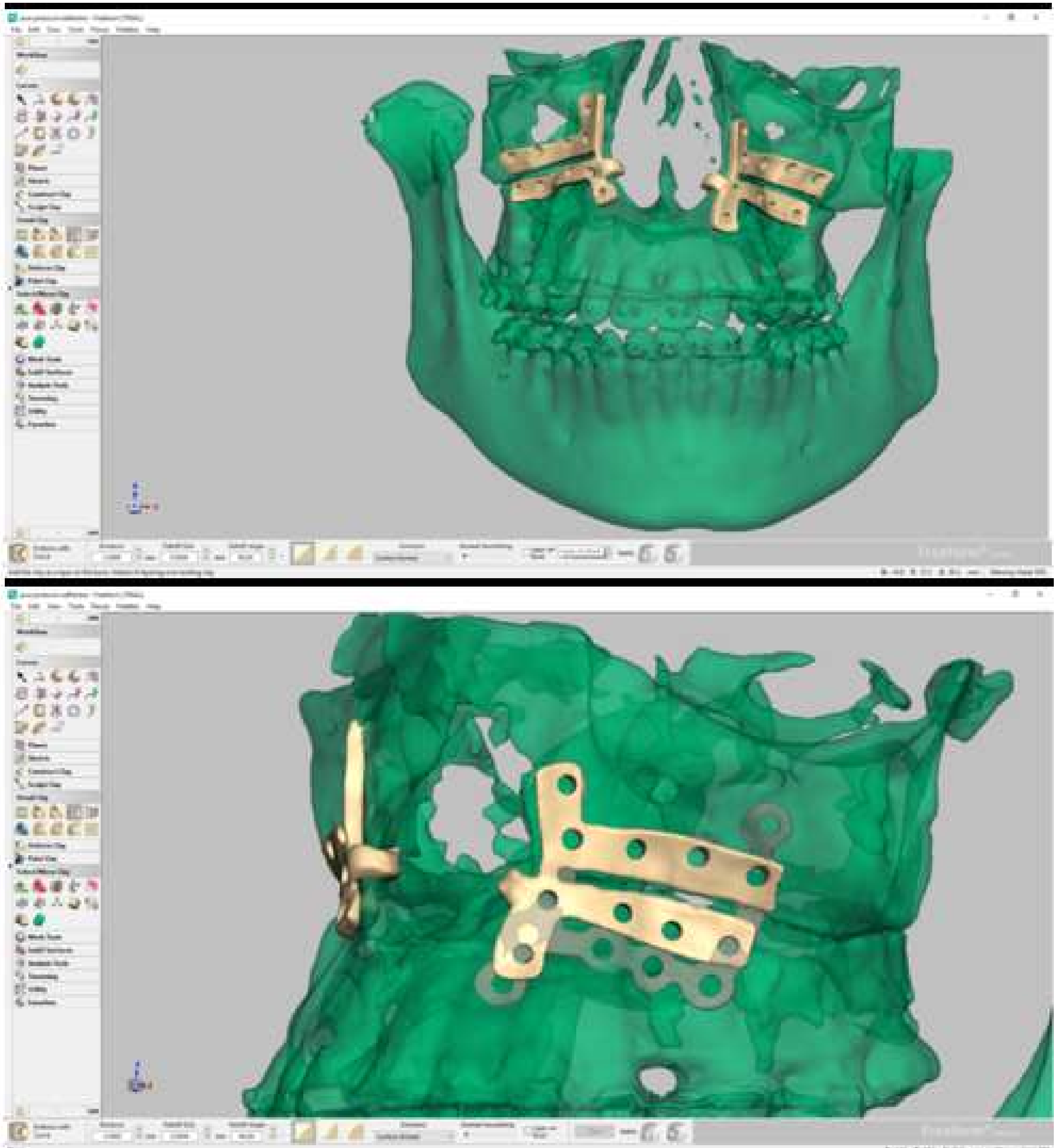

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