3D virtual planning in Orthognathic Surgery and CAD/CAM Surgical Splints generation

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List of Abbreviations

CBCT – Cone-Beam Computerized Tomography
3D – three-dimensional
2D – two-dimensional
FOV – Field of View
TMJ – Temporomandibular Joint
MSCT – Multi-Slice Computerized Tomography
\(\mu\text{Sv}\) – microsieverts
NHP – Natural Head Position
DICOM – Digital Imaging and Communications in Medicine
SSD – Shaded Surface Display
VR – Volume Rendering
MRI – Magnetic Resonance Imaging
CAD/CAM – Computer Aided Design/Computer Aided Manufacturing
BSSO – Bilateral Sagittal Split Osteotomy
\(\text{kV}\) – kilovolt
\(\text{mA}\) – milliampere
\(\text{mAs}\) – milliampere-second
STL – Standard Tessellation Language
PMMA – Polymethyl Methacrylate
MPR – Multiplanar Reconstruction
Abstract

Objective: The purpose of this study is to test a new technique for 3-dimensional (3D) virtual planning in orthognathic surgery, with prediction of postoperative results on hard tissues and manufacture of CAD/CAM (Computer Aided Design/Computer Aided Manufacturing) surgical splints using Nemoceph 3D-OS software (Software Nemotec SL, Madrid, Spain) on one clinical case.

Materials and Methods: The clinical protocol consists of 3D data acquisition by cone-beam computerized tomography (CBCT) and surface scanning of the plaster dental models, with subsequent fusion of the two datasets. The “virtual patient” thus created undergoes virtual surgery and a simulation of postoperative results on hard tissues is produced. Surgical splints are manufactured using CAD/CAM technology, in order to transfer the virtual surgical plan to the operating room. Intraoperatively, both types of surgical splints are compared. A second set of 3D images is obtained after surgery to obtain linear measurements to compare with the measurements obtained when predicting postoperative results virtually.

Results: It was found a high similarity between both types of surgical splints with equal fitting on the dental arches. The post-surgical prediction results were encouraging but not sufficiently accurate. The linear measurements reflect some large discrepancies between the actual surgical outcomes and the predicted results from the 3D virtual simulation, but caution must be taken in the analysis of these results due to several variables.

Conclusion: This study confirmed the clinical feasibility of a computer-assisted orthognathic surgical protocol incorporating virtual planning and its transfer to the operating room using CAD/CAM fabricated surgical splints. Postoperative predictions still lack some reliability and further study with larger sample size is required to confirm the results obtained in this study, as well as further progress in the development of technologies for 3D image acquisition and improvements on software programs to simulate postoperative changes on soft tissues.

Key-words: CBCT; Orthognathic surgery; CAD/CAM; Surgical splint; 3D; Virtual planning
1. INTRODUCTION

Comprehensive visualization and records of the craniofacial complex have always been important goals in orthodontic imaging. These tasks have routinely been performed by means of plaster models, photographs and radiographs. However, Cone-Beam Computerized Tomography (CBCT) has gained considerable acclaim worldwide in recent years as a viable three-dimensional (3D) imaging modality.

The use of CBCT imaging in the oral and maxillofacial region was pioneered in the late 1990s independently by Mozzo et al. (2) in Italy and Arai et al. (3) in Japan and since then there has been an explosion of interest in this new imaging technique in the oral and maxillofacial region (4).

CBCT is a medical image acquisition technique based on a cone-shaped X-ray beam centered on a two-dimensional (2D) detector. The scanner (x-ray source and a rigidly coupled sensor) rotates, usually 360 degrees, around the object to obtain multiple 2D images. The scanning software collects the raw image data and reconstructs them into a 3D data set (a digital volume of cylindrical or spherical shape that is composed of volume elements (voxels)) of anatomical data that can be visualized with specialized software. Voxel is the smallest subunit of a digital volume and in the CBCT they are generally isotropic (with equal X, Y and Z dimension) and range in size from approximately 0.07 to 0.40 millimeters per side. Each voxel is assigned a gray-scale value that approximates the attenuation value of the represented tissue or space. The small isotropic voxel size associated with the large number of gray levels contributes for a very accurate and precise visualization and measurement of anatomical structures (4,5).

Imaging protocol variables in the CBCT technique include voxel size, field of view (FOV), peak kilovoltage, milliampere settings, scan time, sensor sensitivity and the number of image captures, which are variables that contribute for distinct effective dose variations among different CBCT units (5,6).

The operator can control the FOV, matching it to the area of interest and providing substantial dose savings. According to the American Academy of Oral and Maxillofacial Radiology (7), there are three FOV ranges most commonly encountered in orthodontic imaging: the small FOV, which captures a spherical volume diameter or cylinder height less than or equal to 10 cm, limited to a few teeth, a quadrant, and up to two dental arches, but not all of the anatomy of the jaw; the medium FOV, which captures a spherical volume diameter or cylinder height between 10 and 15 cm, including the entire dentition of at least one arch up to both dental arches, and temporomandibular joints (TMJ), but generally does not include the complete soft profile of the chin and nose; and the large FOV, which
captures a spherical volume diameter or cylinder height greater than 15 cm, comprising the TMJ and anatomic landmarks necessary for quantitative cephalometric and/or airway assessment. Therefore, when it’s necessary to comprise the whole craniofacial region in the study, as in cases of cephalometry analyses, a large FOV must be selected.

The use of CBCT technology reduces the patient’s exposure to ionizing radiation compared with the use of Multi-Slice Computerized Tomography (MSCT) technology, but it causes significantly more radiation exposure than do the conventional radiographic imaging procedures routinely used in orthodontics(6). The effective doses for conventional 2D dental imaging range from 1.1 to 3.4 microsieverts (µSv) (digital) and 2.3 µSv (film) for cephalometric radiographs, from 2.5 to 6.2 µSv (digital) and from 3 to 10 µSv (film) for a panoramic radiograph and from 33 to 150 µSv (ranges for film and digital imaging combined) for a full periapical series(8). The radiation dose for some different CBCT equipments using the large FOV ranges from 45 to 59 µSv with NewTom (Quantitative Radiology, Verona, Italy), 135 to 193 µSv with i-CAT (Imaging Sciences International, Hatfield, PA, USA), 477 to 558 µSv with CB MercuRay (Hitachi Medical Systems America, Twinsburg, OH, USA)(8,9), whereas for a MSCT scan of the maxillofacial region varies from 474 to 1410 µSv(6). The effective absorbed radiation dose for a complete CBCT image of the maxillofacial area is within the range of a full-mouth dental periapical survey and one must bear in mind that one cone beam volumetric imaging session can provide all of the other 2D images with the exception of the full-mouth series(10).

There are several advantages related to the CBCT imaging technique, such as its accessibility (potential for in-office imaging and low costs compared with MSCT), easy handling, the obtainment of a real-size 3D dataset, the potential for generating 2D images (e.g. orthopantomogram, lateral cephalogram, TMJ), the potential for vertical scanning in a natural head position (NHP), lower radiation dose compared with MSCT, less disturbance from metal artifacts, and its compatibility with Digital Imaging and Communications in Medicine (DICOM) format(4). Also, CBCT overcomes the limitations of 2D imaging modalities which include magnification, projective displacements, geometric distortion, rotational errors, superimposition of structures, and errors in patient positioning(11,12). The magnification error is eliminated in CBCT because the 3D object is reconstructed from raw data by means of a mathematical algorithm that calculates and eliminates the magnification factor even though the x-rays are not parallel, improving the visual observation of asymmetries and abnormalities(13). On the other hand, MSCT images offer better image quality of the dental and surrounding structures than do CBCT images(6). Other disadvantages are that CBCT cannot be used for the estimation of bone density (due to distortion of Hounsfield Units), movement artifacts can affect the whole dataset, and it has a low contrast resolution and limited capability of visualizing the internal soft tissues(4).
The potential applications of CBCT in orthodontics are being largely studied since the last decade. CBCT can assist in determining the best temporary anchorage device location, is able to provide more accurate airway measurements, provides a precise evaluation of both dental and skeletal asymmetries and location of anatomic structures, and in complex cases such as those involving cleft lip and palate it is a powerful tool for diagnostic assessment and treatment planning. Besides, CBCT can provide 3D evaluations of the TMJ, 3D information regarding impacted teeth location, root resorption, fractured roots, tooth position, tooth development and dental measurements (overjet, overbite, arch width, arch length, mesiodistal tooth width), and 3D cephalometry – many research groups are in the process of developing new 3D norms using anatomic landmarks previously unavailable on 2D images(6,11).

The first computer-based cephalometric systems appeared in the late 1970s and since then several 2D computer-assisted imaging systems were created, allowing for a combination of photographs, tracings, and radiographs. These computer-assisted programs permit rapid measurements and treatment planning, but the validity and reliability of these systems are limited by their two-dimensional nature when dealing with a three-dimensional structure(14).

The validity of comparing conventional 2D cephalometric radiographs and CBCT-generated lateral cephalograms (2D projections from a 3D scan) was studied by Cattaneo et al.(14) and Kumar et al.(15), and it was shown that CBCT-generated lateral cephalograms could replace conventional cephalograms, with similar measurements obtained. Using CBCT-generated lateral cephalograms it is possible to digitally reorient the head position in cases in which the patient underwent scanning without the correct head position, enhance the image quality by virtually extracting extraneous superimposing skeletal structures that are not relevant to the cephalometry measurements, and create separate images of the left and right sides for facial asymmetries assessment(13).

There are several techniques for visualizing a volume in a CBCT reconstruction, including shaded surface display (SSD) and volume rendering (VR). SSD is a software technique which allows the user to set a threshold range for the data on the basis of an attenuation value. The data with an attenuation value outside the selected range will not be visible. This technique is commonly used to visualize soft tissue or bone surfaces. VR is a method that uses all of the voxels but allows the assignment of transparency values to voxels on the basis of their attenuation values. For example, if the superficial soft tissues were assigned a certain percentage of transparency value, then the underlying skeleton could be more or less visualized through the soft tissues(5).

A reconstruction of a CBCT contains the facial soft tissue surface representing the soft tissue, the bone volume representing the facial skeleton and the dentition, but the CBCT
skin is untextured and the dental structures may contain streak artifacts caused by restorations or orthodontic fixed appliances. To improve quality of the virtual face and dentition, it is necessary to superimpose a textured facial soft tissue surface and to upgrade or replace the dental images. 3D data can be fused using three different methods: point based matching with or without the use of a reference frame; surface based matching; and voxel based matching. The methods used to fuse the facial soft tissue surface and the facial skeleton are mapping 2D photographs onto CBCT data or fusing a 3D photograph or a 3D surface scan with the reconstruction of CBCT data. Other imaging techniques can be used for facial soft tissue surfaces, such as Magnetic Resonance Imaging (MRI) or 3D ultrasonography, but 2D and especially 3D photography provide non-invasive high quality images, suitable for 3D image fusion. The imaging methods available to digitize the patient’s dentition to upgrade the dental images of the CBCT reconstruction are: digitization of the plaster cast with a CBCT scanner or a surface laser scanner (methods where is mandatory to pour the cast); a scan of the dental impression of the dental arches with a CBCT scanner or a surface laser scanner (without the need for a plaster cast); and a digital impression obtained by direct intraoral 3D scanning (taken with chairside intra-oral scanning devices). The replacement of the dental images by these methods improves the visualization of the interocclusal relationship and results in precise dental morphology of the surfaces and cusps. With the integral fusion model it's possible to visualize the textured facial surface, as well as the 3D skeletal structures and the dentition without artifacts(15).

Due to technology advancements, new applications arise almost every day: CBCT data will soon be used for 3D virtual models production of higher diagnostic value and fabrication of aligners and retainers, indirect bracket bonding and custom-made brackets and wires for an individual patient(1).

The application of CBCT to orthognathic surgery has been increasingly studied. An accurate diagnostic imaging is essential to achieve a correct diagnosis and treatment plan, leading to accurate repositioning of the craniofacial skeleton, which is essential to achieve optimal aesthetic features and occlusal results(16,17).

Intraoperatively the repositioning of skeletal constructs is conventionally obtained through the surgical splint technique, by the time-consuming and imprecise model surgery(17,18). The 3D fusion model mentioned above replaces the need for model surgery, since the virtual head, aside from the diagnosis and treatment plan, can also be used to design a surgical splint(15).

In the traditional method, in order to achieve a precise diagnosis of the dento-skeletal deformity and to create a treatment plan intraoperatively reproducible, it is necessary to collect data from different sources like photographs, cephalograms, dental casts, physical examination along with face bow record and its transfer to semi-adjustable articulators, and
measurement of plaster casts’ movement according to the surgical simulation (17–19). Errors may be introduced during each of these steps, particularly in patients with complicated deformities of pitch, roll, and yaw (17). In performing the face bow transferring procedure to the articulator and when manipulating the resulting articulated models, it is important to recognize that these instruments are semi-adjustable and limited in the replication of our patients (20). Therefore, despite being an established and accepted method, a detailed analysis of the traditional model surgery technique reveals that theoretically it suffers from several sources of error and inaccuracy, with insufficient control of movements such as rotation and translation with regard to the whole cranial situation (21).

Developments in 3D imaging technology enabled the creation of new computerized tools to assist in preoperative planning and manufacture of surgical splints (22–25). There is a paradigm shift from a 2D imaging concept towards the use of a proper 3D scenario to plan the treatment of 3D deformities and the importance of 3D virtual surgical planning increases with the complexity of the deformity and reconstruction needed to correct it. As a result, surgeons are provided with extra information that could not be obtained from lateral cephalogram alone, improving the quality of the preoperative planning (19, 20). Multiple software programs are available for 3D planning, allowing an interaction with the 3D images to simulate the surgery and visualize the prediction of postoperative outcomes in soft and hard tissues. Surgical splints, manufactured using Computer Aided Design/Computer Aided Manufacturing (CAD/CAM) technology, have been developed to avoid errors in the traditional model process that can lead to suboptimal outcomes (17, 19).

CBCT technology also enhances the evaluation of the outcomes of combined orthodontic and surgical treatment. When assessing treatment outcomes, the process of image superimposition can be challenging due to difficulties related to image fidelity and landmark selection and identification. The introduction of CBCT allows clinicians to perform superimpositions in three dimensions and eliminates errors in traditional lateral cephalometric superimposition, where the information obtained is only from the sagittal plane (13).

The purpose of this study is to evaluate the feasibility and precision of 3D virtual planning in one patient with craniofacial microsomia using Nemoceph 3D-OS software (Software Nemotec SL, Madrid, Spain) to predict postoperative outcomes on hard tissue and produce CAD/CAM surgical splints.
2. MATERIALS AND METHODS

The study was carried out in a 19-year-old female who had a left craniofacial microsomia which required a combined orthodontic-orthognathic surgery treatment.

The conventional preoperative treatment planning was performed by 2 clinicians, following the standard protocol used at the University Clinic of Orthodontics, Department of Dentistry, Faculty of Medicine, University of Coimbra – Portugal. This involved:

- Clinical examination;
- Photographs: pictures of the dental occlusion and frontal, oblique, and lateral views of the face;
- A radiographic study: orthopantomogram, frontal and profile cephalograms (for cephalometric analysis and prediction tracings), and CBCT scan (i-CAT device, version 17-19, Imaging Sciences International, Hatfield, Pa, USA), using a wax bite wafer to keep the patient in centric relation during the study;
- Articulation of the plaster dental models with face bow transferring in a semi-adjustable Hanau H2 articulator (Hanau Engineering Company, Buffalo, USA);
- Production of conventional acrylic surgical splints, by plaster dental model surgery.

The conventional diagnosis revealed a craniofacial microsomia affecting the left side of the patient’s face with associated diminished jugal soft tissues and a lateral lip cleft (macrostomia) – surgically intervened at the childhood and still requiring new intervention to complete the correction, maxillary and mandibular retrusion and vertical maxillary excess.

Preoperative orthodontic treatment was performed for correction of dental compensations, enabling the occlusal coordination of both dental arches. The surgical treatment objectives were maxillary advancement of 3 mm; anterior impaction of 8 mm at the level of the right canine and 4 mm at the level of the left canine, with Le Fort I osteotomy and anterior and counter-clockwise mandibular repositioning with Bilateral Sagittal Split Osteotomy (BSSO).

The surgical plan and acrylic surgical splints generated by conventional planning methods were available as backup during the surgery.

At the same time, the process of obtaining 3D images was initiated, in order to develop a 3D treatment plan and manufacture the CAD/CAM surgical splints. The process followed involved:

A. 3D image generation

Two CBCT scans were obtained: one preoperative (2 months prior to orthognathic surgery) and one postoperative (1 month after), using the i-CAT device, version 17-19
(Imaging Sciences International, Hatfield, Pa, USA) with a FOV set to a height of 17 cm and a diameter of 23 cm, allowing the visualization of all anatomical landmarks required for surgical 3D planning. The radiological parameters used were 120 kV of tube voltage, 5 mA of tube current and exposure of 37.10 mAs, with a voxel size of 0.3 x 0.3 x 0.3 mm.

The images obtained using CBCT were stored in DICOM format and sent to Nemotec CAD/CAM Centre (Centro Integrado Investigación, Madrid, Spain) together with the patient’s dental plaster casts and digital facial photographs (frontal, oblique, and lateral). As expected, the CBCT didn’t provide accurate images of the patient’s dental anatomy, due to the presence of artifacts, preventing an accurate adjustment of the upper and lower dental intercuspation to determine the planned new occlusion. To overcome this problem, it was necessary to scan the plaster models of the upper and lower jaws, which can be done with a CBCT scan or using a dental surface scanner. It would be of interest to scan the plaster models articulated with a wax wafer with the correct new occlusion (determined by the clinician manually) for the following steps of the 3D computerized planning – by scanning each single model and the situation of both models in the determined new occlusion, 3 scanning Standard Tessellation Language (STL) files would be generated. However, in this study the upper and lower dental casts were only scanned independently using a surface laser scanner. This scan gave precise details of the shape and size of the patient’s teeth to incorporate in the 3D image by the image fusion technique previously mentioned (Image 1).

Image 1 – Plaster dental models of the upper and lower jaws (a), surface scans (STL files) of upper and lower plaster dental models (b), STL files fused with the 3D image of the skull (c), overlap of the STL files with CBCT dataset - midsagittal view (d).

Segmentation of the CBCT images sent to the Centre was carried out using mathematical algorithms to convert the DICOM images into 3D images using Nemoceph 3D-OS (Software Nemotec SL, Madrid, Spain), and the incorporation of the plaster dental casts scan in the 3D image of the patient was carried out by the Centre technicians using a semi-
automatic procedure. The result was a precise overlap of the generated STL files and their corresponding anatomic structures in the skull dataset.

The CAD/CAM Centre uploaded onto a PC of our Institute, via the Internet, 3D images of the patient’s craniofacial skeleton together with images of their dental casts superimposed on their dental arches and images of facial soft tissue surrounding these structures, with the possibility to visualize the real facial appearance through the patient’s photographs incorporated in the 3D fusion model (Image 2). Three-dimensional images were now available of hard tissue, teeth and soft tissue.

B. 3D surgical planning

The steps previously mentioned were performed by trained technicians alone (image segmentation procedures, incorporation of the plaster dental casts scan and facial photographs in the 3D image of the patient skull). The following steps of the 3D surgical planning were carried out in the software Nemoceph 3D-OS (Software Nemotec SL, Madrid, Spain), by the clinician along with the trained technician of the Centre, through an online remote conference, so that the surgical plan elaborated by the clinician could be followed accurately with his orientation and supervision.

At first, the whole skull dataset was manually aligned to the NHP, using the photographs of the patient (captured in NHP - a standardized and reproducible position of the head in an upright relaxed posture, with the eyes focused on a point in the distance at eye level(26)) to help in the orientation of the 3D skull dataset. This step was necessary since it was verified that the CBCT scans weren’t performed in an exact natural head position, due to modifications performed by the radiologist in the positioning of the patient’s head, in order to comprise the whole craniofacial region in the limited scanning area, even though the larger FOV of the equipment was selected. Automatic procedures of orientation
would have the disadvantage of including asymmetrical parts of the skull in the calculations, which would lead to inaccuracy.

Using the 3D images it was possible to perform virtual osteotomies, repositioning osteotomized bony structures, control interferences between osteotomized bony structures and regions at the base of the skull, control intercuspation, and simulate the postoperative results on hard tissue in 3D on our computer screen.

**Skull segmentation**

All planning steps are based on virtual segmentation procedures, which are necessary for performing repositioning of osteotomized bony structures. By using predefined Le Fort I and BSSO lines, the upper and lower jaws can be segmented.

**Maxillary repositioning**

At first, the occlusion plane of the maxilla was defined. Using the multiplanar view, it is possible to reposition the maxilla in each single direction. The upper jaw was rotated until the occlusion plane was parallel to the horizontal plane in the coronal view. In the sagittal view, the movements of impaction and advancement were performed according to the amount of movement initially defined in the conventional treatment plan by clinical examination (Image 3).

![Image 3](image3.png)

*Image 3 – 3D surgical simulation showing osteotomy lines, reposition of the osteotomised maxilla and original mandible.*

**Mandibular repositioning**

To reposition the lower jaw, it has to be moved to the position where a correct final occlusion is obtained (Image 4). This was achieved through a semi-automatic procedure and some manual adjustments in order to simulate the correct teeth intercuspation (Image 5). Other method could have been applied, using the third STL file, above mentioned, containing
the determined new occlusion: by aligning the virtual model to the repositioned upper jaw, it would be possible to move the lower jaw fragment into the adequate position, facilitating the process.

C. Surgical splints

**Conventional Surgical splints**

To simulate the planned operative procedures, a model surgery is performed based on clinical assessment and cephalometric prediction tracings. The models are mounted on a semi-adjustable articulator and the relative position of the dentition within the facial form of the patient is simulated. When the dental casts are in their final position, an acrylic splint is fabricated. This acrylic splint is used to transfer the treatment plan to the patient in the operating room, allowing for accurate intra-operative positioning of the maxilla relative to the mandible or of the mandible relative to the maxilla. The acrylic splint ideally contains indentations of the incisal edges and cusps of the teeth, and it is trimmed on the buccal surfaces to permit visual verification of proper seating at the time of surgery.
repositioning of both the maxilla and the mandible is planned (such as in the presented case where bimaxillary surgery was required), an intermediate splint in addition to the final splint is fabricated. This intermediate splint is used to align the osteotomized maxilla to a non-operated mandible, and the final splint is used to position the mandible to the repositioned maxilla (27).

For this study, 3 acrylic splints generated by the conventional planning method were manufactured: the initial splint (Image 8-a), obtained from the plaster casts in centric relationship to enable the surgeon intra-operative registration of the correct condylar position within the glenoid fossa; the intermediate splint, and the final splint. These last 2 splints (intermediate and final) were available as backup during the surgery.

**CAD/CAM Surgical splints**

The treatment plan was transferred from the computer to the patient by means of intermediate and final surgical splints, which were directly generated in the computer and fabricated by a milling machine.

- **Intermediate splint**

To produce the intermediate splint, the repositioned maxilla and the original mandible with their aligned STL files were used to transform the necessary information into a virtual splint (Image 6).

Image 6 – Planned intermediate situation with the virtual intermediate splint set between the dental arches (a), virtual intermediate splint (STL file) – front, top and bottom views (b), overlap of the splint STL file in the planned position with CBCT dataset - midsagittal view (c).

- **Final splint**

To produce the final splint, the repositioned maxilla and mandible with their aligned STL files were used (Image 7).
After these steps, in the CAD/CAM Centre the virtual splints (STL files) were exported to a milling machine which milled the surgical splints on polymethyl methacrylate (PMMA), a transparent rigid thermoplastic material (Image 8-b,c). These two splints returned to our University’s Dentistry Department by courier service within 4 days.

D. Surgery

The bimaxillary surgery was carried out by a surgeon from the Maxillofacial Surgery Department of Coimbra University Hospital.

The surgery was performed under general anesthesia, with Le Fort I and BSSO osteotomies. The intra-operative registration of the correct condylar position within the glenoid fossa was performed using the initial splint (acrylic splint generated by the conventional planning) and the reposition of the osteotomized maxilla and mandible was guided by the CAD/CAM surgical splints using fixation plates and screws (Image 9).

Maxillomandibular elastic fixation was maintained for 6 weeks after surgery allowing proper bone consolidation.
3D virtual planning in Orthognathic Surgery and CAD/CAM Surgical Splints generation

3. RESULTS

A. Comparison of surgical splints

The new splints were clinically evaluated by an experienced clinician regarding its adaptation, passivity and occlusal scheme. There was no need for adjustments, as a perfect fit was obtained during splints try-in performed in the patient’s mouth before surgery.

During surgery, it was perceived by the surgeon that the retention of the splints fitting the dental arches was superior in the upper jaw, with the splints presenting some looseness regarding the mandibular teeth, when the jaws were positioned fitting the interposed splint, before the fixation of that intermaxillary position with wires.

The conventional acrylic splints try-in was also performed intraoperatively (Image 10), after reposition and fixation of the jaws with the CAD/CAM splints, and an equal fitting was verified with both types of splints, demonstrating that both splints were able to transfer the same surgical plan to the patient at the time of the surgery.

Image 9 – Intra-operative situation of the conventional initial splint (a), intermediate CAD/CAM splint (b) and final CAD/CAM splint (c) fitting the dental arches.

Image 10 – Intra-operative situation of the conventional intermediate splint try-in, after reposition and fixation of the maxilla.
B. Analysis of the prediction of the results

One month after surgery, a second set of images of the patient was obtained in DICOM format using CBCT, to assess changes in hard tissues due to surgical procedures. These images were processed, resulting in 3D images that enabled the postoperative measurements to be contrasted with the predicted results obtained from the virtual surgery (Image 11), evaluating the ability of this technology to recreate the orthognathic surgery hard tissue movements in the three planes of space.

Image 11 – 3D image of the preoperative situation (a) and the postoperative virtual simulation of the predicted results on hard tissues after repositioning the mobilized bone structures.

Measurements were performed at the preoperative stage in the 3D simulation, using the Nemoceph 3D-OS (Software Nemotec SL, Madrid, Spain) program for assessment of quantitative changes between the preoperative and the postoperative simulated positions of selected dental and bone landmarks (Image 12-a). At the postoperative stage, the pre- and postoperative CBCT’s were registered based on the cranial base surface, as the cranial base structures are not altered by the surgery, unlike the maxilla and/or mandible. The fully automated voxel-based registration was computed by the open-source software 3D Slicer 4.1 (The Slicer Community) that optimally aligned the pre- and postoperative dataset at the cranial base (Image 12-b). In this superimposition the pre- and postoperative results are overlaid, and visual comparison is possible trough semitransparency tools. The same measurements were performed in this image set to assess the difference between the preoperative and the actual postoperative positions of the same dental and bone landmarks, using the open-source software 3D Slicer 3.6 (The Slicer Community). Because the windows that display the three planes (sagittal, axial and coronal) depend upon the operator’s defined orientation, this variable was controlled by orientating the sets of images in the same way, using as reference the orientation in NHP already defined for the 3D image in the Nemoceph.
3D-OS (Software Nemotec SL, Madrid, Spain) software. A line connecting sella and nasion was used to correct the pitch (x-axis) and it was assumed that the roll (z-axis) and the yaw (y-axis) were the same at the time of CBCT acquisition due to the stabilization devices used for positioning the patient.

![Image 12](image12.jpg)

Image 12 – Sagittal view of the preoperative situation and virtual postoperative simulation (green, blue and red tracing), performed on Nemocceph 3D-OS software (a); pre- and postoperative CBCT’s registered based on the cranial base surface with 3D Slicer 4.1 software (b).

The linear measurements obtained (Table I) demonstrate the displacement of some selected landmarks from the preoperative situation to the postoperative outcome (predicted in the 3D surgical simulation and actually obtained after surgery). These measurements were performed in the x-axis (Depth), y-axis (Width, deviation) and z-axis (Height), for dental landmarks (incisal edge of 11, 41; cusp tip of 13, 23, 33, 43; mesiobuccal cusp of 16, 26, 36, 46) and bone landmarks (Pogonion, Anterior Nasal Spine and Posterior Nasal Spine) (Image 13). At the time of the second CBCT acquisition there was still some postoperative soft tissue swelling, and since the software used does not provide soft tissue simulation, the evaluation of the outcomes was only performed for hard tissues.

![Image 13](image13.jpg)

Image 13 – Display of the three planes (sagittal, axial and coronal) of the registered pre- and postoperative CBCT’s, with 3D distribution of the landmarks on 3D Slicer 3.6 software.
Table I - Displacement of selected landmarks from the preoperative situation to the postoperative outcome (predicted in the 3D surgical simulation and actually obtained after surgery).

<table>
<thead>
<tr>
<th>Linear Measurements</th>
<th>Difference between preoperative and predicted postoperative positions (mm) (Nemoceph 3D-OS)</th>
<th>Difference between preoperative and actual postoperative positions (mm) (3D Slicer 3.6)</th>
<th>Discrepancy between the predicted and actual outcome (mm)</th>
</tr>
</thead>
<tbody>
<tr>
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<td>+6.5</td>
<td>+10.3</td>
<td>3.8</td>
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<tr>
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<td>+6.7</td>
<td>+11.5</td>
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Pegionion (Pg): most anterior midpoint of the chin on the outline of the mandibular symphysis.
Anterior Nasal Spine (ANS): most anterior midpoint of the anterior nasal spine of the maxilla.
Posterior Nasal Spine (PNS): most posterior midpoint of the posterior nasal spine of the palatine bone.
Maxillary midline deviation (Mx Midline Dev.)
Mandibular midline deviation (Md Midline Dev)
Height (vertical movement): (+) upward postsurgical position
Width (transversal movement): (+) distalization of the postsurgical position in relation to the facial midline
(-) mesialization of the postsurgical position in relation to the facial midline
Depth (anteroposterior movement): (+) advancement of the postsurgical position
4. DISCUSSION

The introduction of CBCT specifically dedicated to imaging in the maxillofacial region initiated a true paradigm shift, expanding the role of imaging from diagnosis to image guidance of operative and surgical procedures with the help of diverse software applications(1).

Advantages of the technique

Modern 3D virtual planning for orthognathic surgery has critical advantages compared to conventional treatment planning.

It’s important to first address some particular considerations about the conventional model surgery approach, in order to contrast with the 3D virtual planning method. Simulating the operation on plaster models is difficult, especially in cases of complicated two-jaw surgery, as it requires many laboratory based steps that are time-consuming and may lead to potential errors(28). Transferring the models to the articulator is one of the critical steps, since the characteristics of the articulator are not individualized for each patient and the kinematic face bow transfer record is accompanied by inherent errors in the adjustment of the instrument to the patient’s face, since the anatomy at the level of the external auditory canal and/or the nasal dorsum may be variable, as well as the patients’ cooperation when cast of the face bow is being made. Regarding the anatomic variability, it is particularly critical in cases of facial asymmetry, like the one presented in this study, which are cases in which the localization of the ear, condyle or glenoid fossa may be asymmetrical, with anomalies or even absence of some of these facial structures. Besides, the accuracy of the face bow transfer may differ from one type of face bow to another. Using articulators may also lead to error at the center of rotation of the mandibular condyle which is the same for all patients when working with a semi-adjustable articulator. The inaccuracy in registering and transferring the true hinge axis of the condyle to the articulator inevitably causes errors in predicting mandibular rotation secondary to maxillary surgery. Working with 3D representations of the anatomic structures of each patient can provide a more precise vision of how the condyle will rotate when the mandible is mobilized, although the software applied in this study does not allow simulation of functional movements(19,29). Other source of error is the difference in the patient’s mandibular position when supine and upright, as the mandible tends to be positioned more posteriorly when the patient is lying down and the mouth has been actively closed into the relaxed position of centric occlusion. Also, the vertical and horizontal lines of reference in the models are drawn by hand using two-dimensional instruments (ruler and calliper) on plaster casts that do not represent patient’s
bone structure or the osteotomy lines that will be used in surgery\(^{(19,29)}\). Since the only 3D structures available in the plaster models are the dental arches and no reproduction of the facial skeleton is provided, any interferences between bone structures will not be reproduced in the simulation in the articulator, compromising the exact reproduction of these complex movements in surgery. Moreover, when repositioning the models, rotational and translational movements are insufficiently controlled and it’s difficult to accurately measure the surgical movement of the segments\(^{(19,30)}\). Finally, the splint, which transfers the final relative position of the maxilla to the mandible, summates all of the errors of the previous stages\(^{(30)}\).

When using 3D planning, all the necessary information is provided in images which can be manipulated on a PC, whilst conventional planning makes it necessary to obtain data from different sources (e.g. radiographs, models and articulators, face bow) and to interpret the data before being able to develop a treatment plan\(^{(19)}\). This emerging technology allows us to more closely replicate the actual patient providing access to more and higher-quality information about the patient’s 3D anatomy and improving the ability to identify conditions that are not detectable with 2D conventional imaging techniques, thus improving the accuracy and reliability of diagnosis and treatment\(^{(12)}\). By considering the whole skull asymmetry and not only the situation presented by plaster models, a large anatomic region can be included in the planning process allowing the clinician to focus on 3D facial harmonization rather than on facial profile correction\(^{(31)}\). For example, in patients with severe asymmetry (like the case presented in this study) the anatomical region causing the facial asymmetry can be seen easily and through virtual simulations the maxillomandibular complex can be aligned to the position where the skeletal asymmetry is corrected.

Another advantage of this system is that the condyle-glenoid fossa relationship in centric relation remains stable throughout the planning process. In this study the patient was kept in centric relation during the radiographic study by a wax bite wafer. TMJ centric relation is the most reliable and reproducible reference point for accurately recording the relation of the mandible to the maxilla and is the best position for functional stability. Therefore a determination of the seated condylar position is a prerequisite for the analysis of dental and skeletal relations, as it is proved that a correct diagnosis of the dento-skeletal deformity and the appropriate treatment plan is achieved from a TMJ centric relation\(^{(20)}\).

Unlike conventional model surgery on plaster models, this technology allows to virtually perform multiple simulations of different osteotomies and skeletal movements, in order to evaluate multiple surgical plans\(^{(15,31)}\).

Surgical splints can be manufactured with rapid prototyping techniques in order to accurately transfer the virtual plan to the operating room. These surgical splints reflect the improvements in quality and quantity of the diagnostic data due to the incorporation of all the information of the patient in one single 3D image. The accuracy of the rapid prototyping
procedures for orthognathic surgery is now beyond all question and the reliability of these CAD/CAM-generated splints has already been validated(19,21,23,31–36). The approaches described by other authors (Hernández-Alfaro et al., Gateno et al., Xia et al., Metzger et al., Swennen et al., Choi et al.), differ from the methodology of our study in the way of obtaining the data, and the type of software and hardware used, which makes it difficult to compare the different 3D virtual planning systems.

The possibility to perform a 3D cephalometry is an advancement brought by this new technology. However, this tool needs further investigation regarding its proper use, since recent literature reports that the 3D cephalometric analyses duplicates some of the problems that have been experienced for a long time with conventional 2D analysis, and it is still lacking a stipulated gold standard regarding landmarks and planes to be used for measurements in a 3D cephalometric analyses(20).

Finally, treatment outcome evaluation is possible through techniques of voxel-based rigid registration and superimposition on a 3D reference system(31). These recent software tools allow an optimal alignment of 3D CBCT data sets at different time points with subvoxel accuracy after identification of the cranial-base structures, avoiding observer-dependent traditional techniques based on overlap of anatomic landmarks(37).

3D measurements from CBCT’s can be made in several visualization modes, including multiplanar (MPR), VR and SSD. Of these, point-to-point measurements made in the MPR mode are highly accurate when compared with physical skull measurements, whereas the surface anatomy measured in VR and SSD modes have a measurement error of 2.3% as compared with direct physical measurements(38,39). In order to adjust the location of cephalometric landmarks, slices are more accurate than the 3D view provided, because the 3D projection doesn’t represent real surfaces(40). This fact supports the methodology used in this study, as the measurements were performed in the MPR mode and the cephalometric landmarks were located directly on the slices adjusting the axial, sagittal and coronal views.

Using this methodology, treatment plans can be stored in the computer, where the patient’s records are instantly available, and the plaster models can be discarded after digitalization, saving the space normally taken up by physical elements used in conventional planning: thereby large and expensive storage areas are no longer necessary(19,21).

Clear benefits of computer imaging and simulation have also been shown in the area of patient communication. The diagnosis can be shared with the patient using a 3D image that can be easily understood, and it helps providing clear and realistic pretreatment informed consent(19,41).

This methodology gathers the greatest advantages offered by the telemedicine, as all preoperative information can be easily shared with colleagues in any part of the world for
instant referral or consultation, facilitating the communication and shared decision making(15,19,42).

Limitations of the technique

Despite the great advantages brought by this new technology, there are still some important drawbacks.

Probably the most problematic inconvenience is the fact that although there are advanced 3D imaging techniques capable of individually displaying the facial skeleton, dentition, and soft tissues, there is currently no single imaging technique that can accurately capture the complete triad with optimal quality for orthognathic surgery planning(31).

Besides, the third component of the triad, the overlying soft tissues, is still not reliably represented in the 3D virtual approach, compared with the high accuracy achieved with the facial skeleton and dentition models and, due to the complex nature of combined orthodontic–orthognathic treatment, the prediction of outcomes is very difficult(31). The predictability of treatment depends on the relationship between the hard and soft tissues. However, it is generally accepted that soft tissue changes do not always mimic those of the underlying hard tissues due to individual differences including the variation in the thickness of the soft tissues covering the face, variations in their tonicity, or even due to the surgical approach applied(16). In fact, neither orthodontists nor maxillofacial surgeons have been able yet to develop an objective method to evaluate the soft tissue changes caused by orthognathic surgery(31). The software used in this study doesn’t allow virtual soft tissue simulation at all, however, there are commercially available programs which use spring deformation and morphing programs for soft tissue surgical predictions(43). This is not biomechanically accurate, nor has it been validated(44–46). Since, at the moment, soft tissue prediction is still unclear, the clinician should be careful in communicating this information to the patient(34,47).

Furthermore, the clinician must not forget that 3D virtual models are, despite their accuracy, a static representation of the patient’s tissues at the point of image capture. Hence, detailed physical examination is still absolutely essential in order to obtain the extremely valuable dynamic information for precise orthognathic surgery planning(31). The virtual dynamic diagnosis (four dimensions) of the patient (e.g, smile esthetics, habits) has recently been introduced and will probably be integrated in the future(34).

In cases of 2-jaw surgery, it is particularly difficult to reposition the segments in the same way as in a surgery simulation, because, there is no reliable reference structure for repositioning the maxilla(48) and here relies another limitation of this technique: the impossibility of determining the vertical orientation of the upper jaw. The 3D surgical splint
transfers the entire 3D virtual repositioning of the maxilla (including rotations, translations, and leveling), except for its vertical position to the cranial base(34). The instability of the mandible on which the intermediate splint is placed may directly interfere with the placement of the maxilla in the desired position. In addition, the position of the maxilla serves as the target for mandibular repositioning during the actual 2-jaw surgery, and any malpositioning of the maxilla will be magnified in the mandible. The removal of the exact amount of bone necessary to create enough space for the upward repositioning of the maxilla is difficult and neither traditional splints nor CAD/CAM splints provides guidance for osteotomy(17). Here, conventional techniques, such as measuring the distances between skeletal and dental reference points, still have to be used to determine the accurate vertical level, but the length values are more easily acquired using the virtual planning software after the accurate virtual placement of the upper jaw has been carried out(21). In recent literature, a new approach has been described using individually designed templates that are placed on the fixed maxilla instead of the movable mandible(17,30,47,49,50), which eliminate the potential errors caused by autorotation of the mandible. Thereby, the vertical movement of the maxilla is controlled, and there is no need for stabilization of the intermediate occlusion because the position the maxilla is relocated independently. The position of the mandible can then be calculated using a traditional occlusal splint(17).

Finally, the manufacturing of the CAD/CAM surgical splints is still a time-consuming process. The clinician must upload the virtual treatment planning data to be processed out of office, and the surgical splint or splints need to be sent back to the clinician. Decreasing the time for out-of-office processing or in-office manufacturing could solve this problem(34).

Hardware components such as the CBCT device, the dental surface scanner or the 3D printer demand large initial costs. There is a trend toward integrating CBCT devices into dental offices. The clinician can decide to buy a CBCT device or share the purchase with other colleagues, since the benefits of 3D imaging apply to every dental discipline. However he can also refer the patient to an imaging center, saving the large initial costs to acquire such equipment(10). The plaster models and the virtual splint data can be sent to an institution offering scanning and printing services for splint production(21).

**Steps towards the Future**

Because of the limits in the scanned volume, accurate positioning of the patient in NHP in the CBCT apparatus is sometimes difficult or not feasible. Because of the long scan times, patients might move during image acquisition, resulting in movement artifacts and useless data. Improvements in CBCT hardware and software to allow larger scanned volumes (larger FOV) and decreased scan times are expected to solve these problems in the
near future. Furthermore, the gray values of a CBCT scan have no absolute Hounsfield unit calibration and, of the same tissue, these gray values change between scans and with the position of that tissue in the field of view of the scanner. Because most tissue segmentation algorithms are based on thresholding, some anatomic structures (e.g., sella turcica, condyles, orbital walls) are difficult to visualize anatomically in the 3D viewer. Several improvements in CBCT reconstruction algorithms have already been made and more are expected in the near future(34).

There are a number of potential advantages of registering anatomically accurate 3D facial surface images to CBCT data sets, such as the possibility to correct CBCT surface artifacts caused by patient movement (e.g. swallowing, breathing, head movement) as many of the newer models are vertical and CBCT scans can take anywhere from five to seventy seconds depending on each device and the imaging protocol. Moreover, independently acquired surface images compensate for soft tissue compression from up-right CBCT stabilization aid devices (e.g. chin rest, forehead restraint), and eliminate soft tissue draping from supine CBCT devices. Finally, surface images most notably supplement missing anatomical data (e.g. nose, chin) that occurs with the upright CBCT devices, and they typically provide a more accurate representation of the draping soft tissue that reflects the patient’s natural head position for diagnosis and treatment planning. With a highly accurate 3D surface image of the patient’s face, the practitioner can actually measure the geometric shape changes that result from treatment(14). Therefore, it could be of great interest to fuse CBCT data sets with some emerging imaging technologies like 3D surface images (3D photography or laser surface scanners), ultrasound, or even MRI to isolate soft tissues(14). The most accessible and non-invasive techniques are the 3D photography and laser surface scanning, with the first having a shorter acquisition time, but the second being more accurate if the scanned patient is not moving(34). Regarding the lack of validation that still exists for the soft tissue simulation tools of the commercially available software programs, the usage of an inhomogeneous biomechanical model, which distinguishes the mechanical behaviour of fatty and muscle tissue and considers individual soft tissue thicknesses and properties in the model generation should be further investigated. By individually adapting the input parameters, the validity and reliability of the procedure of soft tissue simulation would be optimized(45,46). These improvements would be of great value considering the large number of patients undergoing this type of surgery for aesthetic reasons(14,19).

In this study, it was necessary to incorporate the plaster dental casts scan in the 3D image to upgrade the precision of dental image details, but this step, as well as the need for dental impressions, could be eliminated when further progress is made in the acquisition of 3D images of dental structures. This may come with the introduction of intraoral scanners
into clinical practice, and in the future, advances in CBCT itself may result in the obtainment of more precise images of patients’ teeth in a single scan\(^{(19)}\).

It could be valuable to incorporate these emerging technologies into surgical training programs. There is potential for great benefit to residents by allowing them to perform surgical procedures in three dimensions before entering the operating room. This virtual training allows them to practice procedures as well as to attempt different surgical scenarios, with the aim of increase the accuracy and decrease the error and the operating time\(^{(43)}\).

**Considerations on this study**

During the virtual repositioning of the maxilla, the movements of impaction and advancement were performed according to the conventional treatment plan obtained by clinical examination. That was necessary since the software does not enable soft tissue simulations and consequently, does not allow the guidance of the jaw movements through visualization of soft tissue corresponding changes until the intended profile projection and the ideal exposure of maxillary anterior teeth are achieved.

The methodology of this study could integrate the use of plaster models to manually determine the post-surgical occlusal relationship. Thereby, the clinician wouldn’t need to abandon haptic involvement, and important details of interdigitation, occlusal anatomy, and wear facets could be precisely transformed into the virtual situation. This would prevent the false appearance of cross-bite or overjet on the monitor screen and other difficulties in virtually aligning the occlusion to obtain the best teeth intercuspation, which are challenging and time consuming\(^{(21)}\).

In the presented case, during the virtual planning it wasn’t found enough space between the two tooth rows to allow insertion of the virtual splint without moving the lower jaw. In this cases, a virtual vertical opening of the lower jaw is unavoidable. Therefore, the software program automatically defines a rotational axis through both mandible joints, which approximately simulates the movement of the lower jaw\(^{(21)}\). However, this simple rotation does not really take into consideration the individual anatomic situation of each patient, which represents a limitation of the protocol.

Knowing that there is a significant difference between the manufacturing of the splints with CAD/CAM technology and conventional methodology, we compared surgical splints manufactured using both techniques in the operating room. The high similarity found between both types of surgical splints allow us to conclude that the CAD/CAM method is a valid and reliable technique for designing surgical splints that will accurately reproduce our 3D virtual planning in the operating room.
During surgery, the lack of retention of the CAD/CAM splints, perceived by the surgeon regarding the mandibular teeth, may be explained by the fact that in the 3D virtual planning, the limit set for the indentations of the mandibular incisal edges and cusps of the teeth in the splints (Image 14) did not have the ideal height to obtain an adequate retention, due to the location of the orthodontic brackets perhaps. However, that wasn’t critical and the surgeon was able to use both the CAD/CAM splints in the surgery.

![Image 14](Image 14 – Virtual generation of the surgical splints showing the limit set for the indentations of the maxillary (left) and mandibular (right) incisal edges and cusps of the teeth in the splints.)

Considering the post-surgical prediction results, we would describe them as encouraging but not sufficiently accurate. As shown in the Table I, the linear measurements reflect some large discrepancies between the actual surgical outcomes and the predicted results from the 3D virtual simulation. Caution must be taken in the analysis of these results. There are several variables which can affect the results, such as the difficulty of locating and placing some 3D anatomic landmarks using CBCT-generated volumetric images and slices (this difficulty was perceived at most on dental landmarks), variables inherent to surgical procedures and the influence of post-surgical relapse on hard tissues. Ideally, the discrepancy between the virtually predicted and the actually obtained post-surgical outcomes should be evaluated by superimposition of this data in the same image. That was not possible due to technical limitations of the softwares used. The discrepancies found particularly in the anterior region of the maxillo-mandibular complex (reflected in the measurements for the anterior teeth (11, 13, 23, 41, 33, 43) might be explained with an excessive anterior maxillary bone removal after Le Fort I osteotomy, leading to a non-predicted excessive mandibular counter-clockwise rotation, perceived in the excessive Pogonion (Pg) advancement. This might be explained with the impossibility of controlling the vertical movement of the maxilla with the surgical splint technique. It is, thus, possible to state that the software studied still does not allow an absolutely accurate prediction of
results, and the impossibility to simulate changes in soft tissues is a limitation that should be corrected in the near future.

The software program used in this study (Nemoceph 3D-OS (Software Nemotec SL, Madrid, Spain)) requires a learning curve, although the graphical user interface tools and functions are familiar and intuitive. To enable the clinician to make this major paradigm shift in routine planning of orthognathic surgery, both image acquisition systems and 3D virtual planning software must become user-friendly, easily accessible, and available at a relatively low cost.

It would be of great interest to expand this study to a larger sample size in order to enable a more exhaustive analysis of the post-surgical prediction results, not only on hard tissues, but also on soft tissues, by means of software tools allowing both types of simulations.

5. **CONCLUSION**

It is extremely important that the orthodontists and maxillofacial surgeons are always updated about the evolution on techniques of obtaining images, fundamental for diagnosis, given that technology is a strong ally for the success of both orthodontic treatment and orthognathic surgery.

Recent advances in three-dimensional medical imaging for orthognathic surgery have enabled a huge evolution on this field and allowed unprecedented virtual diagnosis, treatment planning, and evaluation of treatment outcomes of maxillofacial deformities.

This study confirmed the clinical feasibility of a computer-assisted orthognathic surgical protocol incorporating virtual planning and its transfer to the operating room using CAD/CAM fabricated surgical splints. Postoperative predictions still lack some reliability and further study with larger sample size is necessary to confirm the results obtained in this study.

Further progress is required in the development of technologies for 3D image acquisition and improvements on software programs to simulate postoperative changes on soft tissues.
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References


3D virtual planning in Orthognathic Surgery and CAD/CAM Surgical Splints generation


