Int. J. Oral Maxillofac. Surg. 2013; xxx: xxx–xxx
http://dx.doi.org/10.1016/j.ijom.2013.03.025, available online at http://www.sciencedirect.com

International Journal of Oral & Maxillofacial Surgery

Research Paper
Orthognathic Surgery

New protocol for three-dimensional surgical planning and CAD/CAM splint generation in orthognathic surgery: an in vitro and in vivo study

F. Hernández-Alfaro[1,2], R.Guijarro-Martínez[1]
[1]Institute of Maxillofacial Surgery, Teknon Medical Centre, Barcelona, Spain;
[2]Department of Oral and Maxillofacial Surgery, Universitat Internacional de Catalunya, Barcelona, Spain

F. Hernández-Alfaro, R. Guijarro-Martínez: New protocol for three-dimensional surgical planning and CAD/CAM splint generation in orthognathic surgery: an in vitro and in vivo study. Int. J. Oral Maxillofac. Surg. 2013; xxx: xxx–xxx.

Abstract. Inaccurate visualization of the inter-occlusal relationship has raised an important challenge to virtual planning for orthognathic surgery based on cone beam computerized tomography (CBCT). The aim of this study was to evaluate an innovative workflow for orthognathic surgery planning and surgical splint fabrication. The clinical protocol consists of a single cone beam computerized tomography (CBCT) scan of the patient, surface scanning of the dental arches with an intraoral digital scanner, and subsequent fusion of the two datasets. The ''virtual patient'' thus created undergoes virtual surgery, and the resulting file with the intermediate intermaxillary relationship is used to obtain the intermediate splint by CAD/CAM technology (computer-aided design and computer-aided manufacturing). A proof-of-concept study was performed in order to assess the accuracy and reliability of this protocol. The study comprised two parts: an in vitro evaluation on three dentate skull models and a prospective in vivo assessment on six consecutive patients. Vector error calculation between the virtually simulated intermaxillary position and the intraoperative intermediate intermaxillary relationship revealed high accuracy. The greatest average variation corresponded to the *y* axis. Compared to previously described methods for obtaining an augmented three-dimensional virtual model, this procedure eliminates the need for dental impressions, simplifies the necessary technical steps and computational work, and reduces the patient's exposure to ionizing radiation.

Key words: CBCT; cone beam computed tomography; virtual planning; orthognathic surgery; digital scanner.

Accepted for publication 20 March 2013

The basis for three-dimensional (3D) virtual planning in orthognathic surgery is to obtain a virtual anatomic model of the patient that includes the facial soft tissue mask, underlying bone, and teeth.[1] Although the incorporation of cone beam computerized tomography (CBCT) in conjunction with appropriate computer software and hardware has provided an unprecedented tool for the diagnosis and treatment planning of cranio-maxillofacial anomalies,[2,3] inaccurate visualization of

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the inter-occlusal relationship has raised an important challenge to accurate virtual planning for orthognathic surgery.

The reason for this inaccurate visualization of teeth is the surface representation mechanism of CBCT data. In fact, this is an inherent problem of computed tomography technology. Furthermore, orthodontic appliances and dental restorations may cause significant scattering during the scanning process. As a result, a single scan of the patient does not provide adequate occlusal and intercuspation data for precise orthognathic surgery planning. Thus, for a long time, conventional plaster models have been the only way to accurately establish the occlusion and fabricate surgical splints.[4,5]

Several research groups have studied the incorporation of plaster dental models into physical bone models.[6–11] These methods have achieved simultaneous representation of bony structures and accurate dentition, but unfortunately they have not been suitable for computerized virtual osteotomies.[2] In 2003, Gateno et al.[2] reported the first clinically applicable method to integrate an accurate rendition of teeth into the computerized 3D skull model. Their method consisted of laser scanning the patient's dental impressions with fiducial markers and then incorporating this data into the skull, thereby creating a composite skull model.

Subsequently, Swennen et al.[12] developed an original technique to augment the 3D virtual model of the patient with accurate dental data based on a triple scan procedure (a first CBCT scan of the patient, a second CBCT scan of the patient with a double impression tray in the mouth, and a third CBCT scan of the impression tray alone). Both methods eliminate the need for plaster models; in addition, the technique of Swennen et al.[12] eliminates the need for markers.

The aim of this study was to evaluate an innovative workflow for orthognathic surgery planning and surgical splint fabrication. This workflow is based on a single CBCT scan of the patient, surface intraoral scanning of the dental arches, and subsequent fusion of the two sets of data. The 'virtual patient' thus created undergoes virtual surgery, and the file with the intermediate intermaxillary relationship (either mandibular or maxillary repositioning in a mandible-first or a maxilla-first bimaxillary surgery context) is used to obtain the intermediate splint by CAD/CAM technology (computer-aided design and computer-aided manufacturing). We designed a proof-of-concept study prior to the implementation of this protocol at our centre, in order to assess its accuracy and reliability. The study comprised an in vitro and an in vivo evaluation.

Materials and methods

In order to systematically assess our protocol for 3D planning in orthognathic surgery, two separate evaluations were conducted.

Part I: in vitro study

The first evaluation was performed on three dry dentate skull models. A CBCT scan of each skull was obtained with the IS i-CAT device, version 17-19 (Imaging Sciences International, Hatfield, PA, USA). The radiological parameters used were 120 kV, 5 mA, scan time 7 s. The axial slice distance for each scan was 0.300 mm^3. A 23-cm field of view (FOV) was used. Primary images were stored as 576 DICOM data files. The resulting raw file from each skull was segmented with SimPlant Pro OMS software (Materialise Dental, Leuven, Belgium) in order to obtain a 'clean' 3D representation, which was then stored as an STL file (Fig. 1).

Subsequently, surface scanning of each skull's dental arches was achieved with the Lava Scan ST scanner (3M ESPE, Ann Arbor, MI, USA), thereby producing another STL file. The two STL files were fused using the SimPlant Pro OMS software with a 'best fit' algorithm. The system used surface-based rigid registration using ICP (iterative closest point) in order to minimize rotational and translational differences between the two datasets. A 'virtual patient' was thus generated from each skull's corresponding pair of STL files.

The same software was then used to perform a bilateral sagittal split osteotomy (BSSO) in each virtual patient. A 'mandible-first' protocol was used. Three different virtual scenarios for mandibular repositioning were recreated: skull 1, mandibular advancement; skull 2, mandibular setback; skull 3, mandibular cant correction. Three separate STL files were thus obtained. These files allowed for CAD/CAM fabrication of three intermediate splints out of photopolymerizable resin.

Subsequently, the splints were used to position each mandible in the corresponding intermediate position related to the immobilized maxilla (Fig. 2). Each skull was then 'intraoperatively' rescanned with the IS i-CAT (Fig. 3). The three new STL archives thus obtained reflected the three alternatives for mandibular repositioning that had been planned preoperatively.

Finally, the three virtual planning files were superimposed onto their corresponding 'intraoperative' scans (mandibular repositioning with the intermediate splint) by means of the Mimics software (Materi-

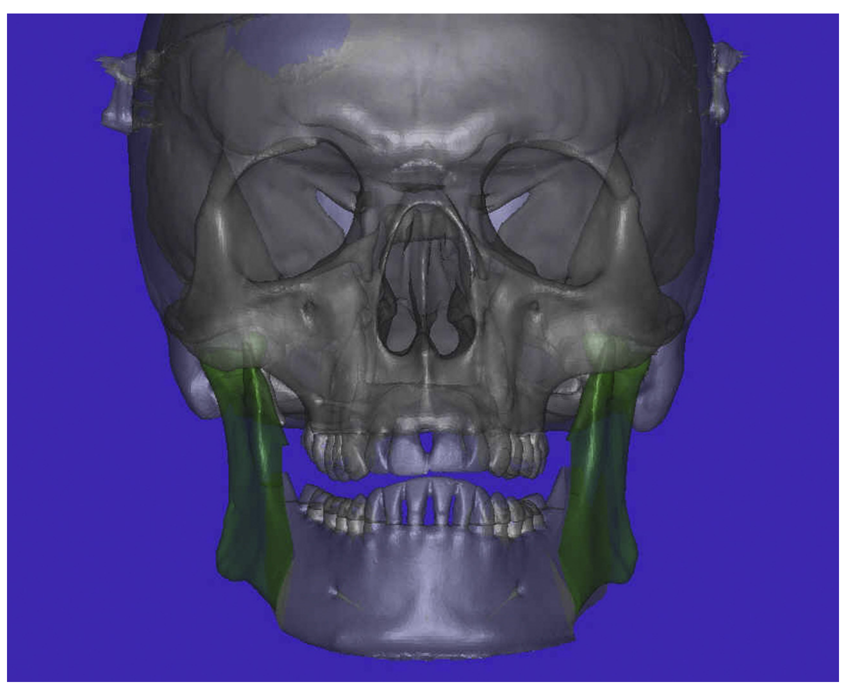

Fig. 1. In vitro study: virtual planning. Mandibular repositioning after bilateral sagittal split osteotomy. The STL file allowed for the generation of a CAD/CAM intermediate splint.

Fig. 2. In vitro study: dry skull 'surgery'. Mandibular repositioning with the CAD/CAM generated splint.

alise Dental) (Fig. 4). In each case, the preoperative plan was superimposed onto its corresponding 'intraoperative' scan by registering the skull and maxilla, i.e., the non-repositioned skeleton. The registration algorithm minimized the distance between the preoperative 3D model of the skull and maxilla and the mask (in other words, the segmentation) of the skull and maxilla in the 'intraoperative' scan. After an initial global registration to achieve a good starting position, a local registration was carried out on the points within a specified distance from the border of the mask. This local registration was repeated until the residual distance error was constant. The software MathWorks Inc. (Natick, MA, USA) was used to calculate the distance between each point of the repositioned mandible in the 'intraoperative' scan and its corresponding point in the virtual planning file. These distances were globally visualized by means of a colour scale overlaid on the 'intraoperative' models (Fig. 5). The range, average distance error, and standard deviation were calculated for each skull. For these calculations, all vertices of the STL representation of the repositioned bone were taken into account. Similarly, the average distance vector, i.e., the average distance between corresponding points on the *x*, *y*, and *z* axes, was calculated.

Part II: in vivo study

The second evaluation within this proof-of-concept study was performed in vivo. Six consecutive patients in whom bimaxillary surgery was indicated were prospectively recruited for this assessment. The guidelines of the Declaration of Helsinki were followed at all treatment stages. Institutional review board approval was obtained.

In all cases, data acquisition for 3D surgical planning began 3 weeks before surgery with a CBCT scan (IS i-CAT device version 17-19; Imaging Sciences International). The same radiological parameters as in part I of the study were used. A 7-s scan was taken with the patient breathing quietly, sitting upright in natural head position (NHP), the tongue in a relaxed position, and the mandible in centric relation with a 2 mm wax bite in place in order to avoid direct tooth contact. The raw file was then segmented with SimPlant Pro OMS in order to obtain a 'clean' 3D representation that was stored as an STL file (Figs. 6 and 7).

On the same day the patient received the CBCT scan, surface scanning of both dental arches was achieved with the intraoral Lava Scan ST scanner (3M ESPE), thereby producing another STL file. The two STL files were then fused using the SimPlant Pro OMS software (Materialise Dental) with a 'best fit' algorithm. A 'virtual patient' was thus generated.

The same software was used to perform the preoperative bimaxillary plan in each virtual patient (Fig. 8). The maxilla was mobilized first in three patients; a 'mandible-first' protocol was used in the remaining three. Six 'intermediate' files were thus obtained. These were electronically submitted to the CAD/CAM centre (Materialise Dental), where the intermediate wafers were produced by means of stereolithography.

All six patients were operated under general anaesthesia by the same surgeon (FHA). At the time of surgery, following Le Fort I osteotomy or BSSO, the maxilla or mandible were brought into relation with the opposing dentition via the CAD/CAM intermediate wafer. Subsequently, an intraoral scan of both dental arches related by the wafer was performed with the Lava Scan ST scanner (Fig. 9).

Postoperatively, the virtual planning file from each patient was superimposed onto the intraoperative file (surface scanning of both arches related by the intermediate splint after mandibular/maxillary repositioning) (Fig. 10). The software MathWorks Inc. was used to calculate the discrepancies between the virtual simulation and the intraoperative scan using ICP surface matching (Figs. 11 and 12). A similar procedure to that explained for the in vitro study was followed.

Results

Part I: in vitro study

Total intraoral scanning time for the three skulls was 15 min 40 s on average (range 12 min 10 s to 16 min 20 s).

The average distance error was greatest for mandibular setback (1.49 ± 0.13 mm,

Fig. 3. In vitro study: 'intraoperative' CBCT scanning of the dry skull after mandibular repositioning with the CAD/CAM splint.

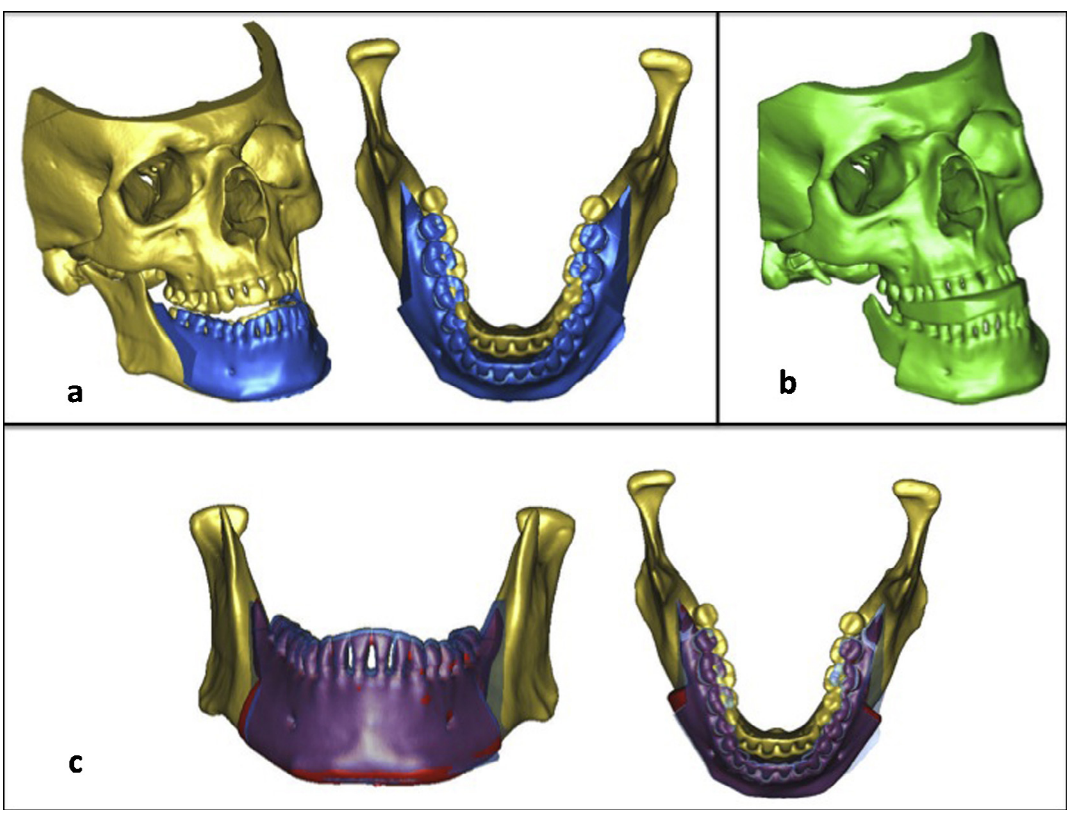

Fig. 4. In vitro study: case example 1 (mandibular advancement). (a) Preoperative planning. The original model is shown in yellow, while the planned position of the mandible is shown in blue. (b) 'Intraoperative' scan after mandibular repositioning with the CAD/CAM splint. (c) Registration ('best fit' superimposition) of the STL archives corresponding to the preoperative surgical simulation and the 'intraoperative' CBCT scanning of the dry skull with the repositioned mandible. The original mandible is shown in yellow, the planned position of the mandible in blue (transparent), and the 'intraoperative' position of the mandible in red. Due to the transparency of the planned model, a purple colour results. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of the article.)

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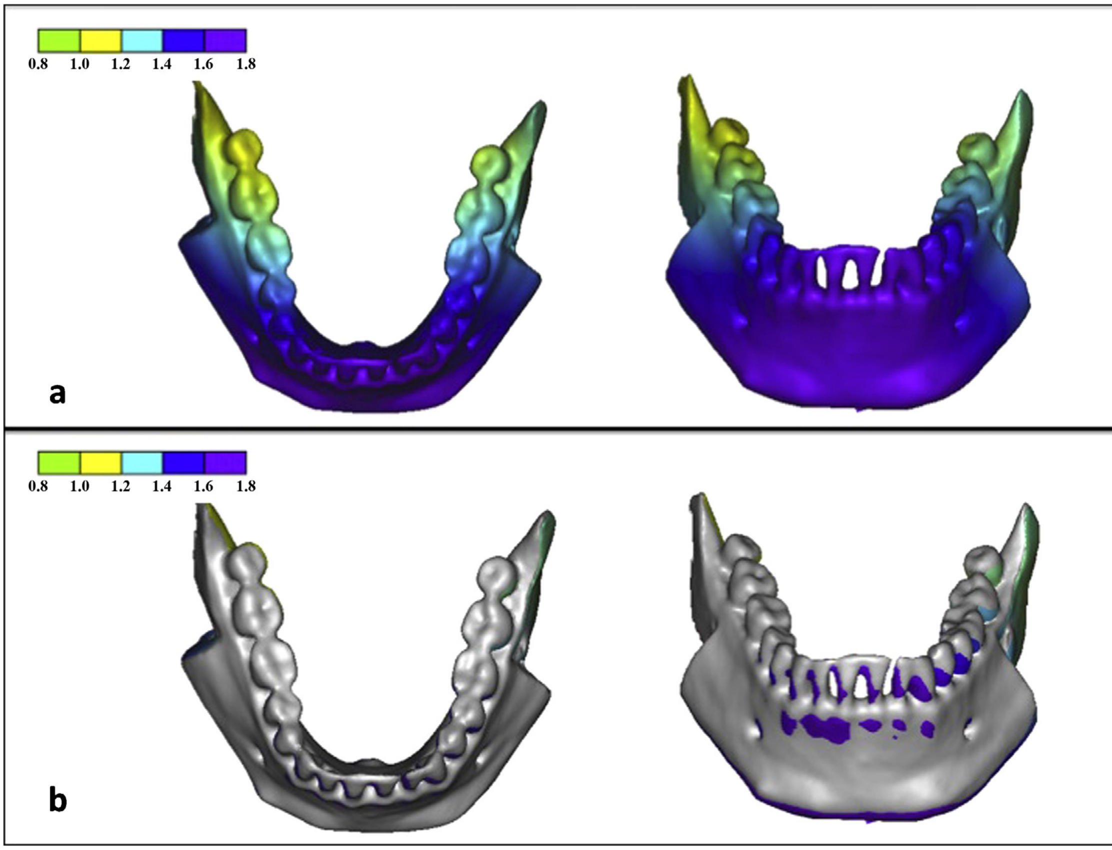

Fig. 5. In vitro study: case example 1 (mandibular advancement). Calculations with MathWorks Inc. (a) Distances between corresponding points (repositioned mandible in the 'intraoperative' scan vs. virtual planning file) are represented with a colour code. (b) Same distance calculations with superimposition of the virtually planned mandible (grey model).

range 1.31–1.77 mm), followed by mandibular advancement (1.35 ± 0.20 mm, range 0.97–1.73), and least for mandibular cant correction (1.15 ± 0.12 mm, range 0.87–1.35 mm).

The average distance vectors for the three superimpositions are shown in Table 1. The greatest discrepancy between the virtually planned position and the actual intermediate position was found in the *y* (vertical) axis.

Part II: in vivo study

The operated sample comprised three females and three males (average age at the time of surgery 23.7 years, range 19–37 years). There were no significant intraoperative or postoperative complications. All six patients were discharged from the hospital 24 h after the procedure. The outcome of the surgery was rated by the patients as 'excellent' in five cases and 'good' in one.

Total intraoral scanning time was 19 min 45 s on average (range 17 min 50 s to 22 min 5 s). The complete surgical procedure (including the intraoral scan) lasted 136 min on average (range 110–156 min).

Average distance error calculations are detailed in Table 2. Globally for the six patients, the average distance error ranged within 0.25 and 1.39 mm.

Average distance vectors for the six patients are shown in Table 3. The greatest discrepancy between the virtually planned position and the actual intermediate position was also found in the *y* (vertical) axis.

Discussion

Modern 3D virtual planning for orthognathic surgery has critical advantages compared to conventional treatment planning. First, the clinician has intrinsic

Table 1. Part I: in vitro study. Average distance calculation for each axis (mm): comparison between the virtually planned position and the actual intermediate position (MathWorks Inc., Natick, MA).

	X	*Y*	*Z*
Skull 1	−0.05	1.11	0.24
Skull 2	0.14	1.25	0.00
Skull 3	0.19	1.41	0.29
Mean	0.09	1.26	0.18

Table 2. Part II: in vivo study. Average distance error calculation (mm): comparison between the virtually planned position and the intraoperative intermaxillary dental relationship (MathWorks Inc., Natick, MA).

	Procedure	Mean	SD	Range
Patient 1	MMA, advancement genioplasty. Maxilla first	0.25	0.12	0.05–0.69
Patient 2	Maxillary advancement, mandibular adjustment, advancement genioplasty. Maxilla first	0.38	0.16	0.10–0.58
Patient 3	MMA, maxillary cant correction, advancement genioplasty. Maxilla first	1.39	0.22	0.09–1.52
Patient 4	MMA, mandibular cant correction. Mandible first	1.04	0.10	0.07–1.21
Patient 5	MMA, posterior maxillary descent. Mandible first	0.53	0.22	0.60–1.06
Patient 6	MMA, maxillary cant correction. Mandible first	0.69	0.14	0.04–1.45

MMA, maxillomandibular advancement; SD, standard deviation.

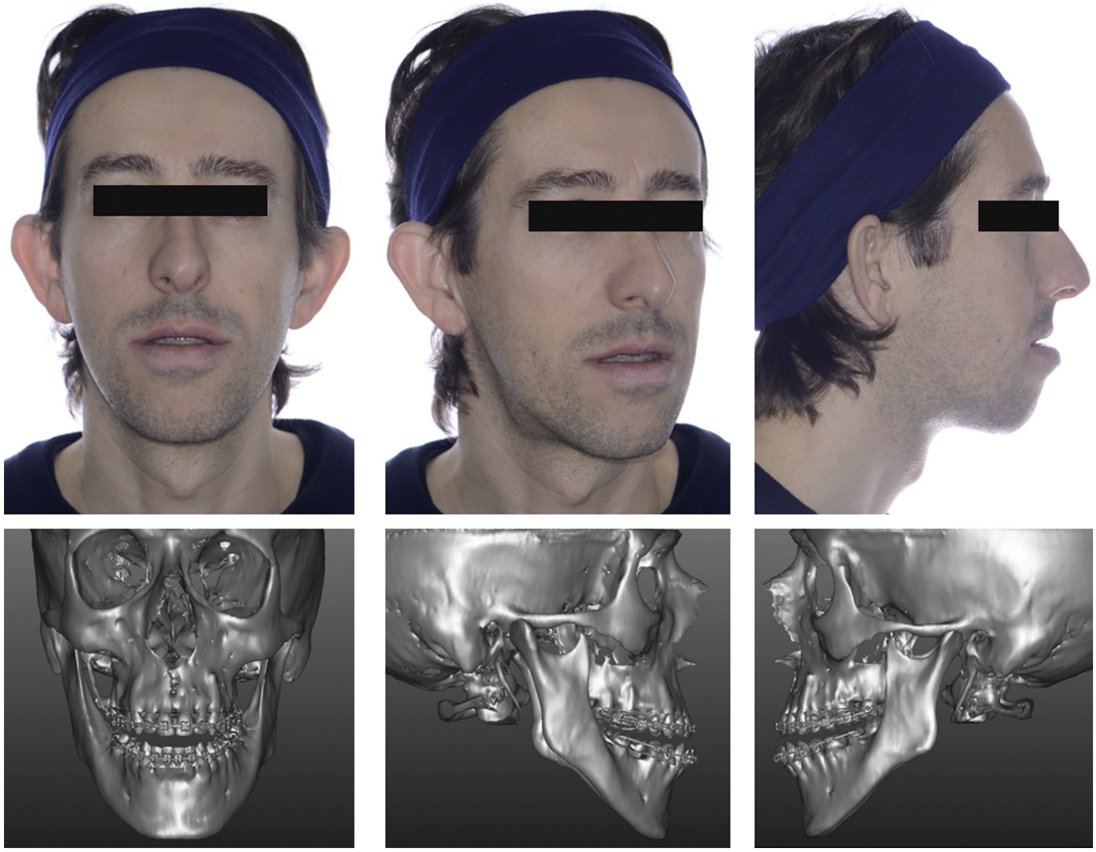

Fig. 6. In vivo study: case example 2. Top: extraoral pictures. Bottom: 3D representation.

access to more and higher-quality information about the patient's 3D anatomy. This allows the clinician to focus on 3D facial harmonization rather than on facial profile correction.[1] Second, as opposed to conventional model surgery on plaster models, infinite surgical plans can be tested on the 'virtual patient' with the appropriate software. Third, surgical splints can be manufactured with rapid prototyping techniques in order to accurately transfer the virtual plan to the operating room. The reliability of these CAD/CAM-generated splints has already been validated.[13,14] Fourth, virtual surgery planning is a powerful communication tool between colleagues, can be used to teach trainees, and is a very illustrative method to explain the treatment plan to the patient. Fifth, treatment outcome evaluation is possible through techniques of voxel-based rigid registration and superimposition on a 3D reference system.[15–17]

Table 3. Part II: in vivo study. Average distance calculation for each axis (mm): comparison between the virtually planned position and the intraoperative intermaxillary dental relationship (MathWorks Inc., Natick, MA).

	X	*Y*	*Z*
Patient 1	0.1	0.9	0.0
Patient 2	0.0	0.8	0.2
Patient 3	0.4	0.1	0.2
Patient 4	0.0	0.1	0.3
Patient 5	0.2	0.4	0.3
Patient 6	0.2	0.7	0.5
Mean	0.15	0.5	0.25

On the other hand, important drawbacks exist. 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.[1,2,12,18–22] In fact, from an image acquisition point of view, it is not expected that this will be feasible in the near future either, because teeth segmentation is extremely difficult as a result of intermaxillary and interdental tooth contact. Teeth require higher segmentation accuracy than bone, and hence there are different resolution requirements for one single scan. Moreover, the required cuspidation detail (0.1 mm) requires that the patient's position does not vary more than 0.1 mm during the scanning process, which is clinically impracticable.[12] This dilemma emphasizes the importance of the fusion of the data provided by the different 3D imaging modalities in order to obtain an augmented virtual model that integrates all three components of the triad.

The search for the method to integrate a precise representation of the dentition into the 3D skull model has been a long road. Several techniques to incorporate an accurate dentition into a 3D milled or stereolithographic skull model were reported,[6–11] after which a clinically applicable method valid for virtual surgery planning was developed.[2] The technique by Gateno et al.[2] consists of scanning the dental impressions with a laser surface scanner and then incorporating them into the CT scan of the skull. The basis for the fusion process is the addition of fiducial markers to the impression tray. In a clinical context, the fiducial markers are spheres that are part of a plastic face-bow that is attached to an acrylic bite registration.[22] The patient is scanned with the face-bow, and subsequently the plaster dental models, bite jig, and face-bow undergo surface scanning. The alignment of the fiducial markers permits the incorporation of the

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Fig. 7. In vivo study: case example 2. Intraoral pictures.

dental data into the skull model. Despite the innovativeness of this method, the titanium spheres cause distortion of lip morphology and posture, thereby interfering with accurate soft tissue rendering.[19] In addition, although this technique has the potential to eliminate the need for plaster dental models, the authors still fabricate them to help them establish the final occlusion.[22]

After considerable research work,[19,23–25] Swennen et al.[12] proposed an alternative way to augment the 3D virtual model of the patient without the use of plaster dental models or markers and without facial soft tissue deformation. Their method is based on a triple CBCT scan procedure: (1) CBCT scan of the patient in NHP, with central occlusion and relaxed lips; (2) second low-resolution CBCT scan of the patient with a double impression tray in the mouth; and (3) high-resolution CBCT scan of the impression tray alone. An additional advantage of this method is vertical CBCT scanning of the patient, as opposed to horizontal CT scanning used in the method by Gateno et al.[2,22] However, two CBCT scans of the patient are required, which inevitably leads to higher radiation exposure. From a computational point of view, the elaboration and valida-

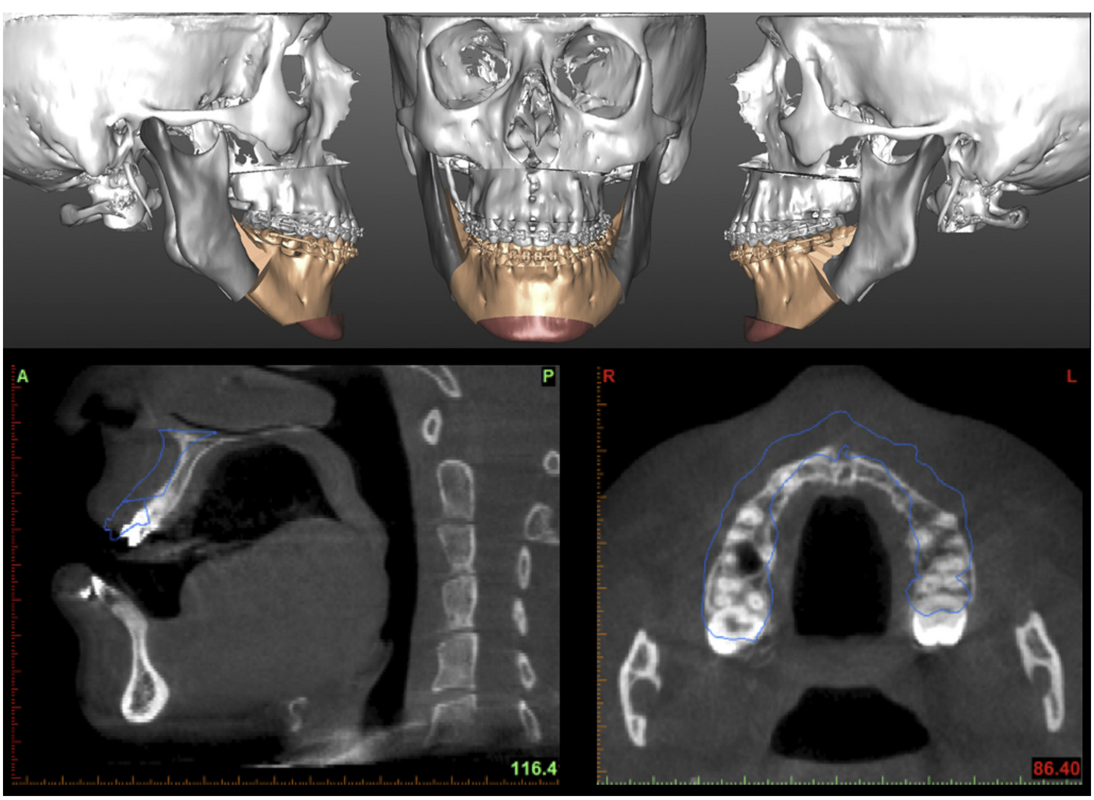

Fig. 8. In vivo study: case example 2. Preoperative planning on the augmented virtual model. A bimaxillary procedure with 7 mm maxillary advancement, mandibular anticlockwise rotation, and 4 mm advancement genioplasty was planned. Top: complete preoperative plan. Bottom: intermediate intermaxillary relationship. In this case, a maxilla-first protocol was followed.

Fig. 9. In vivo study: intraoperative surface scanning of the dental arches related by the CAD/CAM intermediate splint.

tion of the sequential triple voxel-based registrations are very demanding.[12] The risk of patient movement during the first scan is an additional problem, although it can be minimized by shorter-acquisition time scanners. Finally, a high level of patient cooperation is required so that the patient correctly bites into the wax bite wafer (CBCT scan 1) and into the triple impression tray (CBCT scan 2) in order to avoid erroneous registrations.

The authors of this study propose a different method to digitize the patient's dentition for the virtual skull model. This method takes advantage of state-of-the-art digital impression technology such as chairside intraoral scanners, which obtain the 3D data of the dentition directly from the patient, without the need for plaster models or impression materials of any kind.[18] Data acquisition is not based on ionizing X-ray radiation but rather on active wavefront sampling with structured light projection. The 3D data are captured in a video sequence and/or real-time models (approximately 20 3D datasets per second). The resulting STL file is fused with the STL file of the patient's CBCT scan of the head using the appropriate software, thereby incorporating a precise dentition into the skull model. A 'virtual patient' is thus easily generated.

Compared to the previously described methods to obtain an augmented 3D virtual model, this procedure eliminates the need for any dental impressions. Dental data are directly obtained by a single surface scan of the patient's dental arches. Although in the in vivo evaluation of this study it was found that total intraoral scanning (upper and lower arches) needs an average of 20 min, data acquisition times will most likely be reduced in the near future. In addition, the elimination of additional intermediate steps (occlusal bite wafers, dental impressions, or plaster models) and subsequent risk of error accumulation should result not only in an optimization of time but also, and most importantly, an increase in data accuracy. The fact that dental impressions are not necessary is a step forward in patient comfort and technical simplicity. In addition, as opposed to the method by Swennen et al.,[12] the patient receives a single CBCT scan, thereby reducing radiation exposure.

Despite these significant advantages, the authors designed a proof-of-concept study prior to the routine implementation of this protocol. The aims were to objectively assess accuracy and reliability using a two-part study, in vitro and in vivo. The basis for including an in vitro analysis was that surgery itself could introduce a bias in the evaluation of accuracy, such that an in vivo study alone would not be able to differentiate whether the deviation error was associated with the technical protocol itself or whether it was surgeon/surgery-related. The results of part I (in vitro assessment) showed that the pre-planned intermaxillary relationship after virtual mandibular repositioning was very close to the actual position achieved with the use of the intermediate splint. Indeed, the average distance vector error was below 0.20 mm for the x and z axes. The fact that

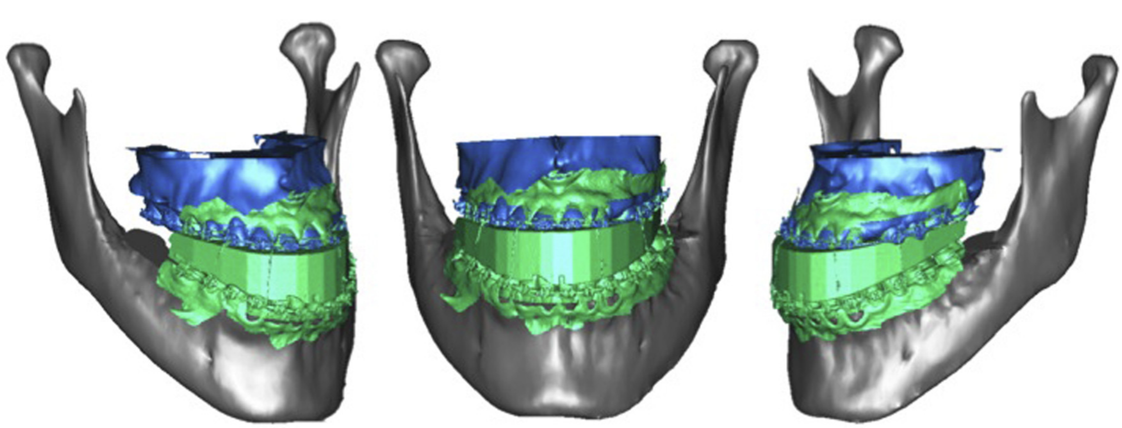

Fig. 10. In vivo study: case example 2. Registration ('best fit' superimposition) of the virtually planned intermediate position (in blue) to the actual intraoperative intermediate relationship (in green). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of the article.)

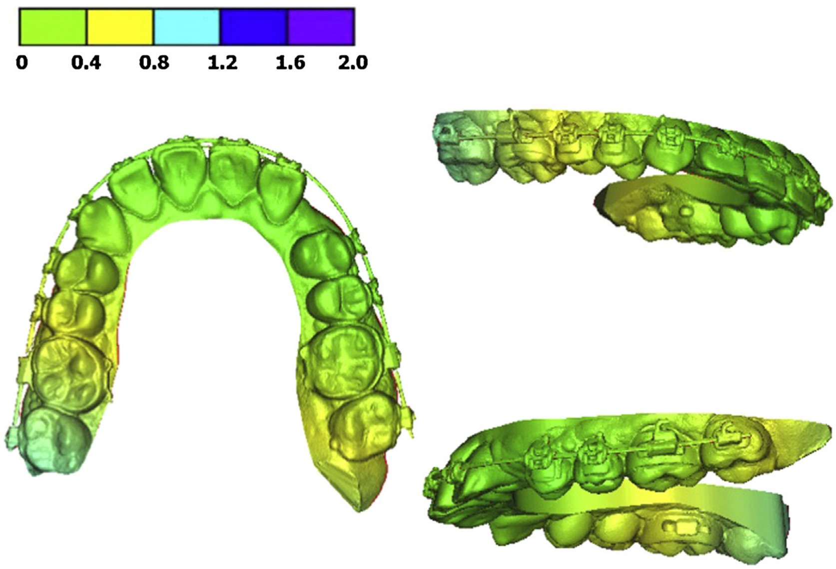

Fig. 11. In vivo study: case example 2. Calculations with MathWorks Inc. The distance between each point of the repositioned maxilla and its corresponding point in the virtual planning file are represented by means of a colour scale. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of the article.)

this error was higher for the *y* axis might represent an imperfect vertical adjustment of the teeth within the intermediate splint. In part II (in vivo assessment), the virtual planning file from each of the six studied patients was superimposed onto the intraoperative file (surface scanning of both arches related by the intermediate splint after mandibular/maxillary repositioning). Obviously, in this second study, only the buccal aspect of both arches (related to each other through the CAD/CAM intermediate splint) was captured. Average vector error calculations were 0.15 mm for the *x* axis, 0.5 mm for the *y* axis, and 0.25 mm for the *z* axis. Again, the *y* axis showed the greatest error. Indeed, it seems that perfect adjustment within the splint is more difficult to achieve in the *y* axis. But the fact that the average distance error was below 1.5 mm for both the in vivo and in vitro assessments indicates a high global accuracy of the intermediate wafers. Clinically, positional variations within the range of 1.5 mm are tolerable when it comes to repositioning the maxilla or mandible. Hence, the average 1.26 mm in vitro distance error and especially the 0.5 mm in vivo distance error represent reasonable accuracy in the *y* axis. Nevertheless, alternative materials for the fabrication of splints should be investigated in order to improve vertical adjustment.

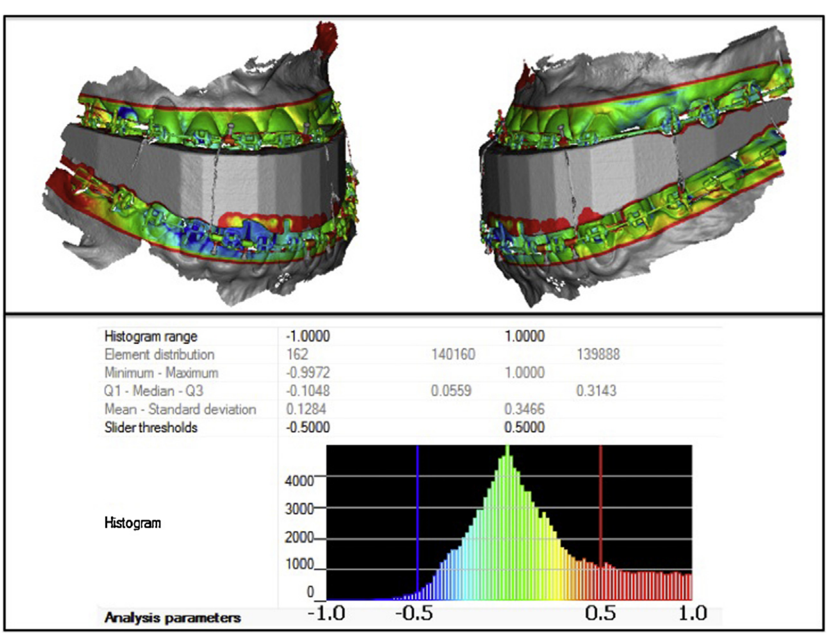

Fig. 12. In vivo study: case example 2. Calculations with MathWorks Inc. Deviation analysis of the intraoperative intermaxillary relationship. The Gaussian curve shows most deviations are within the range of −0.5 and 0.5 mm.

Even though this method achieves a highly accurate representation of the dental and skeletal anatomy with a short series of simple steps, further clinical validation on a larger population sample is still necessary. In addition, the method has inherent limitations that must be acknowledged. First, the use of intraoral digital scanners in the routine clinical setting is still not widespread due to economic issues. Nevertheless, the cost of the device is outweighed by the optimal accuracy of CAD/CAM dental restorations and surgical splints, the ease of data acquisition and processing, and the opportunity to perform detailed 3D volumetric analyses in multiple fields. Second, despite this method achieving a highly accurate model of the facial skeleton and dentition, the third component of the triad, the overlying soft tissues, is not reliably represented. In fact, orthodontists and maxillofacial surgeons have not yet been able to develop an objective method to evaluate the soft tissue changes caused by orthognathic surgery.[18,26,27] At any rate, obtaining an accurate textured facial soft tissue surface was not an aim of this study. Finally, the clinician must not forget that augmented 3D virtual models are, despite their accuracy, a static representation of the patient's tissues at the point of image capture.[22] Hence, detailed physical examination is still absolutely essential in order to obtain the extremely valuable dynamic information for precise orthognathic surgery planning.

Funding

None.

Competing interests

None declared.

Ethical approval

The study received ethical approval from the Ethics Review Board of the Teknon Medical Centre Barcelona (2011-FHA-004).

Acknowledgements. The authors would like to thank Tomás Charles, Veerle Pattijn and José Antonio Alonso for their technical assistance.

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Address:
Federico Hernández-Alfaro
Institute of Maxillofacial Surgery
Teknon Medical Centre
Vilana
12
D-185
08022 Barcelona
Spain
Tel: +34 933 933 185
E-mail: director@institutomaxilofacial.com

Please cite this article in press as: Hernández-Alfaro F, Guijarro-Martínez R. New protocol for three-dimensional surgical planning and CAD/CAM splint generation in orthognathic…, *Int J Oral Maxillofac Surg* (2013), http://dx.doi.org/10.1016/j.ijom.2013.03.025