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Accuracy of a Computer-Aided Surgical Simulation (CASS) Protocol for Orthognathic Surgery: A Prospective Multicenter Study

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Abstract

Purpose—The purpose of this prospective multicenter study was to assess the accuracy of a computer-aided surgical simulation (CASS) protocol for orthognathic surgery.

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Materials and Methods—The accuracy of the CASS protocol was assessed by comparing planned and postoperative outcomes of 65 consecutive patients enrolled from 3 centers. Computer-generated surgical splints were used for all patients. For the genioplasty, one center utilized computer-generated chin templates to reposition the chin segment only for patients with asymmetry. Standard intraoperative measurements were utilized without the chin templates for the remaining patients. The primary outcome measurements were linear and angular differences for the maxilla, mandible and chin when the planned and postoperative models were registered at the cranium. The secondary outcome measurements were: maxillary dental midline difference between the planned and postoperative positions; and linear and angular differences of the chin segment between the groups with and without the use of the template. The latter was measured when the planned and postoperative models were registered at mandibular body. Statistical analyses were performed, and the accuracy was reported using root mean square deviation (RMSD) and Bland and Altman's method for assessing measurement agreement.

Results—In the primary outcome measurements, there was no statistically significant difference among the 3 centers for the maxilla and mandible. The largest RMSD was 1.0mm and 1.5° for the maxilla, and 1.1mm and 1.8° for the mandible. For the chin, there was a statistically significant difference between the groups with and without the use of the chin template. The chin template group showed excellent accuracy with largest positional RMSD of 1.0mm and the largest orientational RSMD of 2.2°. However, larger variances were observed in the group not using the chin template. This was significant in anteroposterior and superoinferior directions, as in pitch and yaw orientations. In the secondary outcome measurements, the RMSD of maxillary dental midline positions was 0.9mm. When registered at the body of the mandible, the linear and angular differences of the chin segment between the groups with and without the use of the chin template were consistent with the results found in the primary outcome measurements.

Conclusion—Using the CASS protocol, the computerized plan can be accurately and consistently transferred to the patient to position the maxilla and mandible at the time of surgery. The computer-generated chin template provides more accuracy in repositioning the chin segment than the intraoperative measurements.

Keywords

computer-aided surgical simulation; orthognathic surgery; computer-generated surgical splint; computer-generated chin template; intraoperative measurements; dentofacial deformity

Introduction

There are a number of problems associated with the traditional planning methods for orthognathic surgery.[1–18] Each one of these problems can result in a less than ideal surgical outcome. In isolation, these problems may be minor, but when added together the results can be significant.[19] The development of computer-aided surgical simulation (CASS) represents a paradigm shift in surgical planning for patients with craniomaxillofacial (CMF) deformities. We have developed a CASS protocol for orthognathic surgery.[19] In this protocol, a computerized composite skull model of the patient is generated to accurately represent the skeleton, the dentition and the facial soft tissue.[5, 11, 13, 20] In addition, the patient's neutral head posture (NHP) is recorded and transferred to the three-dimensional (3D) models.[21–23] Furthermore, the user performs virtual osteotomies and simulates orthognathic surgery.[2, 5, 19, 24, 25] Finally, surgical splints and templates are generated in the computer, fabricated by a rapid prototyping machine, and used during surgery to accurately position the bony segments.[12, 26]

In evaluating a new planning protocol 2 questions should be answered. The first question is whether the protocol results in improved outcomes when compared with the traditional

method. The second question is whether it is accurate, i.e. the actual surgical outcomes are the same as the planned outcomes. Regarding the first question, a recently published study proves that our CASS protocol results in improved outcomes compared to the traditional planning methods.[27] Regarding the second question, we have documented the accuracy of the CASS in several published articles. The first study proved the in-vitro accuracy of the composite skull models[11]; the second proved the accuracy of the computer-generated splints[26]; the third study proved the accuracy of the NHP recording and transfer[23]; and the last one, a pilot study, suggested overall clinical accuracy[28]. Nonetheless, the accuracy of the entire CASS protocol has not been conclusively determined. In this study we complete a large, prospective, multicenter, evaluation of our CASS protocol to determine its accuracy.

Patients and methods

Sixty-five patients were enrolled in 3 centers: the Department of Oral and Maxillofacial Surgery at The Methodist Hospital in Houston, Texas; the Oral and Maxillofacial Surgery Service at Legacy Emanuel Hospital in Portland, Oregon; and the Division of Oral and Maxillofacial Surgery at New York University School of Medicine in New York City, New York. The study began in Houston in April 2005 as a single center study. In May of 2009 the other 2 centers were added. The study was completed in all 3 centers in August 2010. The inclusion criteria for the study were: 1) patients who were scheduled to undergo bimaxillary orthognathic surgery and 2) patients who agreed to participate in the study. The study was approved by Institutional Review Board at each institution. Prior to the enrollment, signed informed consent forms were obtained from all patients. The patient demographics are presented in Table 1.

In order to determine the accuracy of our CASS protocol, the planned outcomes were compared to the postoperative outcomes. The planed outcomes were established following the CASS protocol. The computerized surgical plans were transferred to the patient at the time of surgery using computer-generated surgical splints and templates, as well as the intraoperative measurement for positioning the chin segment. To record the postoperative outcomes, a computed tomography (CT) scan was obtained within the first 6 weeks postoperatively. The postoperative outcomes were compared to the planned outcomes by first registering (i.e., superimposing) the postoperative models to the planned models, then calculating their linear and angular differences. Finally, statistical analyses were performed and the results were summarized. The detailed methodology is described as follows.

CASS Protocol and the Planned Outcomes

Surgeons from each institution (J.G., R.B.B and D.L.H.) planned their own surgeries following the CASS protocol.[19, 27] The first step of the CASS protocol involves the collection of the preoperative records. The records include direct anthropometric measurements, clinical photographs, stone dental models, a patient-specific bite jig, a NHP recording, and a CT scan. The bite-jig records the bite in centric relation using a rigid, dimensionally-stable, material, e.g. *LuxaBite®* (DMG America, Englewood, NJ). A facebow with a set of fiducial markers (Medical Modeling Inc, Golden, CO) is attached to the bite-jig. These markers serve as points of reference to register the digital dental models to the 3D CT[11]. In addition, a digital orientation sensor (3DM, MicroStrain Inc, Williston, VA) is attached to the facebow to record the patient's NHP in pitch, roll, and yaw.[23] Afterwards, a CT scan of the patient's face is obtained with the bite-jig and facebow in place. Once all preoperative records are gathered, they are transmitted to a service center (for this study, we utilized the services of Medical Modeling Inc, Golden, CO).

The second step of the CASS protocol involves data processing at the service center. Four separate but correlated 3D CT models are generated: a midface model, a mandibular model,

a soft-tissue model and a fiducial marker model. Using a high-resolution laser scanner (3D Scan Company, Atlanta, GA), digital dental models are generated by scanning the stone dental models with the bite-jig and the fiducial markers in place. The digital dental models are then incorporated into the 3D CT model by registering the fiducial markers from the 3D CT and the digital dental models. This results in a composite skull model which displays an accurate rendition of bones, soft tissues and teeth. Next, using the fiducial markers as reference, a computer-aided designing (CAD) model of the digital orientation sensor is registered to the composite skull model. The NHP of the composite skull model is then established by applying the recorded pitch, roll and yaw to center of the orientation sensor model.[23] Prior to surgical planning, the models are positioned into a unique 3D coordinate system and cephalometric landmarks are digitized using a surgical planning software (for this study, we utilized SimplantOMS, Materialise Dental Inc, Glen Burnie, MD).

The third step of the CASS protocol is to plan and simulate the surgery in the computer. This procedure is usually completed with the engineers from the service center via a WEB meeting service (for this study, we utilized www.GoToMeeting.com, Citrix Online LLC, Goleta, CA). A check routine is completed prior to surgical planning to ensure the correctness of the NHP, the midsagittal plane definition, and landmark digitization. Once this routine is completed, 3D cephalometric analysis is automatically performed. Guided by real-time cephalometric measurements and clinical measurements, the surgeon plans the surgery by moving and rotating the digitally osteomized bony segments until the desired outcome is achieved. The bony segments at the final desired location served as the planned outcomes.

The fourth step of the CASS protocol is to fabricate surgical splints and templates. These are generated in the computer and fabricated using a rapid prototyping machine.[2, 5, 19, 26] Chin templates for the genioplasty (Fig 1) and other bone graft/ostectomy templates are also fabricated as needed.[2, 5, 19] Splints and templates are used to transfer the computerized plan to the patient at the time of the surgery.

Surgery and Postoperative Outcomes

The surgeries were performed by a single surgeon at each institution (J.G., R.B.B and D.L.H.). During surgery, all surgeons used occlusal surgical splints to place the maxilla and mandible in the desired final position. The maxillary vertical dimension was adjusted using a K-wire positioned at *nasion*. For the genioplasty, surgeons utilized simple intraoperative measurements to reposition the chin segment with the exception of the Houston group, where computer-generated templates were used (Fig 1) for patients with asymmetry (n=8).

A CT scan was performed within 6 weeks postoperatively. This interval was selected to avoid bias caused by the patient's possible growth or orthodontic movement. The postoperative CT scans represented the actual surgical outcomes

Outcome Evaluation

Outcome evaluation started after all the postoperative CTs were completed. The accuracy of the CASS protocol was assessed by comparing the planned outcomes to the actual postoperative outcomes.[28] The primary outcome measurements were: the positional and orientational differences between the planned and actual postoperative maxillae, mandibles and chin segments. The outcome measurements were done with the models registered at the cranium. The secondary outcome measurements were: the difference between the planned and postoperative positions of the maxillary dental midline, and the difference in accuracy between the genioplasties done using the chin templates versus those done using simple intraoperative measurements (not using the chin templates). The purpose of the latter

measurements was to remove the confounding factor of the mandibular position. They were done with the models registered on the body of the mandible.

Both the planned and the actual postoperative CT models were imported into a computer graphic software, 3DS Max (Autodesk Inc, San Rafael, CA). The postoperative CT scans were segmented in 2 parts: the cranium-midface and the mandible. If a genioplasty was performed, the chin segment was not segmented from the mandible. The outcome evaluation was completed by first digitizing a group of anatomical landmarks on both planned and postoperative models. The postoperative models were then registered to the planned models. The differences in position and orientation were finally calculated between these landmarks. The evaluation was completed by 2 examiners (S.H. and J.J.X.). A consensus was reached if there was a disagreement between the examiners during landmark digitization or registration. The detailed evaluation procedure is described as follows.

Step 1: To digitize the landmarks—We adopted the premise that 3 points are sufficient to define the position and orientation of an object in 3D space[28]. To evaluate the maxillary and mandibular position and orientation, 3 landmarks were digitized on the dentition, constructing a triangle. They included: the midline between the 2 central incisors (central incisal embrasure), and the tips of right and the left mesiobuccal cusps of the first molars (Fig 2A). To prevent operator bias during the digitization process, only one model, either planned or postoperative, was displayed at a time. To evaluate the chin position and orientation after genioplasty, we digitized 3 landmarks on each chin segment.[28] The landmarks utilized were Menton and 2 additional points located on the right and left inferior borders of the mandible at a distance of 2 cm from Menton (Fig 2B). Because chin landmarks were difficult to locate, we developed the following “reversed” routine to assure correspondence between the landmarks located on the planned and postoperative models. First, using the surface-best-fit method[28], the chin segments of the planned outcome models were registered (i.e., superimposed) to the corresponding chin segments of the postoperative models. While in this position, the 3 landmarks previously described were simultaneously digitized on both models. Finally, the chin segments of the planned outcome models together with their landmarks were moved back to their originally planned positions.

Step 2: To register the postoperative models to the planned models—Using our previously validated method[28], registration was completed by superimposing the area of each model that was not moved by surgery, i.e. the cranial region. The planned models were kept static, and served as targets. On the planned models, we initially hid all the landmarks and the bony segments that were moved during planning, i.e. Le Fort I segment and mandible (Fig 3A). Only the region that had not been moved, i.e. cranium, was visualized. This was done to avoid operator-bias during registration. The postoperative CT models were registered to the planned models using the surface-best-fit method (Fig 3B). Once the registration was completed all hidden landmarks for the maxilla were displayed and their coordinates were recorded (Fig 3C).

Step 3: To auto-rotate the mandibles of the postoperative models into maximum intercuspation—This step was necessary because some of the postoperative CT scans were acquired with the mouth slightly open. To prevent operator bias, the planned models were hidden during this maneuver (Fig 3D–F). After the mandible had been auto-rotated, all mandibular landmarks were displayed and their coordinates were recorded.

Step 4: To evaluate the position and orientation of the chin segments—We evaluated chin position and orientation from 2 different aspects: 1) in relation to the entire CMF skeleton (as a part of primary outcome measurements), and 2) in relation to the

mandible (as a part of secondary outcome measurements). The purpose of the first evaluation was to assess the overall clinical outcome. The corresponding planned and postoperative models were registered at the cranium. The purpose of the second evaluation was to compare the accuracy of the chin templates with the accuracy of simple intraoperative measurements. The models were registered on the body of the mandible, distal to the ramus osteotomies and proximal to the genioplasty cuts. During all registrations, landmarks were hidden to prevent operator's bias (Fig 4)

Step 5: To calculate the differences—To measure the differences between the planned and postoperative positions the raw coordinates of all landmarks were first tabulated in Excel (Microsoft Corp, Redmond, WA). Afterwards, the centroid of each object (maxilla, mandible and chin) was calculated. The centroid coordinates (x_c, y_c, z_c) were computed using the following equations:

$$x_c=\frac{x_1+x_2+x_3}{3}$$

$$y_c=\frac{y_1+y_2+y_3}{3}$$

$$z_c=\frac{z_1+z_2+z_3}{3}$$

where (x_1, x_2, x_3), (y_1, y_2, y_3) and (z_1, z_2, z_3) were the coordinates of the 3 landmarks on each object. After this initial step, the centroids of the objects in the planned and actual outcomes models were paired and categorized according to dimension (x, y and z), location (maxilla, mandible and chin), and institution. Because the chin outcomes were evaluated in 2 different aspects, i.e., in relation to the cranium and in relation to the body of the mandible, there were 2 sets of measurements for each chin pair.

Differences between Planned and Postoperative Positions: Linear differences in x (mediolateral), y (anteroposterior) and z (superoinferior) directions between the planned and postoperative centroid positions were computed. Discrepancies in maxillary midline position were also calculated. For this purpose we computed the differences between the x-coordinates of the maxillary dental midline landmarks.

Differences between Planned and Postoperative Orientation: The orientation of an object was represented by pitch, roll and yaw. Pitch was defined as rotation around the x axis (mediolateral direction), roll as rotation around the y axis (anteroposterior direction), and yaw as rotation around the z axis (inferosuperior direction) (Fig 5a). Angular differences were computed as discrepancies in pitch, roll and yaw of the centroid coordinate system between the planned and the actual outcomes (Fig 5b & 5c).[29]

Statistical Analyses and Report

Statistical analyses were performed to determine if the outcomes from the different centers were statistically different. The schematic chart for the evaluation of the differences between the planned and postoperative outcomes in maxillary and mandibular positions and orientations is presented in Fig 6A. Two general linear models (GLMs) were used to detect whether there was a statistically significant difference among the 3 centers, one for the linear

and one for the angular differences. Both maxilla and mandible were included in the same statistical model. Between-factor was 3 centers. Within-factors were 3 dimensions (*x*, *y* and *z*) and 2 jaws (maxilla and mandible). The assumptions for the GLM were tested and could not be rejected. If there was a statistically significant difference amongst the 3 centers, the within contrast would be further computed and the results would be reported separately. If there was no statistically significant difference, Box's M test would be performed to further test the homogeneity of the variances of the difference from each center, i.e. whether they were close enough to be considered equal. If Box's M test showed that the variances were heterogeneous, the results amongst the 3 centers would be reported separately, even if there was no statistically significant difference in GLM. Only if Box's M test showed that the variances were homogeneous, would the results from the 3 centers be combined and reported together.

The schematic chart for the evaluation of the differences between the planned and postoperative outcomes in chin positions and orientations is presented in Fig 6B. Two evaluations were completed: one for evaluating the chin position and orientation in relation to the cranium, and the other in relation to the body of the mandible. In each evaluation, 2 GLMs were performed, 1 for the linear and 1 for the angular differences. Each GLM served 2 purposes. The first was to detect whether there was a statistically significant difference with and without the use of the chin template. The second purpose was to detect whether there was a statistically significant difference amongst the groups using only intraoperative measurements. Because only one surgeon used the chin templates for his asymmetry patient population, the differences were thus regrouped into 4 groups: one group with the chin template, and 3 groups without. In these 3 groups, only intraoperative measurements were used. They served as the between-factors. Within-factor was 3 dimensions (*x*, *y* and *z*). The assumptions for the GLM were tested and could not be rejected.

If there was a statistically significant difference between the groups with and without the use of the chin template in the GLM, the results would be reported separately. In addition, if there was no statistical difference amongst the 3 groups not using the chin template, Box's M test would be further performed to determine the homogeneity of the variances of the differences. If Box's M test showed that the variances were heterogeneous, the results from all 3 groups would also be reported separately. If Box's M test showed that the variances were homogeneous, the results from the 3 groups would be combined and reported together.

If there was no statistically significant difference between the groups with and without the use of the chin template, the results would still be reported separately. In addition, Box's M test would also be performed to further detect whether the results amongst these 3 groups could be combined, as described above. Otherwise, the results from the 3 would be reported separately.

Finally, the differences in position and orientation for the maxilla, mandible and chin were reporter using 2 different methods. The first reporting method was the root mean square deviation (RMSD). The RMSD summarizes absolute differences (without positive or negative sign) into a single accuracy measure. It was computed using the following equation:

$$RMSD=\sqrt{\frac{1}{n}\sum_{i=1}^{i=N}\delta_i^2}$$

where N is the total pairs of the deltas δ. For the linear differences, RMSDs were used to report the accuracy of the CASS protocol in mediolateral, anteroposterior and superoinferior directions. For angular differences, RMSDs were used to report the accuracy in pitch, roll and yaw.

The second reporting method was Bland and Altman's method for assessing measurement agreement[30]. Lack of agreement was estimated by the mean differences ($\bar{d}$), 95% conference interval (CI) and standard deviations (SD) between the planned and the actual postoperative measurements. In addition, the lower and upper limits of the differences, called 95% limits of agreement, were estimated by $\bar{d} \pm 1.96SD$. Finally, the 95% CIs for the lower and upper limits of agreement were computed using the equation $l \pm t\sqrt{\frac{3SD^2}{n}}$, where l is the lower or upper limit, t is the critical value for the t distribution corresponding to the area (2 tails at 0.05) under the curve, and $\sqrt{\frac{3SD^2}{n}}$ is the standard error of $\bar{d} \pm 1.96SD$.

To help interpret the results of the accuracy measurements for the maxilla, mandible and chin, we considered positional differences between the planned and postoperative outcomes, of less than 2 mm to be clinically insignificant.[31, 32] We also considered orientation differences of less than 4° to be clinically inconsequential.[33] However, for maxillary dental midline position, the most noticeable parameter, we used a more stringent threshold of 1 mm.

Results

Primary Outcome Measurements

The primary outcome measures were the differences in position and orientation between planned and postoperative outcomes. For the maxilla and mandible, the results of GLMs showed that both the linear and angular differences amongst the 3 centers were not statistically significant [F(2,62)=1.94, p=0.144; and F(2,62)=0.013, p=0.996]. Box's M tests showed that the variances of both the linear and angular differences amongst the 3 centers were homogenous (P=0.151 and 0.697). Therefore, the data from the 3 centers were combined and reported together. Table 2 shows the absolute mean RMSD between the planned and actual outcomes, whereas Table 3 shows their 95% limits of agreement (Bland and Altman upper and lower limits).

The absolute difference, represented by RSMD, in the maxillary position and orientation were minimal. The largest positional difference was 1.0 mm, and the largest orientational difference was 1.5°. The same was true for the mandible where the largest positional difference was 1.1 mm and the largest orientational difference was 1.8°.

For the chin position and orientation in relation to the cranium, the results of GLMs showed that there was a statistically significant difference between the groups with and without the use of the chin templates [F(3,20)=8.42, p<0.001; and F(3,20)=5.45, p=0.007]. In addition, there was no difference among the 3 centers not using the chin templates. The result of Box's M tests showed that the variances from the 3 groups were homogenous in both the linear and angular differences (P=0.139 and 0.193). Therefore, the data from the 3 groups not using the chin templates were combined and reported together (Tables 2 and 3).

The accuracy of the genioplasties varied significantly depending on the method used to reposition the chin segments during surgery. The worse outcomes were seen in the group not using the chin templates, where statistical and clinically significant variances occurred in

anteroposterior and superoinferior directions, and in pitch and yaw orientations. In contrast, the chin template group showed excellent accuracy with largest positional RSMD of 1.0 mm and the largest orientational RSMD of 2.2°.

Secondary Outcome Measurements

Two secondary outcome measurements were computed. The first was to measure the difference between the planned and postoperative positions of the maxillary dental midline. The result of the RMSD calculation showed that the accuracy of maxillary dental midline position was 0.9 mm, and 95% limits of agreement were −1.3 mm and 1.1 mm.

The other secondary outcome measurement was to calculate the difference between the genioplasties done with and without the chin templates. For chin position and orientation in relation to the body of the mandible, the results of GLMs showed that there was a statistically significant difference between the 2 groups [$F(3,20)=9.29$, $p<0.001$; and $F(3,20)=6.06$, $p=0.004$]. In addition, there was no difference amongst the 3 groups not using the chin templates. The result of the Box's M tests showed that the variances in these 3 groups were homogenous in both linear and angular differences ($P=0.225$ and 0.449). Therefore, the data from the 3 groups were combined and reported together (Tables 4 and 5).

The template group also showed excellent accuracy with largest positional RSMD of 1.1mm and the largest orientational RSMD of 1.6°. In contrast, the differences in anteroposterior and superoinferior directions, as well as in pitch and yaw orientations in the group not using the chin templates were statistically larger.

Discussion

CASS protocol is designed to encompass the entire process of orthognathic surgery from planning to execution. The purpose of this prospective multicenter study was to determine the clinical accuracy of our CASS protocol. The results demonstrated excellent positional and orientational accuracy for the maxilla and mandible, as well as excellent accuracy for maxillary dental-midline position. Another important finding of this study is that the results of the 3 centers were consistent. Different surgeons, with different degrees of familiarity with the protocol, working in geographically distinct areas obtain similar results. This finding indicates that our CASS protocol is reproducible.

The accuracy for the chin segment placement varied. At the time of surgery, 2 different methods were utilized to place the chin segment in the planned position. One method, the current standard, utilized simple intraoperative measurements. The other, a new method developed by the Houston group, utilized the chin templates. The results of this study demonstrated that the accuracy achieved with the use of the chin templates was significantly better than the accuracy achieved by simple intraoperative measurements. In the latter group, the differences between planned and actual outcomes were larger than the accepted clinical threshold of 2 mm for position and 4° for orientation[31–33]. This study supports the routine use of the chin templates for increased accuracy, even though the use of the chin template is associated with a small increase in surgical times and a modest increase in cost.

The importance of the workup for the CASS cannot be over emphasized enough. The fabrication of the individualized bite-jig is essential in the CASS protocol. It serves 3 purposes: 1) to accurately maintain the exact relationship of the maxillary and mandibular teeth in both CT models and digital dental models; 2) to accurately capture the centric relationship; and 3) to accurately merge the highly accurate digital dental models to the CT model. If the bite-jig is not correctly fabricated, the error will be carried over to the later steps. The bite-jig should not be too thick (unnecessary large autorotation) or too thin

(fragile). The occlusal indentations on the bite-jig should be deep enough to "lock" the teeth but also shallow enough to avoid undercuts. The authors would like to recommend a 3-layer approach for the bite-jig fabrication. In this approach, the 1st layer is added to the top side of the bite-jig to only capture the maxillary teeth. Before the material is set, the bite-jig should be gently taken off and then repositioned back to the maxillary teeth multiple times to eliminate any possible undercuts captured on the bite-jig. After the material is set, the undercuts are further eliminated by grinding the bite-jig to the appropriate thickness as described above. The 2nd layer is to capture the centric relationship at the labiobuccal region. The bite-jig with maxillary occlusion is placed back to the maxillary teeth. The mandible is then positioned to the centric relationship. This position should be repeated multiple times to ensure its correctness. A 2nd layer of the material is then directly added onto the bite-jig at the labiobuccal side of the mandibular teeth while the mandible is still at the centric relationship. Once the material is set, the 3rd layer is added on the bottom side of the bite-jig to capture the mandibular occlusal surface. The 2nd layer of material at the labiobuccal region serves as a blocker to "lock" the mandible at the centric relationship. Before the material is set, the mandible should also be gently swung open and close to eliminate any possible undercuts captured on the bite-jig. After the material is set, the mandibular side of the bite-jig is ground to the appropriate thickness. Finally, the bite-jig is placed back to the teeth again to check the fitting and centric relationship before its further use.

The authors also would like to recommend a cross-check routine of the bite-jig between the patient and the stone models. In this routine, the dental impressions are made and the stone models are poured prior to the bite-jig fabrication. After the bite-jig is fabricated, it should be fitted onto the stone models as well. If the bite-jig does not fit on the stone models, it indicates either the dental impressions (stone models) are distorted, or there are undercuts on the bite jig. Surgeon should correct the problem accordingly before moving to the further steps in the CASS protocol.

Finally, the importance of correctly capturing centric relationship is demonstrated in a post-hoc analysis of outlier patients, in which 3 patients showed with a large difference (>4 mm) between their planned and actual outcomes. These patients had undergone maxillomandibular advancements to treat severe micrognathia and ended with advancements that were less than predicted. Two of these patients also ended with a large (>2mm) maxillary dental midline deviation. In these patients, the surgical sequence was maxillary surgery first, followed by mandibular surgery. By comparing the condylar positions of the planned and postoperative models, we found that one (in 2 patients) or both (in 1 patient) condyles were in a protruded position in their preoperative models. This most likely occurred when the bite-jig failed to capture the centric relationship, a maneuver that can be extremely difficult, if not impossible, on this type of patient (Fig 7). Because maxillary surgery was done first, their intermediate splints related a repositioned maxilla to an uncut mandible. Unfortunately, their splints related the new maxillary position to a protruded or laterally shifted mandible rather than to a centrally positioned one. Therefore, at the time of surgery, when the surgeon wired the intermediate splint and seated the mandible back into the centric relationship, the maxilla swung laterally and/or was displaced backwards from its planned position. These examples highlight the importance of recording an accurate centric relationship when bimaxillary surgery begins in the maxilla. They also highlight the importance of executing each step of the protocol with precision, as the accuracy of each step is built on the accuracy of the previous. An early mistake will be carried over to all subsequent steps. When encountering a patient on whom recording the centric relationship is impossible, surgeons may consider beginning bimaxillary orthognathic surgery on the mandible, as also suggested by other authors[34].

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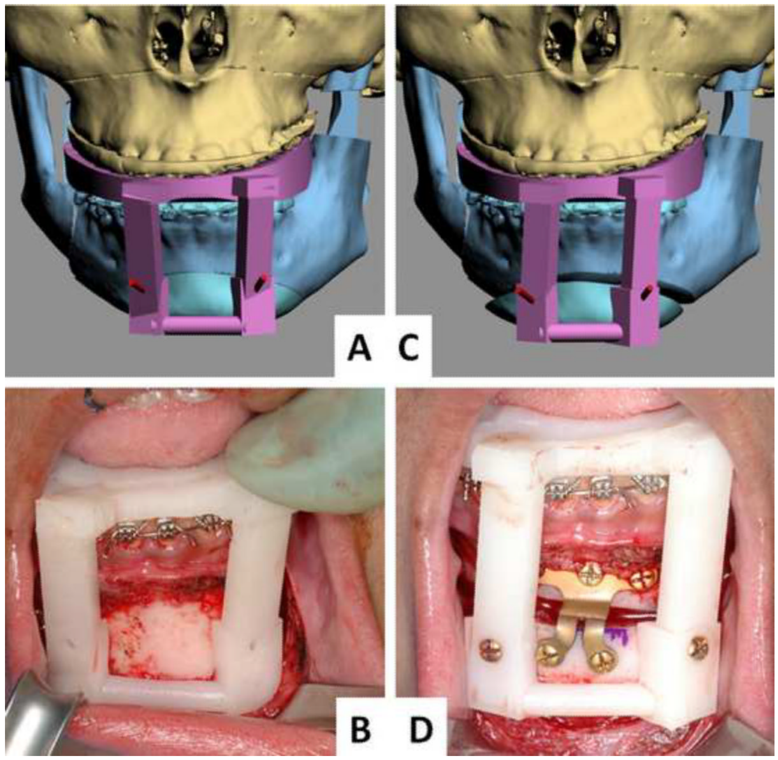


Fig 1.

Chin template includes a set of 2 surgical guides. The first guide is used to predefine the screw holes prior the osteotomy. The second guide is used to bring the chin segment to the planned position and orientation using predrilled screw holes. Both guides use the mandibular dentition as a reference to predrill the screw holes and to position the chin segment.

A) A computer model of the 1st guide to define the screw holes.

B) The use of the 1st guide at the time of surgery.

C) A computer model of the 2nd guide to bring the chin segment to the desired position.

D) The use of the 2nd guide at the time of surgery.

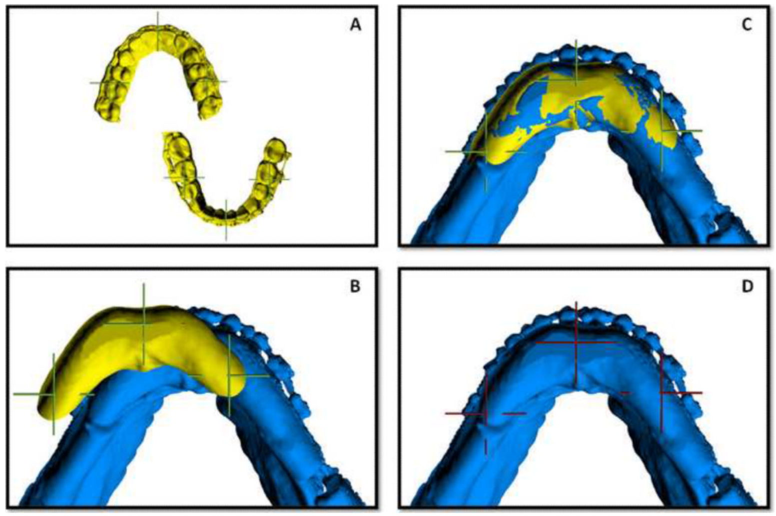


Fig 2.

During the landmark digitization, the landmarks on the planned models are marked in green, and the landmarks on the postoperative models were marked in red.

A) For the maxilla and the mandible, 3 landmarks were digitized on the occlusal surface: the midline between the 2 central incisors (central incisal embrasure), and the right and the left mesiobuccal cusp tips of the first molars.

B) For chin segment, 3 landmarks were initially digitized on the chin segment of the planned model: menton and 2 points located at the right and left lower borders of the chin segment. They were then "glued" to the planned chin segment and duplicated. The first set was hidden and used later as the planned position of the chin segment.

C) The chin segment in the second set was registered to the postoperative chin model using the surface-best-fit method[28], bring the 3 landmarks with it.

D) Once registered, the chin segment of the 2^{nd} set is deleted. The 3 landmarks from the planned model were thus transferred and "reglued" onto the postoperative model.

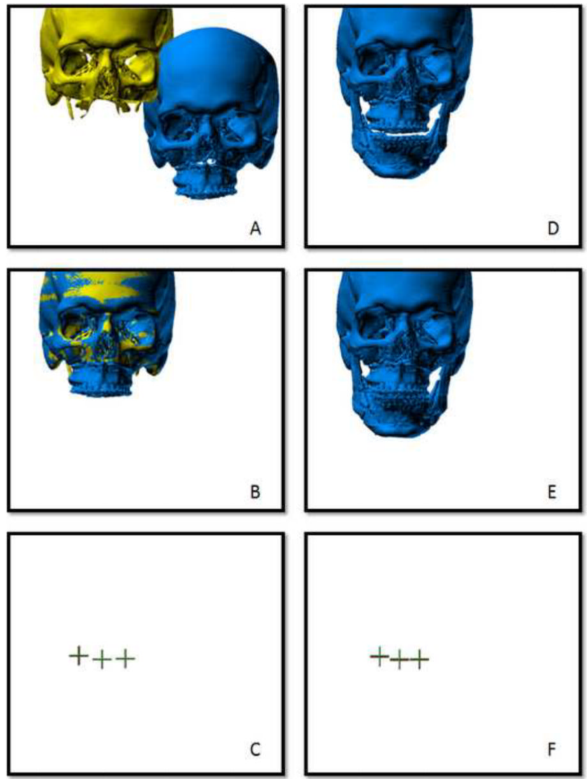


Fig 3.

Registration for the evaluation the maxillary and the mandibular positions.

A) During the registration, the planned models were kept statistic and served as a reference. In addition, we hided all the landmarks, and the bony segments that were moved during the planning, i.e. Le Fort I segment. Only the bones that had not been moved, i.e. cranial region, were visualized.

B) The postoperative CT model was registered to the planned model using the surface-best-fit method.

C) Once the midface was registered, all hidden landmarks for the maxilla were displayed and their coordinates were recorded.

D) After the postoperative midface model was registered to the planned model, all the planned models were hidden. Only the postoperative models were visualized.

E) The mandible was autorotated around the center of the condyles until the maxillary and mandibular teeth were touched.

F) All the hidden landmarks for the mandible were displayed and their coordinates were recorded.

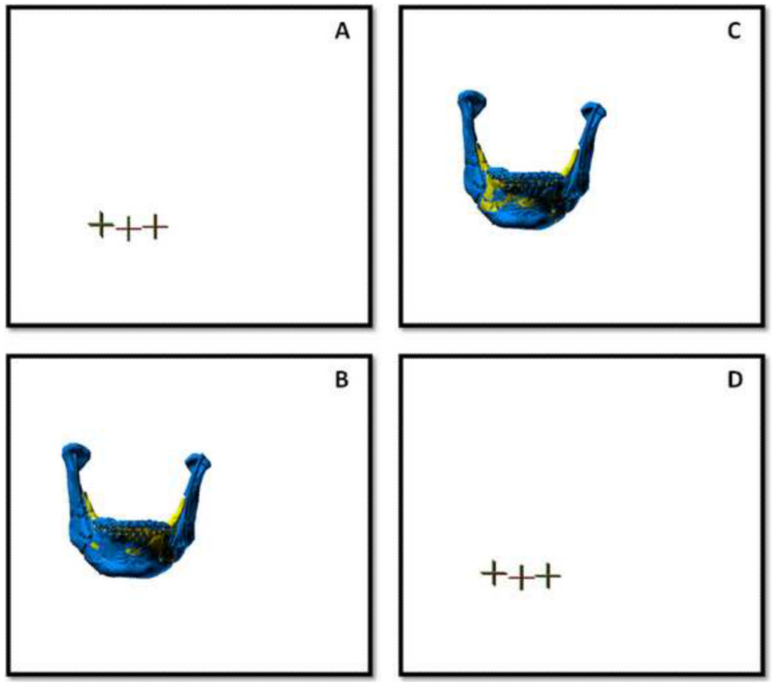


Fig 4.

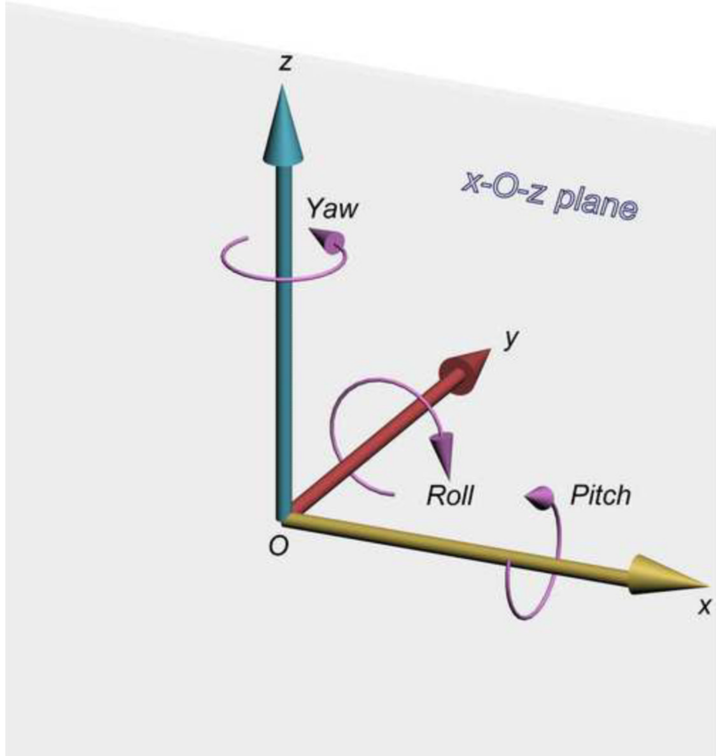
Registration for the evaluation of the chin segment position.

A) All the chin landmarks were also displayed and recorded for the first evaluation of the chin position in relation to the entire CMF structure.

B) The planned chin segment and all the landmarks were hidden.

C) The postoperative mandible was registered to the planned distal segment.

D) Once registered, all the hidden chin landmarks were displayed again and recorded for the second evaluation of the chin position in relation to the mandibular distal segment.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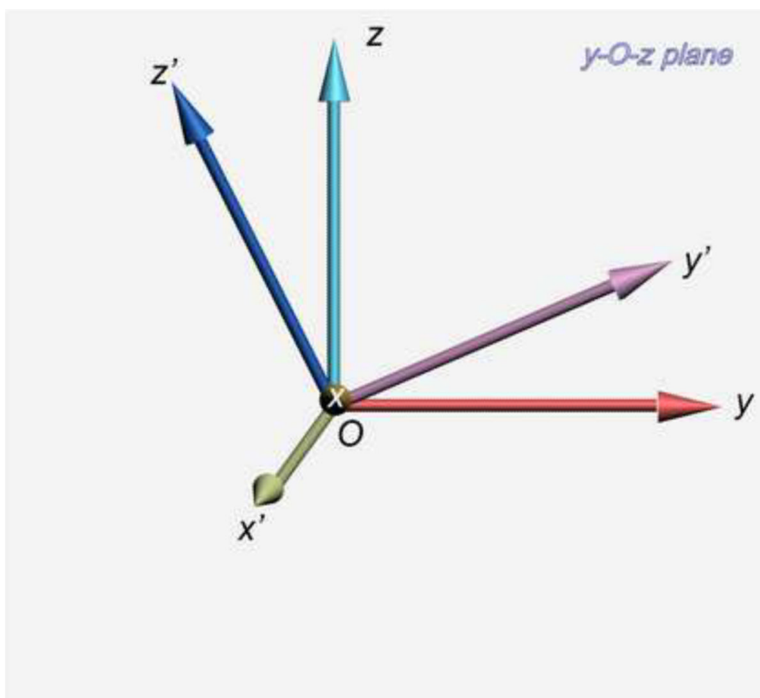
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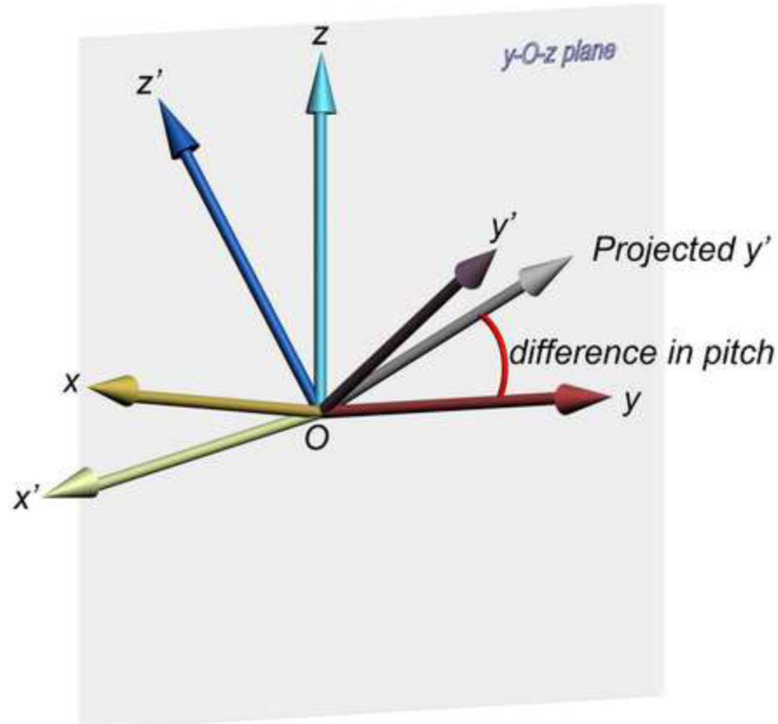

Fig 5.

Computation of the angular difference between planned and postoperative outcomes.

A) From frontal view: Pitch was defined as rotation around × (mediolateral) axis, roll as rotation around the y (anteroposterior) axis, and yaw as rotation around the z (inferosuperior) axis.

B) From lateral view: Before computing the angular differences, the centroid $O'(x',y',z')$ of the postoperative object was translationally registered to the centroid $O(x,y,z)$ of the planned object.

C) From lateral oblique view: The angular difference in pitch was defined as the angle between the projected x'- and the x- axes on the sagittal (y-O-z) plane. By the same token, the angular difference in roll was defined as the angle between the projected z'- and the z'-axes on the coronal (x-O-y) plane, and the angular difference in yaw was defined as the angle between the projected y'- and the y- axes on the axial (x-O-z) plane.

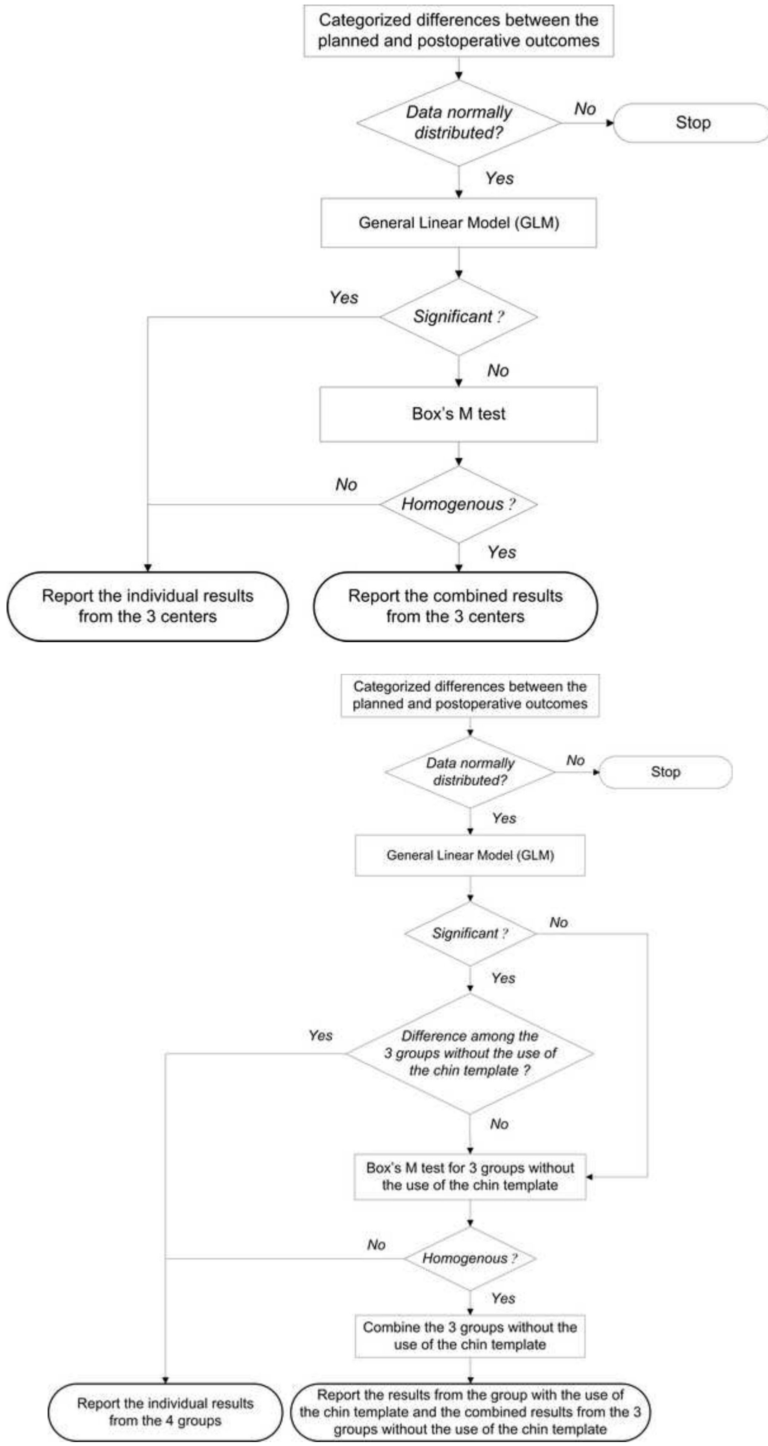

Fig 6.

Statistical schematic charts.

A) For the maxillary and the mandibular evaluation.

B) For the chin evaluation.

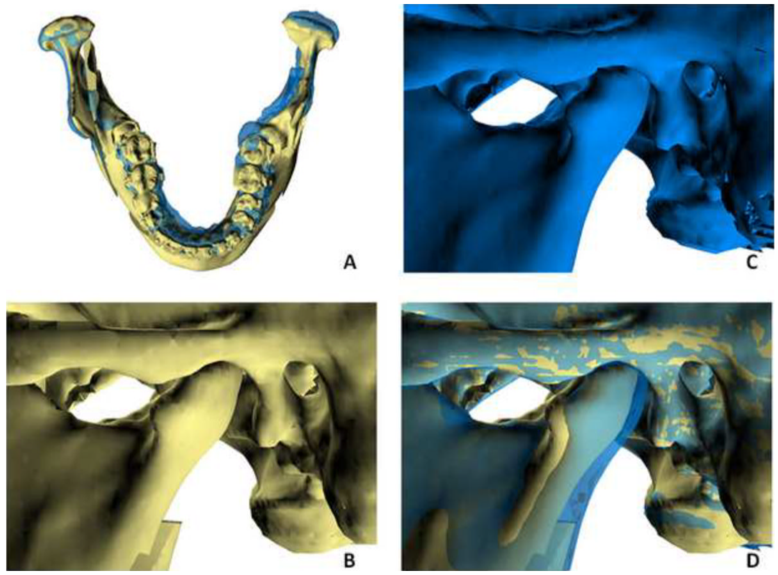

Fig 7.
Unwanted bimaxillary retrusion was caused by a combination of incorrect recording of central relation and the maxillary surgery first.
A) In this unilateral bimaxillary retrusion patient, the midline was shifted to one side (>2 mm).
B) From the preoperative CT model, the condyle appeared in the central relation.
C) From the postoperative CT model, the condyle also appeared in the central relation.
D) When the two models were registered, it clearly demonstrated that the preoperative condyle (yellow) was protruded then the postoperative condyle (blue).

Table 1

Demographics of the patients

	Center 1	Center 2	Center 3
Total Patients	41	11	13
Gender (M/F)	23 / 18	3 / 8	5 / 8
Mean age at surgery (Range)	26.7 (15 to 51)	26.7 (16 to 46)	21.7 (16 to 51)
Bimaxillary Surgery	41	11	13
Genioplasty (using chin template)	12 (8)	8 (0)	4 (0)

Table 2

Accuracy (RMSD) of positional and orientational differences between the planned and postoperative outcomes (models registered at the cranium)

		Positional Difference		Orientational Difference	
Maxilla		*Mediolateral*	0.8 mm	*Pitch*	1.5°
		Anteroposterior	1.0 mm	*Roll*	0.9°
		Superoinferior	0.6 mm	*Yaw*	1.3°
Mandible		*Mediolateral*	0.8 mm	*Pitch*	1.8°
		Anteroposterior	1.1 mm	*Roll*	1.0°
		Superoinferior	0.6 mm	*Yaw*	1.7°
Chin	w/o Template *	*Mediolateral*	1.7 mm	*Pitch*	5.8°
		Anteroposterior	3.5 mm	*Roll*	3.0°
		Superoinferior	2.5 mm	*Yaw*	3.9°
	w/Template *	*Mediolateral*	0.8 mm	*Pitch*	2.2°
		Anteroposterior	1.0 mm	*Roll*	1.8°
		Superoinferior	0.6 mm	*Yaw*	1.9°

* w/o: without, w/: with.

Table 3

Accuracy (Bland and Altman upper and lower limits) of positional and orientational differences between the planned and the postoperative outcomes (models registered at the cranium)

			Positional Difference (95% CI)			Orientational Difference (95% CI)	
			Lower Limit	**Upper Limit**		**Lower Limit**	**Upper Limit**
Maxilla		*Mediolateral*	−1.7 mm (−2.0 to −1.4)	1.4 mm (1.0 to 1.7)	*Pitch*	−2.3° (−2.9 to −1.7)	3.4° (2.8 to 4.0)
		Anteroposterior	−0.7 mm (−0.9 to −0.4)	1.6 mm (1.4 to 1.9)	*Roll*	−1.8° (−3.2 to −1.4)	1.8° (1.4 to 2.1)
		Superoinferior	−0.8 mm (−1.0 to −0.6)	0.9 mm (0.7 to 1.0)	*Yaw*	−2.7° (−3.2 to −2.1)	2.3° (1.7 to 2.8)
Mandible		*Mediolateral*	−1.4 mm (−1.5 to −1.0)	1.0 mm (0.8 to 1.3)	*Pitch*	−3.7° (−4.5 to −2.9)	3.6° (2.8 to 4.3)
		Anteroposterior	−0.9 mm (−1.1 to −0.6)	1.5 mm (1.3 to 1.8)	*Roll*	−2.0° (−2.4 to −1.6)	1.8° (1.4 to 2.2)
		Superoinferior	−0.8 mm (−1.0 to −0.6)	0.7 mm (0.6 to 0.9)	*Yaw*	−3.3° (−4.0 to −2.6)	3.3° (2.6 to 4.0)
Chin	w/o Template *	*Mediolateral*	−2.9 mm (−4.9 to −0.1)	3.9 mm (2.0 to 5.8)	*Pitch*	−9.4° (−15.6 to −3.2)	12.9° (6.6 to 19.1)
		Anteroposterior	−6.2 mm (−10.1 to −2.2)	7.8 mm (3.8 to 11.7)	*Roll*	−5.8° (−9.3 to −2.4)	6.3° (2.9 to 9.7)
		Superoinferior	−5.3 mm (−8.2 to −2.5)	4.6 mm (1.8 to 7.4)	*Yaw*	−7.1° (−11.5 to −2.8)	8.4° (4.1 to 12.8)
	w/Template *	*Mediolateral*	−1.7 mm (−2.6 to −0.7)	1.8 mm (0.8 to 2.8)	*Pitch*	−4.1° (−6.5 to −1.7)	−4.9° (2.5 to 7.3)
		Anteroposterior	−2.1 mm (−3.3 to −1.0)	2.0 mm (0.8 to 3.2)	*Roll*	−4.0° (−6.1 to −2.0)	3.7° (1.6 to 5.7)
		Superoinferior	−1.4 mm (−2.1 to −0.8)	1.0 mm (0.3 to 1.6)	*Yaw*	−4.0° (−6.2 to −1.9)	4.1° (1.9 to 6.2)

* w/o: without, w/: with.

Table 4

Accuracy (RMSD) of chin position and orientation for genioplasties done with intraoperative measurements versus those done with chin templates (models registered at the body of the mandible)

		Positional Difference		Orientational Difference	
Chin	w/o Template*	*Mediolateral*	1.4 mm	*Pitch*	5.0°
		Anteroposterior	2.0 mm	*Roll*	2.6°
		Superoinferior	1.5 mm	*Yaw*	2.9°
	w/Template*	*Mediolateral*	0.6 mm	*Pitch*	1.1°
		Anteroposterior	1.1 mm	*Roll*	1.6°
		Superoinferior	0.5 mm	*Yaw*	1.6°

* w/o: without, w/: with.

Table 5

Accuracy (Bland and Altman upper and lower limits) of chin position and orientation for genioplasties done with intraoperative measurements versus those done with chin templates (models registered at the body of the mandible)

			Positional Difference (95% CI)			Orientational Difference (95% CI)	
			Lower Limit	**Upper Limit**		**Lower Limit**	**Upper Limit**
Chin	w/o Template*	*Mediolateral*	−2.9 (−4.5 to −1.2)	2.9 (1.3 to 4.6)	*Pitch*	−9.7 (−12.8 to −4.9)	10.4 (1.2 to 9.1)
		Anteroposterior	−4.1 (−6.4 to −1.8)	4.0 (1.7 to 6.2)	*Roll*	−5.5 (−7.2 to −3.1)	5.0 (0.2 to 4.3)
		Superoinferior	−3.4 (−5.1 to −1.7)	2.7 (1.0 to 4.4)	*Yaw*	−4.3 (−4.9 to −0.9)	6.6 (2.2 to 6.2)
	w/Template*	*Mediolateral*	−1.2 (−2.0 to −0.5)	1.4 (0.7 to 2.1)	*Pitch*	−1.7 (−2.9 to −0.6)	2.6 (1.4 to 3.7)
		Anteroposterior	−2.1 (−3.4 to −0.8)	2.4 (1.1 to 3.7)	*Roll*	−3.5 (−5.3 to −1.7)	3.3 (1.5 to 5.2)
		Superoinferior	−1.1 (−1.7 to −0.6)	0.9 (0.4 to 1.5)	*Yaw*	−3.5 (−5.2 to −1.7)	3.1 (1.3 to 4.8)

* w/o: without, w/: with.