A Novel Approach to Skull-Base and Orbital Osteotomies Through Virtual Planning and Navigation

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Objective: Computer-assisted planning of osteotomy lines, coupled with navigation-guided performance of planned osteotomies, is a highly innovative approach to skull-base and orbital surgery. The aim of this pilot study is to provide an assessment of the accuracy of this novel approach in guiding the correct positioning of osteotomies in frontal, temporal, and orbital regions, defining the agreement between the spatial position of the planned and performed osteotomies.

Methods: Fifteen patients with orbital, frontal, and lateral skull-base diseases underwent virtual surgical planning. Osteotomies to access the orbit, frontal sinus, and lateral skull base were planned on computer tomography-based three-dimensional models. The planned osteotomies were reproduced on the operating field using a navigation system. The positions of the performed and planned osteotomies were compared. The results were described as the mean positional difference between planned and performed osteotomies and as Lin’s concordance coefficient, and Bland-Altman limits of agreement were also defined.

Results: The overall mean difference was 0.719 mm (95% confidence interval [CI]: 0.472 to 0.965 mm). Overall, Lin’s concordance coefficient was 0.997 (95% CI: 0.996 to 0.998), and overall Bland-Altman limits of agreement ranged from −1.407 to 2.844 mm.

The smallest mean difference (0.587 mm, 95% CI: 0.244 to 0.931 mm) was calculated in the orbit group, whereas the highest mean difference (0.904 mm, 95% CI: 0.428 to 1.379 mm) was described in the lateral skull-base group.

Conclusion: This study’s results support the use of this novel planning and navigation protocol for guiding osteotomy in anterior and lateral skull-base surgery, providing a clinical validation of this technique.

Key Words: Navigation, skull base, orbit, frontal sinus, virtual planning.

Level of Evidence: 4

INTRODUCTION

Image-guided surgery systems are enlarging their applications in the head and neck surgery field and are leading to an integration of the information from a direct view of the operating field with radiological data or preoperative planning.

Surgical navigation is the most commonly used technique, and its indications in craniofacial surgery generally involve trauma,1–4 orthognathic surgery,5–7 surgical oncology,8–10 temporomandibular joint (TMJ),11,12 and reconstructive surgery.13–15

Most of the available literature regarding surgical navigation in the craniofacial field regards a simple description of an application of this technology in a particular clinical setting, such as the use of navigation for foreign body removal, implant positioning, prosthetic placement, orbital reconstruction, or tumor resection, often without an organic description of the actual accuracy of the technique. In fact, only a small number of studies have employed a systematic approach to explore the accuracy of navigational systems,16–22 almost always in the orthognathic and reconstructive field. These reports regard the positioning of maxillary segments or prosthetic elements, whereas the application of surgical planning and navigation to guide craniofacial osteotomies for the optimization of the surgical access to the orbit and the skull base has not been specifically explored to date.

To achieve this goal, the authors developed a novel panning and navigation protocol, specifically for the craniofacial setting, which was previously validated in a preclinical study.24

This protocol provides computer-assisted planning of osteotomy lines using three-dimensional (3D) renderings of computed tomography (CT) images of the patients, which enables surgeons to perform the planned osteotomies under navigational guidance to access the skull base and the orbit.

The aim of this pilot study is to provide an assessment of the accuracy of this technique in guiding the correct...
positioning of osteotomy lines in frontal, temporal, and orbital regions and to define the agreement between the spatial position of planned and performed osteotomies.

MATERIALS AND METHODS

Patients

In this study, 15 patients who were referred to the maxillofacial unit of the Academic Hospital of Udine, Udine, Italy, between 2015 and 2017 for skull base or orbital surgery were enrolled.

Inclusion criteria were the following:

- Disease involving the orbit, anterior skull base, ethmoid sinus, frontal sinus, glenoid fossa of TMJ, temporalis squama, or infratemporal space
- Tumor or osseous dysplasia (including ossifying dysplasia and osseous TMJ ankylosis)
- Need of osteotomies for surgical access.

Fifteen patients met these inclusion criteria and were enrolled. Patient data are summarized in Table I.

All patients underwent preoperative CT scanning with acquisition volume from the vertex capitis to the lower margin of the jaw. The study was approved by ethical committee.

Computer-Assisted Surgical Planning

The software used for CT image analysis and surgical planning was 3DSlicer, a freeware advanced imaging software developed by a partnership between the Artificial Intelligence A.I. Laboratory of MIT Cambridge, MA and the Surgical Planning Laboratory of the Brigham and Women’s Hospital Boston, MA.

In this study, this software was used to plan a set of osteotomy lines and support navigation according to the planning protocol that was developed and validated by the authors in their preclinical study.

The first step in defining the surgical planning for all patients was the 3D reconstruction of the raw DICOM (Digital Imaging and Communications in Medicine) images using the segmentation tools.

Once the 3D model of the patient’s skull was generated, it was possible to plan the osteotomies.

For each patient, multiple osteotomy lines were planned to virtually simulate the surgical procedure.

The volume of the osteotomized areas from the original 3D reconstruction of the CT images was subtracted, thus obtaining a simulation of bony segment removal (Fig. 1).

To support navigation, the 3D simulation of the intervention was converted into a new sequence of bidimensional DICOM images. Therefore, on the navigator’s screen, it was possible to directly visualize the CT images of the patient as modified by the planned osteotomies.

Navigational System

In this study, an optical navigation system, StealthStation Treon Cranial, (Medtronic, Louisville, CO), was used. According to the preclinical protocol, a semiautomatic calibration process based on collecting more than 350 points on the patient’s forehead surface was used to create a correspondence between the real volume of the patient’s head and the virtual volume derived from CT images. The largest error tolerated by the semiautomatic calibration system was 2 mm.

<table>
<thead>
<tr>
<th>Number</th>
<th>Age (yrs.)</th>
<th>Diagnosis</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>26</td>
<td>Frontal sinus osteoma</td>
<td>Frontal sinus</td>
</tr>
<tr>
<td>2</td>
<td>63</td>
<td>Frontal sinus osteoma</td>
<td>Frontal sinus</td>
</tr>
<tr>
<td>3</td>
<td>60</td>
<td>Recurrent orbital squamous carcinoma</td>
<td>Orbit</td>
</tr>
<tr>
<td>4</td>
<td>6</td>
<td>TMJ anchylosis</td>
<td>Lateral skull base</td>
</tr>
<tr>
<td>5</td>
<td>17</td>
<td>Frontal sinus osteoma</td>
<td>Frontal sinus</td>
</tr>
<tr>
<td>6</td>
<td>36</td>
<td>Orbital cholesterinic granuloma</td>
<td>Orbit</td>
</tr>
<tr>
<td>7</td>
<td>5</td>
<td>TMJ anchylosis</td>
<td>Lateral skull base</td>
</tr>
<tr>
<td>8</td>
<td>62</td>
<td>Frontal sinus osteoma</td>
<td>Frontal sinus</td>
</tr>
<tr>
<td>9</td>
<td>54</td>
<td>Pleomorphic adenoma</td>
<td>Orbit</td>
</tr>
<tr>
<td>10</td>
<td>59</td>
<td>Ethmoidal recurrent SNUC (sinonasal undifferentiated carcinoma) with orbital invasion</td>
<td>Orbit</td>
</tr>
<tr>
<td>11</td>
<td>84</td>
<td>Orbital meningioma</td>
<td>Orbit</td>
</tr>
<tr>
<td>12</td>
<td>71</td>
<td>Temporal bone fibrous dysplasia</td>
<td>Lateral skull base</td>
</tr>
<tr>
<td>13</td>
<td>39</td>
<td>Frontal sinus cholesterinic granuloma</td>
<td>Frontal sinus</td>
</tr>
<tr>
<td>14</td>
<td>64</td>
<td>Posttraumatic dystopia</td>
<td>Orbit</td>
</tr>
<tr>
<td>15</td>
<td>41</td>
<td>Post-FESS (functional endoscopic sinus surgery) medial orbit injury</td>
<td>Orbit</td>
</tr>
</tbody>
</table>

Study Description

For each of the 15 enrolled patients, a set of osteotomy lines was planned according to the above described system.

For patients with orbital masses, a superior or suprolateral or superomedial orbitotomy access was planned to access the extraconal space. For patients with anterior skull-base involvement, a complex of osteotomies of anterior cranial fossa was planned to obtain an en bloc resection of skull-base and orbital tumor together with the surrounding infiltrated bone (Fig. 2).

For patients with frontal sinus pathologies requiring an open surgery approach, an osteoplastic flap of anterior frontal sinus wall was planned (Fig. 3). The planned frontal opercle was shaped to reflect frontal sinus morphology, avoiding the access to the contralateral sinus and to the anterior cranial fossa.

For patients with TMJ anchylosis or secondary TMJ involvement, due to a primitive dysplastic process of temporal bone, condylar osteotomy was planned according to the above-mentioned protocol. Condylar resection was simulated for each patient, and in the case of temporal bone osseous dysplasia, a wide temporal squama resection was planned, sparing the anterior part of the petrosal bone and the area of carotid and stenomastoid foramen (Fig. 4).

For all patients, the virtual planning was turned into a DICOM series, enabling navigation.

During the surgical procedure, the position of planned osteotomies was replicated on the real patient by checking under navigational guidance the position of a piezoelectric osteotome (Mectron Piezosurgery, Caraasco, Italy).

The piezoelectric ultrasonic osteotome was coupled with an infrared-reflecting device (Suretrack System, Medtronic) in order to make it traceable by the navigation system.

In this manner, the surgeon was able to directly control the position of the piezoelectric osteotome on the operating field, with reference to the preoperative virtual planning, which led to

TMJ = temporomandibular joint.
the direct reproduction of the preoperatively planned osteotomies.

Each patient underwent a postoperative CT scan from 1 to 10 days after surgery.

A total amount of 77 osteotomy lines (Table II) was considered and used as the sample for statistical evaluation. Measures regarding length and position of the osteotomy lines on each preoperative virtual planning were compared with the corresponding measures taken on 3D reconstruction of postoperative CT images, thereby obtaining a series of coupled values to be employed for concordance and agreement estimation.

Data concerning the whole sample were cumulatively analyzed. Next, the osteotomy line sample (n = 77) was divided into three subgroups: the orbit group (n = 35), the frontal sinus group (n = 21), and the lateral skull-base group (n = 21).

Data about each individual subgroup were separately elaborated, obtaining concordance and limits of agreement.

Intraoperative surgical complications were also recorded.

**Statistical Analysis**

Continuous variables were summarized by the mean and standard deviation (SD). The Shapiro-Wilk test was used to assess whether data were normally distributed.

Agreement between measurements taken on the plan and those taken on the actual skulls was estimated using the Lin concordance coefficient.\(^3\text{3,34}\)

The Lin concordance coefficient describes the strength of agreement: greater than 0.99 indicates almost perfect agreement; 0.95 to 0.99 indicates substantial agreement; 0.90 to 0.95 indicates moderate agreement; and less than 0.90 indicates poor agreement.

Bland-Altman analysis was also performed to estimate the limits of agreement.\(^3\text{5–38}\) Assuming a normal distribution of the differences between the planned and performed osteotomies, it was possible to obtain an interval, in which 95% of these differences could be found.

Statistical analysis was performed using Stata/SE version 14.2 (StataCorp LP, College Station, TX).
RESULTS

Overall Results

The mean difference between preoperative planning and postoperative CT data was 0.719 mm (SD 1.085 mm; 95% confidence interval [CI]: 0.472 to 0.965 mm).

Concordance between preoperative planning and postoperative CT estimated with Lin's concordance coefficient was 0.997 (asymptotic 95% CI: 0.996 to 0.998) (Fig. 5).

Bland-Altman limits of agreement calculated for the difference between preoperative planning and postoperative CT measures ranged from −1.407 to 2.844 mm (Fig. 6).

Orbit Group Results

The mean difference between preoperative planning and postoperative CT data in the orbit group was 0.587 mm (SD 1.000 mm; 95% CI: 0.244 to 0.931 mm).

Concordance between preoperative planning and postoperative CT in the orbit group estimated with Lin's concordance coefficient was 0.998 (asymptotic 95% CI: 0.997 to 0.999).

Bland-Altman limits of agreement calculated for the difference between preoperative planning and postoperative CT measures in the orbit group ranged from −1.372 to 2.547 mm.

Frontal Sinus Group Results

The mean difference between preoperative planning and postoperative CT data in the frontal sinus group was 0.725 mm (SD 1.270 mm, 95% CI: 0.174 to 1.330 mm).

Concordance between preoperative planning and postoperative CT in the frontal sinus group estimated with Lin's concordance coefficient was 0.989 (asymptotic 95% CI: 0.979 to 0.998).

Bland-Altman limits of agreement calculated for the difference between preoperative planning and postoperative CT measures in the frontal sinus group ranged from −1.370 to 3.241 mm.

Lateral Skull-Base Group Results

The mean difference between preoperative planning and postoperative CT data in the lateral skull-base group was 0.904 mm (SD 1.044 mm, 95% CI: 0.428 to 1.379 mm).
Concordance between preoperative planning and postoperative CT in the lateral skull-base group estimated with Lin’s concordance coefficient was 0.997 (asymptotic 95% CI: 0.995 to 0.999).

Bland-Altman limits of agreement calculated for the difference between preoperative planning and postoperative CT measures in the lateral skull-base group ranged from −1.143 to 2.951 mm.

**Surgical Complications and Outcome**

No unwanted intracranial penetration, dural tear, or contralateral frontal sinus involvement has been reported.

No intraoperative deviation from the preoperative surgical planning was needed for any patient.

In patients who underwent conservative craniofacial skeleton dismounting (e.g., osteoplastic flap for frontal sinus pathologies or orbitotomic access for intraorbital lesions), the postoperative reassembly led to a complete restoration of the original anatomy without misalignment of bony segments.

**DISCUSSION**

To date, no planning and navigation protocol has been specifically developed and validated for resective skull-base surgery. In fact, the navigation-guided approaches to the anterior skull base, the orbit, and the frontal sinus generally support endoscopic and open procedures by simply showing the preoperative radiological images.

In such surgical field, virtual surgical planning still has a limited role, primarily confined to the experimental and preclinical ambit, whereas it has a well-established role in orthognathic and maxillofacial trauma surgery, often in combination with computer-aided design/computer-aided manufacturing cutting guides.

The planning and navigation protocol described in this article represents a novel image-guided approach to the anterior and lateral skull-base surgery based on the virtual simulation of osteotomies and skull-base resections to perform accurate craniotomies without the support of rigid cutting guides.

This technique permits planning of the surgical approach in the preoperative phase by using 3D elaborations from CT images and permits using the piezoelectric instrument to accurately perform the osteotomies and the mass resection under the navigational control without the need of rigid cutting guides.

In this pilot study, data from clinical application of this protocol showed an overall mean difference between performed and planned osteotomy lines of 0.719 mm (95% CI: 0.472 to 0.965 mm). This error margin results from the stochastic errors and the systematic errors of the navigation system. Data available in the literature typically document only the systematic error, which is reported to be consistent or higher than experimental data described in this study.
To obtain more informative data regarding system reliability, further statistical evaluations were performed, and Lin's concordance coefficient and Bland-Altman limits of agreement were estimated.

Only a small number of works describe the reliability of surgical planning or navigation systems by exploring the concept of concordance,\textsuperscript{6,20-22} using an interclass correlation coefficient to assess the concordance between different surgeons in performing the same surgical maneuver rather than to assess the degree of congruence between the planned and performed resection.

In this study, overall Lin's coefficient was 0.989 (95% CI: 0.979 to 0.998), thereby showing an almost complete concordance.

**TABLE II.** Planned and Performed Osteotomy Lines.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Intervention</th>
<th>Osteotomies</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Open osteoma resection</td>
<td>Osteoplastic flap (4 osteotomy lines)</td>
</tr>
<tr>
<td>2</td>
<td>Open osteoma resection</td>
<td>Osteoplastic flap (4 osteotomy lines)</td>
</tr>
<tr>
<td>3</td>
<td>Orbital exenteration with anterior skull-base resection</td>
<td>Superior orbitotomy/ anterior cranial fossa resection (6 osteotomy lines)</td>
</tr>
<tr>
<td>4</td>
<td>TMJ ankylosis removal/costochondral graft</td>
<td>Condylectomy/costochondral graft (3 osteotomy lines)</td>
</tr>
<tr>
<td>5</td>
<td>Open osteoma resection</td>
<td>Osteoplastic flap (4 osteotomy lines)</td>
</tr>
<tr>
<td>6</td>
<td>Orbital mass resection</td>
<td>Superolateral orbitotomy (5 osteotomy lines)</td>
</tr>
<tr>
<td>7</td>
<td>TMJ ankylosis removal/costochondral graft</td>
<td>Condylectomy/costochondral graft (3 osteotomy lines)</td>
</tr>
<tr>
<td>8</td>
<td>Open osteoma resection</td>
<td>Osteoplastic flap (4 osteotomy lines)</td>
</tr>
<tr>
<td>9</td>
<td>Orbital mass resection</td>
<td>Superolateral orbitotomy (4 osteotomy lines)</td>
</tr>
<tr>
<td>10</td>
<td>Orbital exenteration with anterior and lateral skull-base resection</td>
<td>Superior orbitotomy/ anterior and middle cranial fossa resection (7 osteotomy lines)</td>
</tr>
<tr>
<td>11</td>
<td>Orbital mass resection</td>
<td>Superolateral orbitotomy (5 osteotomy lines)</td>
</tr>
<tr>
<td>12</td>
<td>Temporal bone resection, alloplastic prosthetic replacement</td>
<td>Temporal bone resection, lateral skull-base resection, condylectomy (15 osteotomy lines)</td>
</tr>
<tr>
<td>13</td>
<td>Frontal sinus wall resection and reconstruction with calvaria graft</td>
<td>Osteoplastic flap/calvaria graft (5 osteotomy lines)</td>
</tr>
<tr>
<td>14</td>
<td>Superior and lateral wall reconstruction</td>
<td>Superolateral orbitotomy (4 osteotomy lines)</td>
</tr>
<tr>
<td>15</td>
<td>Superomedial wall reconstruction</td>
<td>Superolateral orbitotomy (4 osteotomy lines)</td>
</tr>
<tr>
<td></td>
<td><strong>Total Amount of osteotomy lines</strong></td>
<td><strong>77 osteotomy lines</strong></td>
</tr>
</tbody>
</table>

TMJ = temporomandibular joint.

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An important parameter for assessing the actual reliability of the planning and navigation system from the authors' point of view is the concept of Bland-Altman limits of agreement.

This concept is particularly relevant because it provides a description of the actual range in which 95% of the differences in osteotomies could be included and consequently estimates the actual error range of the technique. The Bland-Altman limits of agreement concept has been applied for the first time to the assessment of the accuracy in performing the planned osteotomies by the authors in their preclinical study.23

With reference to the preclinical data, the results shown in this clinical application study describe a higher mean discrepancy between planned and performed osteotomies: 0.044 mm (95% CI from −0.128 to + 0.216) in the preclinical data versus 0.719 mm (95% CI: 0.472 to 0.965 mm) in the clinical series. This finding can be explained by the fact that the preclinical design of the study used skulls instead of patients in the operating setting, excluding several sources of error related to the soft tissue state. In fact, the surface of each skull exactly corresponded to the shape of its CT 3D rendering, whereas the cutaneous layer of the patient during the intervention might not correspond to the surface of the 3D-reconstructed CT image. Moreover, the sliding of the cutaneous layer in reference to the skull surface can affect the accuracy of the calibration process.

However, a mean discrepancy of 0.719 mm (95% CI: 0.472 to 0.965 mm) is far lower than the toleration threshold of most navigation systems (± 2 mm), with no significant clinical impact.

Lin's coefficient showed an almost complete agreement between planned and actually performed osteotomies in both the preclinical and clinical study: 0.999 (95% CI, 0.999 to 1.000) vs. 0.997 (95% CI: 0.996 to 0.998).

Bland-Altman range of agreement in the clinical series was slightly wider than in the preclinical study (−1.407 to + 2.844 mm vs. −1.500 to + 1.589 mm), probably for the soft tissue sliding effect.

In this study, the accuracy of the novel planning and navigation system was assessed in three different anatomic areas: the orbit, the frontal sinus, and the lateral skull base.

The best results were reported in the orbit group. This fact could be explained by the possibility of a very efficient calibration process in this area, which was also supported by the 3D shape of the orbital region that helps in defining anatomic landmarks for further intraoperative positional check.

To date, in the orbital surgery setting, no study has evaluated the accuracy in performing the planned osteotomy lines. The available studies only describe the accuracy of navigational systems in guiding the position of prosthetic implants for orbital wall reconstruction.18,20–22

For frontal sinus surgery, the accuracy in performing the planned osteoplastic flap is reported as submillimetric mean difference with an extremely high concordance coefficient. The available literature regarding navigation-guided osteoplastic flaps only reports the 2-mm tolerance threshold of the navigation system18,20–22 declared by the manufacturer and does not evaluate the actual intraoperative margins of error. All these studies refer to an intraoperative frontal sinus boundary detection rather than to the navigation-guided performance of a planned osteoplastic flap. The slightly higher mean difference and the wider agreement interval described for the frontal sinus group, if compared to the orbit group, can be explained with the complex shape of the planned osteoplastic flaps, leading to a more challenging surgical performance.

In lateral skull-base field, data showed the largest error margins. However, even in this field, the concordance between planned and performed osteotomies was extremely high. This fact can be explained by the anatomical complexity of this area, which leads to more intraoperative difficulties. Moreover, the presence of a mobile structure, such as the temporomandibular joint, could...
affect the exact correspondence between the anatomy registered during the CT examination and the actual condylar position. The medial part of the lateral skull base is also very difficult to approach, leading to an intrinsic surgical inaccuracy. However, such results describe a very high accuracy level, even in such a difficult anatomic region.

In the lateral skull-base field, the use of navigation in temporomandibular joint surgery is well established. However, up to now no study has explored the accuracy of navigation systems in guiding osteotomy maneuvers with reference to the preoperative planning. These results seem to support the use of this planning and navigation protocol in guiding osteotomy procedures of the orbit, frontal sinus, and lateral skull base. The use of an integrated planning and navigation process, in which 3D models of the CT images are set in a system of fixed spatial coordinates, contributes to minimize the systematic error of surgical navigation in guiding the performance of the planned osteotomies.

In this work, besides the description of the accuracy of a novel planning and navigation protocol, specifically for the anterior and lateral skull-base surgery, an innovative and integrative methodologic approach for image-guided surgery systems evaluation is provided.

Use of Bland-Altman limits of agreement compared with the use of the mean difference alone provides more information on the clinical applicability of the tested protocol. A limitation of this study could be represented by the number of enrolled patients. However, the goal of this pilot study is not to assess the clinical outcomes of the patients treated with this technique but to define the accuracy of this novel surgical approach in the clinical setting. For this reason, the study sample is represented by the whole amount of the measures taken on preoperatively planned and actually performed osteotomies.

CONCLUSION
The results of this pilot study support the use of this novel planning and navigation protocol for guiding osteotomy and resection maneuvers in anterior and lateral skull-base surgery. This research proposes an integrated and modern approach to the skull base and the orbit based on spatially accurate and minimally invasive craniometric accesses without the support of rigid cutting guides.

To assess the clinical outcomes of the patients treated with this technique, further studies are required.

BIBLIOGRAPHY