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Simulation Guided Navigation in cranio-maxillo-facial surgery: a new approach to improve intraoperative three-dimensional accuracy and reproducibility during surgery.

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Research Project:

Simulation Guided Navigation in cranio-maxillo-facial surgery: a new approach to improve intraoperative three-dimensional accuracy and reproducibility during surgery.

Index:

1 State of the art

Computer-based surgery is a rapidly emerging and increasingly important area of research that combines a number of disciplines for the common purpose of improving healthcare[1].

Indeed, due to the recent development of 3-dimensional technology for cranio-maxillo-facial surgery, computer software is increasingly being used for diagnosis, analysis, data documentation, and surgical planning to elaborate virtual simulations of patient's skeletal changes and new soft tissue profiles[2].

Many applications for computer-based diagnosis and cranio maxillo-facial surgery have been proposed[3-4-5-6-7-8-9-10-11]. The goal of computer-based surgery simulation for treating maxillofacial anomalies, tumors and trauma is to enable the surgeon to experiment with different surgical procedures (osteotomies, grafts, implants, surgical approach etc.) in an artificial environment and to predict the outcome of a craniofacial intervention before the actual surgery.

Computer-aided operations are increasingly being used to obtain a final result as similar as possible to the simulated results. Good software needs to be highly reliable to obtain a realistic simulation, but the simulation quality is related to the surgeon's ability to reproduce the planned surgery. Many techniques have been proposed to help the surgeon improve reproducibility.

Currently in orthognathic surgery the typical method to reposition jaws in the correct and planned location is based on the use of surgical splints. This procedure clearly has a quite high level of imprecision, particularly because it is not easy to correlate the facial bow to the cephalometric data in a surgical plan that is performed based on the cephalometric data, which are normally bi-dimensional and characterized by some x-rays distortion, while dental casts are three-dimensional, are mounted on a facial articulator, and are quite different from the facial skeleton.[12]

If interocclusal wafers are used, standard and simple transverse and sagittal maxillary repositioning is well predictable.[13]

The most important differences between planned and achieved maxillary movements are in the vertical and rotational positioning[14]-[15] of complex skeletal three-dimensional movements.

Recently, surgical splints have been processed using stereolithografic systems[16] or computer-aided design and manufacturing techniques[17]. Virtual computer-assisted models can improve splint accuracy, especially in terms of the correlation with the skeletal structure, but do not improve vertical control of the maxilla[18].

Several methods have been described for intraoperative maxillary control including intraoral reference points (IRP), extraoral reference points (ERF), intraoperative face-bow transfer, and the three-splint technique with positioning plates [14]-[19]. None of these procedures is able to control the real position of the mobilized fragment in the three-dimensional facial skeleton frame. In general, it is difficult to intraoperatively trace an osteotomy parallel to the skeletal Frankfurt Plane at the Le Fort I level. The obliquity of the osteotomized skeletal surface introduces unavoidable errors when the planned movements are reproduced. Computer-aided surgery should be used more in the coming years to check these three-dimensional movements.

Computerized navigation surgery is a surgical modality based on synchronizing the intraoperative position of the instruments with the imaging of the patient's anatomy obtained by computed tomography.[20]-[21]-[22]-[23]

During orthognathic surgery, and in the same way in trauma surgery, a navigation system controls the position of the mobilized bone and eventually verifies the new bone location. Each bone segment shift can be controlled and modified with the navigation system, synchronizing the intraoperative position of the instruments to a preplanned location within the surgical field.

In the field of traumatology surgeon tries to restore the anatomical situation present before the trauma. If this procedure is generally an easy procedure in a monofocal fracture with low degree of displacement it becomes more and more difficult in plurifragmentary or in a panfacial trauma where it is sometimes difficult to achieve the exact position for each bone fragment. Three dimensional positioning of the fragment via navigation could help the surgeon to reposition the more displaced bone surface; computer mirroring or other technical procedure can help to obtain symmetry and restore the previous anatomy.

In oncology navigation can help to compare the boundaries of the tumor in vivo with CT, MRI, angiography images obtaining a more accurate tumor removal; in the chapter of reconstructive surgery navigation can be useful in positioning bone flap (i.e. to decide in which exact site perform the bone cut in a fibular microvascular flap for mandibular or maxillary reconstruction).

Project description

There are three main field of research in which the concept of “Simulation Guided Navigation” procedures in cranio-maxillofacial surgery have been widely introduced and this approach in the research project has been validated:

1) **Navigation in Orthognathic Surgery.**

In this field the objective was to validate these applications:

- to improve the accuracy in simulation guided navigation;
- bone segments navigation;
- mandibular condyle navigation;
- to develop more accurate surgical intruments (i. e. saw) tracking.

2) **Navigation in H&N Oncology.**

Oncology is the first surgical field where computer-aided surgery has been developed and applied. Navigation of the tumor mass and the surrounding tissues, seeking safe margins, has been the inspirational concept that lays at the root of this technology.

Nowadays oncology is still the head and neck surgical field where navigation is mostly used. Especially for tumors of the splancnocranium or the skull base.

Objective of the project was:

- developement of computer planned resection;

- developement of computer planned reconstruction;
- more accurate navigation of soft tissues.

3) **Navigation in H&N Traumatology.**

Navigation has been recently applied also to complex bone traumatology, especially orbital fractures. One major use of navigation has always been the research of foreign bodies, which are so frequent in the traumatology of the head.

Objective of the project was:

- developement of more accurate computer planned bone repair and reconstruction;
- navigation of the mandibular condyle.

Final objective that the research project should achieve

The final objective was to introduce the concept that many cranio-maxillo-facial surgery procedures could be performed applying the final goal of reproducibility of a presurgical plan and overwhelm the approximate approach based on the surgeon's skill. This final objective has been reached using a validation protocol.

Project articulation and fulfillment time

Patients:

We have enrolled patients with dento-facial deformities, trauma and tumors from January 2011 to December 2013 which would be operated on at the Oral and Maxillofacial Surgery Unit of the S. Orsola-Malpighi University Hospital, Bologna, Italy.

After a clinical evaluation and an approach of many consultants, all patients underwent CT (CBCT – Cone Beam Computer Tomography, for orthognathic surgery procedures and MSCT - Multi Slice Computer Tomography, for traumatology and oncology).

The surgical simulation has ben mapped in all patients with SurgiCase 5.0 by Materialise® (Leuven, Belgium) and the eNlite Navigation System by Stryker® (Freiburg, Germany) with the iNtellect Cranial Navigation platform has been used during each operation (FIG. 1).

Procedures:

All patients were studied and treated according to the following steps:

1. Imaging: cone-beam computerized tomography (CBCT) or multi-slice computer tomography (MSCT) data acquisition;

2. Planning: virtual simulation of the surgical procedure using Materialise® SurgiCase;

3. Intraoperative navigation: performed using the Stryker® eNlite Navigation System, including pre-registration and intraoperative registration, performed using point-to-point and surface registration methods;

4. Validation: after the CBCT/MSCT postoperative scan, a validation will be performed to assess reproducibility.

1_Imaging: a CBCT/MSCT scan of the **orthognathic surgery** patient was performed before surgery using the Newtom 3G Maxiscan® (QR - Quantitative Radiology, Verona, Italy). This tool is designed to study the maxillofacial area. The main feature of the Newtom 3G Maxiscan® is its ability to obtain a complete acquisition of the patient in a single rotation. Furthermore, this tool allows the scan to be performed with the patient in a prone position, which is comparable to the operating theatre position and particularly useful for soft tissue accommodation.

Other features are:

- extremely low radiation dose administered as compared with MSCT.[24-25-26]
- the scanned mass can be virtually "dissected" in all dimensions due the possibility of actively working on the entire volume;

- the safe-beam device used by Newtom 3G Maxiscan® automatically adjusts the emitted radiation dose based on the body's mass and dimensions.

In the patients affected by **trauma or tumor** a MSCT will be perform (mainly a General Electric Hi Speed CT, USA) as in this kind of patients it is mandatory to use a more detailed x-rays analysis even accepting a greater radiation exposure.

2_Planning: CBCT or MSCT scan data were loaded on Surgicase CMF 5.0 by Materialise®, which allows the surgeon to virtually plan and realize the osteotomies to be performed in the operating room according to the analysis and the presurgical planning.

Materialise® Surgicase allows a virtual outcome of the surgery for the surgeon (skeletal surgical simulation). Furthermore, the software elaborates facial soft tissue appearance after repositioning of the bone segments due to an algorithm published by our group in 2006[27].

After creating the virtual osteotomy plan, Materialise provided a conversion from the work-on file to a 3D virtual object in a standard and internationally accepted file format (STL).

3_Intraoperative Navigation

A. Preregistration and Registration

Registration is a crucial procedure and a fundamental preliminary step for the navigation technique, which consists of making the real patient visible and his/her orientation in the space of the operating theatre decipherable by the navigation software in the same coordinate system as the preoperative CT scan.

This technique orients the patient according to the CT scans by indicating well identifiable points on the face and relating them to the virtual patient image shown on the navigator screen. The preregistration process consists of identifying these points on the virtual model of the patient's face. The registration process consists of identifying the same points on the real patient's face (point-to-point registration). The procedure is refined with a surface registration, which consists of collecting casual points on a patient's face and defining a virtual model of the facial surface. The system subsequently identifies relationships between this model and the surface of a patient's 3D CT scan reconstruction[28]-[29]-[30]-[31].

Before preregistration, we have uploaded the STL file of the osteotomized skull or other surgical plan. The system is able to perfectly overlap the fixed bone segments to the native skull and show the spatial discrepancy between the mobilized bone segments before and after repositioning (FIG. 2).

This process have been continued in the operating theatre. First, the tracker have beeb screwed into the patient skull. Then, the registration have been performed according to the preregistration. We have verified the accuracy of the registration procedure by pointing to anatomical landmarks on a patient's face with the pointer tool (we usually chose the teeth of the upper maxilla and eyelid canti). If correct overlap was observed between the real patient's landmarks and the virtual ones, we have confirmed the procedure and we conducted the surgery.

B. Navigation

The surgery wasn't different from routine maxilla-facial surgical procedures. However, with the Navigation System, each bone segment shift could be controlled by pointing to the mobilized position and checking the overlap precision between the planned position, shown on the LCD screen, and the achieved position. If the positions shouldn't been coordinated, the surgeon would have moved the bone until the required position would been obtained. This checking process would have been conducted using the "pointer" of the Stryker eNlite Navigation System as a mobile tracking system (FIG. 3).

The landmarks that usually have been used to check surgical movement were, in orthognathic surgery procedures, the anterior nasal spine, superior and inferior incisors, osteotomy lines, teeth cusps (orthodontic brackets for orthognathic procedures), and mandibular angles. For oncological reconstruction we used the osteotomy cuts designed on the fibular model or the bony part of the flap and in traumatology with the pointer we have checked the surface of the fragment till reaching the planned position. The pointer tip was used to touch these landmarks on the mobilized bony parts, visualizing the navigation system monitor if the corresponding “virtual pointer” touched the analogous virtual landmark, initially on the native bone (native CT scan) and then (after repositioning of the fragment) on the mobilized bone (simulation object overlapped to the native CT scan).

*4_**Validation: Proposed measures to verify the obtained results**:*

*w*e have focused this evaluation on “reproducibility,” i.e., the capacity of the procedure to reach the virtually planned bone segment positions during the operation.

In this case, the validation have evaluate the increase in effective reproducibility provided by the Stryker® eNlite Navigation System compared to the reproducibility we had obtained in a previous study group for the orthognathic procedures, in which no intraoperative navigation was performed, and planned positions were reached only by surgical splints[28.] In oncology and traumatology we have used the pre-operative anatomical structures and, when possible, we have used the unaffected side of the face as a template. In oncology we have compared the presurgical CT data with the reconstructive plan and the post-surgical final result.

A post-operative CT has been conducted from 1 to 6 months after surgery with the same acquisition protocol. The CT has been compared to the 3D virtual object STL file to calculate the overlap error between the images. This procedure has been performed with 3-Matic software, (Materialise®), which matches the two surfaces, and computes the difference in the overlap. The program created an overlapping image for each patient (FIG. 4), in which the operator saw the preoperative simulation surface highlighted with a specific color scale. Each color, as shown in the image, corresponds to a matching error value with respect to the actual postoperative patient’s bony surface.

FIG.1

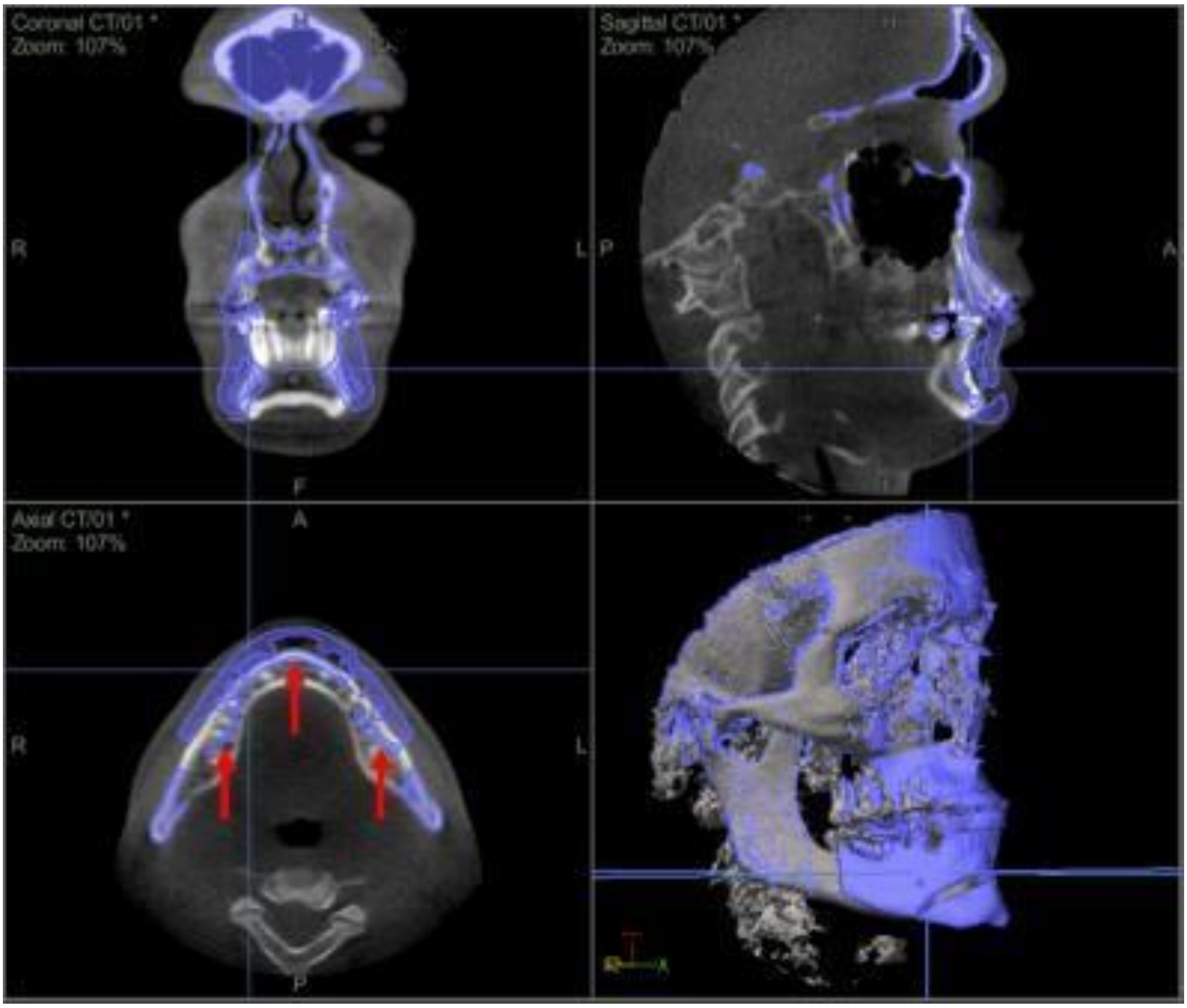
Coronal CT/01 *
Zoom: 107%
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FIG.2

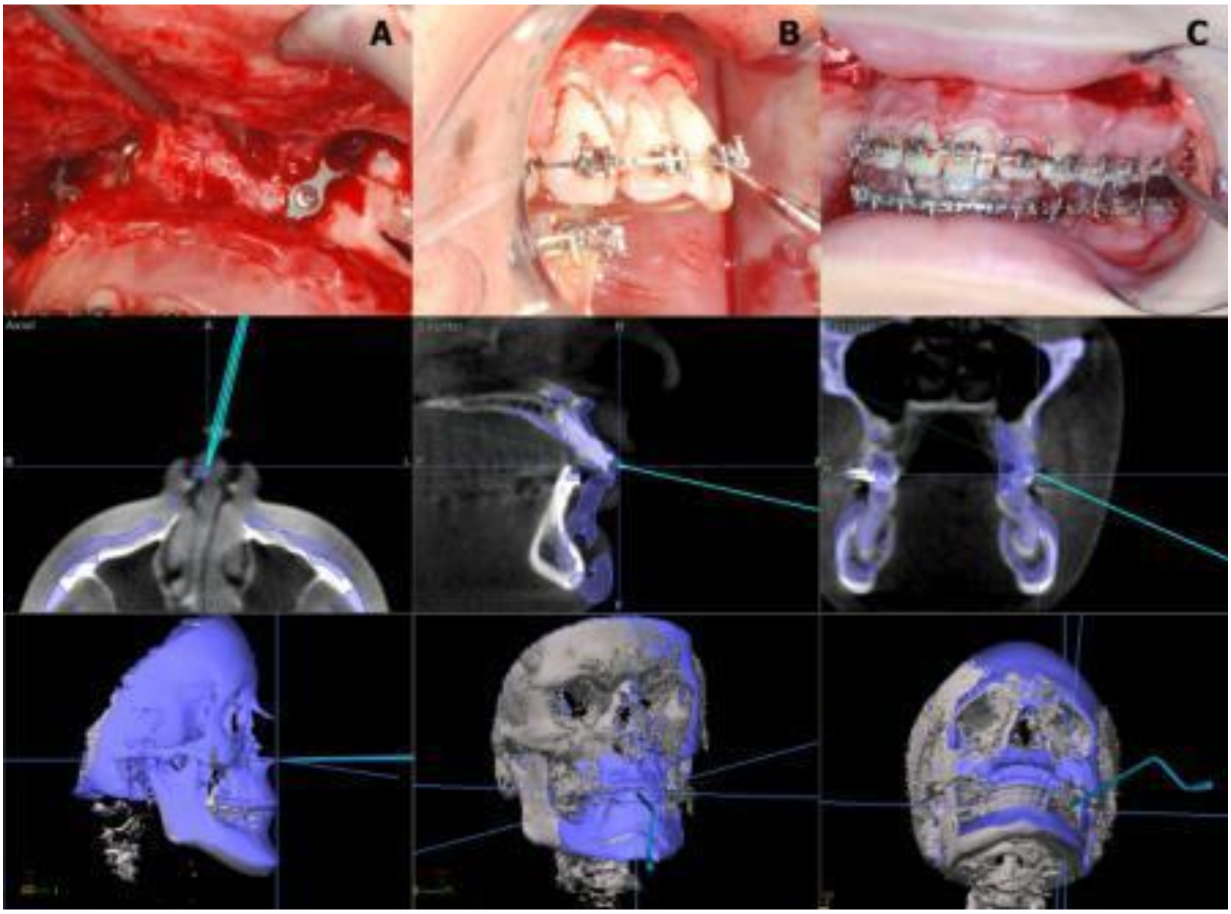


FIG. 3 The correct position of the maxilla is plotted using known landmarks including the anterior nasal spine (A) , the brackets of the incisors (B) , canines and molars (C) .

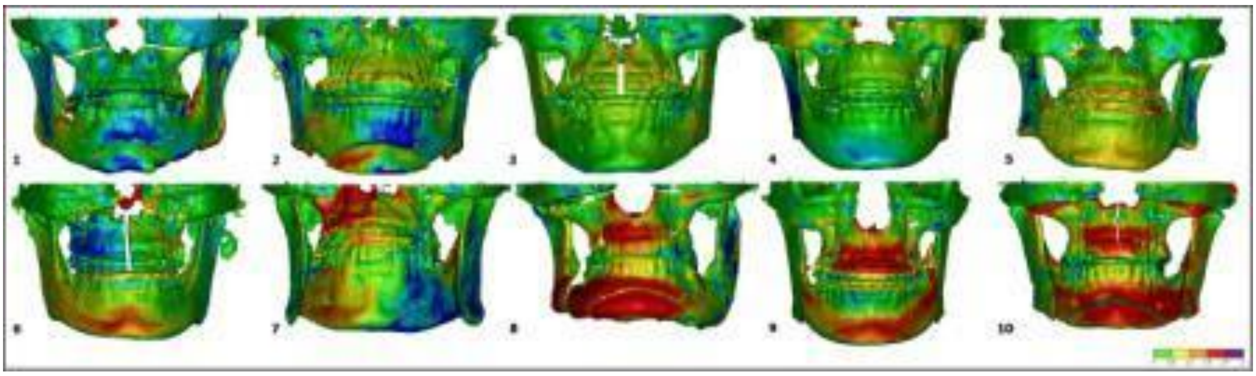


FIG.4

1) Navigation in Orthognathic Surgery.

In this field the objective was to validate these applications:

- **<u>to improve the accuracy in simulation guided navigation</u>** we have developed a project Called:

"New Method of Validation for 3D Simulation Guided Navigation in Facial Anomalies Surgery "

With this aim we analized retrospectively 20 patients enrolled with dento-facial anomalies and treated at the Oral and Maxillofacial Surgery Unit of the University Hospital S. Orsola -Malpighi (Bologna) from November 2008 to December 2011 . The clinical characteristics of the patients are summarized in Table 1.

Patient	Sex	Age	Diagnosis
1	M	43	class III (hypoplasia of the maxillary+ prognathism)
2	F	18	class III (hypoplasia of the maxillary +prognathism)
3	M	35	hypoplasia of the maxillary +prognathism
4	M	25	class II (OSAS)
5	F	17	outcomes of bilateral hemimandibular hypoplasia
6	F	18	class III dentoscheletrica (Sd. Crouzon)

7	F	33	class III (hypoplasia of the maxillary prognathism +)
8	F	18	class II
9	F	22	class III (hypoplasia of the maxillary + prognathism)
10	M	38	class III (hypoplastic maxillary + prognathism)
11	M	22	mandibular asimmetry, Class III (hypoplastic maxillary +prognathism)
12	M	32	class II (maxillo- mandibular hypoplasia)
13	F	44	mandibular deviation in short face type
14	F	18	class III (hypoplasia of the maxillary + prognathism)
15	M	26	class III (hypoplasia of the maxillary + prognathism)
16	F	29	mandibular asimmetry, Class III (hypoplastic maxillary + prognathism)
17	F	22	class III (hypoplasia of the maxillary + prognathism)
18	F	40	class III (hypoplasia of the maxillary + prognathism)
19	F	45	class III (hypoplasia of the maxillary + prognathism)
20	F	49	class II (maxillo- mandibular hypoplasia)

Table 1

After the analysis of the orthodontic and surgical treatment , all patients underwent orthognathic surgery as planned preoperatively , all patients were operated on by the same surgeon . The surgical simulations , performed by the same researcher , were produced with the software SurgiCase 5.0 (Materialise - Leuven , Belgium) on the basis of a cone-beam CT (CBCT) preoperatively. All patients were subjected to computer - assisted intervention according to the method of the Simulation Guided Navigation; all patients were subjected to cone-beam CT to 6 months postoperative , used for the validation procedure .

IMAGING

The preoperative and postoperative CBCT were performed , for the first 10 patients using the system Newtom 3Gmaxiscan (Quantitative Radiology , Verona, Italy) , while the latter 10 patients using the system Newtom VG (Quantitative Radiology , Verona, Italy), which represents an evolution of the first . This change was motivated by an update of the machines in the structure of Radiology where the examinations were conducted , so it is independent of our search intentions . Nevertheless, these devices are both designed specifically for the acquisition of the maxillofacial complex and represent the evolution of each other. Therefore we can assume with good approximation the change does not affect the acquisition system . The only real practical difference between the machines is that the first acquires in the prone position, while the second upright. Since the bony structures our target and being insensitive to the navigation system cervical rotations, we can affirm that there is no difference.

The use of CBCT for this type of procedure is imposed according to the current international standards. Indeed CBCT provides optimal scan of the bony structures of the face in front of a relatively low radioesposizione.15 A multislice CT certainly increase the accuracy of the reconstruction, but given the high level of radiation exposure does not appear adequate for this type of surgery, whereas, moreover, there is also a CT scan at 6 months postoperatively. The timing of 6 months was motivated by the fact that with the same TC our group also performs the validation of soft tissue (according to another research protocol). Six months is a reasonable time in order to minimize the effects of postoperative edema .

PLANNING

The data of CBCT scans were loaded on SurgiCase 5.0 (Materialise , Leuven , Belgium). This software allows you to virtually reconstruct the facial skeleton of the patient and perform on it osteotomies and displacements of the bone segments . This procedure allows you to run an entire orthognathic surgery in a virtual way and save the result in a format file owner (SGC) . In order to convert the file into STL was necessary to send the file to Materialise SGC so that may be performing conversion using the 3Matic software (Materialise, Leuven, Belgium). It ' was specifically asked to produce STL files with a resolution that does not exceed 10Mb of memory. This is because the browser software would be significantly slowed down by the management of a larger file .

NAVIGATION INTRAOPERATIVE

Transfer of STL files

The system navigazone is not natively able to load the STL file in your desktop environment . To achieve this , engineers have provided us with Stryker , under the research collaboration with our group , a string of additional control . The program is then able to place objects in STL format into space graph of TC and the matching is guaranteed by the perfect correspondence between the coordinates of the DICOM CT and STL planning. The result of this command is shown in Fig. 5 .

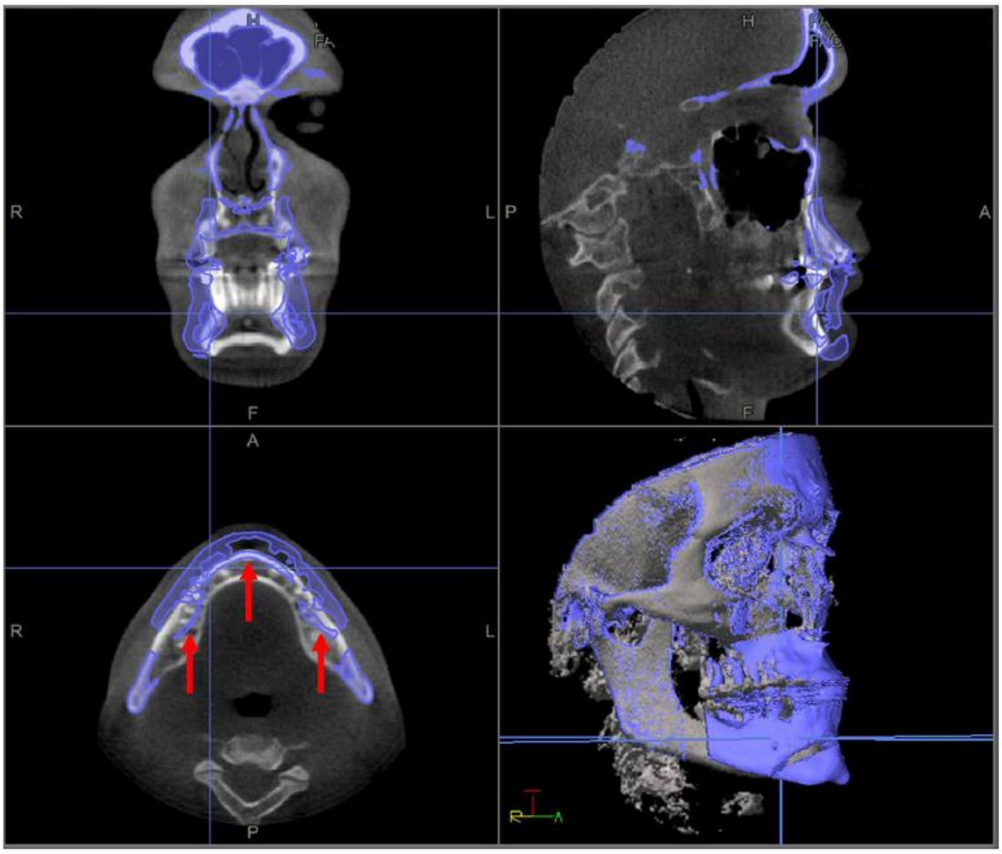


FIG. 5

As represented in the figure, the portions of the skeleton that were not moved coincide perfectly, while the portions which have undergone a shift according to the operative program show a discrepancy relative to the bone that accurately represents the native portion of displacement to be imparted .

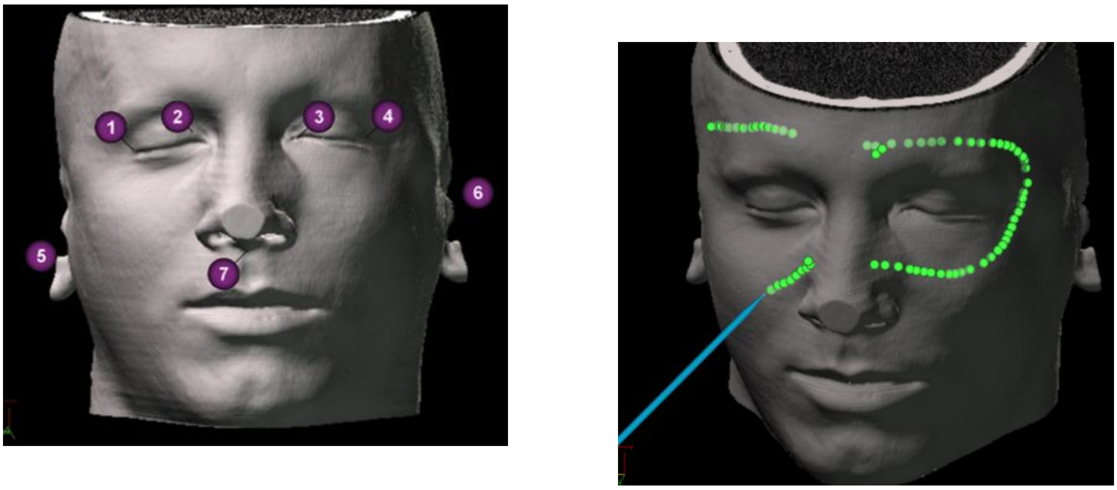
REGISTRATION

As explained above, in order to navigate a surgery is necessary to register the patient and CT. The process of registration, or the creation of spatial correspondence between the two coordinate systems (real and virtual), it can be based on several methods. For our study, we used the combined use of a recording point to point and a surface scan . This procedure can be carried out both on the soft tissues both hard tissue . In our experience, browsing , using CBCT, recording the soft tissue becomes less accurate in terms of Target Registration Error (TRE) calculated by the system, compared to that on the hard tissues . This figure seems intuitive when you consider the relative deformability of the soft tissues compared to hard tissue. In an earlier evaluation, 10 patients (mismatched patients in the present study) recorded through the soft tissues, the final values of TRE ranged between 0.60 mm and 1.00mm with a mean TRE of 0.77 mm (SD 0.13mm) . In contrast, 10 patients (mismatched patients in the present study) recorded through the bone tissues, we obtained values of TRE between 0.10mm and 0.50 mm, with a TRE average 0.32 mm (SD 0:06 mm). The difference is significant, so where possible we prefer to register on the bone tissue .

Registration on soft tissue

Point To Point

The points considered are the medial and lateral eyelid songs to both eyes , the subnasale point (moderately distorted by the presence of naso-tracheal intubation) and left and right earphones traghi. If the patient has more points easy to localize (eg a detected nevus) we use also them (Fig. 6A).



A B

FIG. 6 Soft tissues: A. Point-to-Point Registration; B. Surface Registration

Surface Refinement

With extreme care to not deform the skin (the tip of the scanning tool , which is the pointer must touch the skin and plotted it only slightly) , we proceed to draw random points on the forehead, periorbital regions, the bridge of the nose and temporo- zygomatic regions (Fig. 6B) .

Registration on hard tissue

Point To Point

This procedure takes advantage of the presence of orthodontic brackets . Infact they represent fixed points with a relatively stable support to the tip of the pointer. We used the central incisor and canine brackets and bands on the first or second molars on both sides, and will last with the nasal spine and both infraorbital foramina. It goes without saying that this process can be completed only when the skeletonization of the maxilla occurred (Fig. 7) .

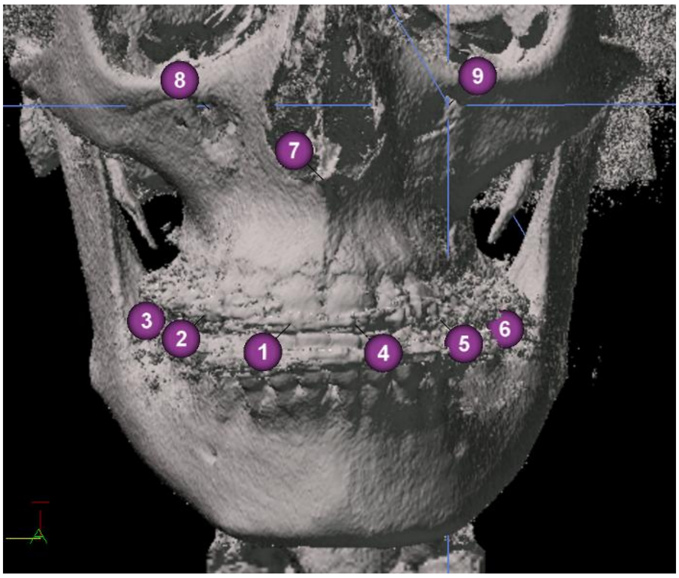


Fig 7 Hard tissues : Point- to-Point Registration

Surface Refinement

The procedure is completed by scanning the anterolateral surface of the maxilla skeletonized, in a manner not different from what happens for the registration of the soft tissues, with the important advantage of not deform the surface that you are scanning .

In both cases, the proper registration occurs on the surfaces and cusps of the dental surface, as well as - in the second case - on the bone surface.

ACTUAL NAVIGATION

The surgery is conducted in a manner no different from a normal orthognathic surgery . Having mobilized the maxillary bone segment, it is tracked in space and in its movements by the pointer, which goes to locate known points (or cusps dental brackets , anterior nasal spine , ...) or surfaces in order to verify that the newly - position corresponds to that represented in the project (Fig. 3, 8). This procedure allows to adjust the position of the jaw to obtain a good position. If the system should find out that the programmed position is not reachable (can not be eliminated bone pre-contacts, soft tissue resistance, ...), the case was excluded from the study and the decision taken in the operating room can not be changed anymore. This exclusion criterion in retrospect is important because what we are going to test is not the ability to move the upper jaw exactly where we planned regardless of any other factor, but the ability to verify that the jaw, positioned to the programmed position, is faithful, and the system can further increase the accuracy. If there are extrinsic factors that prevent a shift whole, it is therefore appropriate to exclude cases in which this is done, although it could be argued, however, the utility of the navigator, showing it the objective impossibility of achieving the result .

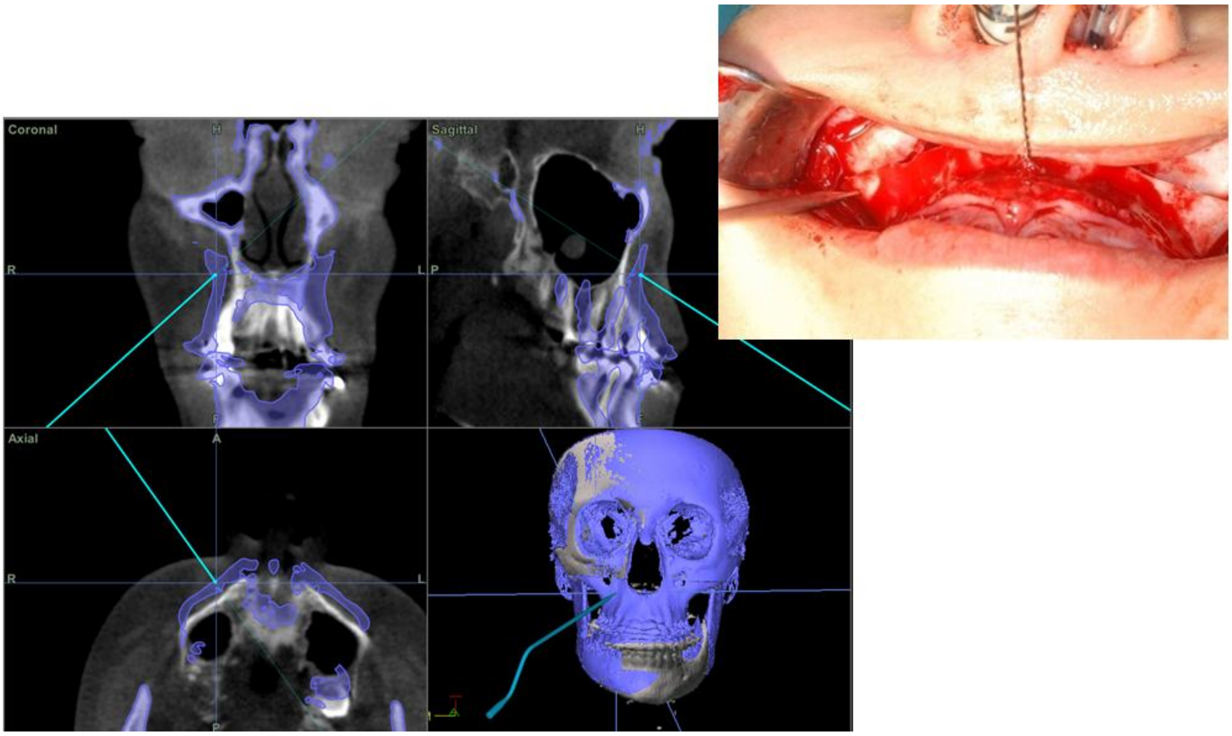


FIG. 8. The correct position of the upper jaw is drawn also by scanning the surface of the bone segment osteotomized and mobilized .

VALIDATION

The validation procedure was performed for all patients by the same operator (Mr. Andrea Roncari, BIC) .

We will look at the method, but it is primarily present the software with which this validation was conducted.

Lhp Builder

Lph Builder is an application developed by the Multimod Application Framework (MAF), whose specific objective is to provide a supportive environment for rapid development of applications for CAM / CAS computer aided medicine / surgery . MAF is currently undergoing further development through collaborative development initiative OpenMAF Open Source and distributed under a BSD-like license, which allows for the development of using MAF royalty -free commercial applications. Lhp Builder is compatible with the Microsoft Windows platform.

The software was developed at the Laboratory of Medical Technology (LTM) of the Rizzoli Orthopedic Institute (Bologna), and then transformed into a commercial product Scs (Bologna). The use of this software it was possible through the collaboration in the BIC (Laboratory of Computational Bioengineering) , part of LTM .

An essential feature of lph Builder is the ability to import any type of biomedical data in a hierarchical structure in which each block of data is called Virtual Medical Entity (VME) . Each VME contains the dataset, the array of poses that defines the position and orientation of the dataset , and a number of metadata attributes (textual data associated with the data itself) .

The software can import 3D volumes generated by nearly every type of imaging (CT, MRI , PET, SPECT , ultrasound 3D) and written in DICOM format , the input can also be formed by dynamic MRI , cardioTC, and other 4D imaging modalities. Finally you can import STL files from polygonal surfaces or VMRL .

The software is currently used by the BIC for numerous studies in orthopedics (Fig. 9) . The collaboration with our group represents its first use in maxillofacial surgery .

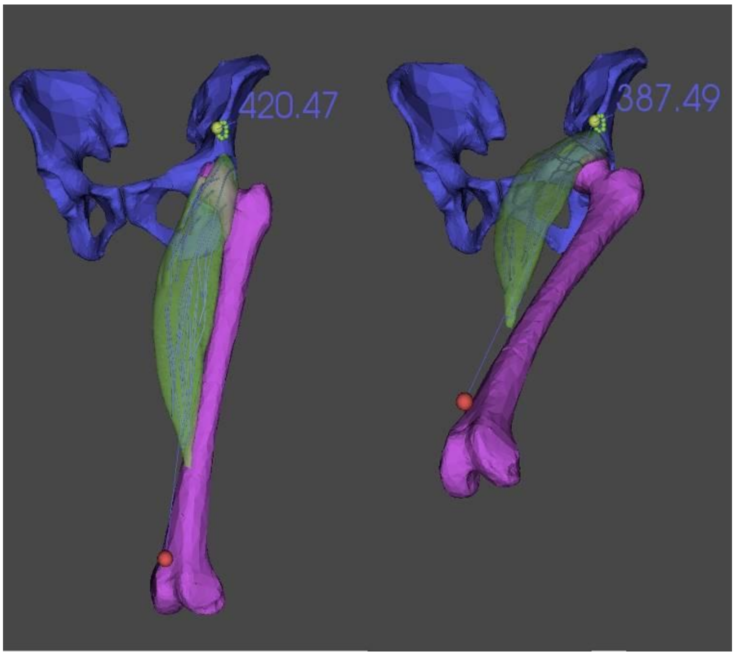


FIG. 9

In Figure 9 is shown as figure shows the lph Builder graphic setting (in the specific example, in a case of testing of musculoskeletal models) : on the right you can see the tree hierarchically ordered VME .

Procedure

To assess the reproducibility of the planned bone surgery, the bone surface extracted from postoperative CT is compared with that of the STL of the simulation.

STEP 1: The STL file of the simulation (hereafter referred to as SIM file) is imported to Lhp Builder (Fig.10).

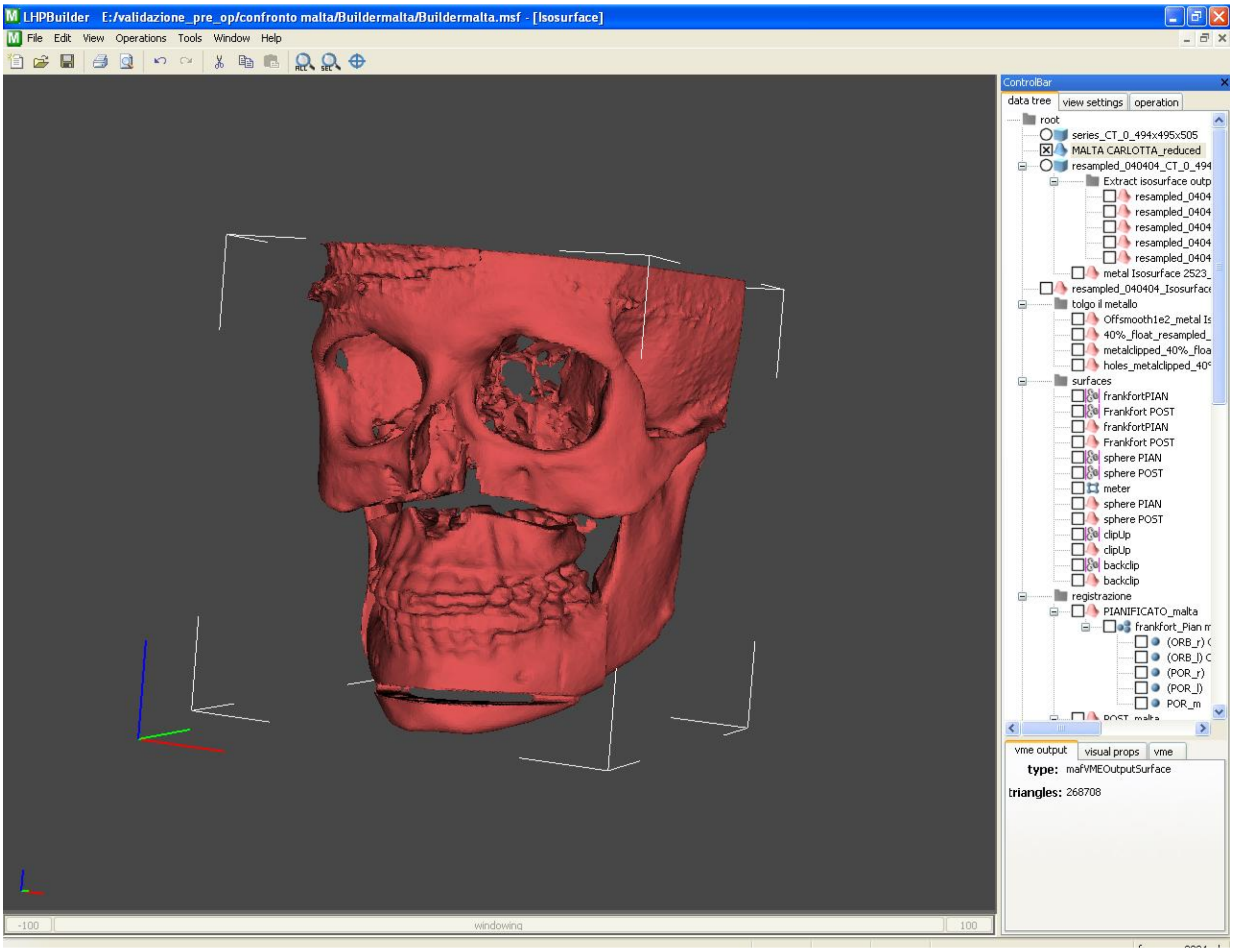


FIG. 10

STEP 2: Take a postoperative CT DICOM data , we extract the 3D volume of the patient's skull (the file named POST) , choosing the best thesholding based on the skill of the operator and the similarity with the look and feel STL , having given for thesholding assumed that the latter is the optimal choice for the operator (Fig. 11) .

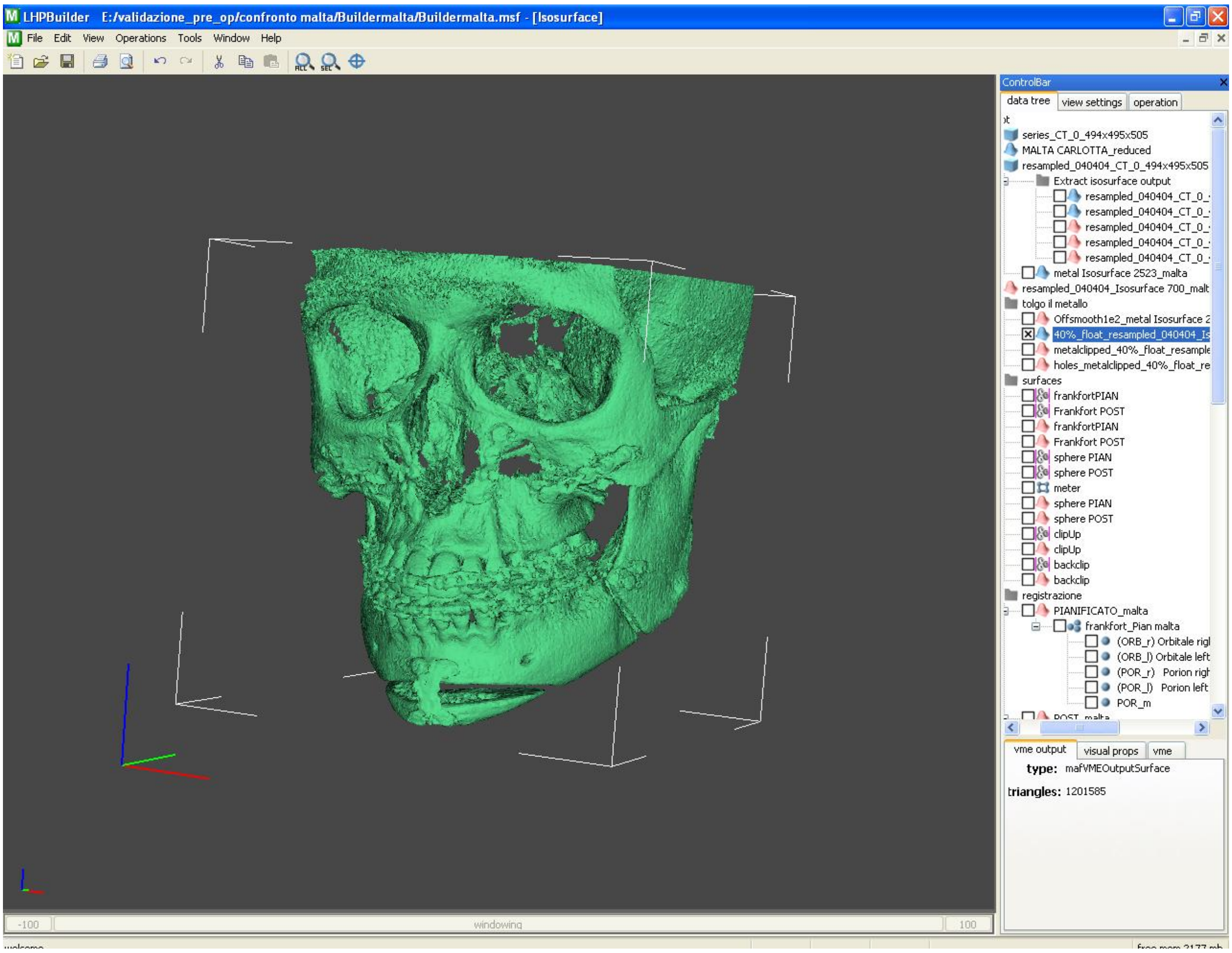


FIG. 11

STEP 3: It reduces the resolution POST from 3,000,000 to 1,000,000 ca of triangles so that it is easily manageable by Lhp Builder (this reduction is the ideal solution to make the file "light" but very accurate) .

STEP 4: This segment metallic components (POST osteosynthesis titanium) (Fig. 12).

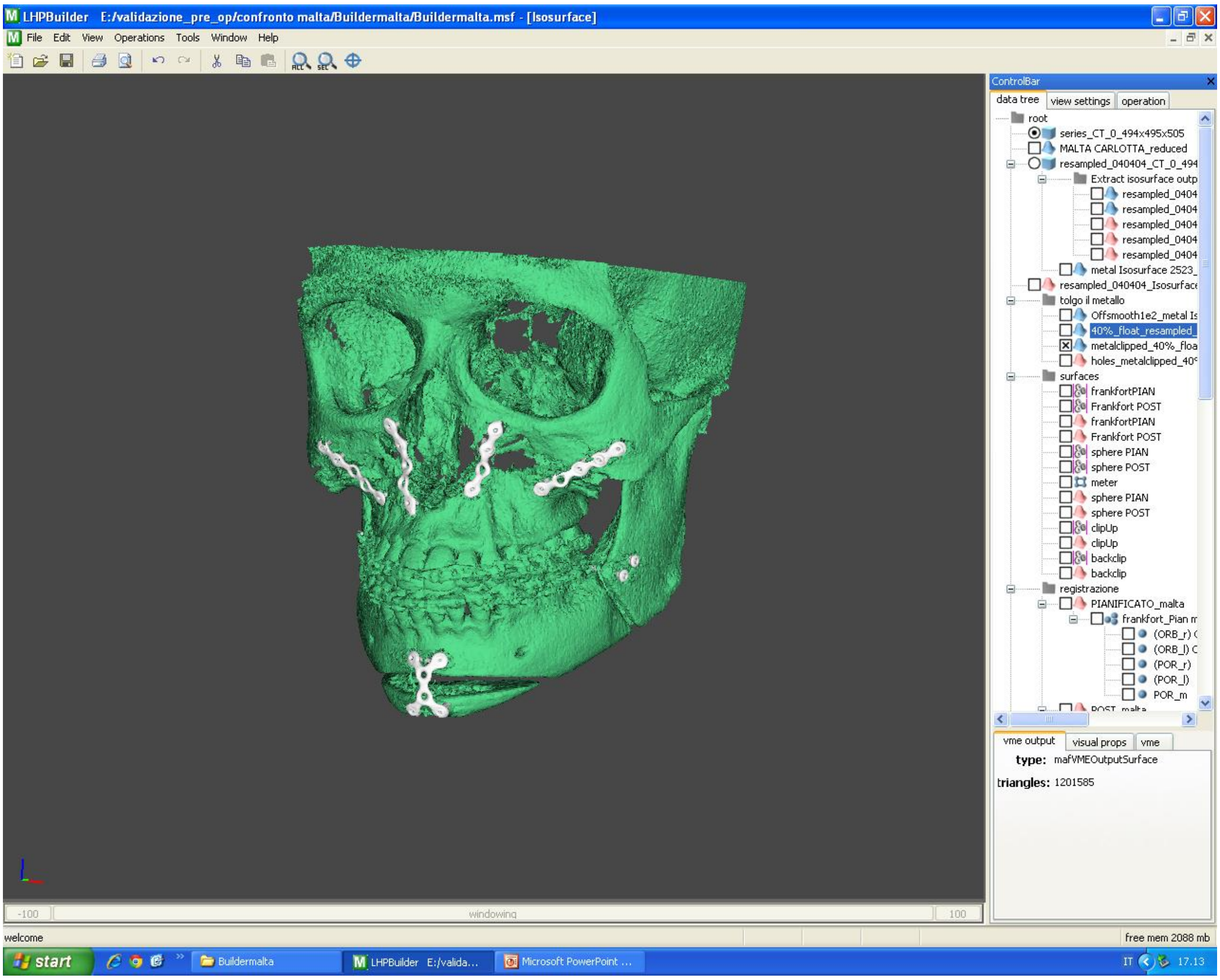


FIG. 12

STEP 5 : You remove the plates osteosynthesis by POST, after incremental offset of the surface , to be sure to remove all their volume and any artifacts (Figs. 13-14) .

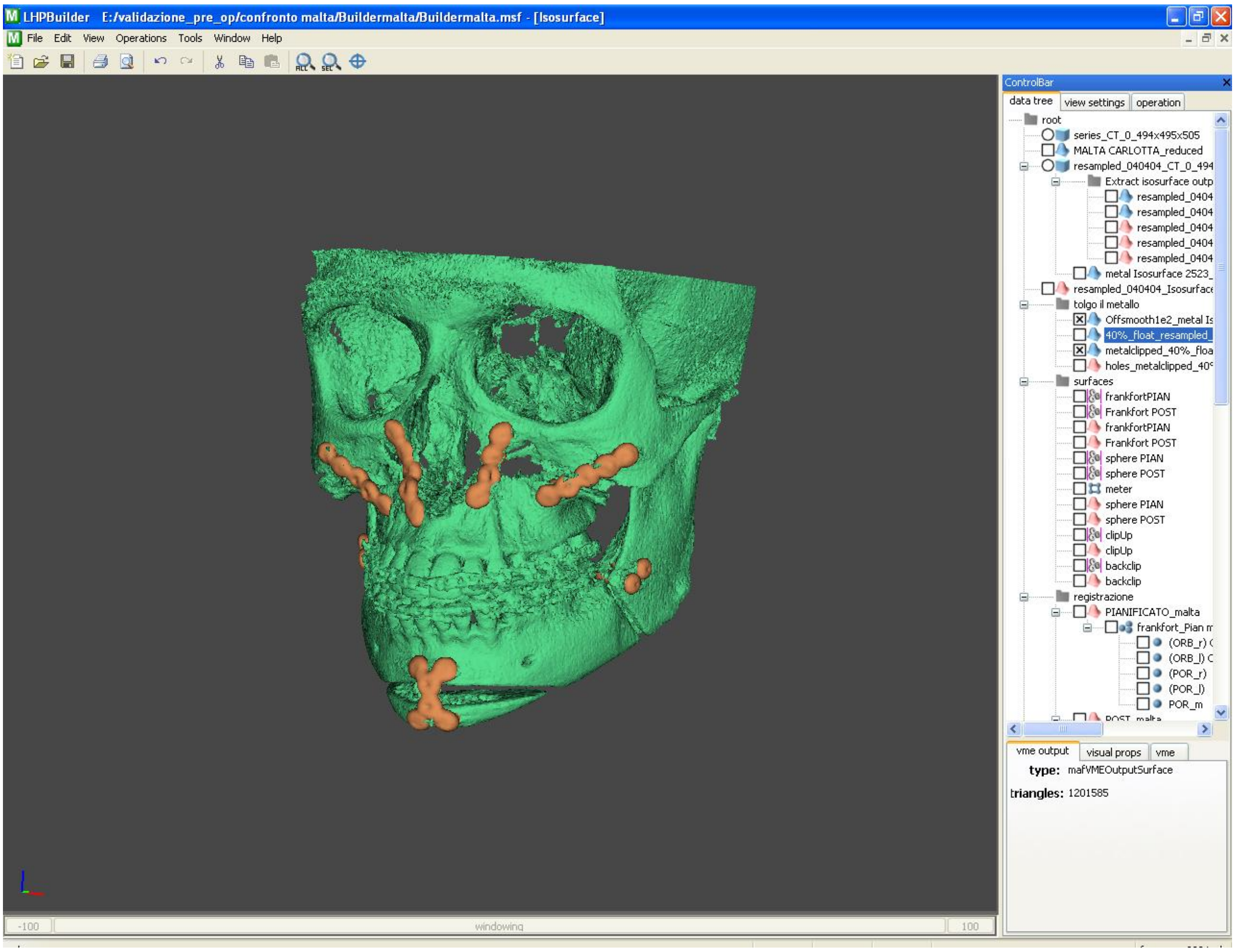


FIG. 13 Offset of osteosynthesis

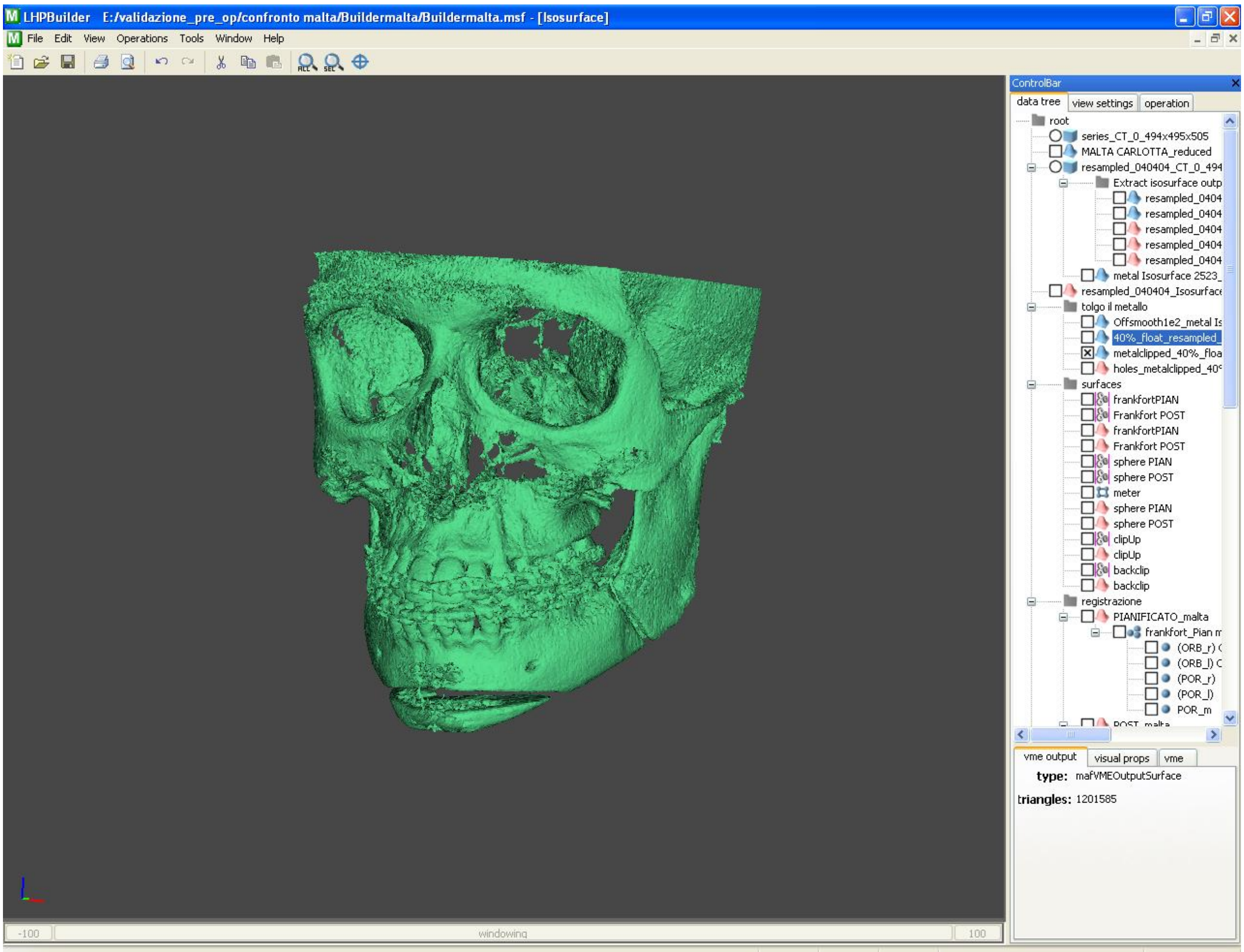


FIG. 14 Removing the means of osteosynthesis .

STEP 6 : It will fill the gap left by the previous operation subtractive through a linear function of connect between edges, in this way the gap are occupied by flat surfaces, probably less likely, but more standardizable of a curved surface drawn by the operator (Fig. 15) .

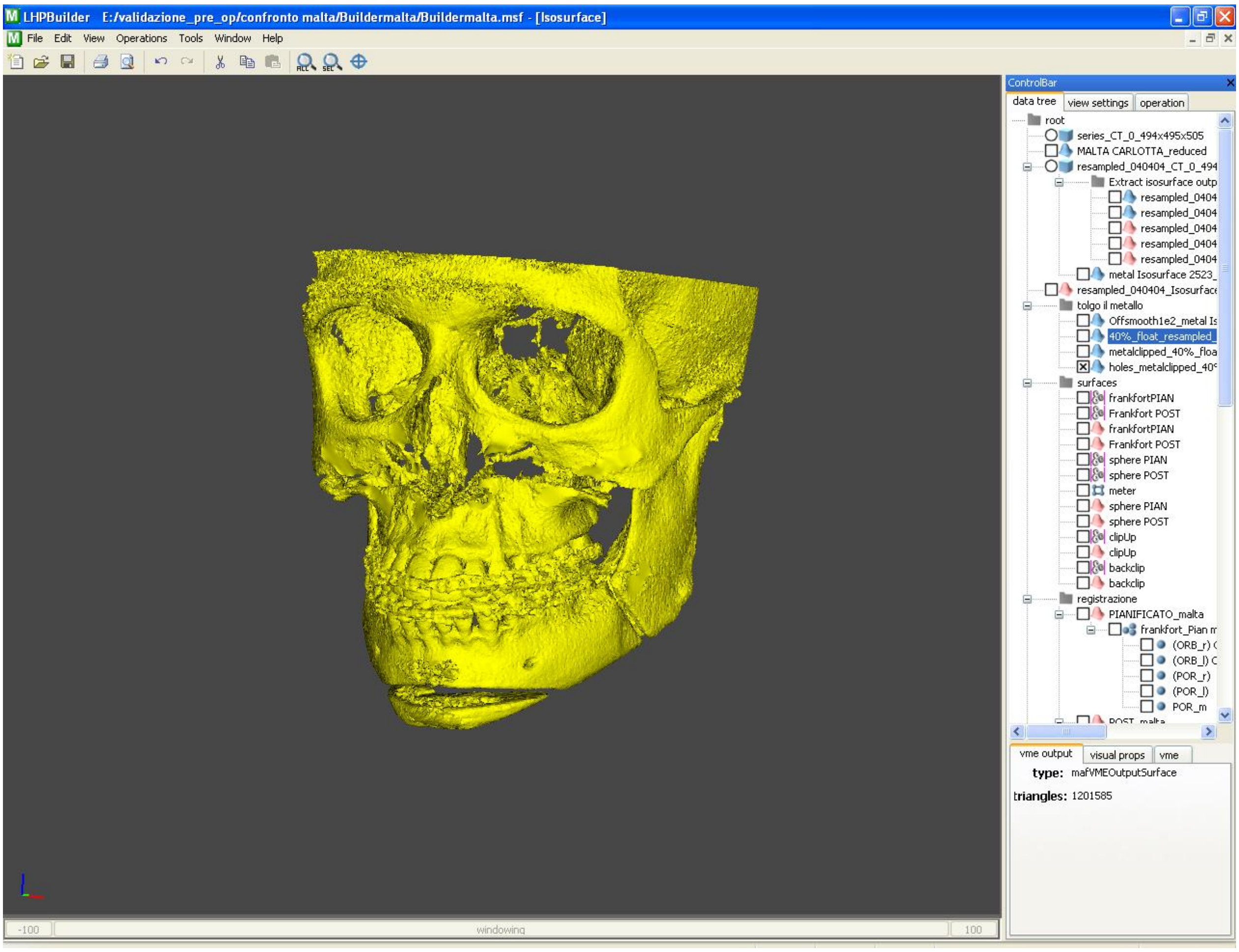


FIG. 15

STEP 7: You build the Frankfurt plane, using its bony points (Or Right Or Left and the midpoint between left and right Po) on both SIM and POST (Fig. 16) .

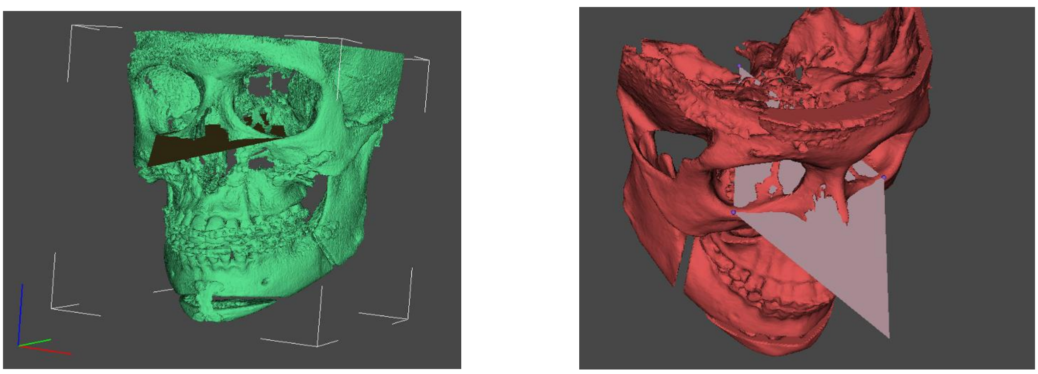


FIG. 16

STEP 8: Subtract from the region of the skull base SIM and POST a spherical volume centered on the midpoint of the center and radius Po -Po. In this way you delete a region that is not affected by the validation but could generate significant discrepancies overlap (eg . Mobility of the cervical vertebrae) (Fig. 17).

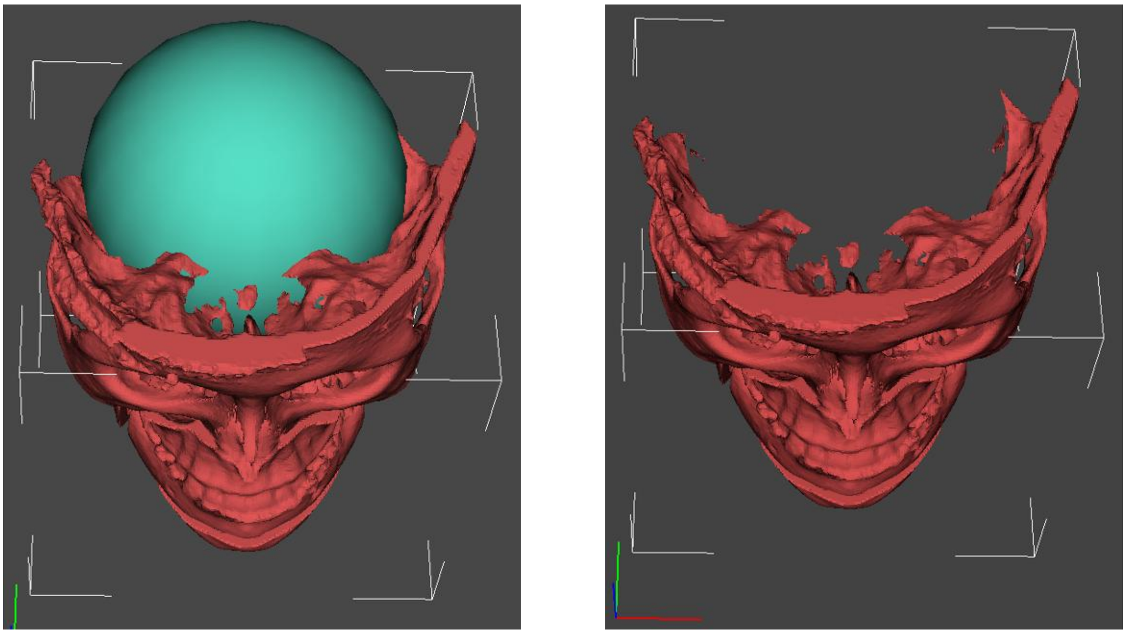
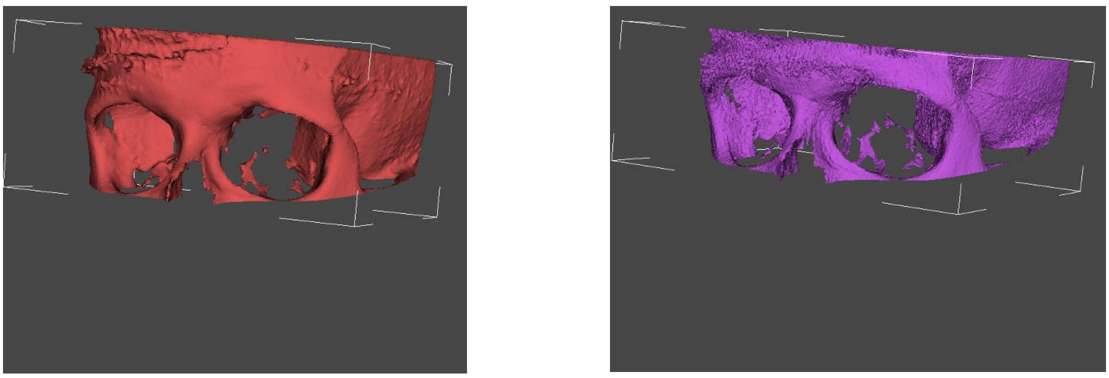


FIG. 17

STEP 9: We dissect the 3D models on the basis of the Frankfurt plane in Orbito - cranial portion and the jaw portion (Fig. 18) .



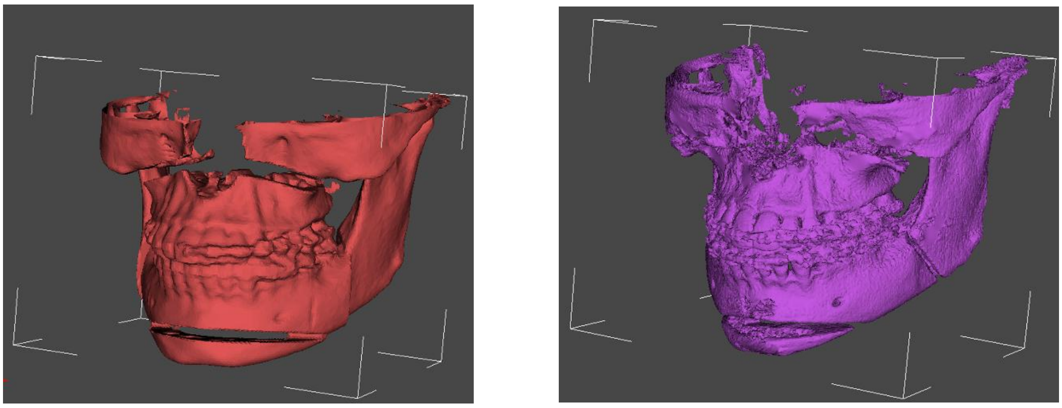


FIG. 18

STEP 10: Continue recording Orbito - cranial portions of a point cloud using standard (glabellar point average, sovraorbitari foramina, fronto - zygomatic sutures, angle between the bridge and the posterior edge of the zygomatic frame, side of the orbit and any additional points that are well recognizable on both surfaces) and a procedure ICP (Iterative Closest Point) that also returns the value of the error of recording (Fig. 19) .

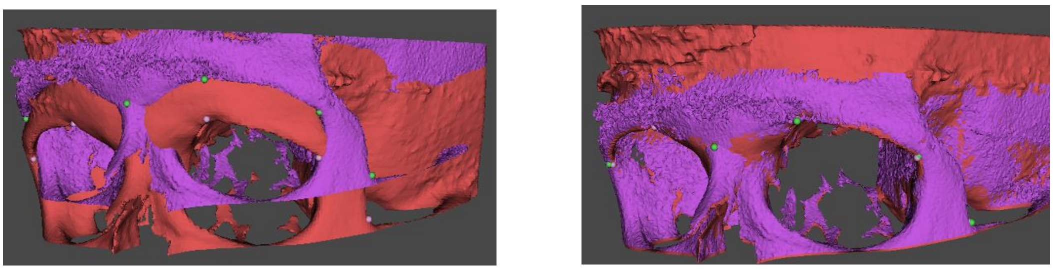


FIG. 19

STEP 11: It is the same matrix of laying the jaw portion, also obtaining the registration of these two segments (Fig. 20).

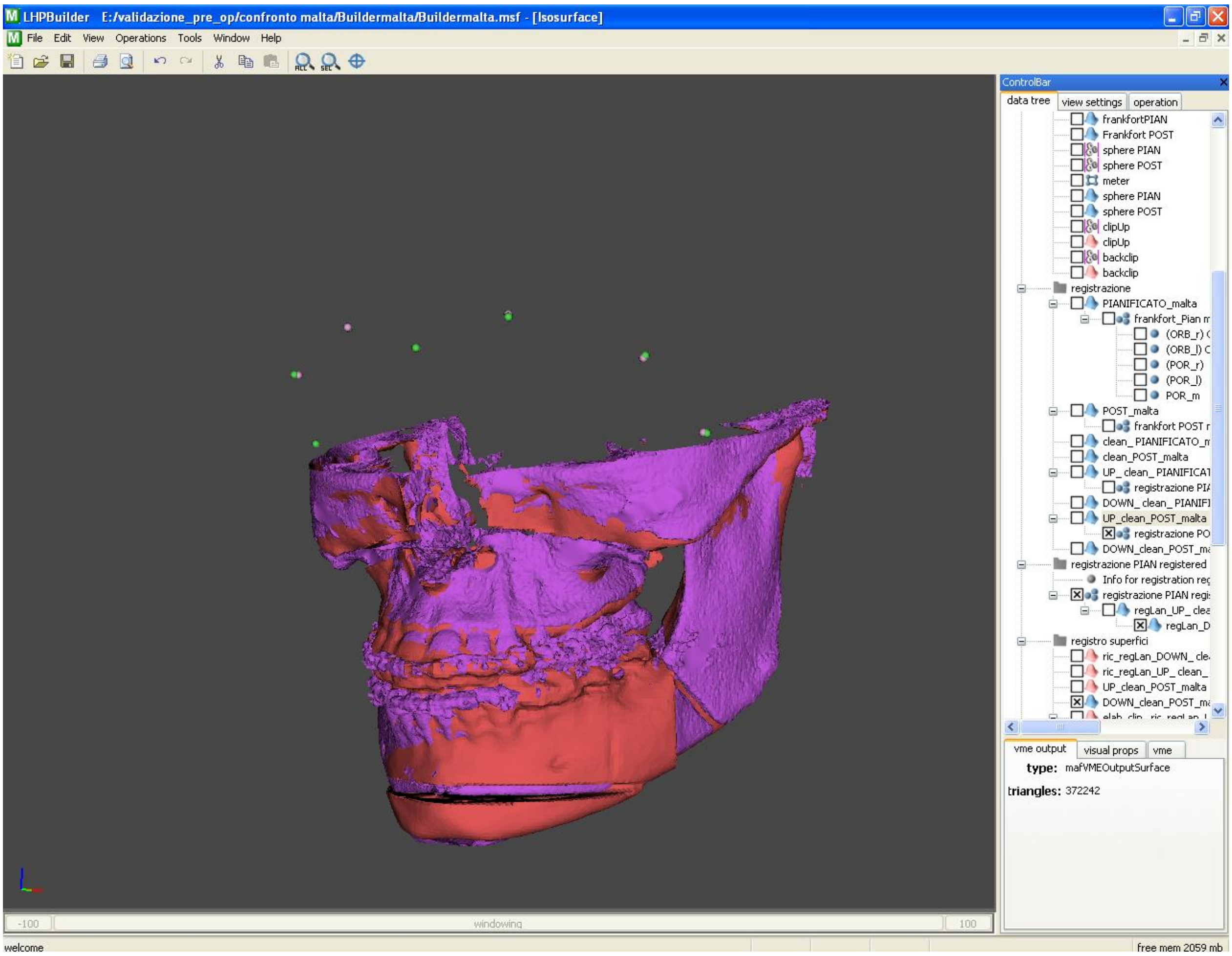


FIG. 20

STEP 12: You draw a cutting plane common to both SIM and POST on the braces and making the separation of the maxilla from all that is under the top or upper portion of the crown of teeth and the entire mandible (Fig . 21) .

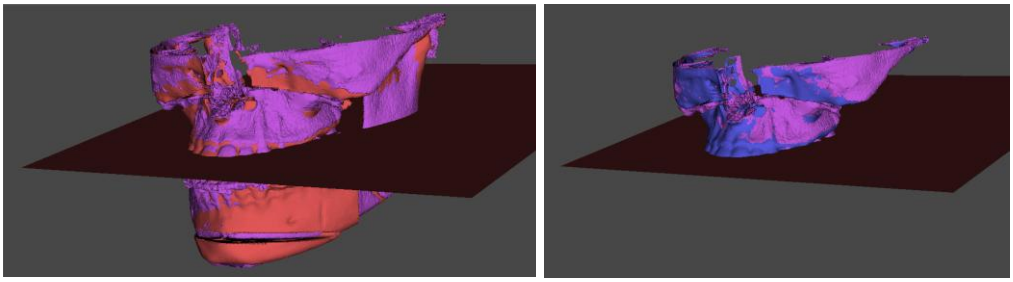


FIG. 21

At this point we have two 3D objects of the maxilla, one derived from SIM (MxSIM) and one derived from (POST MxPOST) (Fig. 22).

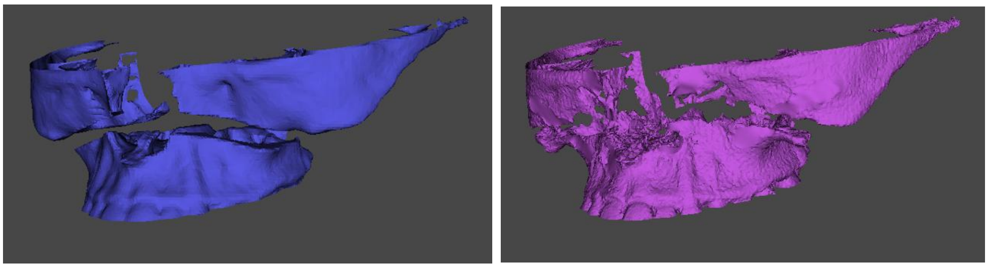


FIG. 22

These two - dimensional surfaces are then being compared with Hausdorff Distance (HD) . The Hd is calculated for each vertex of the triangle. Each validation provides a very high number of measurements. We evaluated the minimum and maximum values and the mean values. For the purpose of validation we consider only the mean values (Fig. 23).

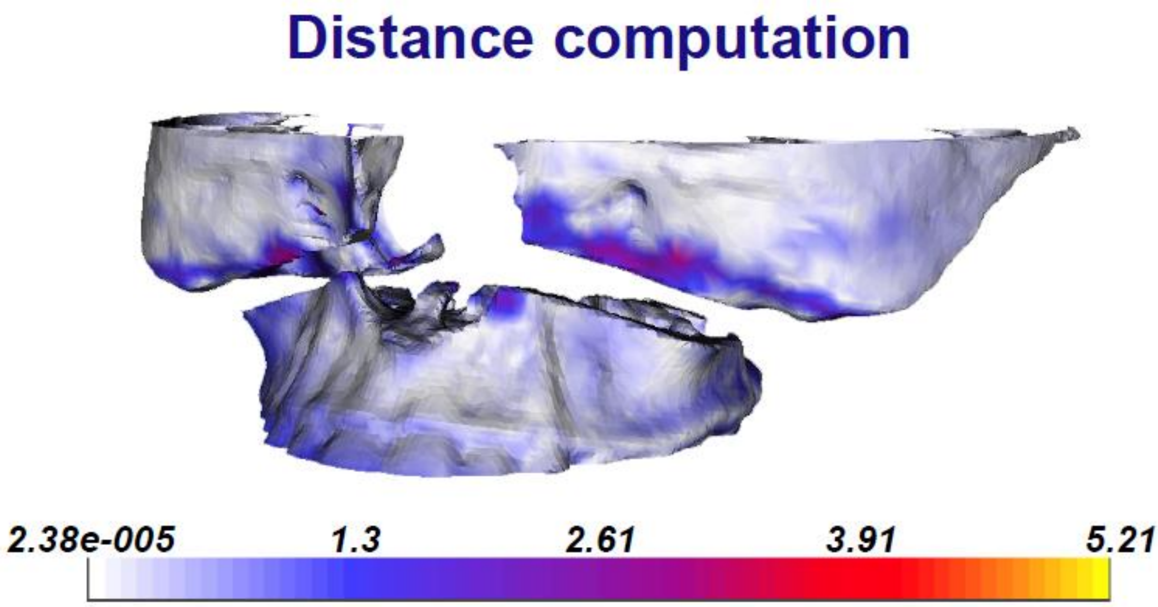


FIG. 23

As previously said , the Hd is not equal if using as a reference the first surface or the second . In symbols Hd (A, B) ≠ Hd (B, A), that it means that the procedure is not symmetric. The concept is intuitive if you think about how the function Hd: the distance is calculated by measuring the distance between each vertex of a triangle surface and the closest point (perpendicular) of the other surface . It 's obvious that the two surfaces do not have the same spatial arrangement of the triangles . It follows that the perpendicular constructed on the vertices of the area A will be different from those built on the vertices of the surface B and will touch the other surface at different points, realizing different distances . Therefore, for each comparison we obtained two values (SIM to postop and postop to SIM). It was decided to choose the worst of the two values.

Once you have the distance, was carried out the % of measurements below the threshold of 1mm, considered by AA . as appropriate limit to consider the result as " accurate " . Obviously in this case we got two values (SIM towards postop and postop towards SIM) and also in this case we chose the worse of the two .

The Problem of Thesholding

As stated previously, the degree of thesholding with which is extracted from the 3D TC surfece is potentially different for each patient, since the operator chooses subjectively the threshold that makes the best 3D reconstruction from the graphical point of view. Normally the values chosen roam all around a number of Hounsfield Units, but can vary significantly. In addition, the threshold values for CBCT are different and much more unstable comparing the traditional CT threshold values .

It is evident that this may create a discrepancy between a validation and an other. To analyze how this factor might affect we have made some tests varying in excess and defect in the Hounsfiled Unit around a value subjectively considered as optimal threshold. In the case of our study, the problem is affecting POSTOP, because SIM is already supplied in STL format. During the simulation performed with SurgiCase 5.0, the operator chooses by itself to use a thesholding reconstruction. You may, however, consider the operator as an "expert " in the choice of a value graphically optimal and consider it as a standard of comparison: for postop was chosen value of thesholding as similar as possible to the SIM and in any case that it could return a good result in graphic terms. Then we were able to conduct the analysis by changing only the values of the second surface and observed how they vary Hausdorff distances .

RECORDING ERROR

The procedure included in the ICP software Lhp Builder provides the value of the error logging. In addition we have also calculated the HD for the orbital-cranial segments . This calculation expresses intuitively (also expressed as % under 1 mm), the goodness of the recording and associated with the error makes the procedure very solid .

RESULTS

The results are shown in Tables 2, 3, 4 and 5.

In **Table 2** are gathered the results of the recording of the orbital- cranial segment. The table also contains columns for the thesholding used, and error logging .

Table 3 contains the most important data on the other hand , since Hd collects the maxillary segments .

In both tables shows the maximum and minimum values of HD and the average value . The last section contains the percentages of the error below 1 mm. Each section is divided into two sub-columns, which represent the different comparisons SIM to POST and POST to SIM (please note that the HD is not symmetric). Of these two sets of values we always chose the worst , highlighted by a colored box.

Table 4 summarizes the averages of those assessments. Then contains the actual results expressed in the work, which is the average error and the mean % of distances < 1 mm.

Table 5 contains an example of a thresholding analysis (patient 1) . It shows how to change the thesholding in default or in excess of 100 HU, Hd values do not vary as significantly .

TABLE 2: ANALYSIS OF ORBITO-CRANIAL PORTIONS

			Max Hausdorff		Min Hausdorff		Mean Hausdorff	
Pts	Thesholding	Registration Err.	sim > post	post > sim	sim > post	post > sim	sim > post	post > sim
1	710	0,416507	8,28959	7,47755	9,86E-06	1,46E-06	0,442212	0,400142
2	700	0,334961	4,2163	11,7923	5,55E-06	3,27E-07	0,328554	0,364395
3	550	0,388194	9,73516	10,484	1,03E-05	1,22E-06	0,416126	0,40415
4	710	0,459846	6,03007	9,96279	4,35E-05	3,11E-06	0,502648	0,501029
5	700	0,74706	7,57571	6,44455	2,26E-04	2,85E-06	0,845805	0,606748
6	700	0,609507	6,30253	10,5213	1,13E-05	1,18E-05	0,665027	0,696421
7	800	0,522494	8,32787	9,07556	1,05E-04	4,18E-06	0,585261	0,754869
8	700	0,859879	6,49702	7,85217	1,39E-05	6,08E-06	1,02774	1,06627
9	700	0,344228	8,89965	9,94617	4,45E-06	1,05E-06	0,332947	0,634513
10	600	0,36744	6,48721	6,31681	1,92E-05	3,82E-07	0,373715	0,695087
11	750	0,379831	5,12222	6,16356	2,00E-05	3,33E-07	0,402618	0,713764
12	750	0,446596	7,73181	7,42255	2,78E-05	5,21E-07	0,412761	0,380503
13	800	0,482026	7,62776	7,34107	4,16E-06	2,14E-06	0,440745	0,287865
14	750	0,554368	7,29266	6,71196	1,96E-05	3,96E-07	0,525072	0,320162
15	700	0,421456	5,33607	4,81844	8,31E-06	2,10E-05	0,477864	0,831098
16	700	0,550944	4,51196	6,31188	4,64E-04	2,22E-05	0,799229	1,1471
17	600	0,460645	4,39796	5,73273	9,67E-05	3,35E-05	0,656348	0,854028
18	500	0,313056	4,43813	6,22556	8,83E-05	1,88E-05	0,325316	0,449792
19	500	0,821053	8,09085	7,81271	9,76E-06	2,54E-07	0,957483	0,676552
20	700	0,322579	4,64831	10,8666	2,01E-05	3,68E-06	0,364013	0,649296

TAB . 3 ANALYSIS OF MAXILLARY PORTIONS

			Max Hausdorff		Min Hausdorff		Mean Hausdorff	
Pts	**Thesholding**	**Registration Err.**	**sim > post**	**post > sim**	**sim > post**	**post > sim**	**sim > post**	**pos**
1	-	-	13,9604	7,38307	0,000103723	6,57E-06	1,31135	1,1
2	-	-	7,86154	6,63615	1,80E-05	5,28E-05	1,07098	0,9
3	-	-	6,78077	6,2751	3,80E-05	9,10E-06	0,735118	0,7
4	-	-	7,65546	4,9962	5,85E-05	2,55E-05	0,790782	0,7
5	-	-	12,3013	16,0275	4,03E-05	1,25E-07	0,901015	0,7
6	-	-	6,06041	6,94549	0,000219247	1,33E-05	0,810408	1,1
7	-	-	8,98814	9,39591	7,36E-05	9,18E-05	0,954985	0,9
8	-	-	4,16773	8,85705	1,43E-04	9,18E-06	0,7854	1,0
9	-	-	5,21005	6,1745	2,38E-05	3,20E-06	0,629698	0,9
10	-	-	5,51114	4,50106	3,37E-05	9,27E-06	0,761876	0,7
11	-	-	5,42102	6,04491	2,20E-05	1,79E-06	0,915649	1,0
12	-	-	15,913	18,321	2,66E-05	1,80E-05	0,821026	0,6
13	-	-	7,61646	9,35328	0,000251847	2,01E-05	1,22116	1,1
14	-	-	8,66294	6,64724	1,87E-05	1,08E-05	1,24069	1,1
15	-	-	7,75536	6,69326	3,75E-05	1,17E-05	0,745265	0,9
16	-	-	10,1964	15,7054	0,000173848	8,31E-05	0,924179	1,4
17	-	-	8,92052	13,9538	0,000166323	1,54E-05	1,00403	1,4
18	-	-	5,4509	12,1805	6,10E-05	1,28E-05	0,609733	0,6
19	-	-	10,4458	8,55773	0,000143372	4,00E-05	2,07901	1,5
20	-	-	6,50922	6,40913	7,64E-07	3,09E-06	0,895876	0,8

TAB . 4 SYNTHETIC MEANS

	Media	DS
ORBITO-CRANIAL		
Hausdorff Distance (Hd)	0,669974	0,228971
% di Hd <1	80,42936	10,42234
Registration Error	0,490134	0,160861
MAXILLA		
Hausdorff Distance (Hd)	1,071745	0,321583
% di Hd <1	62,68844	9,564548

TAB. 5 EXAMPLE OF THRESHOLDING ANALYSIS (PTS. 1)

		Max Hausdorff		**Min Hausdorff**		**Mean Hausdorff**	
Δ Thesholding	**Registration Error**	**sim > post**	**post > sim**	**sim > post**	**post > sim**	**sim > post**	**post >**
610 -100	**0,476051**	**4,17715**	**11,1225**	**1,60E-06**	**2,03E-06**	**0,508888**	**0,967**
660 -50	0,384668	7,6096	10,2262	1,25E-06	7,45E-07	0,391817	0,551
710	0,416507	8,28959	7,47755	9,86E-06	1,46E-06	0,442212	0,400
760 +50	0,640738	10,8482	5,62975	8,57E-06	5,42E-06	0,725713	0,474
810 +100	0,769344	6,43962	7,9664	5,56E-05	8,21E-06	0,966622	0,627

- **bone segments navigation;** is still a field of research
- **mandibular condyle navigation;** is still a field of research
- **do develop more accurate surgical intruments (i. e. saw) tracking.**

a. Development of a way to control and apply the cutting guide and the prebended plates

b. Development of the Piezonavigated approach

Regarding point (a): Development of a way to control and apply the cutting guide and the prebended plates, a research project is been designed. This project has been called:

"CAD-CAM Cutting Guides and Customized Titanium Plates for Upper Maxilla Waferless Repositioning"

Introduction

Recent advances in computer-assisted orthognathic surgery, especially virtual planning software tools, have provided a valuable aid for diagnosis, treatment planning and outcome evaluation in the therapy of maxillofacial deformities [31].

The goals of computer assisted surgery for maxillofacial anomalies are to let the surgeon experiment with different surgical procedures and to predict the outcome of an intervention before the actual surgery. However, an innovation comparable to the virtual planning technology which could help the surgeon in the operative room is still lacking.

To achieve satisfactory occlusal function and facial aesthetics, a high degree of precision and predictability is required in positioning the jawbones. Quality of the result is nowadays still related to the surgeon's ability to reproduce the planned surgery.

Currently, the typical method to reposition jaws in the correct and planned location is based on the use of surgical splints. This procedure includes face bow transfer, use of a semi-adjustable articulator and measurement of surgical movements on plaster cast: errors may be introduced during each part of this process [32].

Surgical splints, manufactured using the computer-aided design and manufacturing (CAD-CAM) technique, have been developed to avoid some errors of the traditional model process. However additional preparatory work, such as dental plaster casts scanning, is still necessary; moreover, instability of the mandible, where the intermediate splint is placed on, may directly interfere with the repositioning of the maxilla in the desired position. Furthermore, the use of CAD-CAM surgical splints could not improve vertical control of the maxilla [33] as well as other mistakes are introduced when the planning based on standard 2D cephalometric tracings and subsequent 2D movements are transferred on the patient who is three-dimensional. This leads to an intrinsically wrong procedure.

The purpose of this study was to develop a CAD-CAM technique for the fabrication of surgical cutting guides and fixation titanium plates to reposition the upper maxilla in the correct planned position without the aid of a surgical splint. In our intention, the surgical cutting guides pilot the virtually planned osteotomy line during surgery and the custom made fixation titanium plates allow the desired reposition of the maxilla.

Materials and Methods

To evaluate the benefit of the presented procedure, we analysed the reproducibility of the computer-aided surgical plan in a group of patients submitted to orthognathic surgery at the Oral and Maxillofacial Surgery Unit of S.Orsola-Malpighi University Hospital in Bologna (Italy) and we compared the results with a published previously operated sample of similar patients in which the maxillary repositioning was obtained with a standard surgical intraoperative dental splint and the aid of a surgical navigation system [40]. The protocol was submitted and approved by the Institutional Review Board (Ethical Committee) of our Institution and compliance with the World Medical Association Declaration of Helsinki on medical research protocols and ethics was granted.

The group of 10 patients was recruited during the pre-surgical orthognathic clinical examination at our surgical Unit; patients were informed regarding the procedures and we obtained their permission.

The complete *CAD-CAM Workflow* in orthognathic surgery involved, as usual, three steps: 1) *Virtual Planning* of the surgical treatment; 2) *CAD-CAM and 3D Printing* of the customized surgical devices; and 3) *Computer-Aided Surgery*.

Virtual planning

Planning began with the acquisition of a CBCT scan of the patient's craniofacial skeleton and soft tissue. Patient's specific imaging was obtained using the CBCT scanner New Tom VGI (QR, Verona, Italy). Voxel-based data were acquired following these parameters: 0.625mm slice thickness; 0.312 slice spacing; 0° gantry tilt; 512 × 512 pixel resolution. Data were exported in DICOM format and processed by the surgeon using Surgicase CMF 5.0 software (Materialise, Lueven, Belgium). After a suitable threshold value was set, the software allowed the volumes segmentation and creation of 3D virtual models of the maxillofacial skeleton and facial soft tissues. This led the surgeon to a complete 3D planning of surgery: 3D cephalometric analysis, 3D simulation of the maxilla and mandible planned movements and, if required, simulation of soft tissues appearance after surgery [41,42] (fig. 24-1 a,b). The planned movements were exported as both numerical data and sent to the laboratory for the CAD-CAM device production, together with the DICOM data of the CT scan.

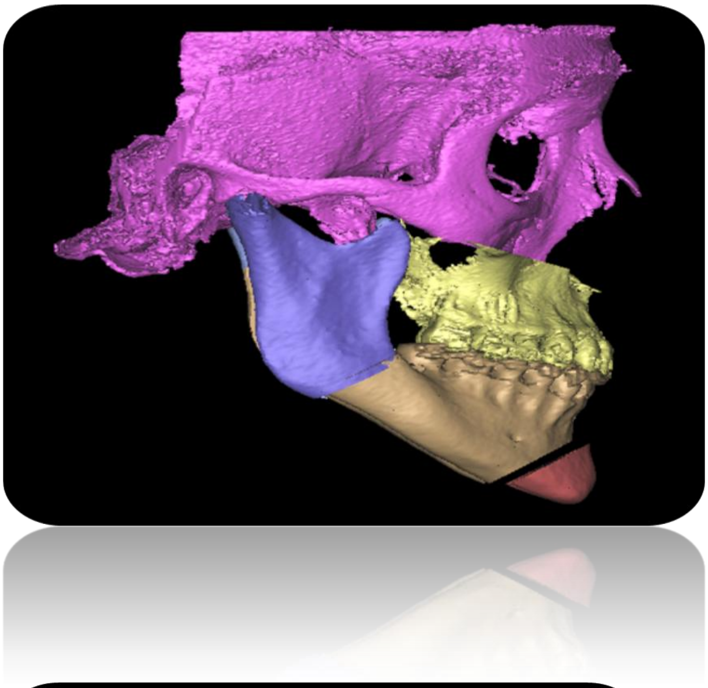


FIG. 24 a FIG. 24 b

CAD/CAM and 3D Printing

The laboratory which provided the CAD-CAM device production was SINTAC (Padua, Italy). The surgical planning data were sent to the laboratory and used to design and manufacture the customized surgical devices: a) *cutting guides* and b) *fixation bone plates*.

The computer-aided design of the surgical devices was provided by Rhino 4.0 software (Robert McNeel & Associates, Seattle, WA, USA). DICOM data were used to obtain the three-dimensional virtual model of the patient's facial skeleton in this specific 3D environment.

After that, customized cutting guides were designed to let the surgeon precisely transfer the site and orientation of the osteotomy line from the virtual plan into the surgical environment. Cutting guides were virtually modeled on the two sides of the maxilla, trying to cover most of the bone surface exposed during surgery, and were designed following the natural curvature of the maxillary-zygomatic buttress and the anterior maxillary walls. This was the assumption to obtain the best stability, adhesion and correct positioning during the actual surgery. The exact position of the osteotomy line was drawn by the surgeon using a web-based remote control service (e-works meeting by e-works srl, Campogalliano, Modena, Italy), provided by the SINTAC laboratory. Eight holes (2.0-mm diameter) were inserted to allow fixation of the guide with titanium screws (fig. 25a).

CAM

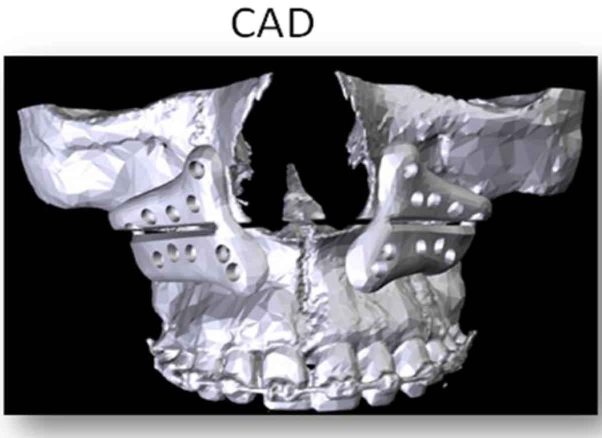


FIG. 25 a

The holes for screw fixation were carefully placed to avoid damaging of tooth roots, while inserting screws.

The customized fixation bone plates are the second component of the device. The plates permit the reposition of the upper maxilla in the planned location. They were designed following the desired sagittal, transverse and vertical movement of the maxilla. The planning was transmitted as numerical data to the SINTAC laboratory and inserted in the 3D virtual environment used for the design process. The virtual osteotomized maxilla was moved following these indications and using the standard 3D coordinates system based on Frankfort Plane (Right Orbitale - Left Orbitale – middle point between Right Porion and Left Porion). All virtual operations were followed by the surgeons using the web-based remote connection. This way, the whole planned spatial movement of the maxilla was completely stored in the fixation plate. Holes created for cutting guide positioning were also used to fix the plates (“Transferring Principle”) (fig. 25 b,c,).

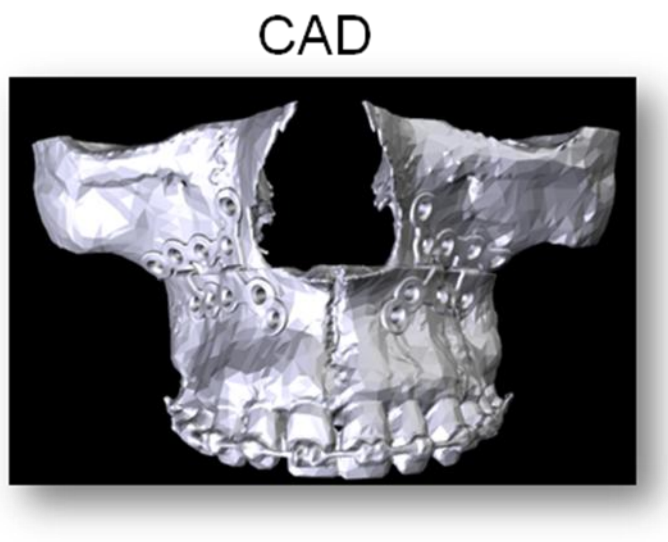


FIG. 25 b

FIG. 25 c

The STL files of the cutting guides and plates were then manufactured through Direct Metal Laser Sintering (DMLS) using the EOSINT M270 system (Electro-Optical Systems, GmbH, Munich, Germany). DMLS process fuses metal powder into a solid form and melt it locally with a focused laser beam. Like other additive manufacturing technologies, the components were built up additively in layers. The cutting guide (fig. 25a) was created using EOS CobaltChrome MP1 (Electro-Optical Systems), a multipurpose cobalt–chrome– molybdenum-based superalloy powder that has been optimized for DMLS on EOSINT M systems. The bone plates (fig. 25 c) was produced using EOS Titanium Ti64 (Electro-Optical Systems), a pre-alloyed Ti6AIV4 alloy in fine-powder form with excellent mechanical properties and corrosion resistance, low specific weight, and good biocompatibility, which make it particularly suitable for the production of biomedical implants.

To let the surgeons train themselves preoperatively and achieve a better understanding of the intervention, “biomodels” of the maxilla in preoperative conditions and after the planned osteotomy were manufactured directly using a 3D Dimension Soluble Support Technology (SST) RP machine (Stratasys, Eden Prairie, MN, USA).

All physical parts of the device were then sent to the surgeons before the actual surgery. Surgeons received also an STL file of the cutting guides in the planned position, which was used for the computer-aided surgery.

Computer-aided Surgery

The upper maxilla repositioning was performed wafer-less using the CAD-CAM device under the control of a navigation tool, according to the Simulation-Guided Navigation concept [39]. The navigation tool was the eNlite Navigation System with the iNtellect Cranial Navigation Platform 1.0 (Stryker, Freiburg, Germany).

The upper maxilla was accessed through an intraoral incision. The cutting guides were introduced into the field and stabilized in the correct position using the good anatomical engagement granted by the natural curvature of the maxillary-zygomatic buttress and the anterior maxillary walls. The use of the navigation tool ensured the correct allocation of the guide. Cutting guides boundaries, surfaces and screw holes were used as reference. When the surgeon was induced by the navigation check to slightly move the guide from the initial manually obtained position, the event was recorded. The cutting guide was fixed with titanium screws, and a piezoelectric saw was used to create the osteotomy (Mectron, Sestri Levante, Genova, Italy). The cutting guides were then removed and the Le Fort I osteotomy was completed (26 a).

FIG. 26 a

After that, the fixation bone plates was used to reposition the upper maxillary bone in the correct location. As mentioned above, bone plates were designed to fix the maxilla using the same holes through which the cutting guides had been previously fixed. This ensured the correct mutual positions of the two components (fig. 26 b).

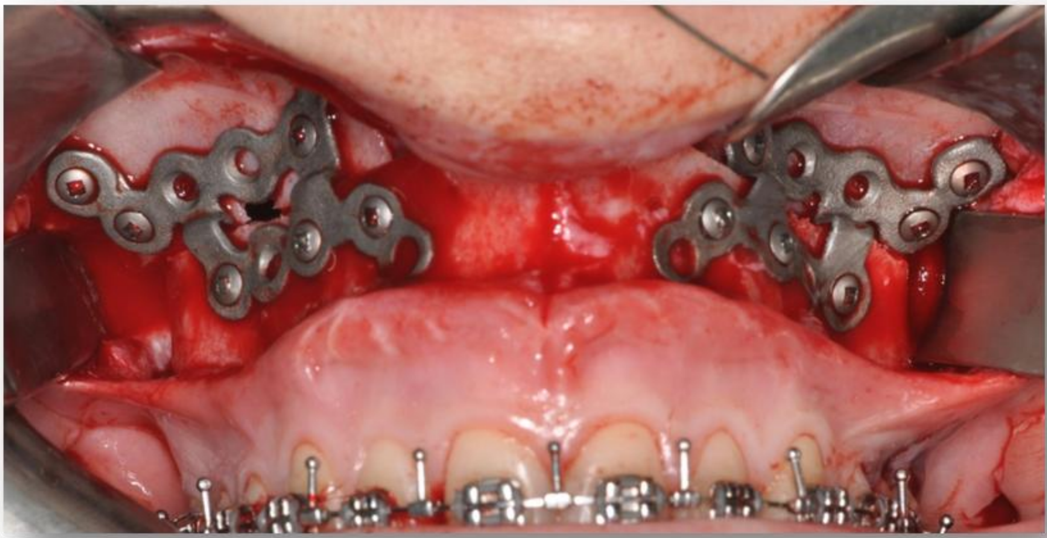


FIG. 26 b

The surgical team was always the same with same roles on the operative field.

Accuracy evaluation

To evaluate the accuracy in reproducibility according to the CAD-CAM Orthognathic Surgery method, the virtually planned position of the upper maxilla and actually achieved one were compared.

A postoperative CT scan was obtained 1 month after surgery using the same machine and parameters of the preoperative CT scan. After setting suitable threshold values, the DICOM dataset was processed to create a 3D model of the postoperative maxillofacial skeleton (300 Hounsfield Units (HU) and a 3D model of the positioned bone plates alone (1900 HU). The pre- and postoperative datasets were compared using Rapidform XOS2 software (INUS Technology, Seoul, Korea), evaluating the discrepancy between the virtual and actual positions of the upper maxilla and fixation plates (fig. 27 a, b, c) using the Hausdorf function.

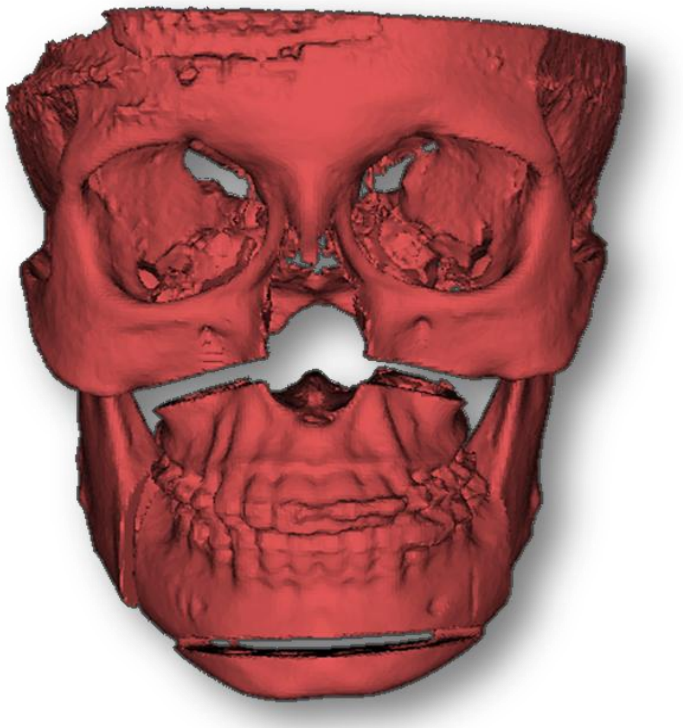
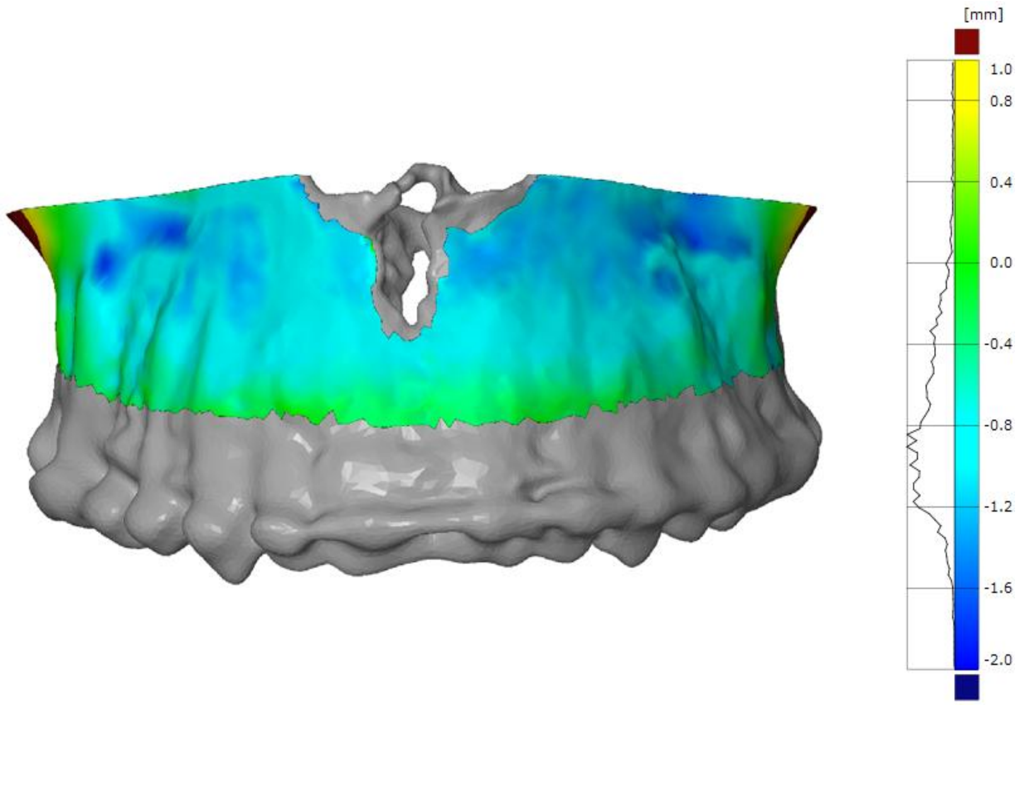


FIG. 27 a: virtual planning

FIG. 27 b: post-operative CBCT Data

FIG. 27 c: discrepancy between the virtual and actual positions of the upper maxilla and fixation plates

Surface deviation was also represented on a color map (fig. 28).



Results

Results are represented in Table 6.

Patients	Sex	Diagnosis	Error	% E<2mm	%E<1mm
1	M	III classe Angle	-3.4 / +3.2	72	22
2	M	III classe	-2.0 / +1.2	100	53
3	M	III classe	-0.6 / +0.7	100	100
4	F	III classe + asimmetria	-0.08 / 0	100	100
5	F	II classe	0 / +2.4	93	52
6	F	III classe	-0.07 / 0.02	100	100
7	M	III classe	-1.6 / +1.2	100	83
8	F	III classe	-1.6 / 0	100	87
9	M	III classe	-1.0/+6.0	62	20
10	F	III classe + asimmetria	- 0.8 / +1.4	100	83

TABLE 6

We have evaluated the overlapping error considering a threshold value < to 2 mm. Following this definition. We obtained an error of 100% in 7 patient; values ranged between 62% and 100%, with a medium value of 92,7%. The error interval was maximum in patient n. 1 from -3,4 to 3,2 and minimum in patient n.6 from 0,07 to 0,02.

Cutting guides initial positioning was found correct by the navigation check in 7 cases and required small adjustments in 3 cases. The number of holes on the plates was always sufficient to grant a stable fixation even if one or more holes were excessively drilled and the screw failed to fix. No plate was unused or substituted with standard plates intraoperatively. All the patients healed uneventfully with no infection of the DMLS bone plates.

Discussion

For good aesthetic and functional results in orthognathic surgery, the correct reposition of the upper maxilla according to the preoperative plan is essential. The maxillary relocation is the keypoint in orthognathic surgery, because this bone segment is the center of the face and usually guides all other movements of the facial bones, particularly for the opposite jaw. Nevertheless, the three-dimensional control of intraoperative maxillary movements during surgery still remains controversial.

The traditional method used to reposition the maxilla intraoperatively is based on the use of surgical splints and intra or extra-oral measurements. These measurements are roughly inaccurate and the splints are typically made manually using model surgery, so that many potential errors may be introduced and could lead to unsatisfactory outcomes with a 5 mm maximum maxillary malposition [44] . However, the greatest part of maxillofacial surgeons around the world still use this method.

In 2010, our group tried to overcome this problem introducing the routine use of the assistance of a navigation system during orthognathic surgery, a procedure called Simulation-Guided Navigation [39]. The 3D preoperative planning, loaded as a 3D object in the software of the navigation system, let the surgeon visualize the mismatch between the native bone and the planned position of the osteotomized fragment and allowed the operator to check real-time if the actual repositioning respected the planned one. Using this method we found a 86.5% mean reproducibility (error <2mm) of the preoperative surgical plan. Those results were especially promising for the vertical control of the maxilla, because the method, despite the intrinsic limitations of a multiple not-simultaneous reference points check, was the first concrete attempt to introduce a strict reproduction of the vertical movements.

In spite of this, navigation has not become a standard yet, even if many groups have been working on it since then. This is probably related to both the high costs of navigation systems available for purchase and the requested investments in research to overcome the current technical limitations.

Therefore, nowadays, splints fabricated using modern CAD-CAM techniques are making their way in orthognathic surgery as a new affordable solution to bridge the gap between the virtual planning and the operating room. In fact, virtual casts can definitely improve splint accuracy, especially in terms of correlation with the skeletal structure; however they do not improve the vertical control of the maxilla [35].

To avoid this limit, Zinser et al. [31] described a system, adopted in eight patients, to reposition skeletal segments using 3 sequential occlusal wafers: the first splint for the definition of reference points on the skull, the second splint for the reposition of the maxilla, the third splint for the final occlusion. The advantage of this technique was that the maxilla could be relocated independently in all positions permitting, according the authors, a precise vertical and horizontal leveling in relation to the cranial base.

Polley et al. [36] introduced the concept of an occlusal-based devices to transfer virtual surgical planning to the operating field. An initial drilling guide is used to establish stable references or landmarks. After mobilization of the skeletal segment, a final positioning guide, referred to the drilled landmarks, is used to transfer the skeletal segment according to the virtual surgical planning. The device was designed using a three-dimensional CAD-CAM technology and manufactured with stereolithographic techniques. It was adopted successfully in 24 patients.

Bai et al. [37] introduced in their case series the use of a CAD-CAM locating guide accompanied with pre-bent titanium plates on stereolitographic model.

In a preliminary study, Li et al. [38] presented their experience in six patients with a new CAD-CAM template to guide the osteotomy and the repositioning of the upper maxilla during bimaxillary orthognathic surgery. The preliminary results obtained comparing the postoperative CT scan with the virtual plane showed an “error” in the position of the maxilla < 1mm.

However, all these protocols seemed relatively complex or time-consuming if compared to standard surgical splints. Moreover, we aimed to overcome the results obtained with navigation finding a faster and less expensive method. Therefore we developed this CAD-CAM method based on the use of surgical cutting guide and customized bone fixation plate to reposition the maxillary bone.

The results that we obtained with this method are promising: we improved our reproducibility from 86,5% to 92%.

The cutting guides were found to be easy to place and relatively able to ensure a univocal positioning. They definitely helped the surgeon to reproduce the planned Le Fort I osteotomy line, allowing the exact bone removal if the maxilla had to be moved upwards or a tilting of the occlusal plane was necessary. Moreover, the method allowed to carefully design the position of the predrilled holes in order to choose sites where the anterior walls of the maxillary sinus were thick enough to ensure a stable fixation of the bone plates and to avoid tooth roots.

But the real innovation of this method is represented by the fixation bone plates that guide the maxillary repositioning phase. Using the predrilled holes derived from the cutting guide, CAD-CAM plates revealed to be very easy to be placed. This made possible to control the sagittal, transversal and vertical movements according to the preoperative virtual plan avoiding all potential errors caused by the autorotation of the mandible.

All the papers cited above defined a reference system for the cutting or repositioning guides, mainly an occlusal reference. In our device, cutting guides were placed manually without any mechanical reference system. However, we used a navigation system to check if this positioning was correct. We found that in most cases this condition occurred, but not in all cases. This suggests we must improve the shape-related positioning feature in the future.

Operative times were found to be shortened by the procedure, which certainly lengthened the phase of the osteotomy but made much shorter the modeling of plates and the check of the final maxillary position.

Conclusion

In conclusion, these results seem to confirm that CAD-CAM cutting guides and customized titanium plates for upper maxilla repositioning are a promising method to realize an accurate reproduction of the preoperative virtual planning without the use of a surgical splint. Benefits of this technique are several: it allows direct operative transfer of virtual surgical plans in the operating room, it is easy to use, relatively inexpensive, clinically efficient and it can shorten surgical times.

Regarding point (b): the Development of the Piezonavigated approach a research project is been designed. This project has been called:

"Computer-assisted Piezoelectric Surgery: A Navigated Approach toward Performance of Cranio-maxillofacial Osteotomies"

Introduction

The anatomical field of the cranio-maxillo-facial area is characterized by the presence of many extremely delicate vascular and nervous structures which must be preserved during surgery. Many procedures including orthognathic surgery, craniofacial surgery, tumor resection, those required to treat trauma sequelae, oral surgery, and pre-prosthetic surgery, require bone osteotomies. However, manual or standard electric instruments (drills or burrs) can damage nerves, vessels, and (in the upper part of the face) the orbits and meninges. Use of piezoelectric instruments renders it possible to greatly improve the accuracy of bone cuts. The tips of the instruments are very thin, greatly reducing the numbers of soft tissue lesions created during osteotomies in the oral and maxillofacial areas [43, 44, 45, 46], particularly in orthopedic patients [47, 48].

Piezoelectric tools have changed the manner in which osteotomies are performed during maxillofacial surgery. Surgeons can now reduce the extent of bone exposure and (sometimes) perform flapless procedures [49, 50]. The use of such tools in orthognathic surgery seems to significantly reduce damage to the mandibular nerves [51, 52, 53, 54]. Similarly, many orthodontic surgeons now use piezoelectric scalpels [55, 56, 57]. Several applications of such tools have been reported in the fields of craniofacial surgery [58, 59, 60, 61, 62] and pediatric maxillofacial surgery [63, 64, 65]. In the ENT field, piezosurgery has increased the approaches available for treatment of the middle and inner ear [66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78], and the technique has found ready application in neurosurgery [79].

These developments strongly suggested to us that piezosurgery should be employed to render cranio-maxillofacial surgery less invasive than is currently the case. Piezoelectric osteotomy should be particularly valuable in this context. The procedure we have developed is termed Computer-Assisted Piezoelectric Surgery (CAPS), which combines effective during-surgery navigation with use of a piezosurgical tool. Commencing in November 2008, the Unit of Oral and Maxillofacial Surgery at the S.Orsola- Malpighi University Hospital in Bologna (Italy) has performed a large number of surgical procedures with the aid of simulation-guided navigation (SGN) [38]. Simultaneously, piezosurgical instruments were used daily over many years in oral and cranio-maxillofacial surgeries, including bone harvesting [70, 71, 72, 73, 74, 75, 76]; inlay placement in pre-prosthetic surgeries [77, 78]; sinus lift augmentation techniques [79, 80, 81, 82, 83, 84, 85, 86]; various osteotomies of the maxilla and mandible [41, 42, 87, 88, 89, 90, 91] (especially when it was essential to avoid teeth roots, for example during multi-segmented maxillary osteotomy [39, 42]); surgically assisted rapid maxillary expansion; and mandibular symphyseal distraction [92]. In the field of pediatric craniofacial surgery, piezoelectric tools have been used to perform corticotomies, distraction osteogenesis procedures [53, 54] and osteotomies to treat craniosynostosis or cranio-facial stenosis [48, 49, 50, 51]. In oncology, piezosurgery has been used to safely perform bone osteotomies [93], resections, and microvascular bone flap modeling during mandibular and maxillary reconstruction [94].

However, in several of these procedures, use of a piezosurgical instrument (although safe) [95, 96, 97, 98, 99] requires construction of a wide-open field so that the precise position of the tip of the instrument can be directly viewed. We sought to combine the safety of the piezosurgical instrument with precise three-dimensional (3D) tip localization afforded by a navigation tool. CAPS was the result and, herein, we present some applications of the technique.

Materials and Methods

CAPS combines a piezosurgical instrument with a navigation system featuring a general instrument-tracking tool and a calibration device. The piezoelectric instrument used was the Piezosurgery Medical (Mectron, Genoa, Italy) . The navigation system employed was the eNlite System with inbuilt iNtellect Cranial Software 1.0 (Stryker, Freiburg, Germany). CAPS employs standard surgical navigation and features the following steps, which can be performed outside the operating theater unless stated otherwise.

1. Data acquisition via CT or MRI DICOM.

2. Importation of DICOM data to the navigation software suite.

3. Three-dimensional virtual reconstruction using the software suite.

4. (SGN only) Loading a virtual simulation (created using third-party software) to the navigation software suite.

5. (Theater) Registration to ensure precise tracking of the patient.

6. (Theater) Linking of the tracking tool to the handpiece of the piezoelectric instrument and registration and calibration of the cutting tip.

7. (Theater) Surgery using CAPS.

Tracking the Piezosurgical Instrument

The piezosurgical instrument and the navigation system are linked using the Stryker NavLock clamp, an adaptable tool that can be mounted on any instrument 13–20 mm in caliber (Fig. 29A). Instrument tip registration is achieved with the aid of the Stryker eNlite calibration tool (Fig. 29B-C), completing the set-up procedure.

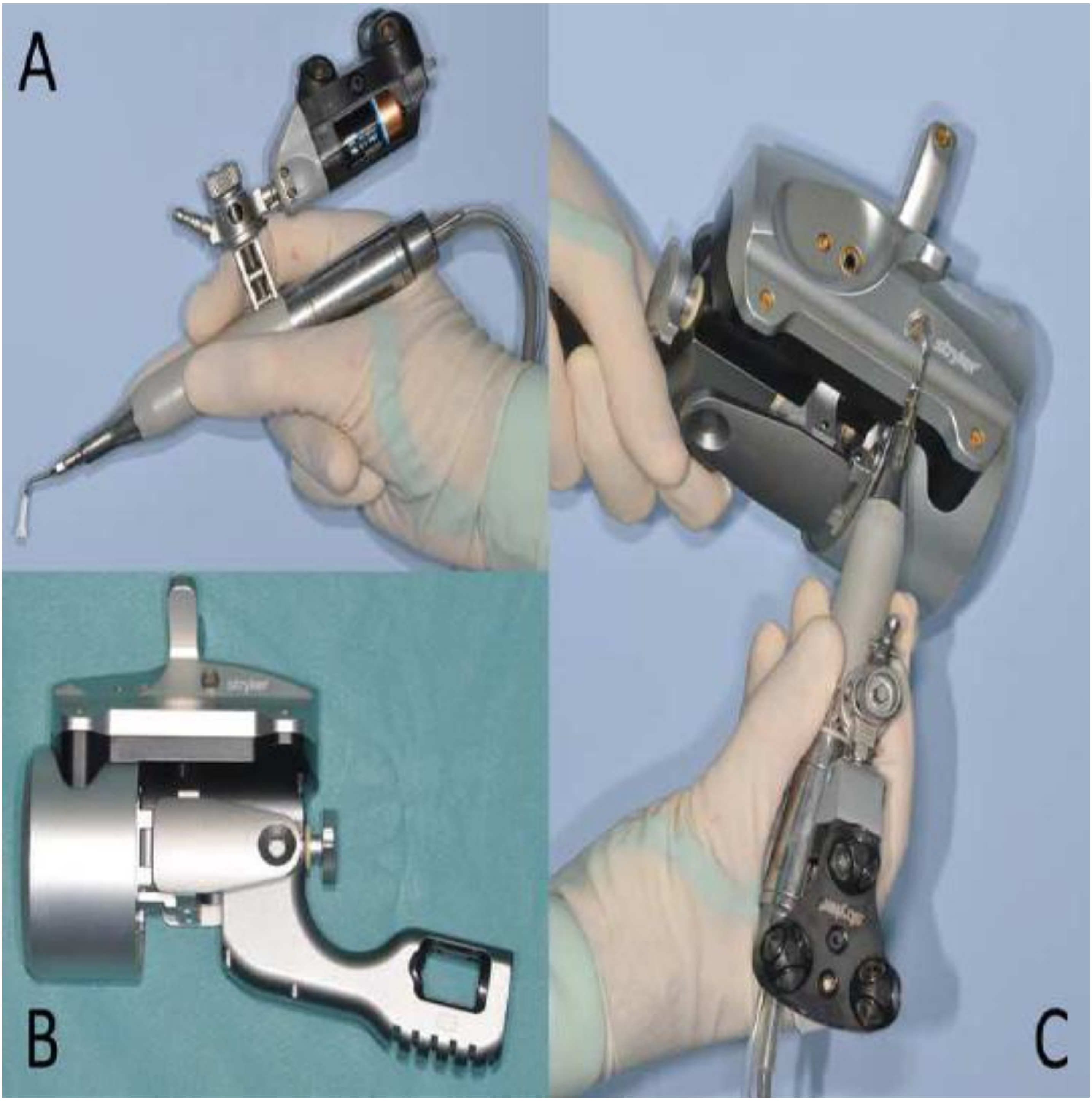


FIG. 29

In this figure the connection between the piezoelectric instrument and the navigation system is showed; **A** shows the piezoelectric handpiece with the clamp-mounted tracker; **B** shows the calibration tool of the navigation kit, which is used in **C** to realize the registration process of the piezoelectric instrument tip.

Eighteen (18) patients were treated using the CAPS technique in the interval 2010–2013, and may be divided into the following four groups:

A. Orthognathic surgery (LeFort 1 osteotomy); 10 patients;

B. Mandibular distraction osteogenesis corticotomy, 6 patients;

C. Orthodontic corticotomy, 1 patient;

D. Oncology (tumor resection), 1 patient.

Group A. Orthognathic Surgery

Ten patients underwent orthognathic surgery performed with the aid of CAPS. All DICOM data were obtained using a cone-beam CT-scanner, the NewTom VGi (QR, Verona, Italy). We always used the SGN protocol [38]. Virtual surgery was performed using Surgicase 5.0 (Materialise, Leuven, Belgium). Each surgical plan was converted to an .STL file and loaded into the eNlite Navigation System. iNtellect Cranial

Software was used to superimpose the plan onto patient-specific CT scan data (Fig. 30A), and the surgeon could thus follow the planned osteotomy line. The skull was used for patient tracking. Registration employed dental and bone reference points refined using bone surface data. The mean target registration error (TRE) was 0.30 mm (SD 0.12 mm). Le Fort 1 osteotomy was performed with the aid of the navigation system. The Stryker navigation software displays the tip of the instrument as a yellow cross centered on the apex of the tip per se (Fig. 30B). The 2D/3D images can be zoomed without loss of precision. CAPS was used to correctly reproduce the osteotomy line created in the virtual project. During surgery, CAPS was also used to check the instrument tip position in real time, ensuring that the tip was always in a safe region and that significant anatomical structures were avoided. Figure 31 shows one clinical case where CAPS has been performed.

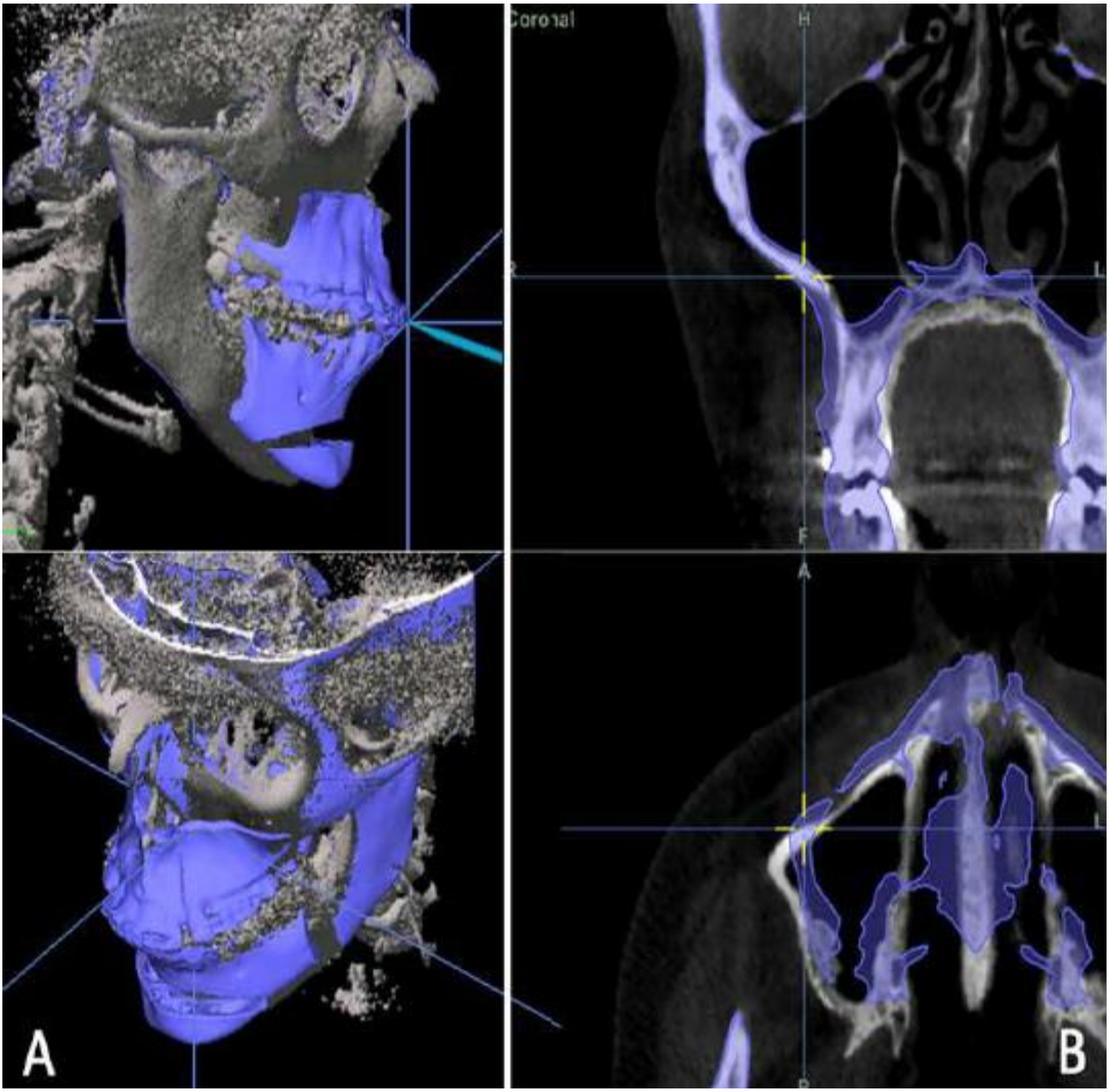


FIG. 30

This figure shows in **A** the virtual surgical planning of the orthognathic procedure (in blue) matched with the native CT scan; in **B** the virtual appearance of the navigated tip of the piezoelectric instrument is showed as a yellow cross on the navigation system screen; again, the planning is in blue.

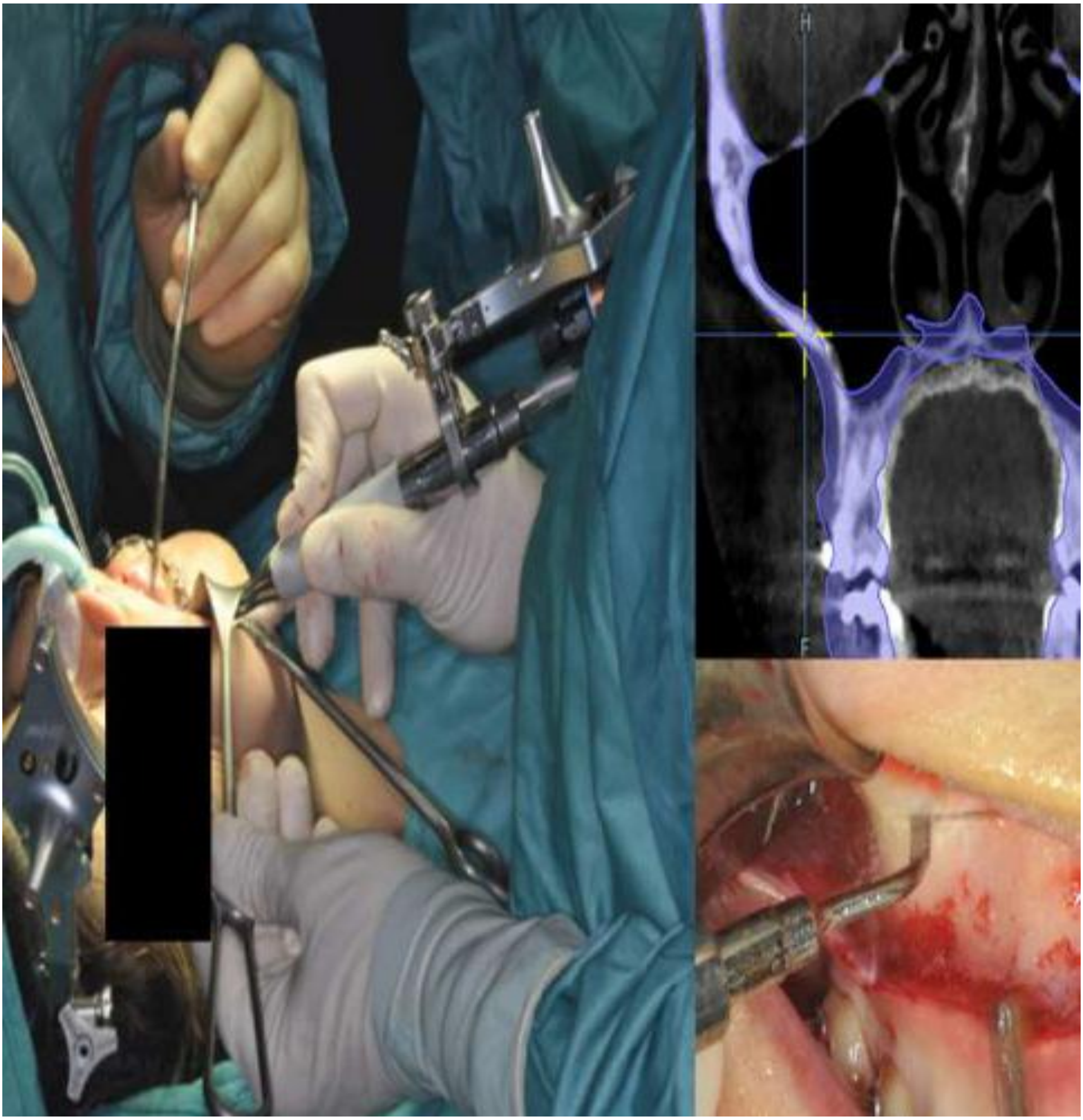


FIG. 31

This figure shows the clinical application of the CAPS to an orthognathic surgery procedure; **A** shows the handpiece with another version of the clamp-mounted tracker, which works in the same way; **B** shows once more the virtual appearance of the navigated tip of the piezoelectric instrument on the navigation system screen; **C** shows the detail of the piezoelectric saw on the patient’s maxilla during the LeFort1 osteotomy in the same position showed in **B**.

Group B. Distraction Osteogenesis

Six patients underwent distraction osteogenesis of the mandible with the aid of CAPS. DICOM data were obtained in different ways. Four patients underwent multislice CT scanning (slice depth 1.25 mm) using the Optima CT 660 (General Electric, Fairfield, CT; and two cone-beam CT scanning using the QR NewTom VGi. Virtual surgery was performed in three cases using Surgicase 5.0 and in the other three employing LHP Builder (SCS, Bologna, Italy). The latter software is experimental in nature and was used in collaboration with the Rizzoli Orthopedic Institute of Bologna (Italy). Surgical planning considered the position of the distractor and the cutting plane to be used for corticotomy (Fig. 32A). Surgical planning data were converted to .STL files and loaded into the eNlite Navigation

System. Also, iNtellect Cranial Software was used to superimpose plans on real CT data to allow the surgeon to follow planned osteotomy lines. The skull was used for patient tracking. Registration of pediatric mandibular surgery patients was achieved using upper-face soft tissue reference points, refined by reference to the skin surface. The mandible was next indirectly registered using a dental splint. The mean TRE was 0.73 mm (SD 0.21 mm) and a TRE over 1.0 mm was not accepted. Mandibular corticotomy was performed with the aid of the navigation system. CAPS was used to correctly reproduce the corticotomy lines devised in the virtual projects (Fig. 32B) and to check the position of the tip of the instrument in real time, ensuring that the tip was always in a safe region (thus away from significant anatomical structures, such as the germ of wisdom teeth; Fig. 32C) and to check the position of the distractor (Fig. 32D). Figure 33 shows one clinical case where CAPS has been performed.

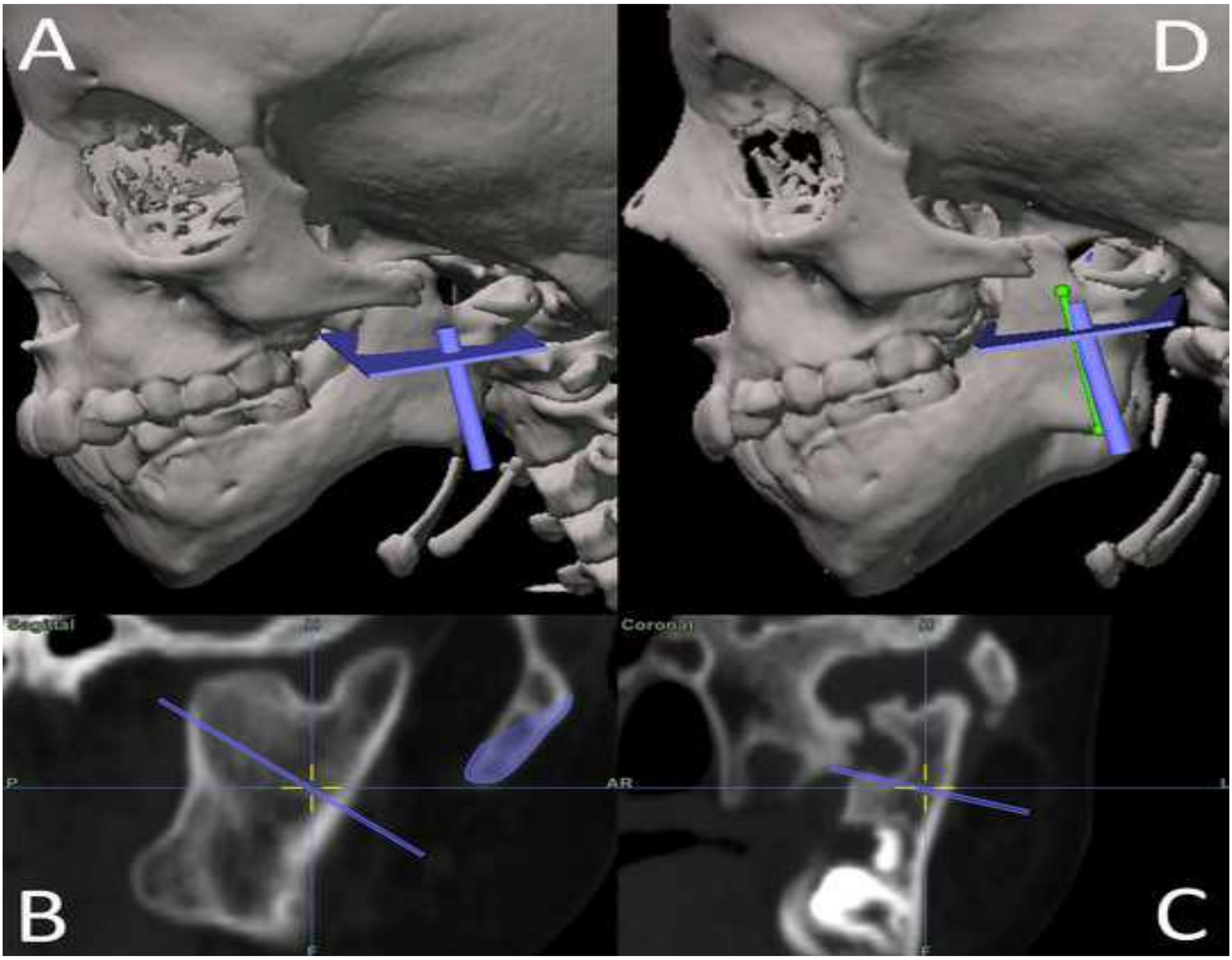


FIG. 32

This figure shows the use of CAPS in distraction osteogenesis of the mandibular ramus; **A** shows the virtual surgical planning with the osteotomy line (designed to avoid dental germs and mandibular nerve) and the position of the distractor vector; **B** shows the navigated tip following the osteotomy line; the same in **C** where the wisdom tooth germ is avoided by keeping the tip on the planned osteotomy line; in

D surgery has been performed and the realized distractor vector is detected and outlined by the navigation system and compared to the virtual project.

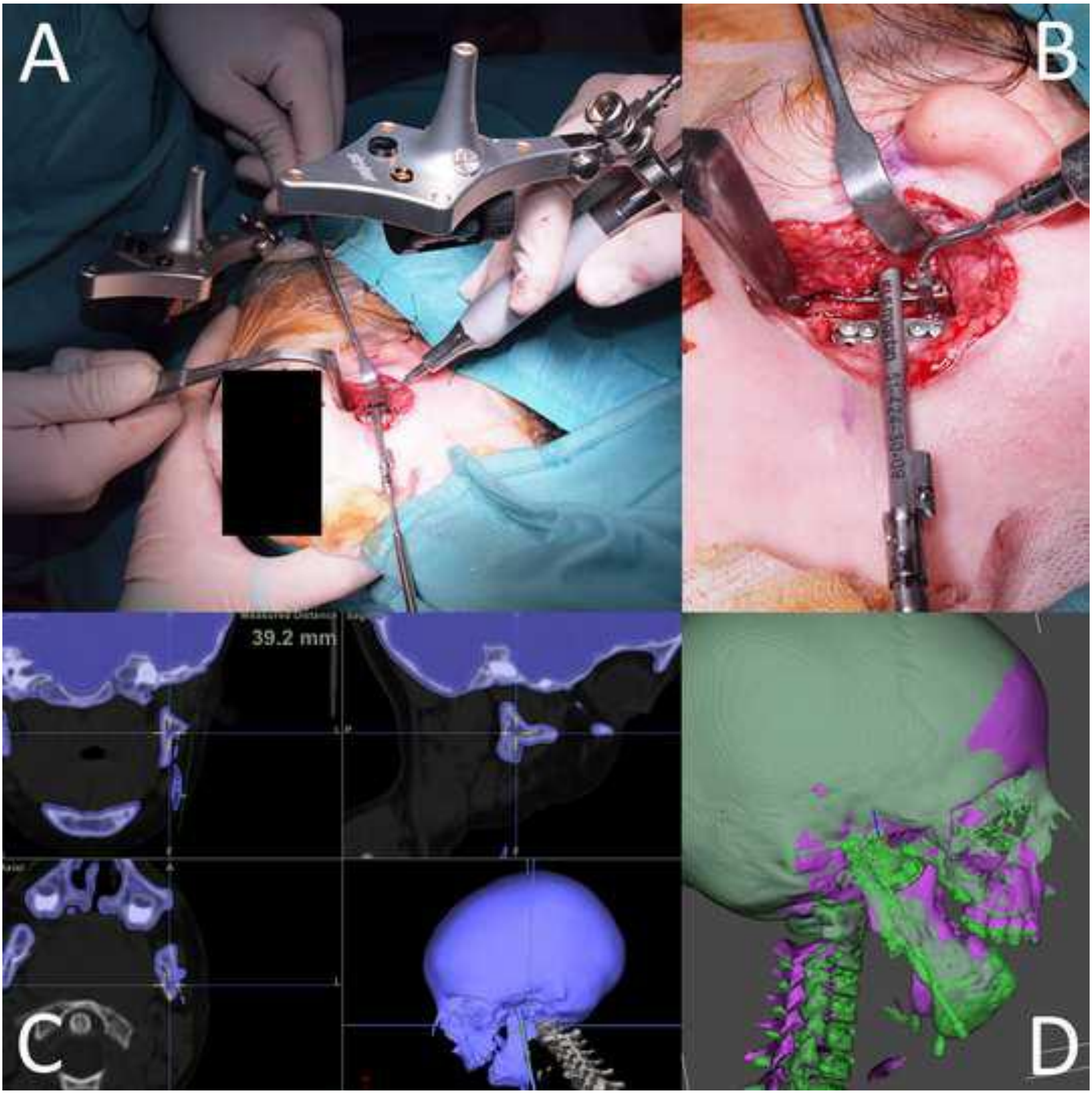


FIG. 33

This figure shows CAPS applied to a distraction osteogenesis clinical case of Treacher-Collins-Franceschetti Syndrome; CAPS is performed bilaterally; **A** shows the surgeon performing the mandibular ramus osteotomy with navigated piezoelectric instrument; **B** shows the navigated tip during the osteotomy; **C** shows the navigation system screen where the piezoelectric instrument tip is displayed as a yellow cross inside the mandible; the osteotomy line is here represented as a discontinuity of the virtual planning in blue; **D** shows the three-dimensional result of the distraction compared to the preoperative CT scan.

Group C. Orthodontic Corticotomy

One patient underwent mandibular orthodontic corticotomy with the aid of CAPS. DICOM data were obtained using the QR NewTom VGi cone beam CT scanner. The skull was used for patient tracking. Registration employed upper-face soft tissue reference points refined by reference to the skin surface. The mandible was next indirectly registered using a dental splint. The TRE was 0.50 mm. A vestibular corticotomy (from the inferior right to the left canine) was performed with the aid of the navigation system (Fig. 34). Three vertical mucosal incisions were made and the dental roots were avoided despite use of a semi-buried approach.

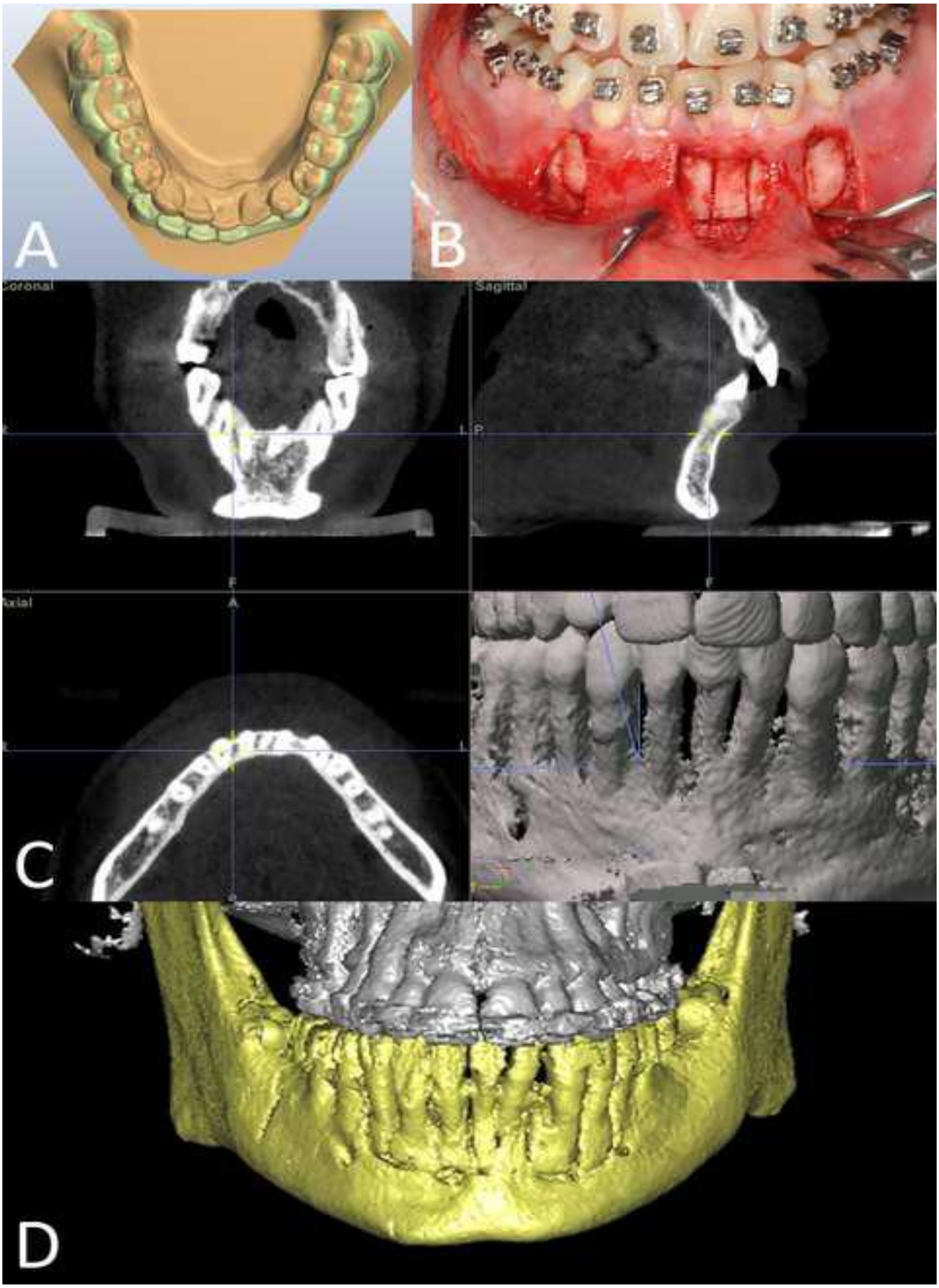


FIG. 34

This figure shows CAPS used for orthodontic surgery (corticotomies); **A** shows the comparison btween the preoperative mandibular arch and the virtually planned goal of orthodontic therapy; **B** shows the three vertical incisions used to perform surgery in a semi-buried approach; **C** shows the navigation system screen durging CAPS, where the technique allows to check real-time if the piezoelectric tip is cutting the interproximal alveolar bone; **D** shows the three-dimensional reconstruction of the surgical result.

Group D. Oncology

One patient underwent oncologic surgery with the aid of CAPS. A total hemi-maxillectomy was performed to resect a large mixoma. DICOM data (slice depth: 1.25 mm) were obtained using the multislice Optima CT 660 CT scanner of General Electric. The skull was used for patient tracking. Registration employed upper-face soft tissue reference points refined by reference to the skin surface. The TRE was 0.60 mm. Surgical planning was performed with the aid of the Sintac Company (Sintac, Trento, Italy) because reconstruction involved formation of a CAD-CAD mesh plate. The surgical plan was converted into a .STL file and loaded into the eNlite

Navigation System. Maxillary osteotomies (palatal, orbital, and malar) were performed with the aid of CAPS. Figures 35-36 show the case.

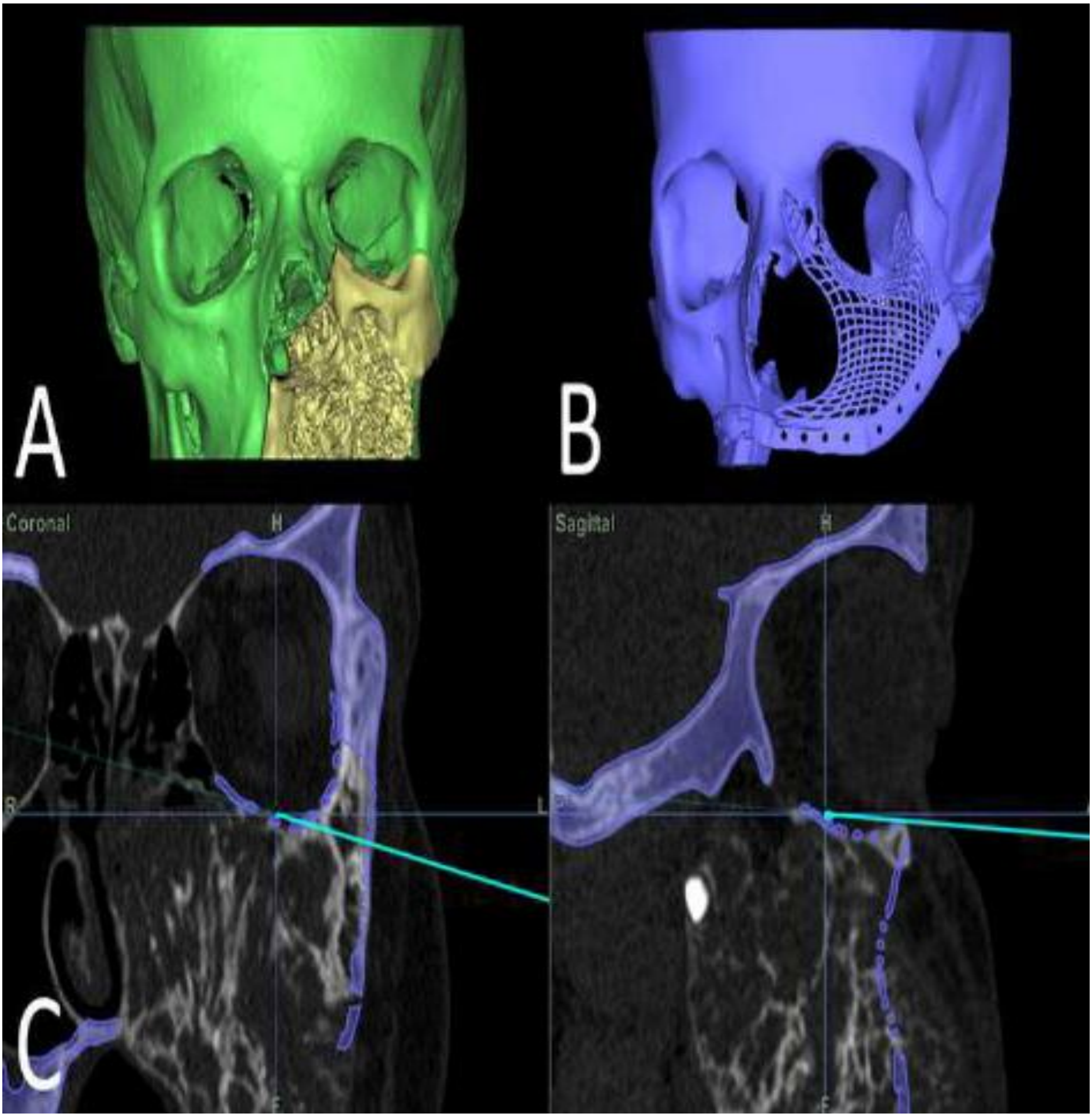


FIG. 35

This figure shows a clinical case of large mixoma of the maxilla; **A** shows the lesion and the preoperative virtual plan of the osteotomies (alveolar, zygomatic and nasal are mainly visible and have been performed with CAPS – see Fig.8); **B** shows the CAD-CAM mesh plate used for the reconstruction in the planned position; **C** shows the intraoperative check of the correct positioning of the mesh plate in the orbital region.

FIG. 36

This figure shows CAPS applied to the clinical case of Fig.7; **A** shows the alveolar osteotomy through CAPS displayed on the navigation system screen and the actual osteotomy on the maxilla; similarly, **B** shows the zygomatic osteotomy and the actual osteotomy on the zygomatic arch; similarly again, **C** shows the nasal osteotomy and the actual osteotomy on the nasal root.

The present study is retrospective in nature. The study was conducted in accordance with the tenets of the WMA Declaration of Helsinki in the context of Ethical Principles for Medical Research Involving Human Subjects and was granted exemption by the local IRB of our Institution.

Results

We seek to introduce our new technique, which will be further refined in future. We present our initial clinical and surgical data. Use of CAPS in the treatment of Group A and C patients allowed us to use minimal mucosal incisions when performing Le Fort I osteotomies and orthodontic corticotomies in a semi-buried manner. During Le Fort I procedures, CAPS afforded 3D control of the cutting instrument, allowing dental roots to be avoided and ensuring that no fistula was created in the palatal mucosa. Osteotomy could be more readily performed when the cutting tip was kept in the pterygoid area and the region surrounding the palatine channel. This ensured that no vascular lesion would be created. When surgery was performed under SGN, CAPS rendered it possible for the surgeon to follow osteotomy lines planned during 3D virtual surgery, thus maximizing the quality of operation. CAPS afforded even greater advantages in Group B patients. During pediatric skeletal distraction, it is essential to avoid dental germs and the thin neurovascular structure of the mandible. Our technique allows a surgeon to perform both corticotomy and osteotomy, if necessary, in a safe and reliable manner. Again, surgery can be conducted in a semi-buried manner, avoiding extensive periosteal detachment, and reducing tissue exposure and scarring. In Group C patients, CAPS allowed use of a semi-buried approach with minimal periosteal detachment. The risk of tooth damage during inter-radicular corticotomy was greatly reduced. CAPS allowed the surgeon treating the Group D patient to check the limit of the lesion on bony surfaces and (and much more relevantly) deep inner bone structures, and to choose generous resection margins

Discussion

A major fear of the maxillofacial surgeon using a standard drill with rotating tips is creation of soft tissue lesions triggering major hemorrhage or nervous impairment (at worst), or dental injury (at best). Damage to the cranial and orbital area caused by a rotating drill can include meningeal or brain lesions, CSF leakage, hemorrhage, and insult to the orbital or optic nerves. Some surgeons prefer to use reciprocating saws, the safe use of which requires a great deal of experience. Soft tissue lesions caused by rotation and grinding may thus be reduced in extent, but, paradoxically, the saw causes tissue contusions and compression [68, 79].

Piezoelectric tools have dramatically changed the manner in which bone surgery is performed, as evidenced by the explosion of literature on the topic over the past 10 years. The tools allow surgical approaches to be both precise and minimally invasive, affording better bone recovery because a cavitation mechanism is employed [69]. However, even if the piezoelectric instrument is both small and thin, wide exposure of the surgical field is often necessary. If, however, the tool is employed in concert with surgical navigation, the precise anatomical site requiring surgical attention is defined, and the position of the tip can be precisely checked by reference to CT data from the patient. This ensures safety and precise surgical orientation, even in deep regions. A semi-flapless approach is possible. Combination of the two technologies is synergistic. First, the piezoelectric instrument is the only saw that can be safely tracked using a navigation system. It might be observed that standard surgical micro-saws, drills, or burrs can in fact be tracked, but movement of the micro-saw tip, vibration of the handpiece, and the danger of taking the eyes away from the surgical field to watch a monitor, combine to render such techniques unacceptable. The piezoelectric instrument is steady, barely vibrates, and the surgeon can safely pause to look at a screen. Second, use of a piezoelectric instrument is associated with a degree of precision allowing it to be used in combination with SGN. The surgeon can follow virtually planned osteotomy lines or planes, displayed in 3D on a screen. It is easy to avoid important anatomical structures (because osteotomy was planned with this in mind) and the preoperative plan can be precisely fulfilled. Third, even when SGN is not used, CAPS helps a surgeon to avoid tissue damage, because the technique affords real-time control of the position of the saw tip. This is particularly helpful when deep bone surgery is underway; the surgeon cannot see clearly even if the field is wide open. Fourth, a combination of the second and third points above means that CAPS allows the surgeon to cut bone located in semi- or fully buried sites. Fifth, in the oncological field, CAPS allows the surgeon to change his approach to a bone cut if the navigation system shows that the tip of the instrument tip is too close to pathological tissue.

Conclusion

Computer-aided piezoelectric surgery (CAPS) is a new surgical approach useful when osteotomies are required in oral and cranio-maxillofacial regions. CAPS features marriage of a piezoelectric instrument and a navigation system. The surgeon can work more safely when the two devices form a single synthetic tool. Moreover, CAPS should find ready applications in Schools of Medicine and Teaching Hospitals, allowing younger or less-experienced surgeons to approach deep and highly sensitive anatomical structures more safely. More studies are planned. In particular, the use of SGN within CAPS shows great promise. The accuracy and reproducibility of surgery conducted in this manner are presently under meticulous evaluation in our hospital.

Navigation in H&N Oncology.

Oncology is the first surgical field where computer-aided surgery has been developed and applied. Navigation of the tumor mass and the surrounding tissues, seeking safe margins, has been the inspirational concept that lays at the root of this technology.

Nowadays oncology is still the head and neck surgical field where navigation is mostly used. Especially for tumors of the splancnocranium or the skull base.

Objective of the project was:

- developement of computer planned resection;
- developement of computer planned reconstruction;
- more accurate navigation of soft tissues.

This study was developed by a PHd Thesis by Dr. Simona Mazzoni, MD, PhD at our post-graduated PhD School in Surgical Science, University of Bologna. Here we show just an exemplification case of tumor resection and reconstruction according to the Simulation Guided Navigation Project.

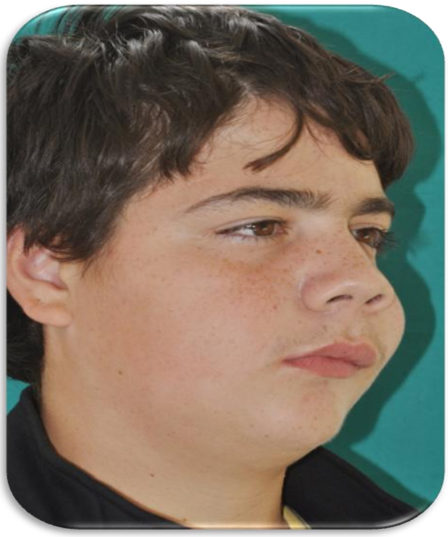
a  b  c

FIG. 37, a,b,c: presurgical view of a pt. with an orbito-maxillo-zigomatic tumor.

FIG.38: intraoral view

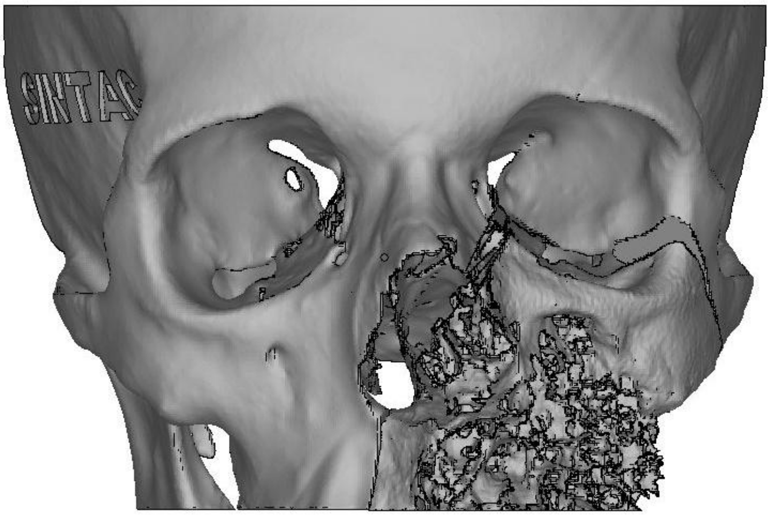
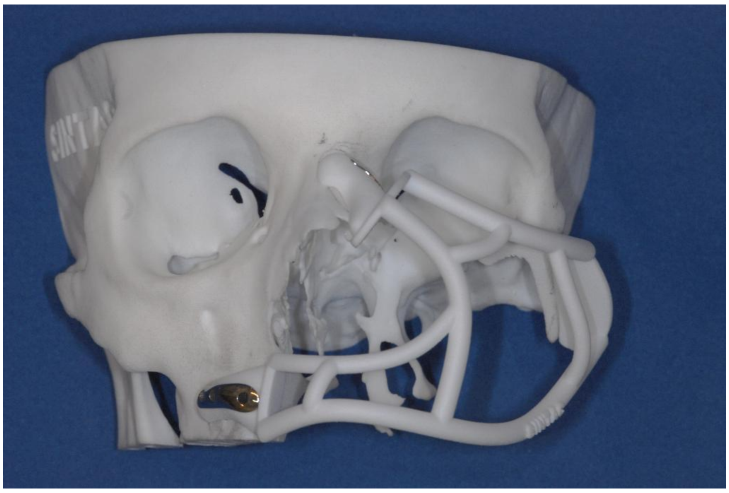


FIG. 39: MSCT data 3D reconstruction with the resection project



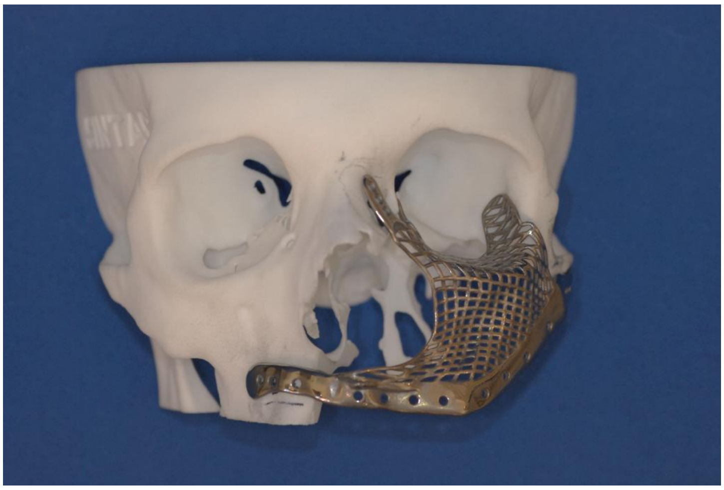


FIG. 40: cutting guides (above) and CAD-CAM laser sintering reconstruction plate (below).

FIG. 41: intraoperative piezonavigated resection (left), intraoral resection view (right)

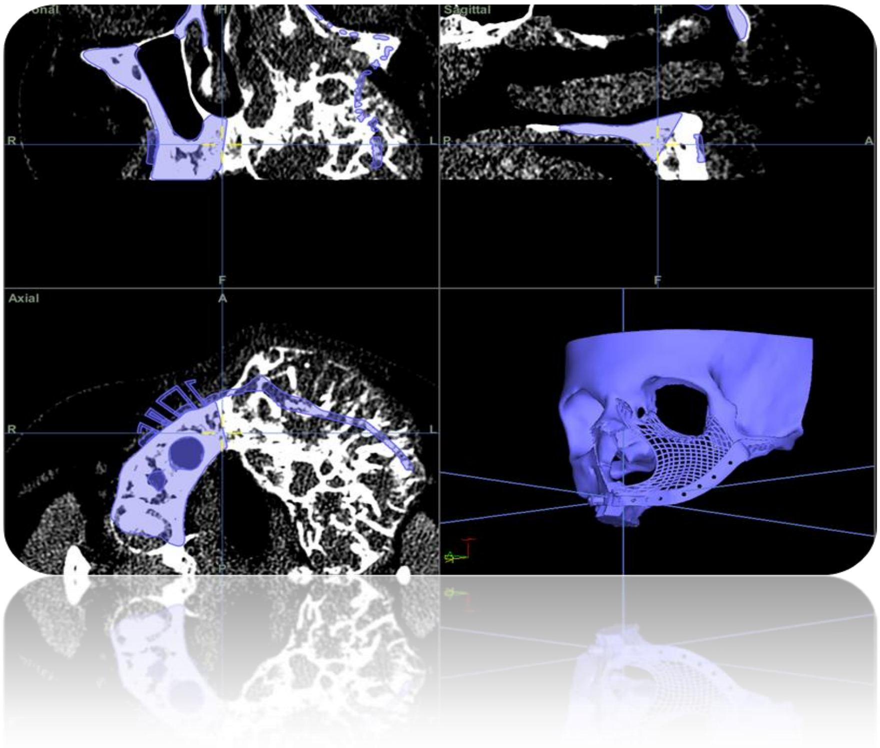


FIG. 42: Simulation Guided Navigation Project

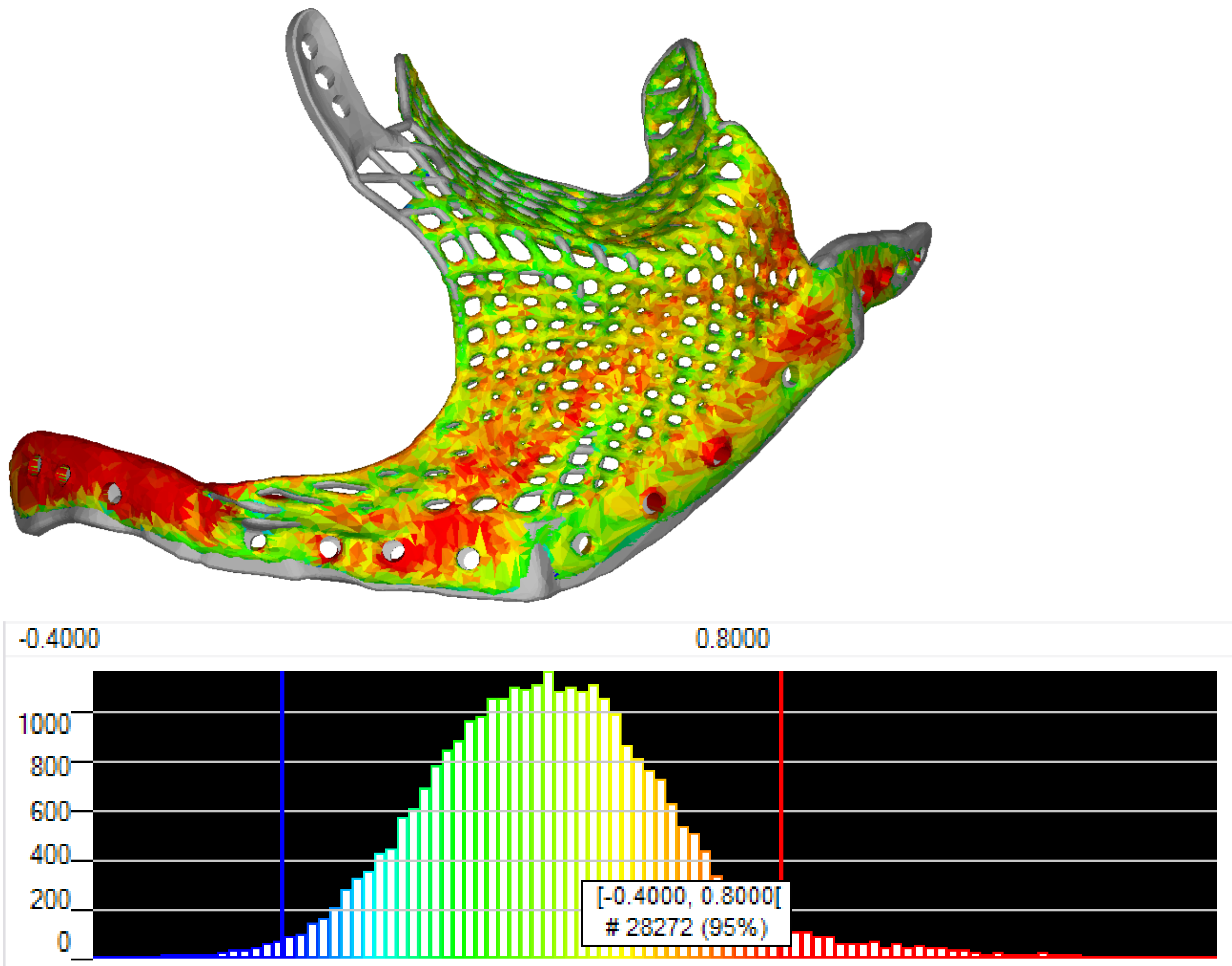
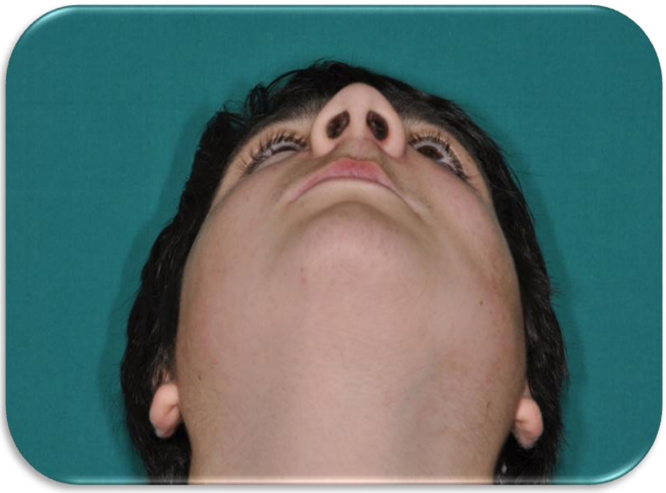


FIG. 43: Validation of the positioning of the reconstruction plate compared with the post-operative result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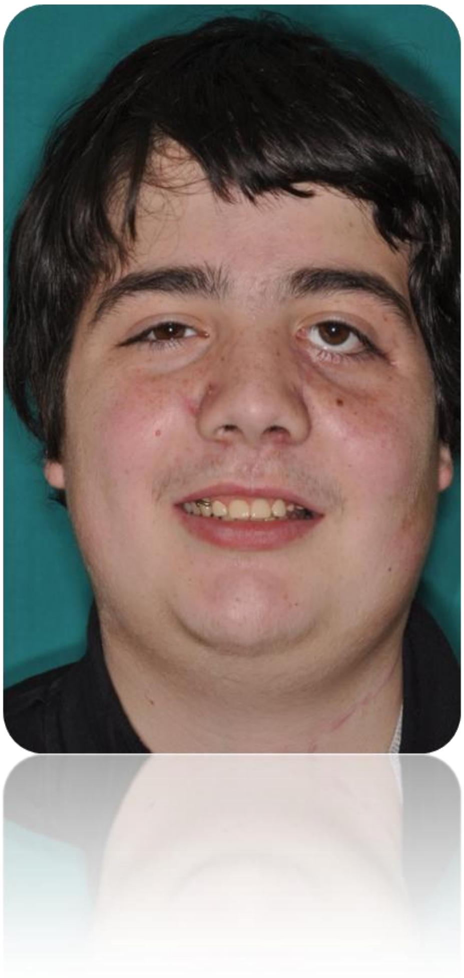
b


c

FIG. 44 a, b, c : post operative result before implant positioning

Navigation in H&N Traumatology.

Navigation has been recently applied also to complex bone traumatology, especially orbital fractures. One major use of navigation has always been the research of foreign bodies, which are so frequent in the traumatology of the head.

Objective of the project was:

- developement of more accurate computer planned bone repair and reconstructionnavigation of the mandibular condyle. (research in fieri)

Final objective that the research project should achieve

The final objective was to introduce the concept that many cranio-maxillo-facial surgery procedures could be performed applying the final goal of reproducibility of a presurgical plan and overwhelm the approximate approach based on the surgeon's skill. This final objective has been reached using a validation protocol.

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Lista delle pubblicazioni del candidate Dr. Albeerto Bianchi nel periodo AA. 2010-2013:

1. Bianchi A., Muyldermans L., Di Martino M., Lancellotti L., Amadori S., Sarti A., Marchetti C. Facial Soft Tissue Esthetic Predictions: Validation in Craniomaxillofacial Surgery with Cone Beam Computed Tomography Data. J Oral Maxillofacial Surg 68: 1471-1479, 2010 (IF: 1,500)
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