**Università degli Studi di Milano**
**Department of Biomedical, Surgical and Dental Sciences**

PhD thesis in Oral Sciences:

# "Accuracy of Splint vs Splintless technique for virtually planned orthognathic surgery: A voxel based three-dimensional analysis"

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*To my late father Daniel*

*for my love and appreciation for him*

*is forever imprinted in my heart*

# Table of Contents

# Preface

Virtual planning in orthognathic surgery has nowadays become a clinical reality and has introduced important advantages in terms of accuracy and planning duration when compared to conventional surgical planning. One of the main concerns regarding virtual planning is the method that is used to transfer the virtual surgical plan into the operation theater. With the many transferring methods proposed, the evidence is confusion regarding the accuracy of each of these methods for reliably transferring the virtual plan. Furthermore, the accuracy analysis itself, has been performed with numerous techniques and not all of them are capable of producing reliable results on the accuracy of different transferring methods.

The purpose of this study is to compare two transferring methods, the CAD/CAM intermediate splint and the customized surgical guide with fixation plates, by means of a voxel-based landmark free accuracy analysis.

# *List of abbreviations*

| | |
|---|---|
| CSP: | Conventional Surgical Planning |
| VSP: | Virtual Surgical Planning |
| CBCT: | Cone Beam Computed Tomography |
| 3D: | Three-dimensional |
| STL: | Standard Tessellation Language |
| ROI: | Region Of Interest |
| BSSO: | Bilateral Sagittal Split Osteotomy |
| CAD/CAM: | Computer Aided Design/ Computer Aided Machinery |

# Chapter One: Planning of Orthognathic surgery – State of the Art

**Main question: CVP vs VSP- which one is more advantageous?**

Orthognathic surgery is a discipline within maxillo-facial surgery that aims to correct dento-facial skeletal abnormalities. Although it counts more than 100 years of history, in the last two decades its path has been marked by important changes and evolution of thoughts, mostly regarding its planning process, for which there are nowadays two options: the conventional surgical planning and the virtual surgical planning[1].

## *1.1 Conventional surgical planning (CSP)*

The CSP process goes through the following steps:

1. Clinical evaluation

The first step for any planning method of orthognathic surgery is the clinical evaluation of each case. The clinician goes through a thorough extra-oral and intra-oral examination of the patient. It includes the visual examination of patients' extra-oral characteristics such as face height, proportions or asymmetry as well as its intra-oral characteristics such as molar and canine relationship, midline discrepancies etc.

2. Photos, Radiographs and Impressions

As a second step, a series of intraoral and extra-oral photos of the patient are taken, as well as two radiographs: an orthopantomography, in order to evaluate patients' dentition, and a cephalometry, which is the key factor in the analytical planning of the orthognathic surgery. This documentation is combined with alginate impression taking of the upper and lower dental arch in order to produce the model casts that are going to be used for the model surgery process. Together with the impression taking, a face bow is used to register the three-dimensional orientation of the maxilla (Fig.1).

3. Diagnosis

In the CSP workflow, the cephalometric analysis is crucial for patients' skeletal diagnosis and for deciding the surgical approach. This process is usually combined with prediction tracings: first an acetate paper is put on the cephalometric radiograph and the profile of the face as well as the contour of maxilla and mandible are designed. Than the acetate paper is moved in the desired direction in order to simulate the new position that is aimed to be achieved. This way, the contour of the new position can be visualized and some measurement for the movements of maxilla and mandible can be registered (Fig.2).

4. Surgical simulation

The aim of this step is to simulate the preliminary surgical plan (Fig.3). First the face-bow registration is used to fix the maxilla cast in the articulator and then the mandible cast is fixed using the occlusion registration. Afterwards, the maxilla cast is separated from the articulator and cuts are made on it simulating the osteotomy lines that are going to be performed in the surgery room. The maxilla cast is also moved in all directions that correspond with the surgeons' plan for the treatment of that specific case, and remounted in the articulator in the new desired position. The mandible cast is than separated from the articulator, occluded with the maxilla cast in the ideal desired occlusion and remounted in the articulator. Once the ideal relationship between the two cast is fixed, an acrylic splint is fabricated in order to register their new relationship and help transfer it in the operating room.

5. Surgery

Depending on the complexity of the case, the surgical procedure can involve only one jaw, or can be a two-jaw surgery. Apart from surgeons' experience, the method of transferring the surgical plan into the operating theatre is one of the most crucial factors that determines the success of this step.

The CSP has been used for more than 50 years now and is still being taught at most, if not all maxilla-facial residency programs throughout the world. It has certainly resisted time and has been proven to have an overall acceptable accuracy[2,3]. However, it remains a very time-consuming process with many steps and materials used during the way which have the potential to introduce errors and inaccuracies[4,5]. Furthermore, being a twodimensional analysis, it has no consideration for the transversal dimension of the face and also for the sagittal direction its values are superimposed, therefore averaged[6]. Moreover, the CSP gives no possibilities to visually simulate the possible result, leaving the patient with no approximate idea on what to expect[7]. Lastly, the increased demand for facial aesthetics and the rapid development of technology in the last 20 years, has introduced to surgical planning of orthognathic surgery new challenges as well as new means for a more accurate result.

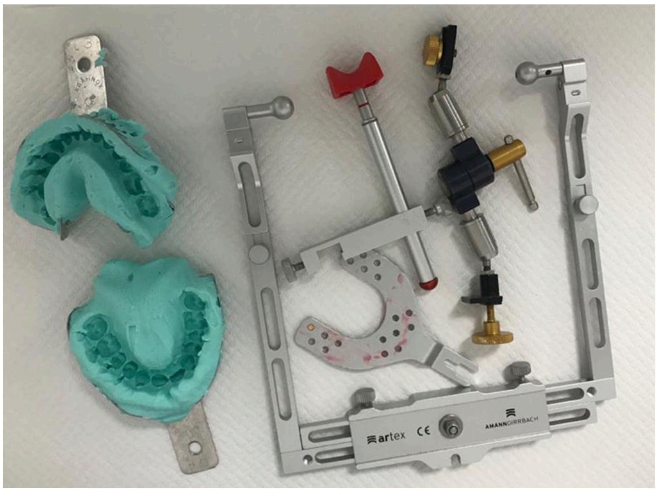



Fig.1 Face-bow for maxilla orientation and alginate impressions for model casts

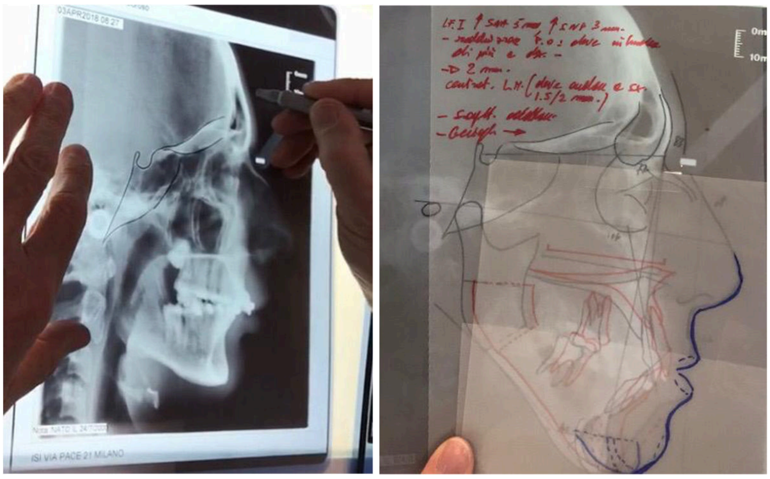


Fig.2 Cephalometric analysis and prediction tracings

Fig.3 Treatment plan simulation on model surgery

## *1.2 Virtual Surgical Planning*

Virtual planning of orthognathic surgery has emerged as one of the most important milestones achieved in this field, with a direct influence in the everyday clinical activity of maxilla-facial surgeons[8]. In a general search on Pubmed with the search string "Virtual planning AND orthognathic surgery", a total of 344 articles and a total of 28 reviews show up as results. One of the first studies to propose a workflow for virtual planning in orthognathic surgery, emerged in 2000[9]. Since then, there has been an increased interest in this subject, aided by the tremendous 3D technology development.

The step by step procedure for VSP includes:

1. Data gathering and Diagnosis

The first steps of VSP are similar to those of CSP. Data gathering starts with the clinical examination and evaluation of aesthetic and functional intraoral and extraoral parameters by the surgeon. Examination photos are taken for each case and 2D radiographs (orthopantomography and cephalometry) are gathered. In the case of VSP, the 2D cephalometry analysis is not of essential value as modern software for virtual planning have incorporated tools for cephalometric analysis from the CBCT data. CBCT examination is the essential part and the original data where the virtual planning process is applied. Impression taking for model cast is usually preferable to be taken, and model casts positioned in the desired occlusion by the surgeon before sending the models to the company owing the software for virtual planning. However, nowadays, this step can be done completely digitally by scanning intraorally patients upper and lower arches and occlusion, and send the information as an STL data to the company.

2. Pre-planning preparation

The third party company, once having received all this information, starts the process of pre-planning preparation in order to be able to stimulate the desired surgical movements of the jaws. This includes the 3D model preparation from the dicom dataset and segmentation, 3D model orientation based on a reference plane that may vary depending on the software (Frankfort line or Natural Head Position), the creation of the composite model and finally the design of the osteotomy lines in the maxilla and the mandible.

*The composite model*

The creation of the composite model is an important step in the overall accuracy of the process. The CBCT data acquisition, because of its intrinsic limitations but also because of the presence of scattering effects in the mouth (e.g. the presence of an orthodontic appliance), is not capable of creating an accurate representation of teeth surface. As a result, the determination of a correct inter-occlusal relationship based solely on the CBCT becomes impossible, with two important negative consequences:

- The difficulty in applying the correct virtual jaw movements
- The difficulty in producing a correct intermediate or final splint

To overcome this problem, a new dataset of teeth shape and surface should be taken and incorporated to the CBCT dataset, and the final product is named composite model. The first to propose a method for the composite model creation was Gateno in 2013[10]. He used an impression tray in which four titanium spheres serving as fiducial markers were incorporated (Fig.4). The tray was used to take an analogue impression of the dental arch, which was then laser scanned and through a specific software the positive model was obtained as an .STL file. Afterwards, with the same impression tray on, the skull underwent a CT acquisition. The two datasets were merged by using the titanium spheres as references for the superimposition. Following Gateno, other authors proposed similar methods by means of external fiducial markers[11]. However, the presence of such markers, interferes with the position of the upper or lower lip, which can produce important limitations or inaccuracies during the planning process[7]. Another proposed method was that of Swennen et al, in 2009[12]. It consisted of a triple scan procedure: First the CT of the patient was taken, followed by a second CT of the patient with a triple impression tray in the mouth, and lastly a third CT scan of the triple tray alone was taken. The three CT datasets were superimposed by means of a voxel-based registration in the correct inter-occlusal relationship (Fig.5). This technique was a step forward in some ways, because it eliminated the need for fiducial markers and consequently the problem of lip distortion. However, the need for a triple Scan procedure, two of which performed on the patient, brought some concerns in terms of radiation safety. Furthermore, it required a good collaboration from the patient during the procedure, making it susceptible to possible inaccuracies. In 2013, Alfaro et al[7] proposed an innovative method for the composite model creation. It consisted of a single CBCT acquisition of the patients' skull and a subsequent digital ST scan of the dental arches. The two .STL files are than merged by means of a best-fit algorithm offered by the specific software (Fig.6). This method eliminates the need for more than one CBCT acquisition as well as for fiducial markers, and relies on algorithms for the correct merging of the files. Other methods have been proposed as well, including that of Bobek et al in 2015[13], which introduced the concept of internal fiducial markers. This method eliminated the risk of lip distortion by the external marker, but still remains a technique-sensitive approach, with a double CBCT acquisition (one for the patient and one for the model casts) and the need for analogue impression taking. In our study, we used a technique similar to that of Alfaro et al, by merging the CBCT dataset with the .STL file of the intraoral digitally scanned dental arches, by means of a best-fit algorithm.

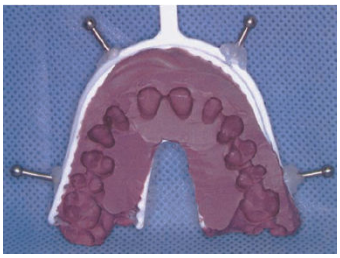


Fig.4 Analogue impression taking with titanium spheres as fiducial markers. Method proposed by Gateno et al.

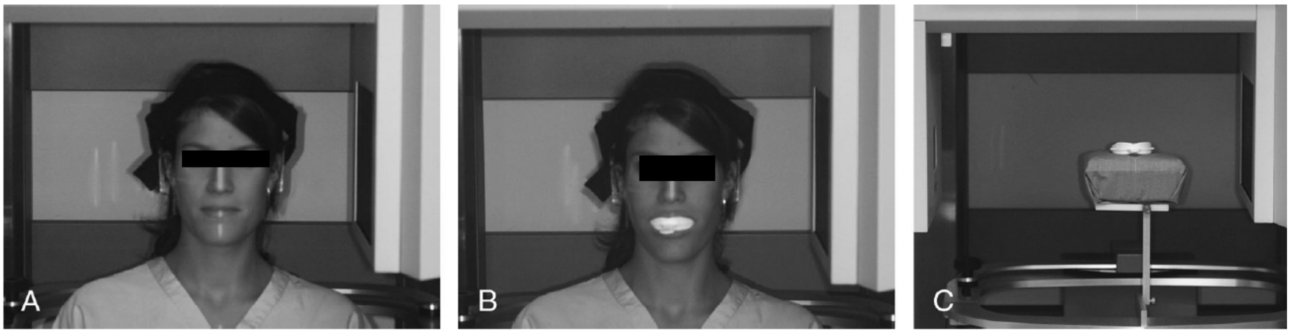



Fig.5 Swennen et al method for composite model creation, consisting of A) patients' CT, B) CT of patient with triple tray, C) Triple impression tray CT.

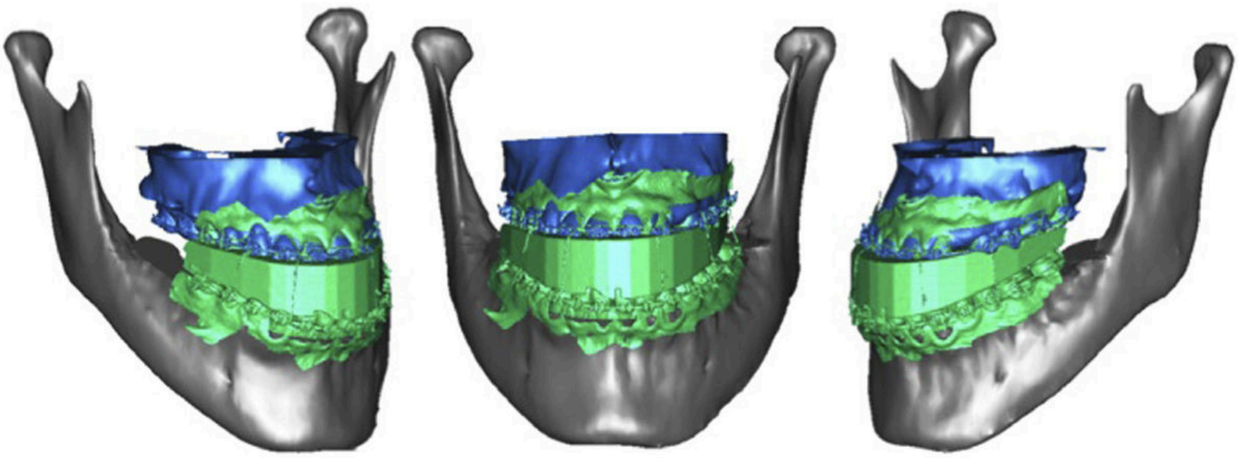


Fig.6 Alfaros' method of merging the ST dental scan with the CBCT dataset by means of best-fit algorithm.

## 3. Surgery simulation

Once the preparation of the 3D model has been concluded, the surgery simulation session can be undertaken. It consists of a web meeting with the engineers of the third-party company offering the planning software. Based also on the intraoral and extraoral photos of each case, the surgeon determines the type of movements he wishes to perform on the specific case in all three axes: antero-posterior, lateral and vertical movements. Also, any rotation of the bi-maxillary complex, as well as midline discrepancies or canting presence can be addressed during this stage (see materials and methods). Once the final position has been confirmed, the transferring method is decided.

4. Surgery

Several weeks after the virtual planning session, the surgery can be undertaken. The surgeon must have in his possession the transferring method which will guide him in the final position of the osteotomized jaws (See chapter two).

Since its first introduction by Xie et al[9], VSP has followed a constant path of advancement mainly due to two factors: First, the development of the CBCT as an easily accessible, cost-effective and low-radiation mean of 3D image acquisition, and second, the rapid technological development of software for 3D image visualization. Furthermore, VSP has gained much interest among surgeons and orthodontist all around the world, due to the following advantages it offers:

a- Being a 3D representation of the skull, it gives the surgeon much more information when compared to the 2D analysis, which helps the planning process and the achievement of a better treatment outcome[2].

b- Many studies have already investigated the accuracy of the VSP and reported very satisfying results and better accuracy when compared to the CSP[6,14,15]. The main difference between the VSP and CSP process is the laboratory work that needs to be engaged for the CSP. After following the first steps of examination and data gathering which are the same for the two methods, an intense and prolonged laboratory procedure starts for the CSP, aiming to simulate the desired surgical movement on the model casts. All the materials and the small procedures involved during this step, such as impression taking, pouring, model mounting in articulator by means of the Facebow, three-dimensional movements of the ostotomized dental casts and re-mounting, can introduce inaccuracies in the overall outcome. The fact that in the VSP pathway all this process is bypassed, is certainly a factor that increases its accuracy.

c- VSP is a time saving procedure. Several studies have confronted the two methods in terms of duration of the planning, by performing on the same sample of patients the planning with both methods. Because of the reasons explained above, the VSP resulted in a significantly reduced duration when compared to CSP[5,16,17].

d- VSP gives the opportunity to incorporate to the planning, sophisticated transferring methods such as CAD/CAM Splints or Customized fixation plates (see chapter 2), that are not possible with the CSP method given its incapability of representing bone[7].

e- VSP is an excellent tool of 3D visualization, making it easier not only for the patient to comprehend the possible treatment outcome, but also facilitating the professional communication between different surgeons.

Despite these advantages, some limitations are still present within VSP:

a- The need for a third-party company that takes care of all the pre-planning preparation, the web meeting for the planning session as well as the post-planning fabrication of transferring methods, increases the cost of the procedure.

b- The inability of the CBCT acquisitions to represent teeth in good quality, makes it mandatory a process of composite model creation which again needs the support of a third-party company.

Overall, in a review conducted by Haas et al[14], it was concluded that the current investigations are very heterogeneous and that a systematic review with meta-analysis is not possible in order to determine which of the techniques is more accurate. Nevertheless, there is enough evidence in the literature supporting the idea that VSP offers a higher level of accuracy and it is nowadays considered superior to CSP mainly in terms of accuracy and time efficiency. Being these two factors of crucial importance, VSP is expected to completely dominate the surgical planning scene in the near future.

# Chapter Two: Transferring the virtual plan into the operation room

**Main question: How to transfer the virtual plan?**

Once the virtual surgical simulation is concluded, the transferring method of the virtual plan in the operating theatre needs to be decided. This is a step of particular importance, because it directly influences the position of the osteotomized jaws, therefore the outcome of the treatment. Over the years, different transferring systems have been proposed, but four of them are best appreciated: the splint method, the surgical navigation, the repositioning guide, the customized surgical guide and fixation plate.

## *2.1 The Splint transferring method*

This is the original and the most common method of transferring the surgical plan in the history of orthognathic surgery. It has experienced several changes during the years as described below:

### *2.1.1 The conventional splint*

It's the one splint that is produced once the conventional surgical planning is performed. It consists of an acrylic material that is adopted at the occlusal surface of the maxillary and mandible teeth once the model surgery is performed and the desired occlusion is fixed. The most common technique of implementing it in the operating theater is by producing an intermediate and a final splint. The intermediate splint is used to fix the osteotomized maxilla in the native mandible and then the complex is fixed in the new position. The final splint is used to stabilize the inter-occlusion in its final position[1],[18]. Another technique has been proposed named "single-splint technique" which consists of a single splint used to fix the osteotomized maxilla and mandible in their correct interocclusal position and then the maxilla-mandible complex is directed free-handed in the final position[19]. This technique has been generally abandoned given its high inaccuracy and dependence on surgeons' experience.

Despite having been used for a long time, the conventional splint has some significant limitations[20]. First, it is created based on a 2D analysis of the case, which inevitably introduces inaccuracies. Moreover, the simulated surgery on model casts as well as the facebow itself, have intrinsic inaccuracies that will then be reflecting on the splint, mainly on its inability to achieve a good correlation with the 3D skeleton of the patient. Furthermore, several studies have reported the lack of vertical and rotation control for this kind of splint, with some of them having reported an error of up to 5mm[20,21]. The lack of rotation control makes it impossible to ensure the correct position of the condyles. Also, in cases with asymmetry, the accuracy of the conventional splint is limited.

### *2.1.2 The integrated splint*

Given that the lack of vertical and rotation control is the most serious limitation of the conventional surgical splint, attempts have been made by different investigators to overcome this shortcoming by implementing additional references. Among them the Intra-oral reference points, the extra-oral reference points, the intra-operative facebow etc, aimed to give solution to the vertical control of the splint[22] (Fig.7). However, all these methods only identified anterior points of the maxilla, and the vertical control of the posterior maxilla was not considered. Consequently, most of these techniques couldn't find any practical application. Santler et al[23] reported a new device named 3D-Cosmos, which mechanically transfers the surgical plan. It has found little application in clinical practice but it made it logical the further step of 3D planning (Fig.8).

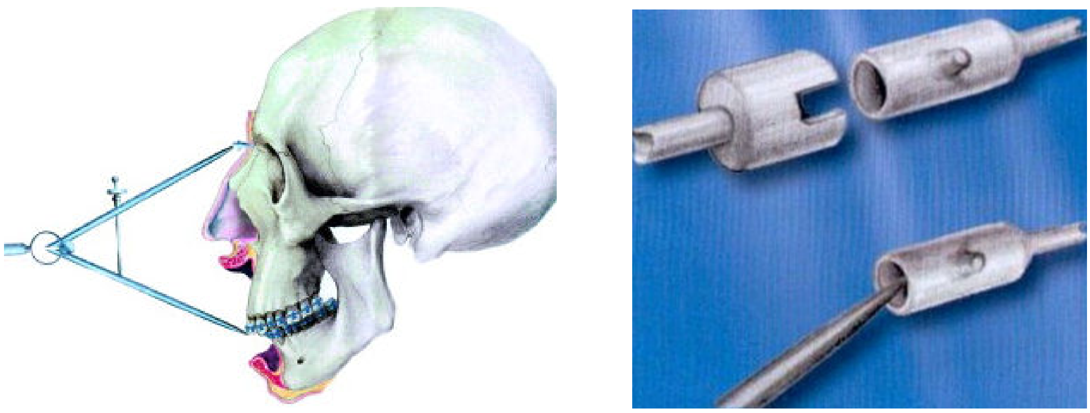


Fig.7 Kretschmers' extraoral pins on nasofrontal bone for vertical control of maxilla

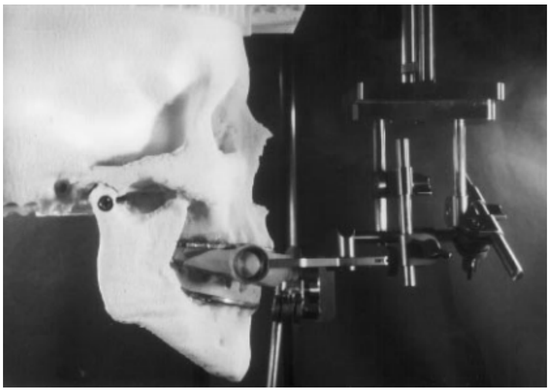


Fig.8 The 3D Casmos transfer device used to mechanically transfer the position of maxilla

### *2.1.3 The CAD/CAM Splint*

The increased development of software technology that can assist the surgical plan, has encouraged investigators to think about the virtual version of the conventional splint. Once the virtual plan is concluded and the final position of the jaws as well as their occlusal relation with each-other is determined, the process of virtually designing the splint starts (see materials and methods in chapter 4). With the final virtual splint designed, the CAM technology is used to fabricate it. This method of producing the splint improved the accuracy when compared to the conventional splint. This mainly due to the bypassing of the laboratory processes of dental cast surgery and facebow utilization. It also improved the correlation with the 3D skeleton of the patient and the rotation control due to the 3D analysis and virtual planning on which the splint was constructed[24]. The limitations of this method include a vertical control still insufficient as well as no guide for the osteotomies. However, given that few studies have reported comparative results for the accuracy of this method compared to other transferring methods, more investigations need to be undertaken in order to better assess the accuracy of CAD/CAM splints.

## *2.2 The Surgical Navigation method*

The Surgical Navigation system is an advanced technological system that allows the intraoperative synchronization of the osteotomized jaws with their position in the virtual plan[25]. Once the data gathering and the surgical virtual plan is decided, a specific navigation system is used to upload the data: The initial CBCT images of patients' skull, the .STL file of the virtual plan, and the real time visualization of patients' skull in the operating theater. First a surface-based registration is done between the pre-CBCT dataset and the STL of the virtual plan, in order for the surgeon to visualize the amount of movement predicted for each jaw. Subsequently, a point-to point registration is done between the pre-CBCT image and the real-time visualization of patients' skull, by choosing some reference points first at the pre-CBCT and then choosing the same reference points at the intraoperative visual image. Once this initial stage of preparation and registration is done, the computer-assisted surgery can be performed. Technically it consists of the same procedure as a normal orthognathic surgery, with the addition of checking the position of the ostetomized jaws based on the surgical navigation system.

Many systems have been proposed. In 2010, Mazzoni et al[20], described a surgical navigation system that follows approximately the steps of the above described procedure (Fig.9). They had a sample of 10 patients and reported an error of less than 2mm for each direction (fig). In 2013 Zinser et al[26], proposed another system with the addition of a visual display incorporated in the main navigation system, with the advantage of an enhanced intraoral visualization of the osteotomized jaw (Fig.10). However, on a sample of 16 patients, the authors reported good accuracy for the sagittal and transversal direction, but lower accuracy for the vertical direction. The same authors reported a comparison study between three different transfer methods: the conventional splint, the CAD/CAM splint and the navigation system. They reported that the conventional splint was significantly inferior in terms of accuracy when compared to the other two techniques[27].

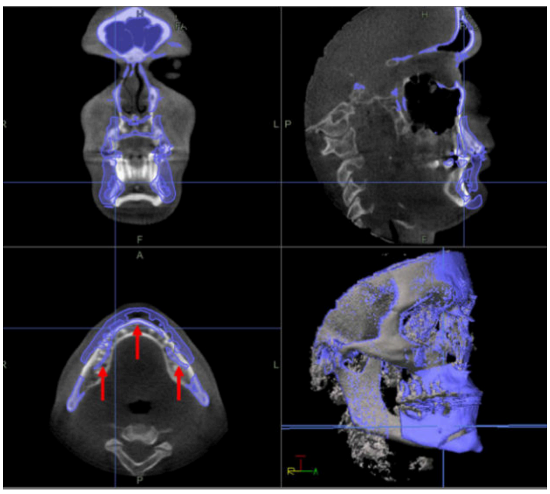


Fig.9 Superimposition of the pre cbct images and .Stl file of the virtual plan, as reported by Mazzoni et al.

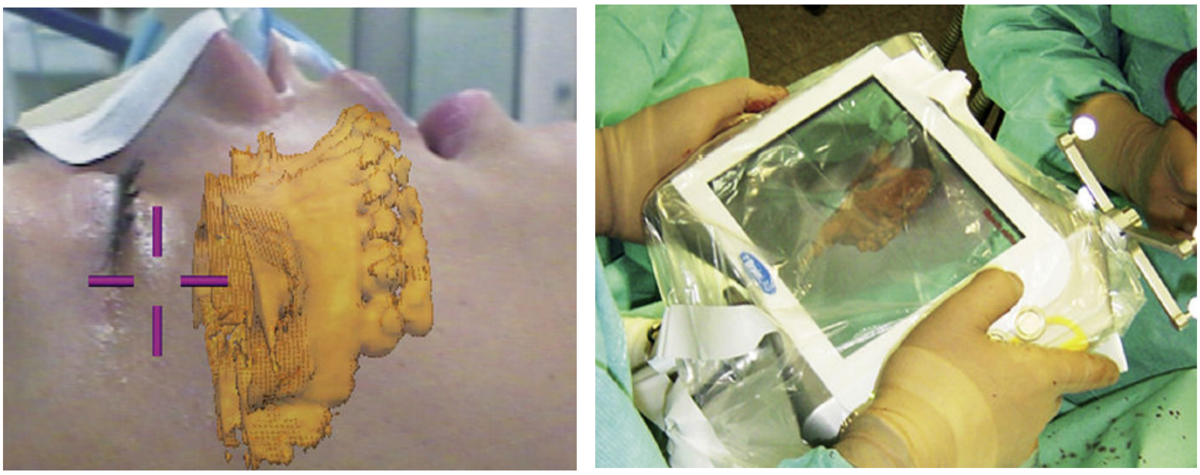


Fig.10 Zinsers' visual display integration to the navigation system

## *2.3 The repositioning guide*

The splint method explained in paragraph 2.1 is incapable of positioning maxillary jaw without being influenced by the mandible. This led to the investigation of other ways of independently transferring the surgical plan. The next idea that was proposed was the repositioning guide, which aims to not only determine the position of the osteotomized maxilla independently with no need for intermediate splint, but also to serve as a guide for the osteotomy lines. Li et al[28] proposed such system, composed of two parts: The osteotomy guide and the repositioning guide. The osteotomy guide is a template which is constructed based on the 3D virtual plan of the surgery and has a horizontal part which fits the occlusal surface of the maxillary teeth and two vertical parts that fit the outer surface of the maxillary bone. The osteotomy guide is screwed and used to perform the osteotomies. Subsequently, the repositioning guide is fixed by following the complementary parts with the osteotomy guide, and conventional fixation plates are used to fix the maxilla in the new position oriented by the repositioning guide (Fig.11). Chang et al[29] reported a combination of surgical navigation and repositioning guide for maxillary positioning. They performed a virtual surgical planning and after 3D designing the repositioning guide on that plan, they used the navigation system to reposition the maxilla aided by the repositioning guide (Fig.12).

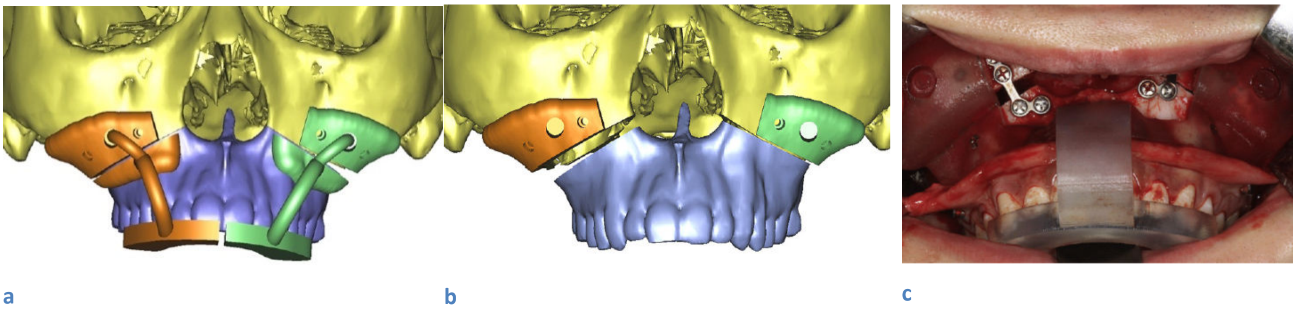



Fig.11 Li et al proposed transferring method, a) The osteotomy guide positioned, b) the osteotomy performed, c) the repositioned guide in place

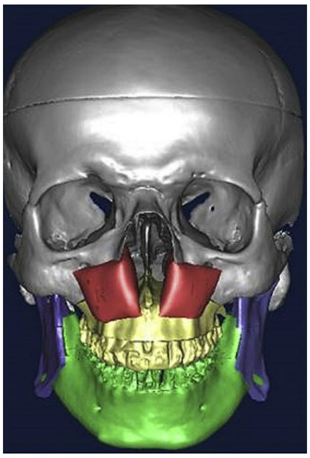


Fig.12 Chang's design for the repositioning guide

The surgical repositioning guide method was certainly a step forward in the acquisitioning of a better understanding on an accurate transferring method. It eliminated the need for an intermediate splint and offered the possibility for an independent position of the maxilla. It also introduced the innovative idea of a surgical template for guiding the osteotomy line positioning, by attempting so to eliminate another source of inaccuracy[25].

## *2.4 The customized surgical guide and fixation plate*

The above method, the accuracy of which was measured with techniques that need to be improved as explained in Chapter 3, has a limitation: the necessity of an occlusal splint in order to determine the position of the repositioning template, and the subsequent utilization of regular fixation plates. In 2004, two publications introduced a new idea: the utilization not only of a surgical guide for the osteotomy lines, but also of a customized fixation plate which could be positioned without the need of an occlusal splint. Gander et al[30] study was a case report of a one-jaw surgery and the proposed customized surgical guide and fixation plates were used for repositioning of the osteotomized maxilla (Fig.13)

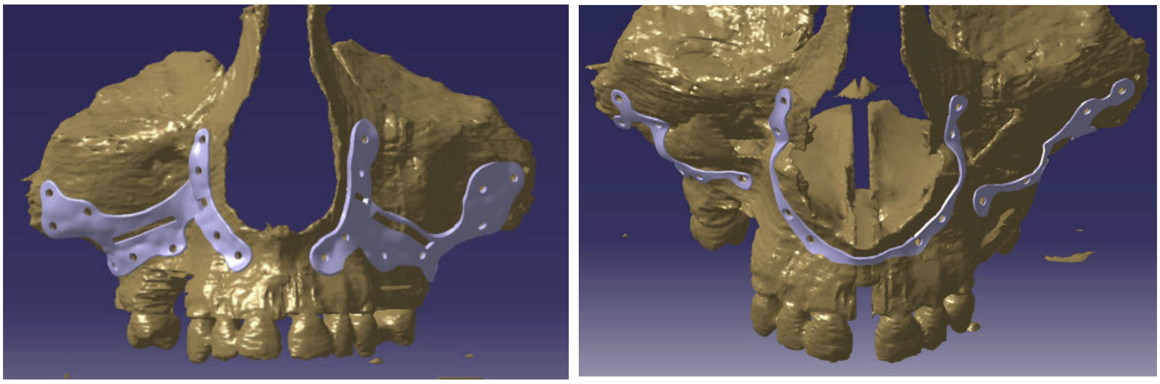


Fig.13 Gander et al design of the surgical guide and fixation plate

At the same time Mazzoni et al[31] reported a case series of ten patients, for the maxillary reposition of which a similar system was used (Fig.14). These two proposals have been considered a thrilling scientific idea, and gave start to a new investigation interest for surgeons and 3D technology companies in the scientific and orthognathic surgery field.

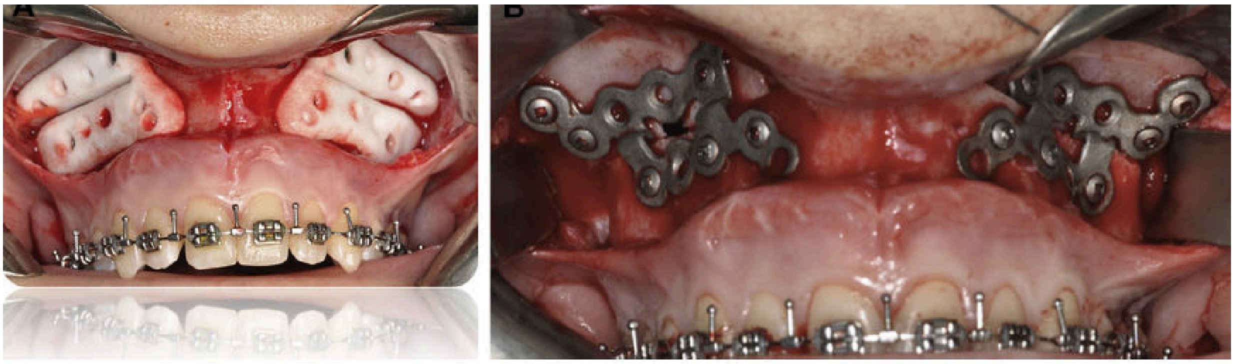


Fig.14 Mazzoni et al design of the cutting guide and fixation plate

A Similar design was proposed by Kraeima et al[32] for maxillary positioning in a three-cases report (Fig.15a) and by Suojanen et al[33] in 32 cases (Fig.15b). All these studies have in common the fact that they proposed surgical guides and fixation plates only for maxilla, as well as the fact that in all cases the fixation system was a two-pieces plate.

Subsequently, two publications reported their cases of bi-jaw surgery for which surgical guides and fixation plates were used both for maxilla and mandible. Brunso et al[34] reported a cases series of six patients where a surgical guide was used for the oseteotomies of maxilla and mandible, and a customized plate was designed in order to fit the created screwing holes (Fig.16). The positioning of the osteotomized mandible was done by means of an occlusal splint. At the same time, Li et al[35] reported ten case of a similar design (Fig.17a and b).

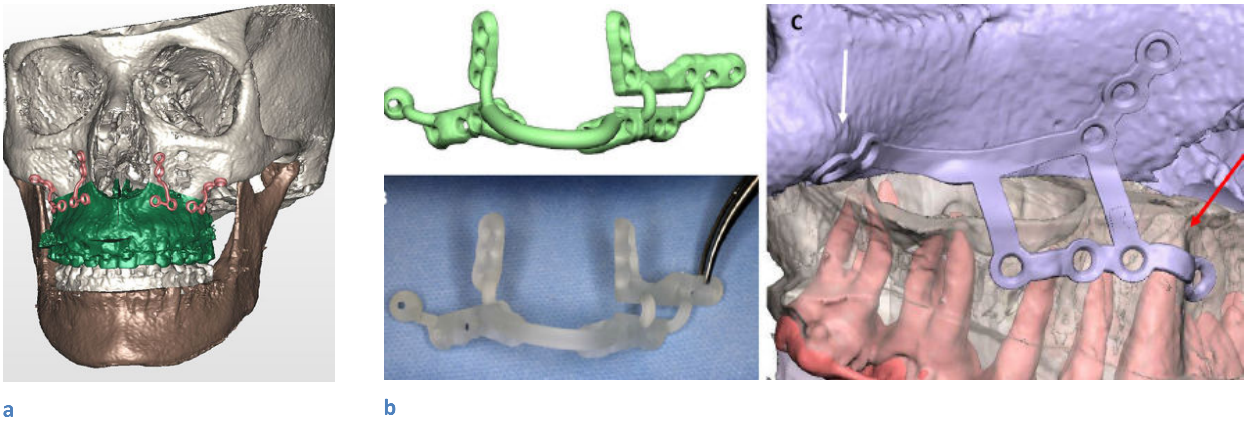



Fig.15 a) Kraeima's and b) Soujanen's design for maxillary surgical guide and fixation plate

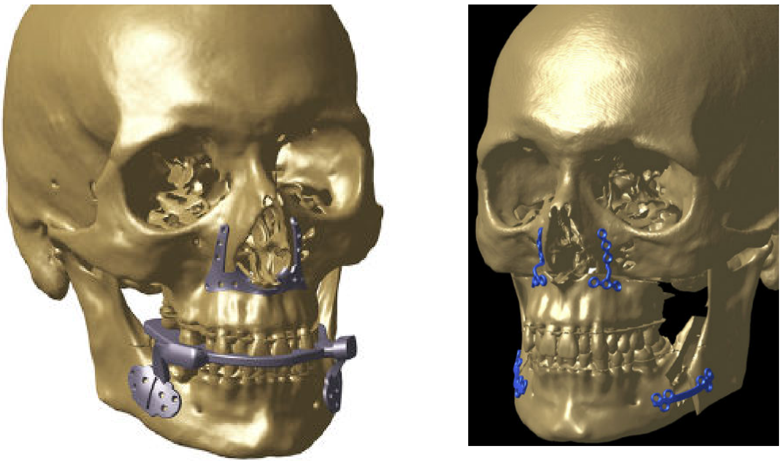


Fig.16 Brunso et al design for surgical guide and fixation plate

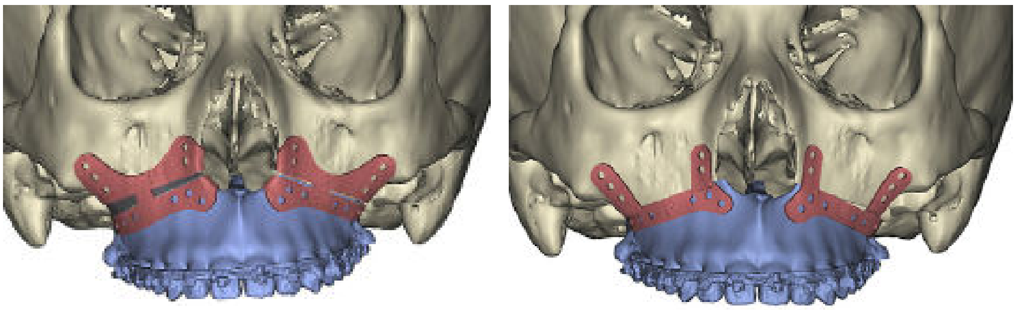


Fig.17a Li et al design for the maxilla surgical guide and fixation plate

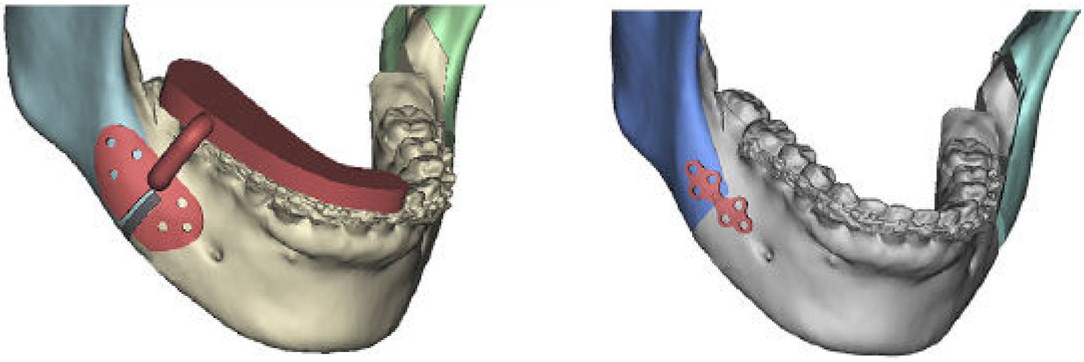


Fig.17b Li et al design for mandible surgical guide and fixation plate

In 2017, Heufelder et[36] al were the first to report a different design for the surgical guide and fixation plate of maxilla, consisting of a single piece instead of a two-piece guide and plate (Fig.18).

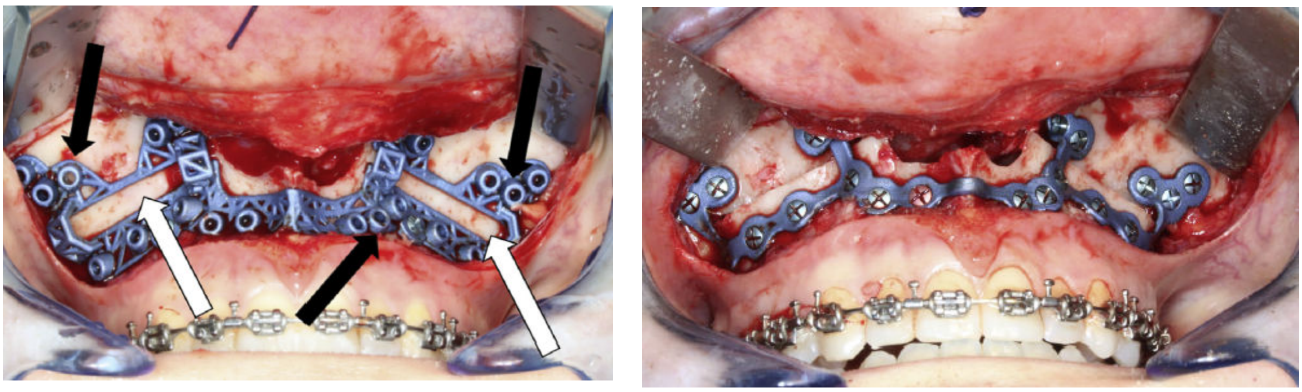


Fig.18 Heufelder et al one-piece design for maxillary guide and plate

The amount of evidence regarding different methods of transferring the virtual plan into the operation theatre increases constantly, with new design and materials being proposed and praised as advantageous and accurate. In these circumstances, studies aiming the evaluation of the accuracy of different methods of transferring, became necessary.

# Chapter Three: Evaluation of accuracy for virtual planning

**Main question: The most reliable method for Accuracy analysis?**

In the past 20 years, numerous investigations have been published regarding virtual planning in orthognathic surgery. The variability of available programs for virtual planning, has led to countless reports on different protocols for virtual planning[37,38]. The next inevitable question was: are these methods of virtual planning accurate? How do we know that the virtual planning project and the actual result of the patient after surgery are similar if not the same? To answer these questions, an accuracy analysis was necessary. Many have been the protocols and the programs proposed and reported as useful for such analysis[39]. This has produced a confusing situation in terms of understanding which is the correct method to investigate the accuracy of a virtual planning process. Nowadays, there is no consensus on this argument, but some publications have made efforts to shed some light on the current state of the art.

Two publications, Shehab et al[40] and De Riu et al[41], used 2D images to investigate the accuracy of the virtual planning. This method carries all the shortcomings of a 2D analysis for three-dimensional structures, making it not reliable. A study of Centenero et al[42] proposed a method or accuracy analysis that consisted of linear and angular measurements on the pre-op 3D model where the surgery was simulated and the result was predicted, and afterward the recording of the same measurement on the 3D model obtained after surgery. The intraclass correlation coefficient was used to determine the precision of the prediction. No registration was done between the pre and post 3D model or between the predicted 3D model and the post one. Despite being a step forward, it still remains similar to a 2D analysis as it carries an important risk for human error on measuring the same parameters twice.

It is today accepted that a correct process of Accuracy evaluation for the 3D virtual planning or orthognathic surgery, requires two steps[39].

1. Registration
2. Accuracy analysis

## *3.1 Registration*

It consists of the superimposition of the pre-surgery and post-surgery data in a single coordination frame in order to see the difference between them. The pre-surgery data might be the pre-surgery dicom file of the initial situation of the patient, or the 3D model of the patients' skull after the virtual planning. This way the investigators can choose to superimpose the pre-dicom data with the post-dicom data in order to see the degree of movement of the jaws, and compare this finding with the movement that was planned during the planning. Alternatively, they can choose to superimpose the 3D model of the virtual planning with the post-dicom dataset, in order to directly evaluate the degree of discrepancy between them.

The registration process can be performed in three different methods (Fig.19):

a. The landmark-based registration

b. The surface-based registration

c. The voxel-based registration

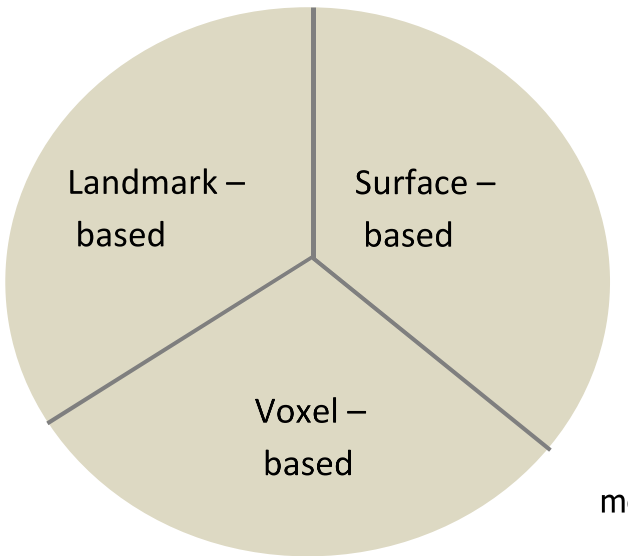



Fig. 19 The three methods of registration

Landmark registration or Point-to-point registration, consists of the recognition of some specific points on the pre-dicom data and on finding the same points on the post-op dicom dataset, and finally superimpose the two datasets based on these landmarks (Fig.20). It hasn't introduced any advantage in the superimposition process, as it is similar to 2D superimposition of cephalometric radiographs, but with a higher level of difficulty as it is more complex to identify specific points in a 3D dataset. Also, it is very difficult to find the exact same point at the post-op dicom, which inevitably introduces a significant human error in the process[37].

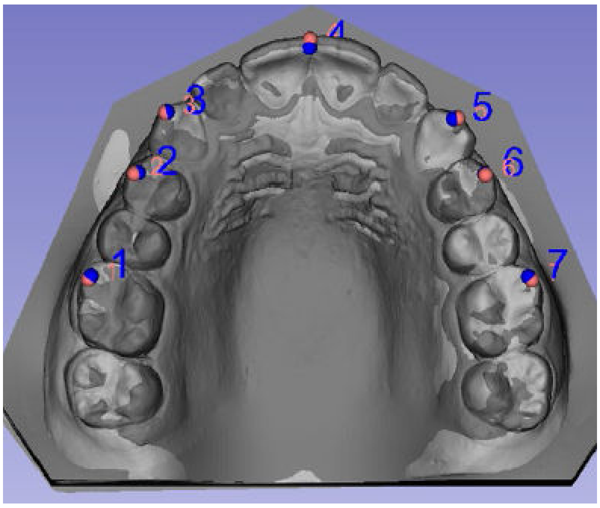



Fig.20 Cevidanes illustration for landmark-based registration of two 3D models

The surface-based registration instead of specific points, uses the outer surface of the 3D model to achieve the superimposition (Fig.21). It has been shown to have good outcomes, but still has some limitations mainly due to the fact that it completely ignores the inner information of a 3D model and only focuses on the outer information of its surface. Also, the surface of the pre and post 3D model must be of a high quality in order for the superimposition to be accurate[37].

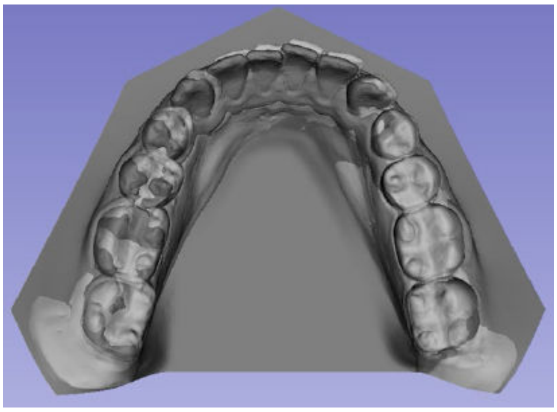


Fig.21 Cevidanes illustration for surface-based registration of two 3D models

Both landmark-based and surface-based superimposition of 3D data, require inevitably an initial step of segmentation, which represents a complex process with the potential to introduce additional errors[8].

1.The thresholding process during the segmentation is subjective and is done based on the judgement of the operator on what is going to be the best fit for each case.

2.The dicom dataset obtained by the CBCT image, despite its many advantages, is of a lower quality when compared to the traditional spiral CT. This might lower the quality of segmentation

3.The presence of artefacts in the dicom dataset mainly due to the presence of fixed orthodontic appliances in orthognathic patients, may contribute in a lower quality of the image.

The third option for 3D superimposition is the voxel-based registration, which instead of landmarks, relies on gray scale as its base for registration. It was first introduced by Cevidanes et al in 2005[43] (Fig.22), and since then validated by several other studies[39]. Today, the common judgment of the scientific evidence is that landmark-based registration is the least accurate method for the superimposition and comparison of 3D data. When it comes to the comparison of the surface-based and voxel-based registration, despite few publications[44] who reported no difference of accuracy between them, the majority of the reports agree that the voxel-based registration is superior to the surface-based one, mainly because it considers the vast inner information of the 3D model, and it's a completely automatic process[39].

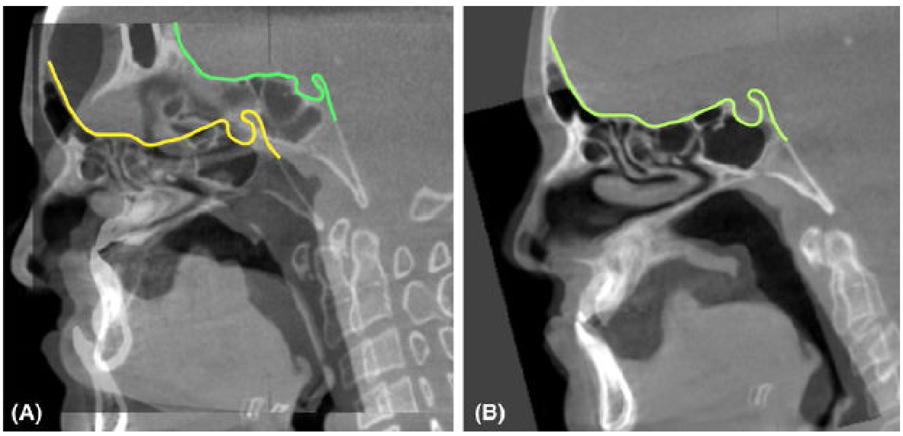



Fig.22 Cevidanes illustration of voxel registration on cranial base

## *3.2 Accuracy analysis*

With the considerable amount of evidence produced on virtual surgical planning, the Accuracy of the analysis of these methods has become of crucial importance. Many studies reported their method for accuracy analysis which led to the logical question: Which of these methods is correct? Are we evaluating the accuracy of virtual planning in the right way? What is the point of evaluation the accuracy of one method if the process of evaluation such accuracy is not sufficiently accurate?

There are currently four different protocols for the accuracy analysis of 3D orthognathic surgery:

1. The intraclass correlation coefficient

This method was reported by Centenero et al[42] in. it consists on applying measurements on pre and post 3D models separately and on evaluation the difference among them. Given that it is a separate analysis with no superimposition of the 3D models, its level of accuracy is not reliable.

2. Linear and angular measurements

It has been the most common method for accuracy analysis for a long time, and it can be applied in two different ways:

a) by measuring the difference of coordinates of specific points

First, specific landmarks are identified on the 3D model of the virtual plan. Then the virtual model and the post-surgery model are registered on a surface-based registration, and the same landmarks are identified. The coordinates of the landmarks on the virtual and post-model are calculated and the mean difference is registered as the error of accuracy. Such method was used in studies like Hsu et al[45], Stokbro et al[46], etc.

b) by measuring the distance of specific points to specific planes.

First, some specific points and planes are identified on the 3D virtual model, and then on the post-surgery model. The distance from points to planes is calculated on each model and the difference between these distances is registered as the error of accuracy. Such method was used in studies like Zhang et al[47], Fawzy et al[48], etc.

3. Surface distance

In this method, the post-surgery dicom dataset is converted into an .STL file and a surface-based registration is done between it and the .STL file of the virtual planning. Afterwards, an algorithm is used to calculate the distance between different surface regions of the 3D model. The result can be presented as a color-coded map where different colors show the distance between the surfaces, with green color usually showing the lack of distance, meaning zero error of accuracy[8,49,32].

All of these methods have in common the fact that specific landmarks must be manually appointed. This process is associated with a human error reported by other studies up to 2.47mm[50]. Furthermore, even the identification of the same specific points of the pre-model to the post-model is associated with an inevitable error[51], which is added to the previous one. Additionally, the surface distance method has the disadvantage of applying the "closest point correspondence" concept. This means that a specific point of the pre-model is not necessarily linked to the specific corresponding point, but to the closest corresponding point instead, adding so error to the accuracy of the method. Another problem with color mapping system, is that being a surface-based registration, it necessitates a pre-process of segmentation, which, as explained above carries possible errors. Also, the surface-based registration eliminates the inner information of the 3D model and is very much dependent on the quality of the surface that is being analyzed. All these factors, make the process not reliable for the accuracy analysis[52].

4. Landmark Free calculation of translation and rotation.

To overcome these limitations, some authors proposed methods that make the process independent on landmarks[36,51]. It consists of first registering the pre and post dicom dataset through a voxel base registration, which is done twice: on cranial base and maxilla base and the coordinates of the specific points previously identified on the pre-dicom data is automatically calculated on the post-dicom data. This way the movement of jaws from pre to post dicom is calculated. In the same way, the .STL file of the pre-dicom and the STL of the virtual plan are surface-based superimposed in order to calculate the coordinates of the specific points after the virtual plan. The two datasets of coordinates in the post-dicom and virtual plan are confronted.

The numerous methods for accuracy analysis raised the necessity for systematic reviews in order to clarify the argument. The two systematic reviews[38,14] published on this regard, concluded that it is impossible to compare different studies on the accuracy of virtual planning and combine their results because of the un-standardized methods they used for the accuracy analysis and for the presentation of the outcomes. The review of Gaber et al[39] concluded that the best way to perform an accuracy analysis, should involve a voxel-based registration and a landmark free accuracy analysis.

# Chapter Four: Accuracy of Splint vs Splintless technique for virtual planning in Orthognathic surgery

## *Introduction*

In the last 20 years orthognathic surgery has experienced important changes and developments mainly correlated to the planning procedures. The rapid technological development has spread its influence in orthognathic surgery as well, with countless programs and software available to improve surgical outcomes.

Since its first introduction, virtual planning in orthognathic surgery gained immediate attention from clinicians who saw in it a potential for improving numerous aspects of their treatment strategies. Virtual planning has been proven to overcome different shortcomings of the conventional planning, mainly in terms of accuracy and timing. The bypassing of the laboratory procedures of traditional model surgery, not only reduced the duration of the planning process, but it also increased the overall accuracy of the outcome. However, there are still controversies regarding virtual planning in orthognathic surgery, mainly linked to two aspects: which is the most reliable method to transfer the virtual plan into the operation theater, and which is the most reliable accuracy analysis for the confrontation of the virtual plan with the actual final outcome.

Regarding transferring methods, countless systems have been proposed, differing from their design and process of fabrication. They can generally be divided in two groups: The splint group, which includes all those methods that rely on an intermediate splint for the positioning of the osteotomised jaws, and the splintless group, which has no need for intermediate splint, but uses three-dimensional visualization systems (such as surgical navigation) or virtually planned surgical guides and fixation plates.

The considerable amount of evidence produced on the transferring methods, led to the necessity of accuracy analysis on the reliability of each method in accurately transferring the virtual plan into the actual outcome. But again, the evidence on the accuracy itself is confusing and not standardized.

The purpose of this study, is to confront two methods of transferring the virtual surgical plan into the operating theatre: The CAD/CAM intermediate splint, and the customized surgical guide together with the fixation plate. The main parameter of this confrontation is the accuracy with which they are capable of reproducing the virtual plan into the actual result after the surgery, through a voxel-based landmark free analysis.

## *Materials and Methods*

The present is a prospective clinical study, approved by the Ethical Committee of the Policlinico di Milano, Milan, Italy. All procedures performed were in accordance with the Ethical Principles for Medical Research Involving 'Human Subjects", adopted by the Helsinki Conference, June 1964, and informed consent was obtained from all participants. The population of this study consisted of a total of sixteen patients who were consecutively recruited and underwent a two-jaw orthognathic surgery at the Unit of Oral and Maxillo-Facial Surgery of Fondazione Ca' Granda IRCCS Ospedale Maggiore Policlinico di Milano, in the period between September 2017 and March 2019. *The inclusion criteria were*: Adult patients capable of signing an informed consent; patients with dentofacial deformities requiring two-jaw orthognathic surgery; patients with a good health condition based on ASA classification system (ASA-1 and ASA-2). *Exclusion criteria were*: Skeletally immature patients; suspected or confirmed pregnancy or lactation; patients with a previous history of one or two-jaw surgery. Overall, the timeline of this study is shown in fig.23.

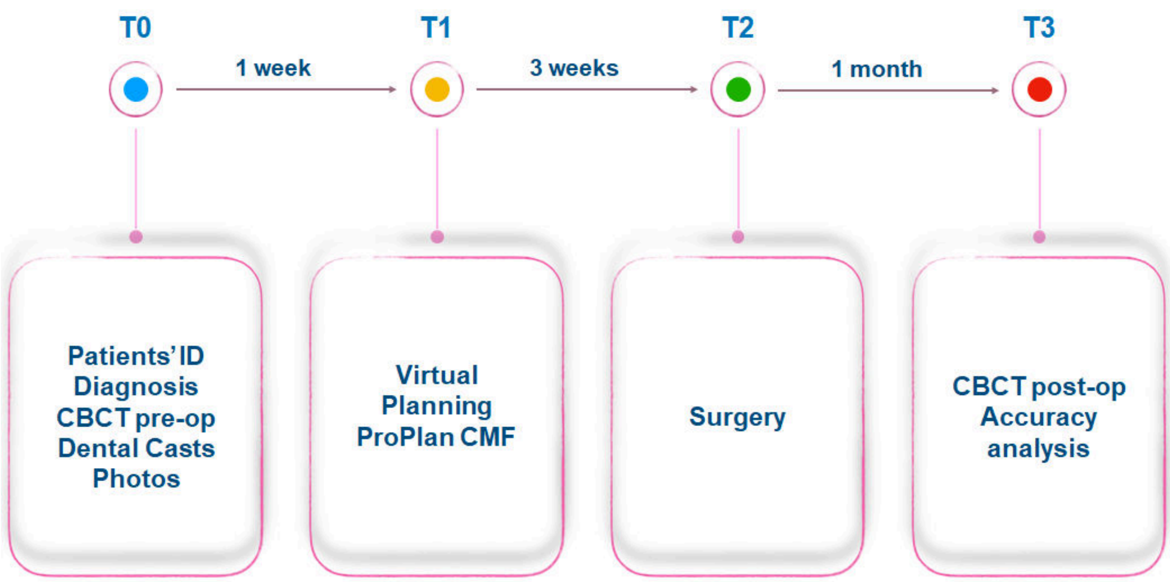



Fig. 23: Schematic demonstration of the study workflow and timeline


## *T0: Patients' documentation*

The first step of the study was patients documentation. For all sixteen patients, a thorough documentation was obtained, including: registration of their dento-facial diagnosis, intra-oral and extra-oral photos, impression taking for dental casts fabrication, and a CBCT acquisition (table 1). An overall summary of patient' characteristics is shown in table 1. All patients had previously undergone the necessary orthodontic treatment, based on the initial diagnosis and treatment plan. The CBCT imaging for the T0 phase, was taken immediately after the initial orthodontic treatment.

| **Patients** | **16** | |
|---|---|---|
| **Sex** | **7 Male** | **9 Female** |
| **Splintless** | **8** | |
| **Splint** | **8** | |
| **Mean Age** | **25** | |
| **Skeletal Pattern** | **8 III** | **8 II** |

Table.1 Main characteristics of patients included in this study

Dental casts for each patients were mailed at the Materialise NV offices in Leuven, Belgium, and were subsequently scanned using oral scanners, creating so an STL file as a final product. Prior to the virtual planning, an image processing process was undertaken, with the aim to convert the DICOM datasets in 3D surface models. Such process was done through the following steps (Fig.24):

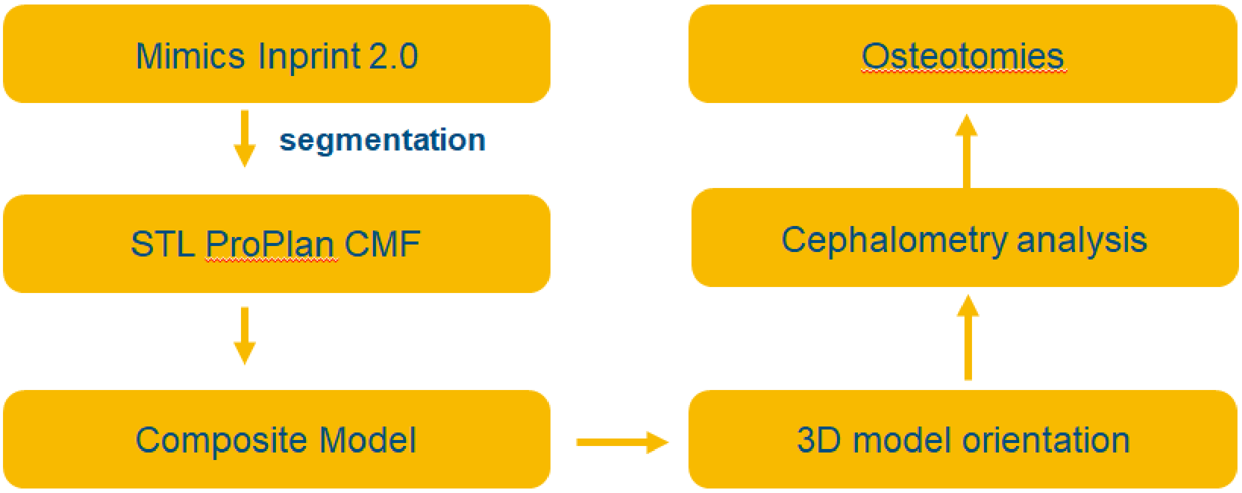



Fig.24: Image processing workflow

### 1. Segmentation

The most important step of image processing is Segmentation, which refers to the partitioning of images in regions of interest (ROIs), each representing different anatomical structures[53]. In our case, the aim of the segmentation was to separate skull bone from other tissues, and currently the most commonly used method for medical bone segmentation is global thresholding, which is reported to have an accuracy of under 0.62 mm ± 0.76 mm[54]. For our study, we used the Mimics InPrint 2.0 Software (Materialise NV, Leuven, Belgium) and a manual global thresholding method to separate the skull and mandible and produce an STL file (Fig.25).

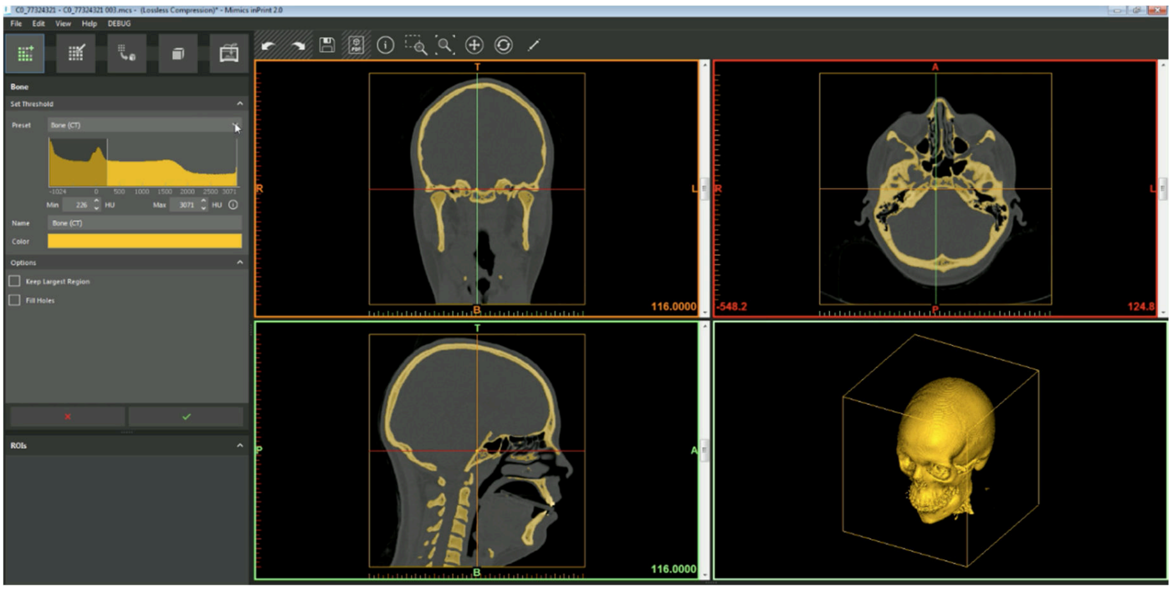


Fig.25 Segmentation process on Mimics Inprint 2.0

## 2. Exporting of the STL file to ProPlan CMF

After the STL file was created it was exported to the PROPLAN CMF® Software (DePuy Synthes Switzerland and Materialise, Leuven, Belgium), which allows the 3D visualization of the segmented structures and the virtual planning procedure (Fig.26).

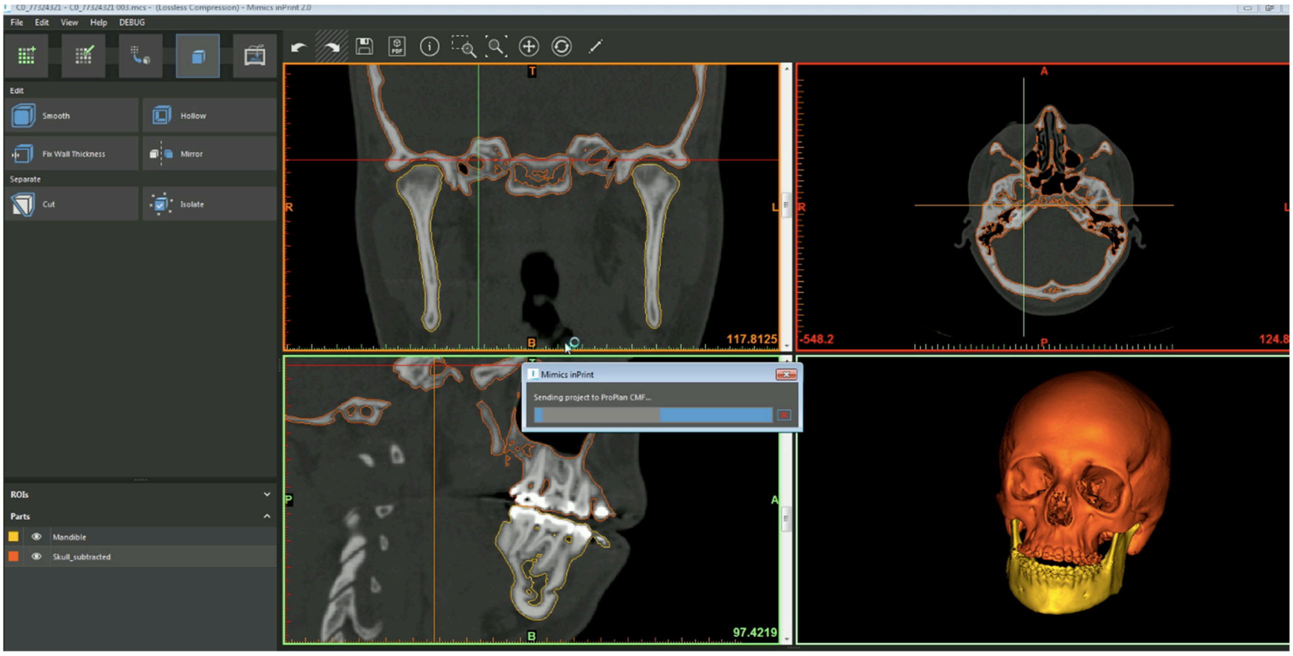



Fig.26 Exporting the STL file to Proplan CMF

## 3. Composite Model

This step refers to the merging of the digitally scanned dental cast and the 3D model produced by the CBCT scan. Given that the scanned dental cast is capable of representing dental arches with a much higher quality when compared to that of the CBCT, the purpose of this step is to create a final composite model with a more detailed surface information regarding teeth (Fig.27). As explained in previous chapters, the overall purpose of creating the composite model is that of improving the quality of the virtual planning, as well as providing the possibility of producing a splint-like transferring method that could perfectly fit teeth surface.

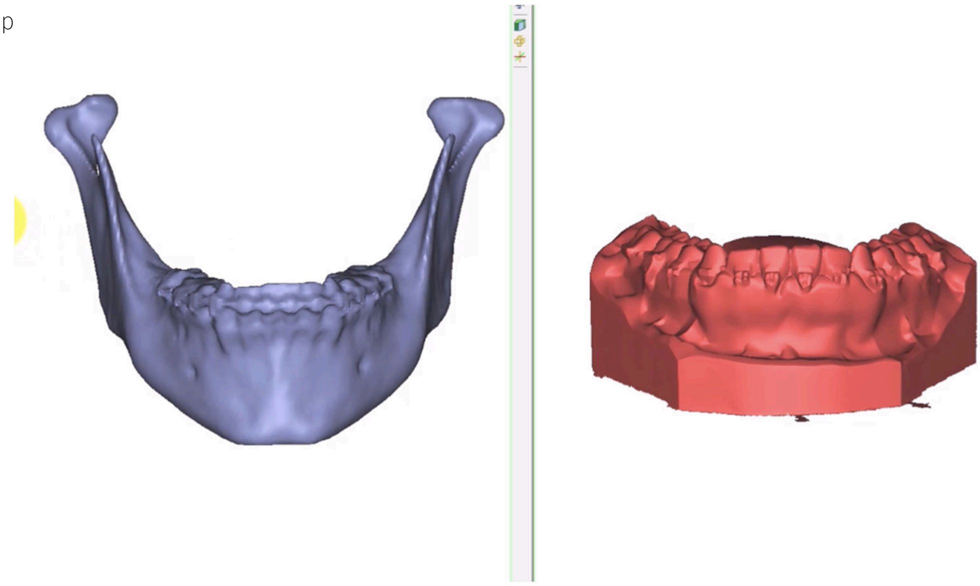


Fig.27 The difference in quality of teeth surface representation between CBCT (left) and scanned dental model (right)

**4. 3D Model orientation**

This step in undertaken in order to secure a standardized orientation for all models based on the same reference plane. The 3D models were oriented based on the Frankfort plane, and for this purpose, three points were tracked on the model: left porion, right porion and left orbital point (Fig.28). The 3D model was automatically oriented afterwards.

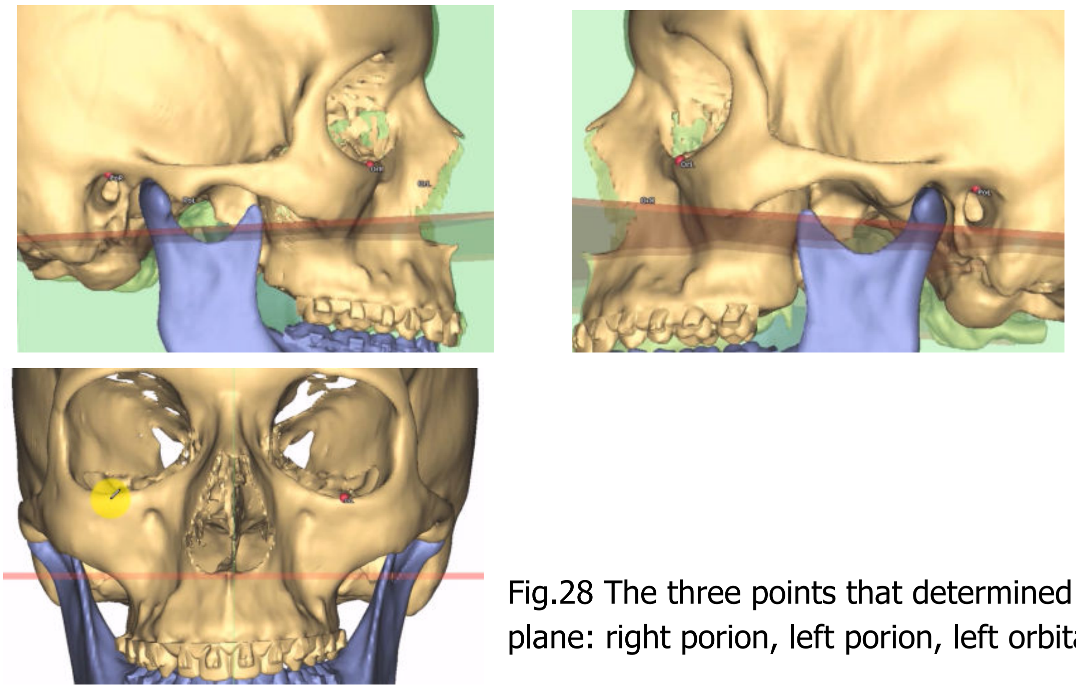
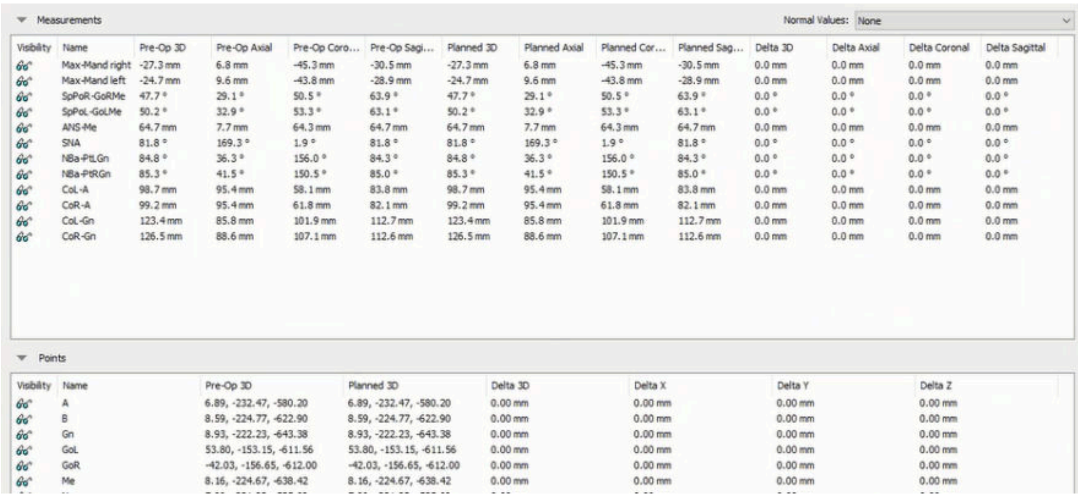


Fig.28 The three points that determined the Frankfort plane: right porion, left porion, left orbital point

## 5. Cephalometric analysis

The cephalometric analysis was done to all pre-surgery models, planned 3D model and post-surgery model in order to compare the differences between the three of them. The Proplan CMF software offers the possibility to automatically have the data of the cephalometric analysis by selecting the type of cephalometry we prefer. We used the McNamara cephalometry analysis for our cases (Fig.29).



Measurements

Normal Values: None

| Visibility | Name | Pre-Op 3D | Pre-Op Axial | Pre-Op Coro... | Pre-Op Sagi... | Planned 3D | Planned Axial | Planned Cor... | Planned Sag... | Delta 3D | Delta Axial | Delta Coronal | Delta Sagittal |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Max-Mand right | -27.3 mm | 6.8 mm | -45.3 mm | -30.5 mm | -27.3 mm | 6.8 mm | -45.3 mm | -30.5 mm | 0.0 mm | 0.0 mm | 0.0 mm | 0.0 mm |
| | Max-Mand left | -24.7 mm | 9.6 mm | -43.8 mm | -28.9 mm | -24.7 mm | 9.6 mm | -43.8 mm | -28.9 mm | 0.0 mm | 0.0 mm | 0.0 mm | 0.0 mm |
| | SpPoR-GoRMe | 47.7 ° | 29.1 ° | 50.5 ° | 63.9 ° | 47.7 ° | 29.1 ° | 50.5 ° | 63.9 ° | 0.0 ° | 0.0 ° | 0.0 ° | 0.0 ° |
| | SpPoL-GoLMe | 50.2 ° | 32.9 ° | 53.3 ° | 63.1 ° | 50.2 ° | 32.9 ° | 53.3 ° | 63.1 ° | 0.0 ° | 0.0 ° | 0.0 ° | 0.0 ° |
| | ANS-Me | 64.7 mm | 7.7 mm | 64.3 mm | 64.7 mm | 64.7 mm | 7.7 mm | 64.3 mm | 64.7 mm | 0.0 mm | 0.0 mm | 0.0 mm | 0.0 mm |
| | SNA | 81.8 ° | 169.3 ° | 1.9 ° | 81.8 ° | 81.8 ° | 169.3 ° | 1.9 ° | 81.8 ° | 0.0 ° | 0.0 ° | 0.0 ° | 0.0 ° |
| | NBa-PtLGn | 84.8 ° | 36.3 ° | 156.0 ° | 84.3 ° | 84.8 ° | 36.3 ° | 156.0 ° | 84.3 ° | 0.0 ° | 0.0 ° | 0.0 ° | 0.0 ° |
| | NBa-PtRGn | 85.3 ° | 41.5 ° | 150.5 ° | 85.0 ° | 85.3 ° | 41.5 ° | 150.5 ° | 85.0 ° | 0.0 ° | 0.0 ° | 0.0 ° | 0.0 ° |
| | CoL-A | 98.7 mm | 95.4 mm | 58.1 mm | 83.8 mm | 98.7 mm | 95.4 mm | 58.1 mm | 83.8 mm | 0.0 mm | 0.0 mm | 0.0 mm | 0.0 mm |
| | CoR-A | 99.2 mm | 95.4 mm | 61.8 mm | 82.1 mm | 99.2 mm | 95.4 mm | 61.8 mm | 82.1 mm | 0.0 mm | 0.0 mm | 0.0 mm | 0.0 mm |
| | CoL-Gn | 123.4 mm | 85.8 mm | 101.9 mm | 112.7 mm | 123.4 mm | 85.8 mm | 101.9 mm | 112.7 mm | 0.0 mm | 0.0 mm | 0.0 mm | 0.0 mm |
| | CoR-Gn | 126.5 mm | 88.6 mm | 107.1 mm | 112.6 mm | 126.5 mm | 88.6 mm | 107.1 mm | 112.6 mm | 0.0 mm | 0.0 mm | 0.0 mm | 0.0 mm |

Points

| Visibility | Name | Pre-Op 3D | Planned 3D | Delta 3D | Delta X | Delta Y | Delta Z |
|---|---|---|---|---|---|---|---|
| | A | 6.89, -232.47, -580.20 | 6.89, -232.47, -580.20 | 0.00 mm | 0.00 mm | 0.00 mm | 0.00 mm |
| | B | 8.59, -224.77, -622.90 | 8.59, -224.77, -622.90 | 0.00 mm | 0.00 mm | 0.00 mm | 0.00 mm |
| | Gn | 8.93, -222.23, -643.38 | 8.93, -222.23, -643.38 | 0.00 mm | 0.00 mm | 0.00 mm | 0.00 mm |
| | GoL | 53.80, -153.15, -611.56 | 53.80, -153.15, -611.56 | 0.00 mm | 0.00 mm | 0.00 mm | 0.00 mm |
| | GoR | -42.03, -156.65, -612.00 | -42.03, -156.65, -612.00 | 0.00 mm | 0.00 mm | 0.00 mm | 0.00 mm |
| | Me | 8.16, -224.67, -638.42 | 8.16, -224.67, -638.42 | 0.00 mm | 0.00 mm | 0.00 mm | 0.00 mm |

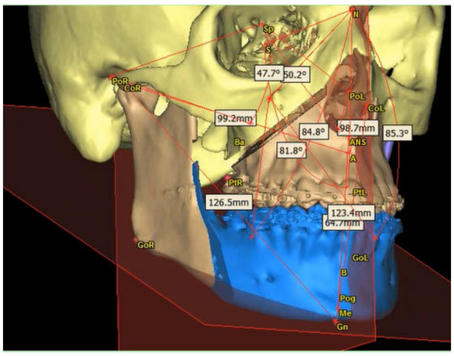



Fig.29 Example on how the Proplan CMF software exposes the cephalometric findings

## 6. Osteotomies

Finally, the last step of the preparation for the virtual planning, is the assignment of the osteotomy lines. For all cases, a two-jaw surgery was done, and the Le Fort I technique was used for the maxilla while for the mandible the BSSO was the chosen technique.

By selecting the chosen technique for each jaw, the software automatically projects the osteotomy lines on the 3D model. A manual  adaptation of the correct position of such line can be done, paying particular attention not to interfere with the roots of the upper teeth. Once the osteotomy lines are position, the final model is ready to undergo the virtual planning process (Fig.30a-d).

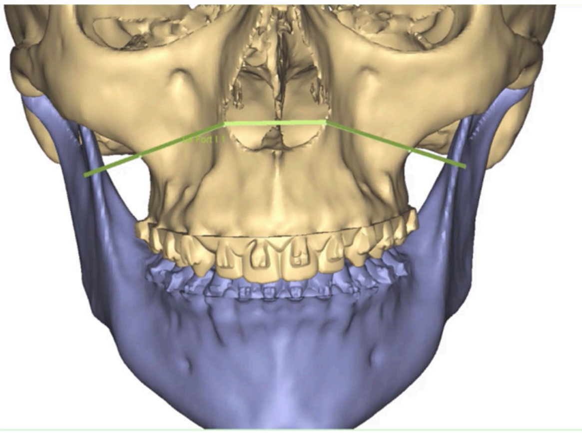


Fig.30 a: LeFort I osteotomy line

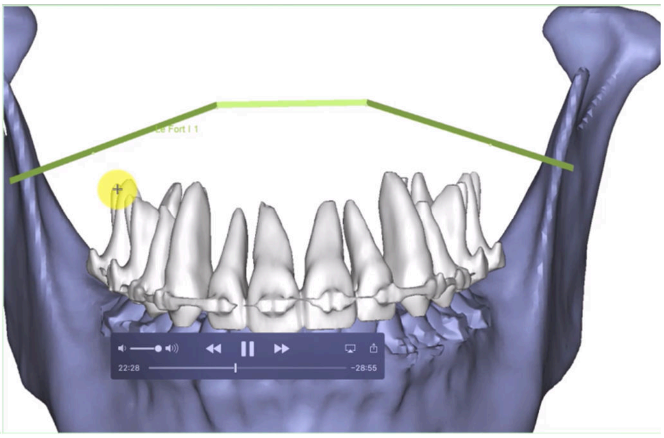


Fig.30 b: Verifying distance from root apexis

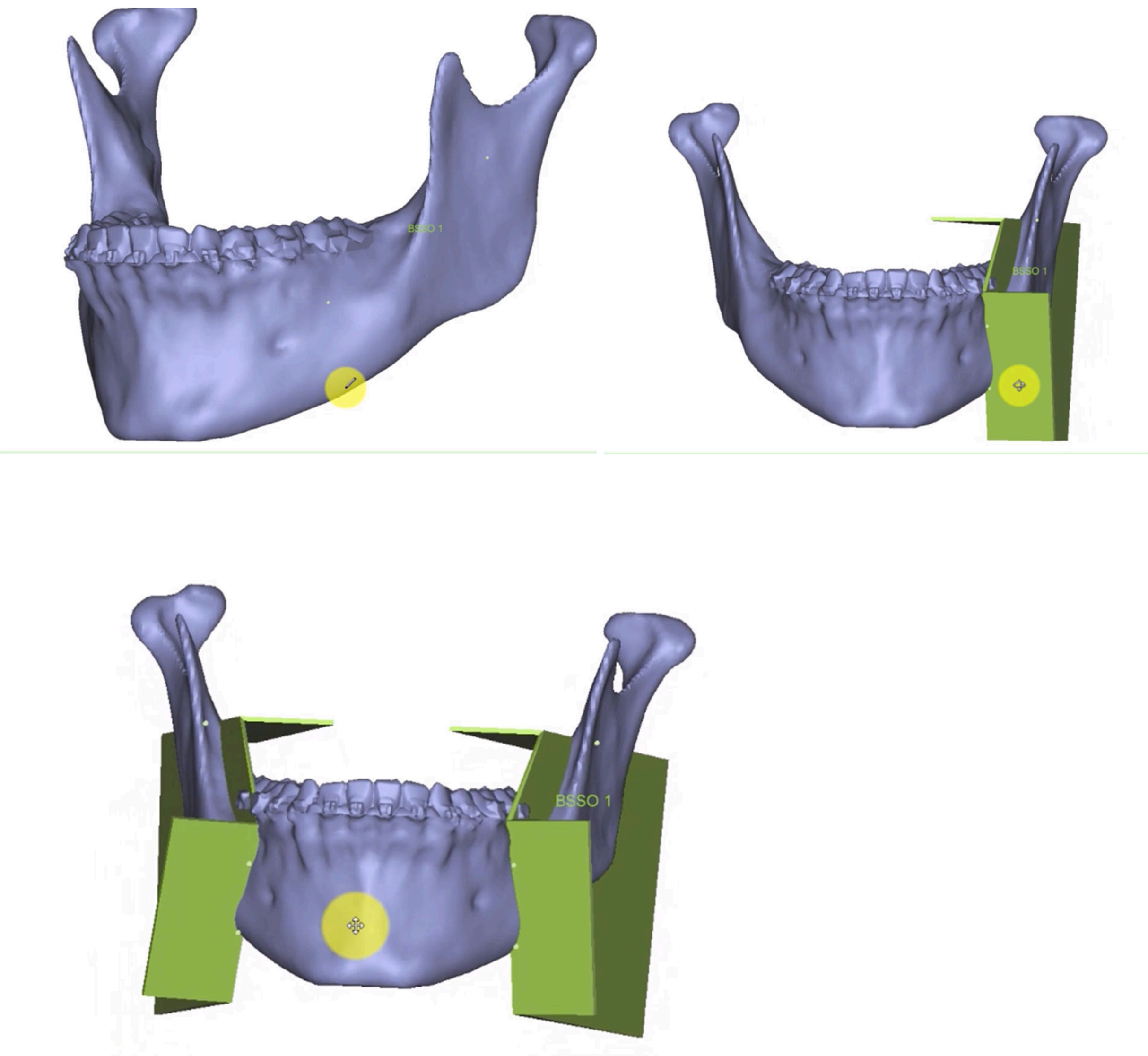



Fig.30c BSSO Osteotomy lines

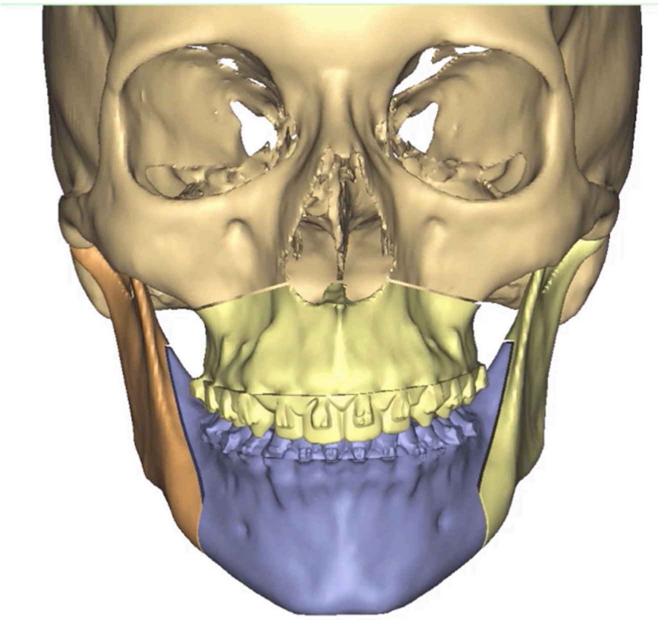


Fig.30d The 3D model ready for virtual planning


## *T1: Virtual Planning*

The final 3D model obtained by the image processing and preparation was used as the initial point for the virtual planning process. The later consisted of a web meeting between the oral surgeon, the orthodontist and the clinical engineer of the Materialise company. Each webinar meeting was planned approximately one week after all the documentation and 3D model preparation of the case was concluded. The intraoral and extraoral photos of the patients were used to help the clinical judgement for the corrections. The Virtual planning process consisted of the following three steps.

## I. Occlusion Registration

First the osteotomized maxillary cast was merged with the scan of the dental casts placed in the desired occlusion. This process was done first by assigning at both components a total of three corresponding points, and then by detailing the registration using an alignment tool. Once the maxilla cast was registered and fixed, the registration of the mandible cast was done by following the same process: First the merging of the osteotomized mandible cast with the same occlusion scan where the maxilla cast was registered, and then a more detailed registration was done by means of the same alignment tool.

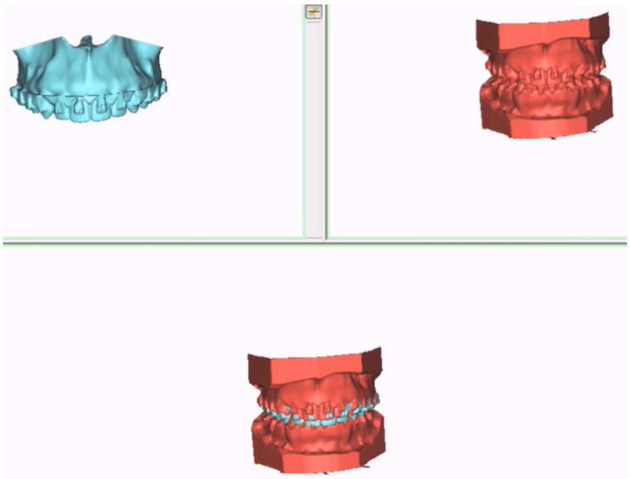


Fig. 31a. Initial merging of the ostetomized maxillary cast with the scan of the desired occlusion.

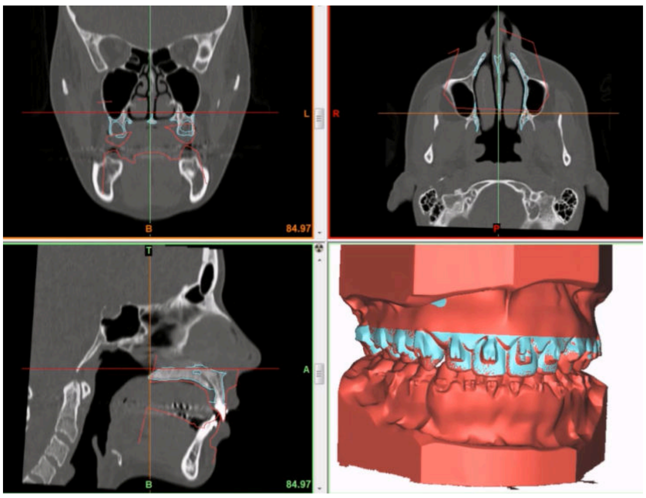
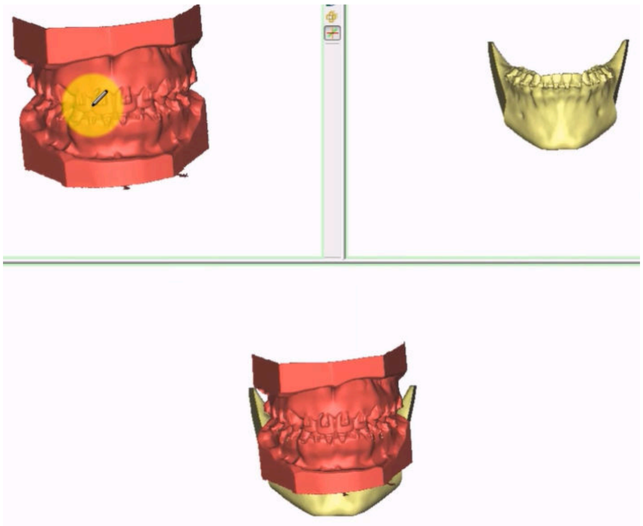


Fig. 31b. Detailed registration of the maxillary cast with alignment tool



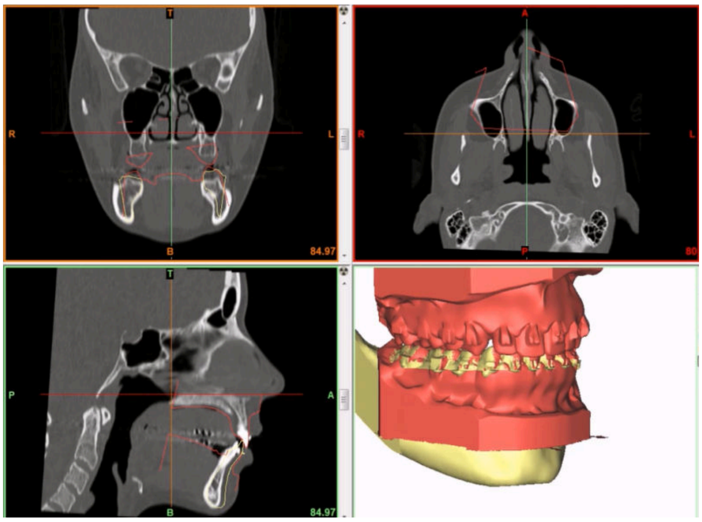


Fig. 32a. Initial merging of the ostetomized mandible cast with the scan of the desired occlusion.

Fig. 32b. Detailed registration of the maxillary cast with alignment tool

## II. Reposition

Right after the occlusion registration phase, the maxilla-mandibular complex is considered a single unit, and all movements judged necessary for the final surgical outcome are virtually simulated. All virtual planning cases were done using the same software as for the preparation of the 3D model, ProPlan CMF. First the canting of the occlusal plane is examined and corrected by setting a rotation point and applying the desired rotation movement. Than the midline is examined and when necessary adjusted by left or right translation movement. After that, any advancement or impaction of the maxilla-mandible movement is planned based on the sagittal view of the 3D model. From the same view, any sagittal rotation is considered and applied by setting an anterior or posterior rotation point. From the bottom view any yaw or asymmetry correction is done. Also, any overlapping of the mandible ramus with the mandible body is corrected by setting a rotation point at the condyle and moving the two pieces apart (Fig.33-37).

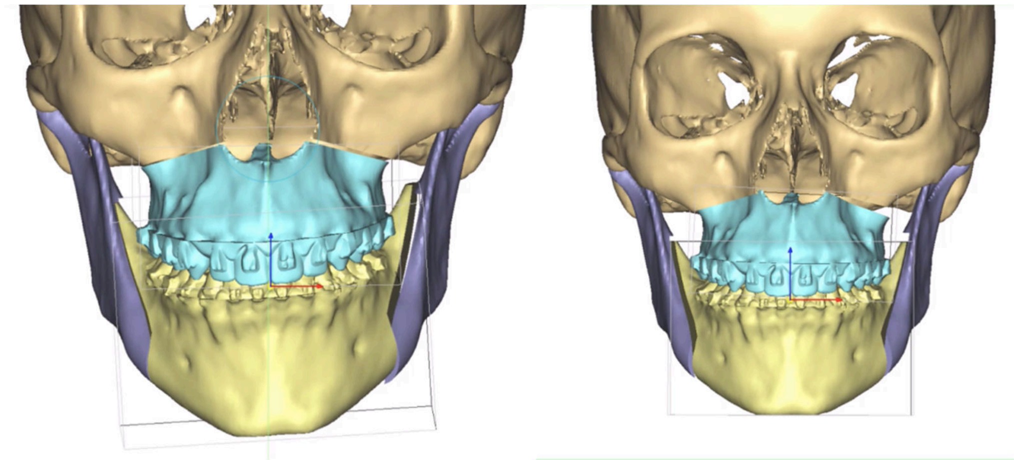


Fig.33 Occlusal plane canting correction

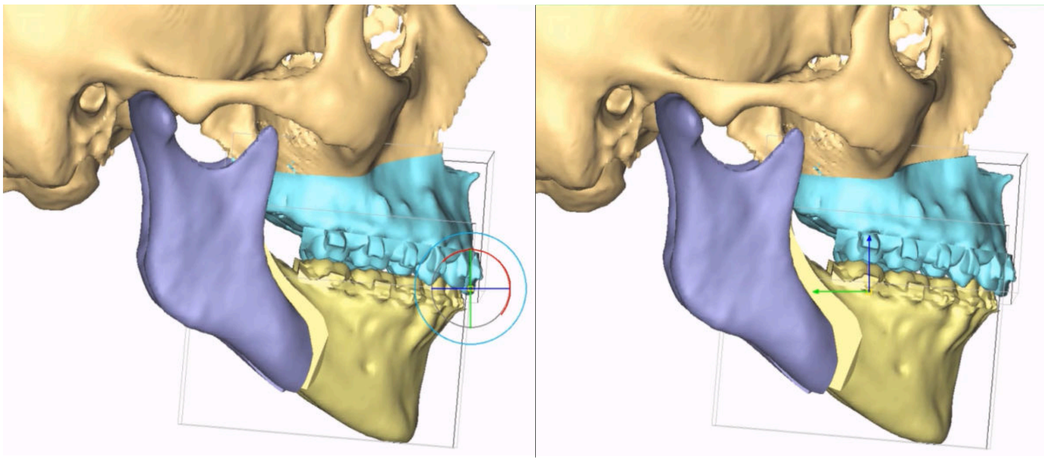


Fig.34 maxilla-mandible complex anterior advancement

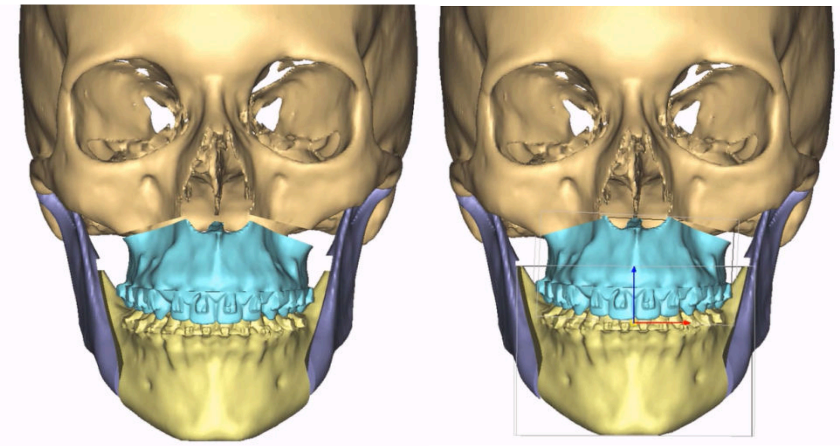


Fig.35 maxilla-mandible complex impaction

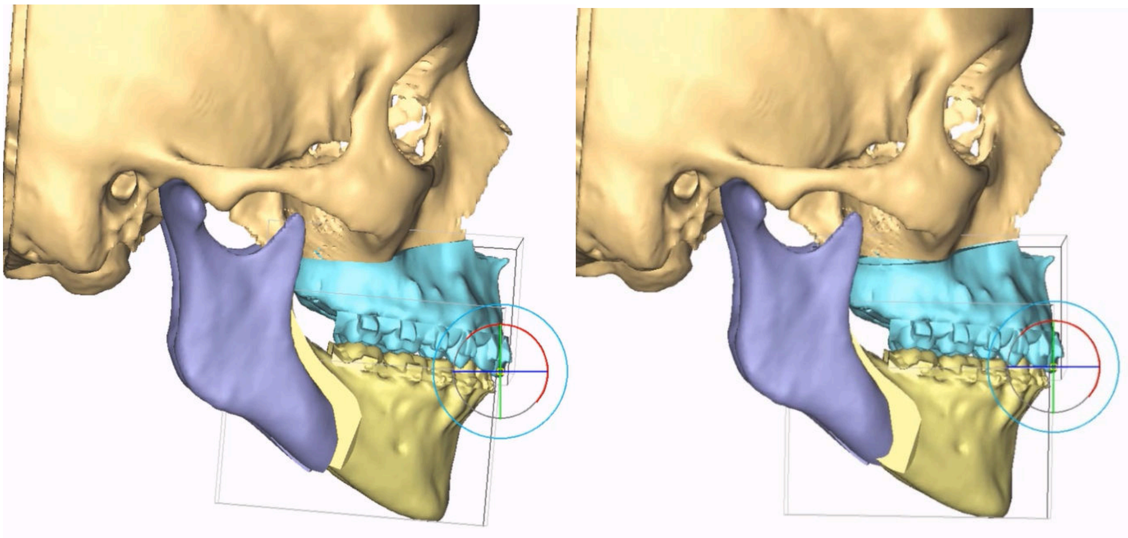


Fig.36 Counter clockwise rotation

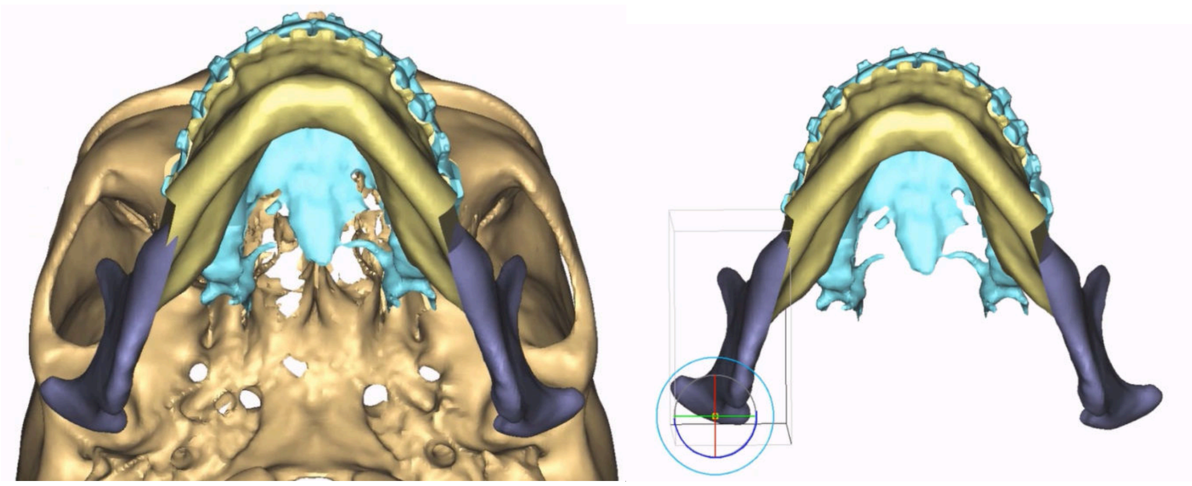


Fig.37 Correction of the overlap between mandible ramus and body

## III. Soft tissue simulation

The virtual planning software allows the automatic simulation of the soft tissue changes before and after surgery, which is a further information that the team might use in order to judge the overall expected result of surgery (Fig.38). However, the accuracy of such process is not the aim of this study.

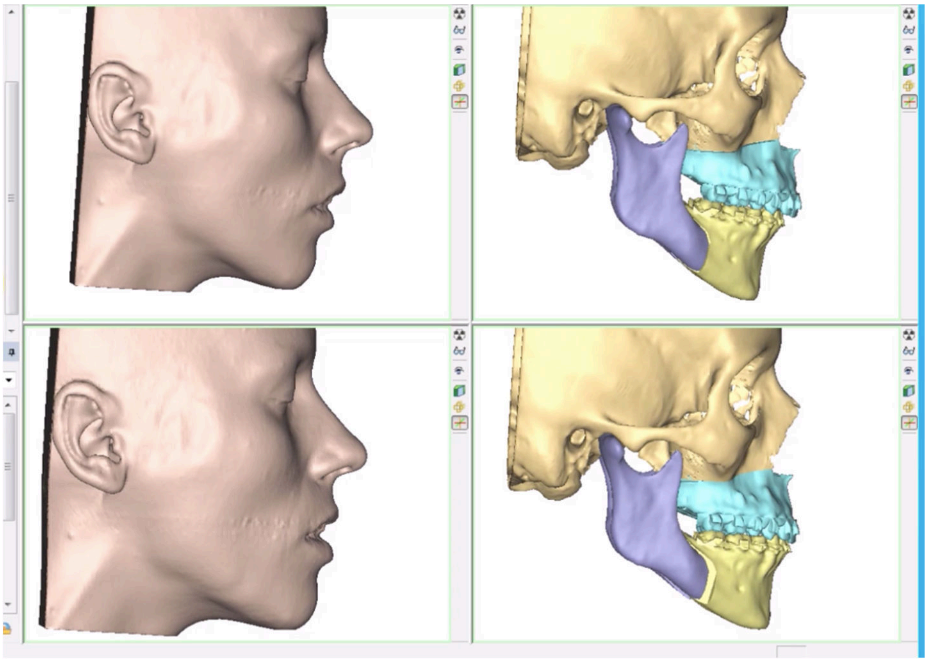


Fig.38 Simulation of soft tissue changes after surgery

Once all the desired movements are decided, the software automatically quantifies them in mm.

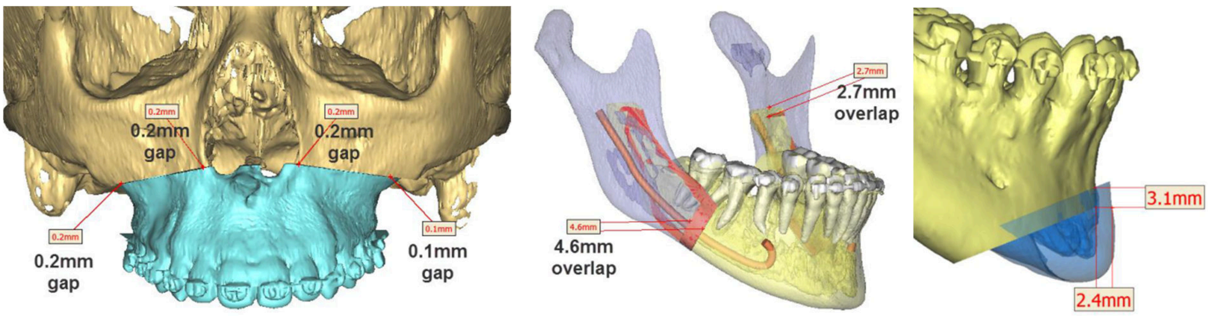



Fig.39 Planned movements quantification in mm

## IV. Planning of transfer method

The last step of the planning process consists of the projection of the transferring method for the virtual surgical plan into the operation room.

In this study, patients were divided in two groups: The splint group and the splintless group.

*The Splint Group:*

A total of eight patients were included in this group. The chosen  transfer method of the virtual plan was a CAD/CAM fabricated intermediate occlusal splint. For the planning of the splint, first its occlusal component was determined by choosing occlusal point on the upper and lower teeth (Fig.40a). Than the position of the wiring holes was specified which consequently determined the lateral offset of the splint (Fig.40b). Finally the final intermediate splint was automatically generated and fabricated using CAM technology (Fig.40c)

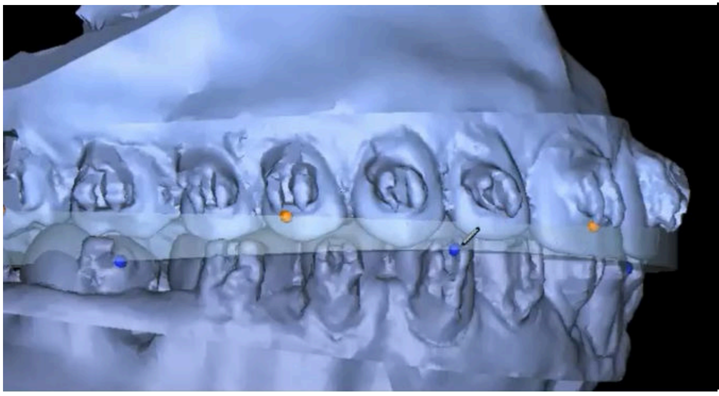


Fig.40a Occlusal component of the splint

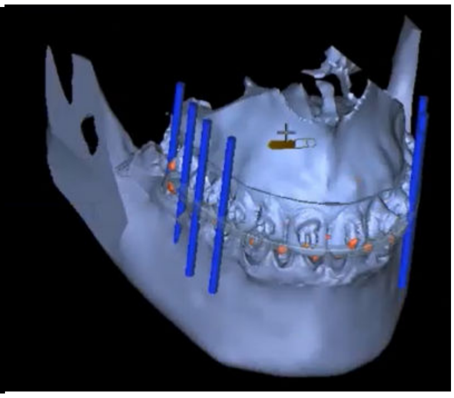


Fig.40b Wiring whole position

Fig. 40c Intermediate splint

### *The Splint-less group*

A total of eight patients were included in this group. The transfer method for the virtual plan was a customized transfer system consisting of two components: First a Titanium surgical guide was projected on the final position of the virtual plan and 3D printed for maxilla and/or mandible (Fig.41a-b). It was used to guide the positioning of the osteotomy lines during surgery and also to create the fixation holes which are used to temporary fixate the surgical guide, and permanently fixate the customized plate. The fixation is done by means of screws with a diameter of 1.5-2mm.

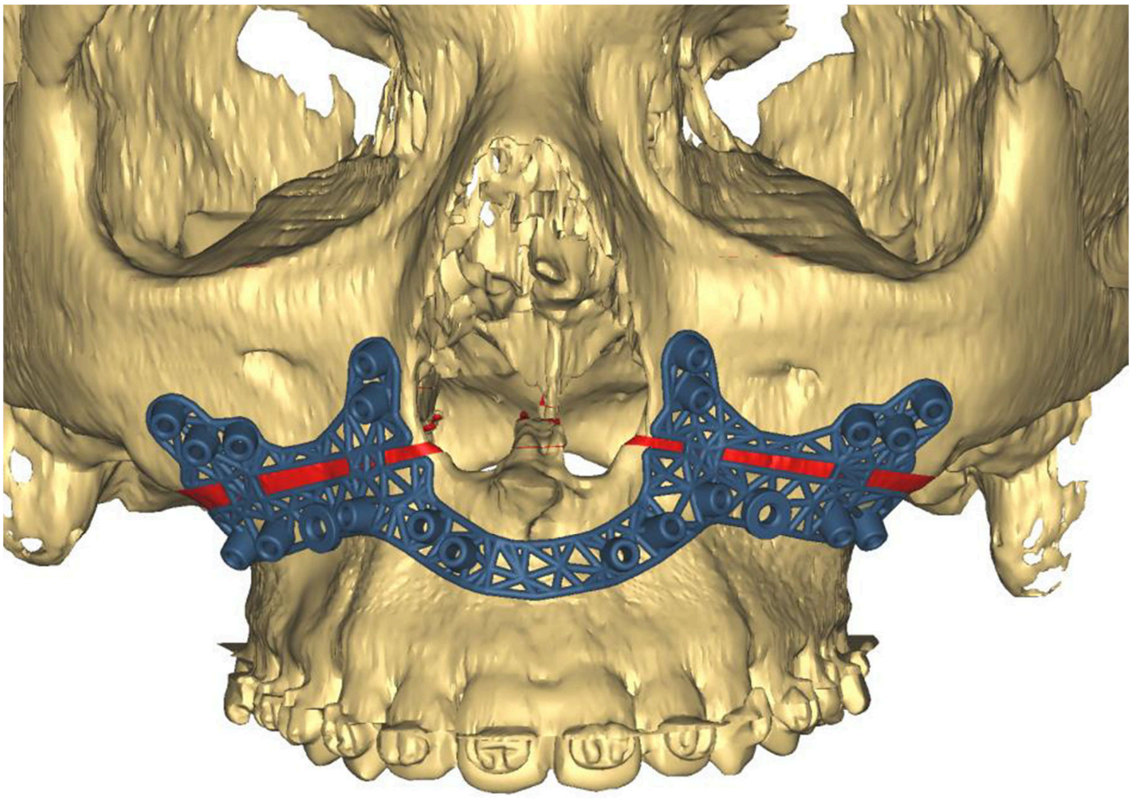


Fig.41a customized titanium Surgical guide for maxilla

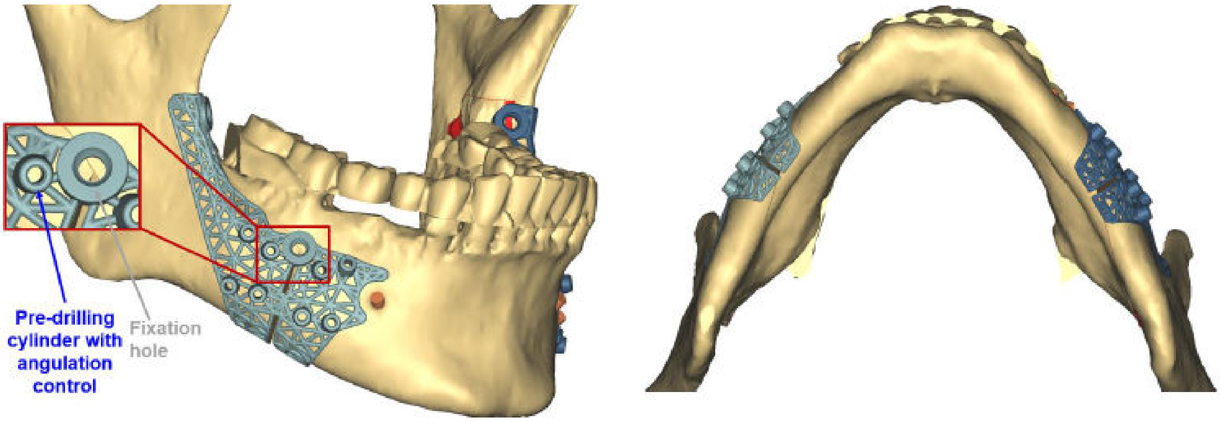



Fig.41b Surgical guide for the Mandible

The second component is a Titanium fixation plate which is again planned on the final virtual plan of the surgery and subsequently 3D printed. It has a thickness ranging from 1mm to 2mm and it has holes whose location should correspond with the already created holes of the bone following osteotomies and drilling with the surgical guide (Fig.42a-b).

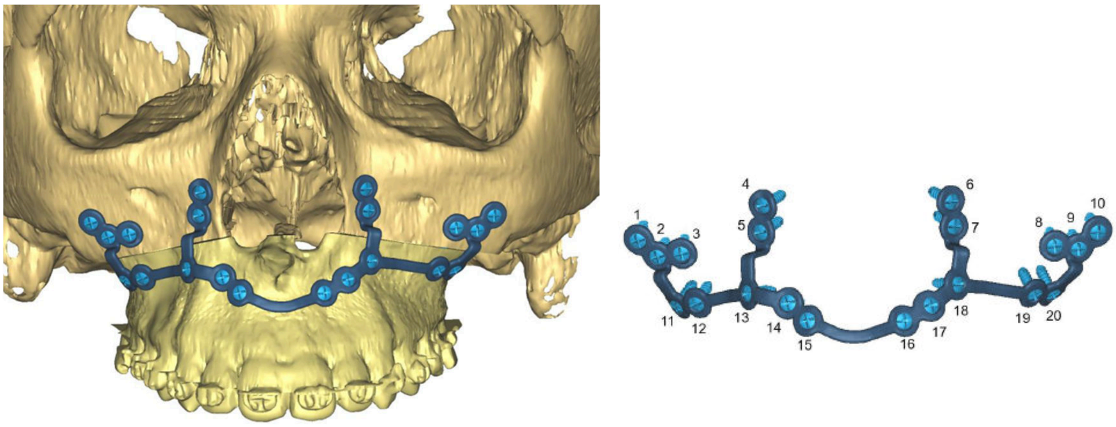



Fig.42a Maxilla Titanium fixation plate

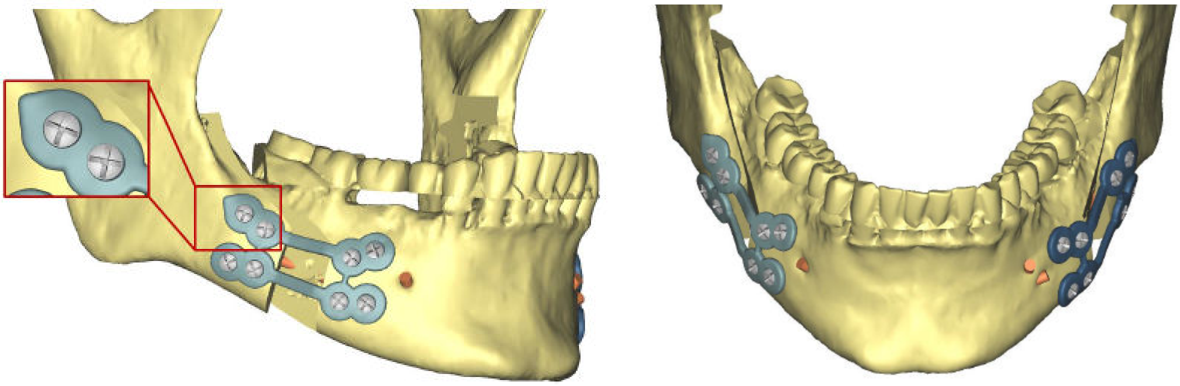


Fig.42b Mandible fixation plate

For both groups, a final splint was CAD/CAM fabricated.


## *T2: Orthognathic Surgery*

Approximately three weeks after the web meeting for the virtual planning, surgery was scheduled. All surgeries were performed by two surgeons with more than 10 years of clinical experience. A two-jaw surgery was carried out for all patients, and the chosen techniques were Le Fort I osteotomy for maxilla and BSSO for the mandible, as thoroughly described in the literature[1].

For the splint group, osteotomies were directly executed by the surgeons without any guide, an intermediate splint was used to position the osteotomized jaw with respect to the other jaw, conventional fixation plates were used for stabilization and a final splint was delivered.

For the splintless group, osteotomies were guided by the surgical guide. The references for the correct positioning of the surgical guide were:

For the maxilla: Spina nasale anterior and the shape of the external borders of the nasal cavity. For the mandible: The inferior mandible border inferiorly, and the linea oblique externa superiorly. Once it was positioned, the holes of the surgical guide were used to drill the underlying bone and screws were placed to secure the guide. Subsequently, osteotomies were performed with a saw following the osteotomy lines designed on the surgical guide. Once osteotomies were performed, the surgical guide was unscrewed and the final customized fixation plate was placed. The holes  present in the fixation plate should perfectly feet with those of the underlying bone (Fig.43a-f).

After surgery, a standardized regime was followed for all patients which included 1gr acetaminophen and 10mg ketorolac 3 times/day for two days. The third day after surgery each patient received analgesics only if it was needed.

Fig.43a surgical guide and plate ready to be used

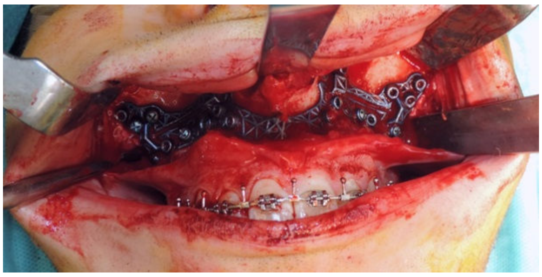


Fig.43b Fitting the upper guide

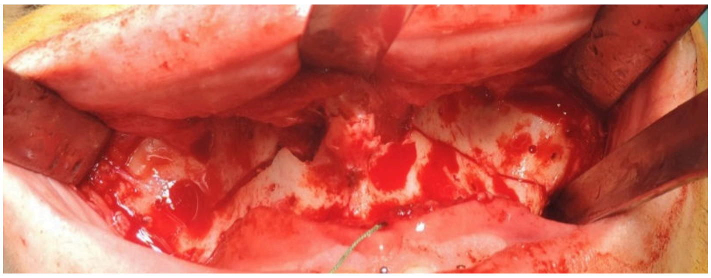


Fig.43c osteotomies after guide removal

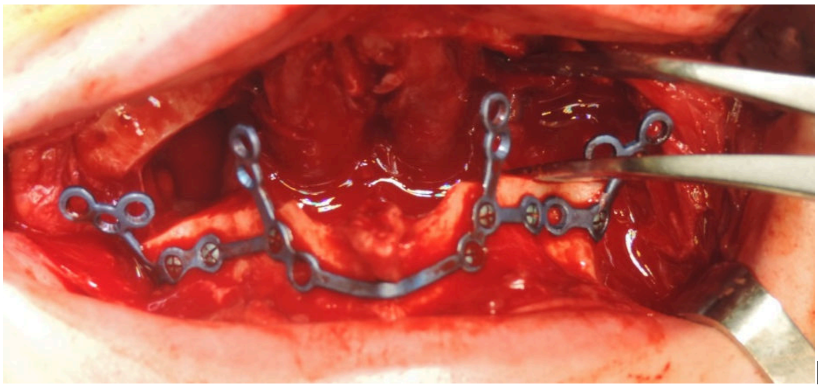


Fig.43d Positioning the plate

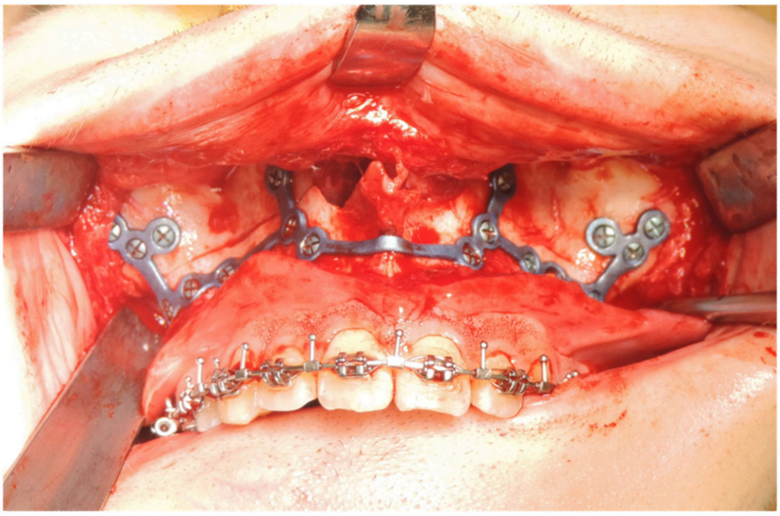


Fig.43e Final position of the maxillary fixation plate

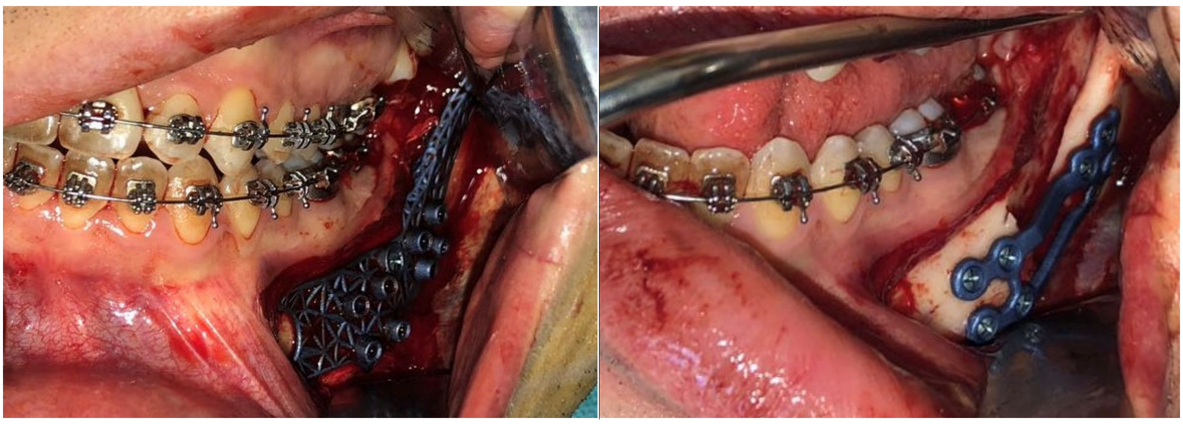


Fig.43f Positioning of the mandibular guide and plate


## *T3: Accuracy Analysis*

One month after surgery, each patient received a post-operative CBCT using the same machine and same parameters as the pre-surgery one. The pre and post-surgery CBCTs as well as the STL file of the virtually planned surgery, were used to undertake the accuracy analysis, which was done by using a dedicated software. All procedures involved in this process, were performed at the University of California, Los Angeles, Department of Growth and Development, Division of Orthodontics.

The workflow for the accuracy analysis consisted of the calculation of the displacement of the points by comparing the pre and post-surgery CBCT. The result of this comparison was confronted with the planned displacement during virtual planning. The analysis was done separately for the maxilla and for the mandible (Fig.44).

For the maxilla, rotational and translational movement from the pre-surgical model to the post-surgical model was measured using voxel-based registration. We executed two registration to compute the relative movement of maxilla with respect to cranial base: One registration used the cranial base as region of superimposition and the second one used the palate region, and we combined the two registration to compute the relative movement. The voxel-based registration was done by maximizing mutual information of two volume data obtained from DICOM files. The calculated relative movement was applied at the landmarks already appointed at the pre-op CBCT, and the coordinates of the same landmarks at the post-op CBCT were outputted.

The seven landmark points taken into consideration for the maxilla were (Fig.45a-b):

*A:* maximum concavity in the midline of the alveolar process of the maxilla.
*ANS:* most anterior midpoint of the anterior nasal spine of the maxilla.
*U-Mid:*most mesial point of the tip of the crown in between upper central incisors
*UL3:* most inferior point of the tip of the crown of left upper canine.
*UR3:* most inferior point of the tip of the crown of right upper canine.
*UL6:* most inferior point of the mesial buccal cusp of the crown of left upper molar.
*UR6:* most inferior point of the mesial buccal cusp of the crown of right upper molar.

The procedure for maxilla accuracy is demonstrated through Figures 46a-h. Displacement of each landmark was computed from the coordination of each landmark on the initial model and the movement of maxilla. We assumed that little bone deformation existed, thus displacement of each point was calculated by applying rigid body movement of maxilla to each point and computing the difference of coordination. The software for the registration was implemented using C++ language and a linear algebra library (Eigen 3.3, Benoît Jacob and Gaël Guennebaud).

The displacement of landmarks was compared with the displacement that had been planned before surgery. Rotational and translational movement which we planned was measured using surface-based registration between the STL file generated by the pre-op CBCT and the STL file of the virtual planning, and iterative closest point algorithm. Displacement of each landmarks were computed in the same way as the actual movement.

The exact same procedure was followed for the evaluation of the accuracy of mandible displacement as well. The voxel based registration of the pre and post-surgery CBCT was done by using as a region of superimposition the lateral body of the mandible unaffected by the surgery. The eight landmarks for the displacement evaluation of the mandible were:

B: maximum concavity in the midline of the alveolar process of the mandible
*PoG*: most anterior midpoint of the chin on the outline of the mandibular symphysis.
*Me:* most inferior midpoint of the chin on the outline of the mandibular symphysis.
*L-Mid:* most mesial point of the tip of the crown in between lower central incisors.
*LL3:* most superior point of the tip of the crown left lower canine.
*LR3:* most superior point of the tip of the crown right lower canine.
*LL6:* most superior point of the mesial buccal cusp of the crown of left lower molar.
*LR6:* most superior point of the mesial buccal cusp of the crown of right lower molar.

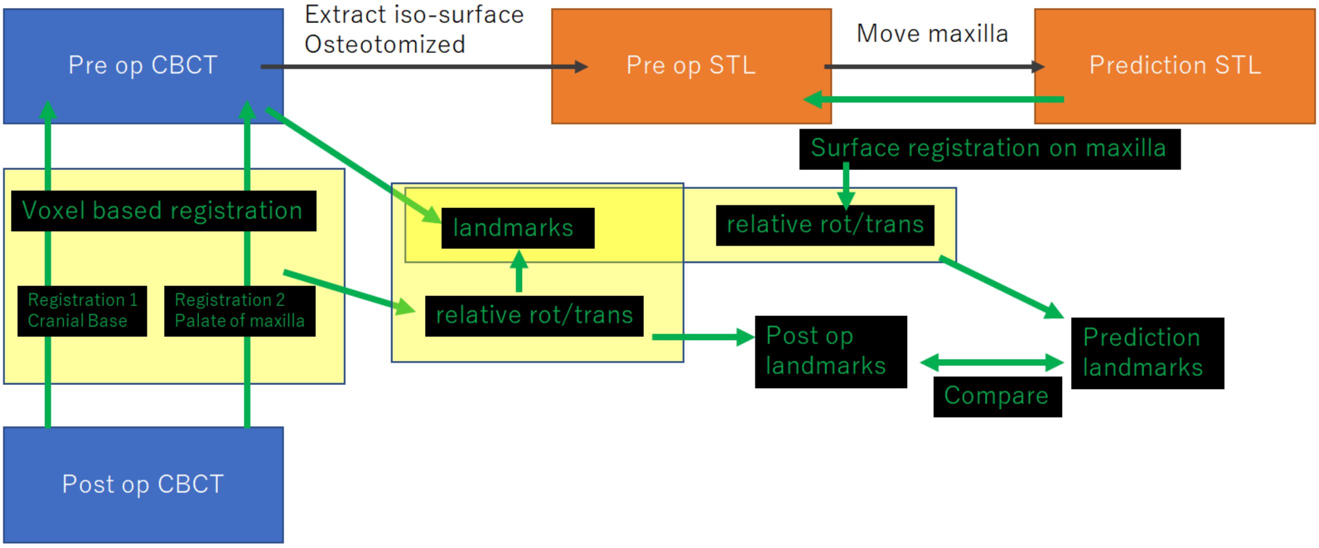



Fig.44 Schematized workflow for the accuracy analysis for maxilla

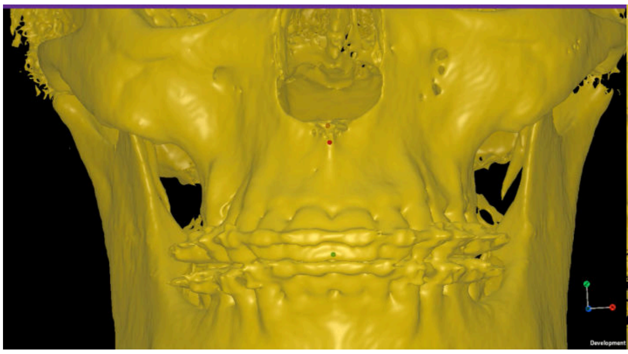


Fig.45a Anterior landmarks on pre-op CBCT

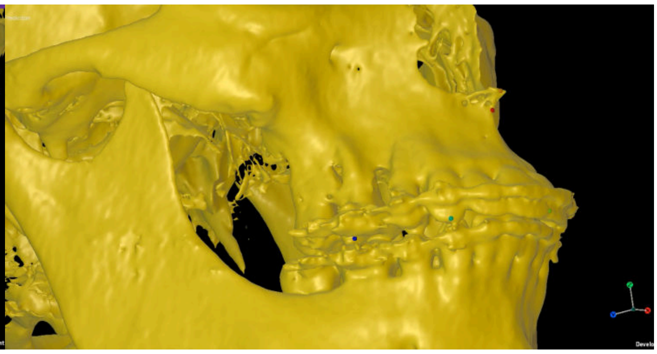


Fig.45b Lateral landmarks on pre-op CBCT

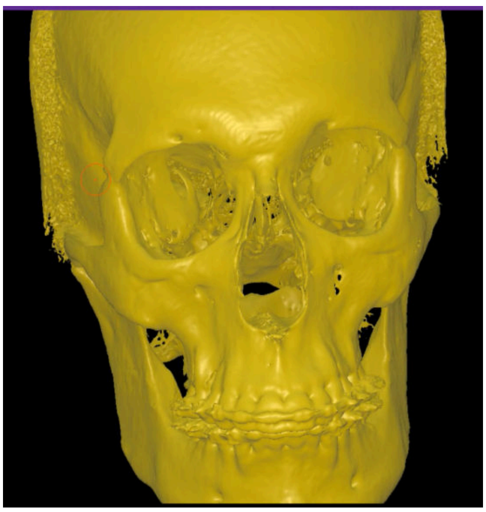


Fig. 46a Pre-op CBCT

Fig. 46b Post-op CBCT

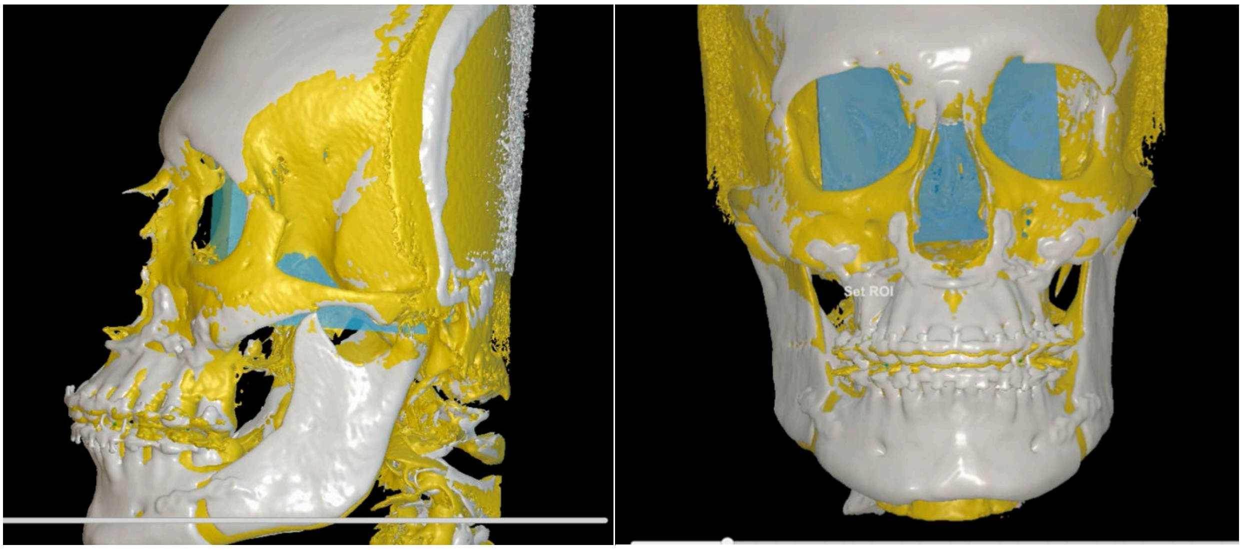



Fig.46c Registration 1 – cranial base

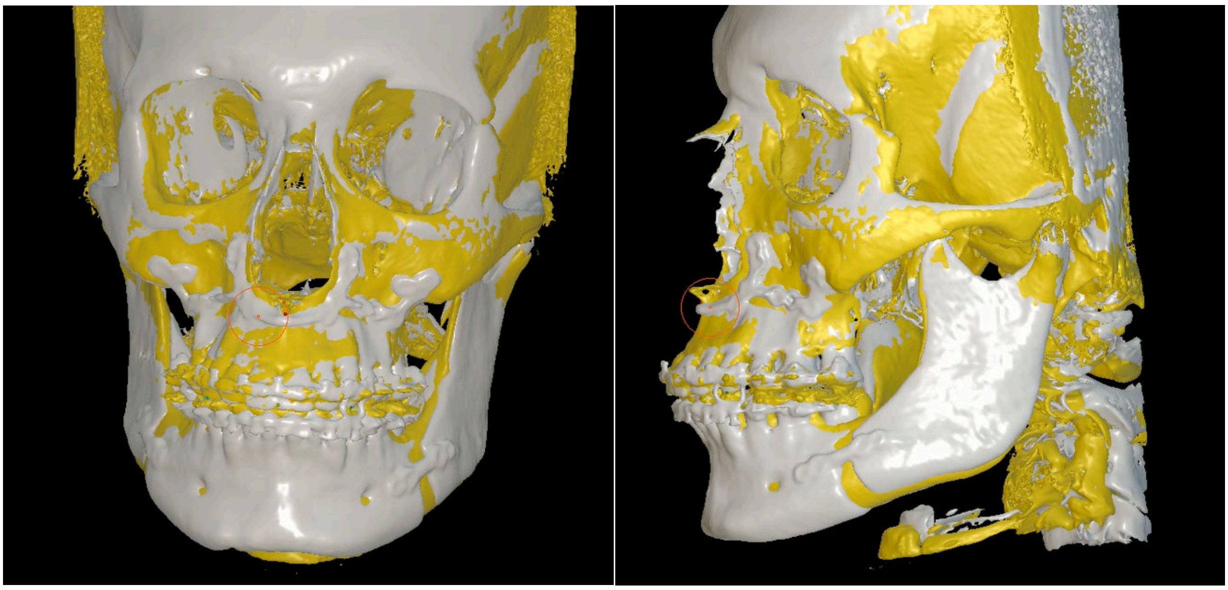


Fig. 46d Registration 2 – Palate maxilla

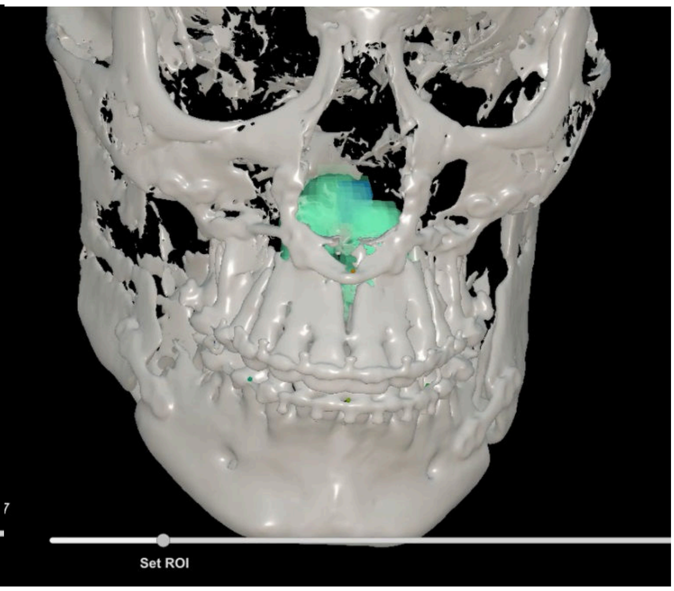



Fig. 46e ROI for  Registration 1

Fig. 46fROI for Registration 2

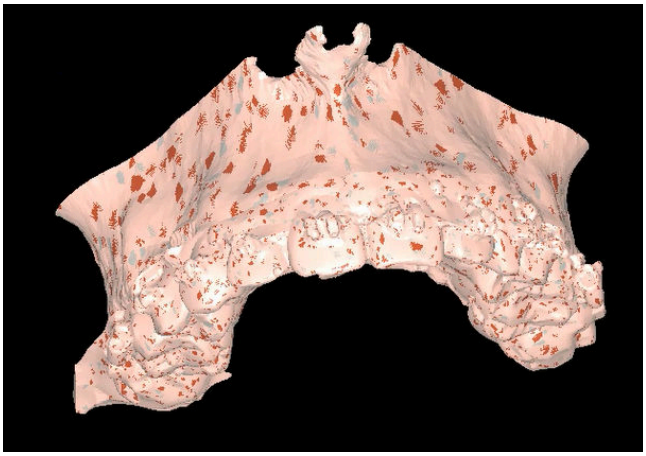


Fig. 46g Surface based registration of the STL file of the pre-op maxilla with the STL file of the virtual planning maxilla

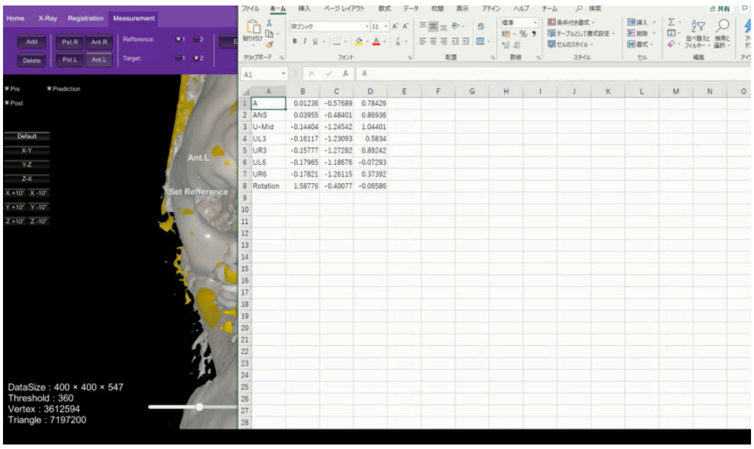



Fig. 46h Exporting results on an excel file

Overall, two parameters were evaluated in this study:

1. The translation movement of the selected landmarks in the three axes.
2. The rotation movement in the three axes

## Statistical analysis

The overall statistical analysis was carried out with GraphPad Prism 5 Software. First, an analysis of the distribution was done with the D'Agostino and Pearson test. Given that the distribution of our data was not normal, a non-parametric two-tailed test (The Mann-Whitney Test) was used for the evaluation of the statistical differences between groups. The significance threshold was set to 0.05.

## *Results*

A total of 16 patients, 9 females and 7 males, with a mean age of 26.4±6.25 were included in this study. They were divided in two groups with 8 patients each, based on the transfer method of the virtual plan into the operating room: The splint group and the splintless group. Their characteristics and surgical procedure details are described in Fig.47. All the patients of the splint group received a Maxilla first sequencing of their surgery, whereas among the splintless group, four patients received a maxilla first, and the other four a mandible-first surgical approach (Fig.48).

*Maxilla accuracy*:

The raw data for the mean discrepancies between the actual translation movement and the predicted one for each point in all three axis are shown in Fig.49 for the splint group, and Fig.50 for the splintless group, and the p-values are shown in Table 2. A statistically sisgnificant difference was found between splint and splintless group for the accuracy of point A and ANS with splintless group being more accurate. The raw data for the mean discrepancies between the rotation movement in all three axis are shown in Fig.51 for the splint group and in Fig.52 for the splintless group, and the mean absolute rotation error together with the p values are shown in Table.3 A statistically significant difference was found between the two groups in the y and z axes with the splintless group being more accurate.

*Mandible accuracy:*

The raw data for the mean discrepancies between the actual translation movement and the predicted one for each point in all three axis are shown in Fig.53 for the splint and Fig.54 for the splintless group, and the p-values are shown in Table 4. A statistically sisgnificant difference was found only for B point in the x axis, with splintless group being more accurate. The raw data for the mean discrepancies between the rotation movement in all three axis are shown in Fig.55 for the splint, and Fig.56 for the splintless group, and the mean absolute rotation error together with the p values are shown in Table 5. No statistically significant difference was found between the two groups.

| Group | Patient | Sex | Skeletal Pattern | Type of Surgery | Sequencing | Maxilla Osteotomies | Genioplasty |
|---|---|---|---|---|---|---|---|
| Splintless | 1 | M | Class II | BSSO & LeFort I | Mandibular first | one piece | no |
| | 2 | M | Class II | BSSO & LeFort I | Mandibular first | one piece | yes |
| | 3 | M | Class III & Asymmetry | LeFort I & BSSO | Maxilla first | one piece | yes |
| | 4 | F | Class II | LeFort I & BSSO | Maxilla first | one piece | yes |
| | 5 | M | Class II | BSSO & LeFort I | Mandibular first | one piece | no |
| | 6 | M | Class II | BSSO & LeFort I | Mandibular first | one piece | no |
| | 7 | M | Class II | LeFort I & BSSO | Maxilla first | one piece | no |
| | 8 | F | Class III | LeFort I & BSSO | Maxilla first | two piece | no |
| | | | | | | | |
| Splint | 9 | F | Class III | LeFort I & BSSO | Maxilla first | one piece | no |
| | 10 | M | Class II | LeFort I & BSSO | Maxilla first | two piece | no |
| | 11 | F | Class III | LeFort I & BSSO | Maxilla first | one piece | yes |
| | 12 | F | Class III | LeFort I & BSSO | Maxilla first | one piece | yes |
| | 13 | F | Class II | LeFort I & BSSO | Maxilla first | one piece | yes |
| | 14 | F | Class III | LeFort I & BSSO | Maxilla first | one piece | no |
| | 15 | F | Class III | LeFort I & BSSO | Maxilla first | one piece | yes |
| | 16 | F | Class III | LeFort I & BSSO | Maxilla first | one piece | yes |

Fig.47 Patients divided in two groups based on the transfer method, and surgical characteristics

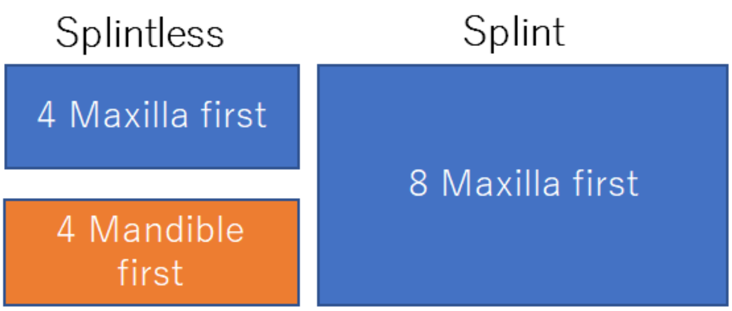



Fig.48 Patients division in two groups and the sequencing surgical techniques used for each group

Fig.49 Raw data of the predicted and actual translation movement for all maxilla points of the splint group, and the absolute error between prediction and actual movement.

| | | | prediction | | | actual | | | difference | | | absolute | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Point | | x | y | z | x | y | z | x | y | z | x | y | z |
| A | 1 | 1,47746 | -5,16363 | -1,76017 | 1,08 | -5,03308 | -0,0191 | 0,397 | -0,131 | -1,741 | 0,39746 | 0,13055 | 1,74107 |
| | 2 | -0,43449 | -4,08423 | 4,97262 | -0,02409 | -4,05912 | 2,91348 | -0,410 | -0,025 | 2,059 | 0,4104 | 0,02511 | 2,05914 |
| | 3 | -0,08339 | -4,67432 | -0,51872 | 0,09828 | -5,97425 | 0,48733 | -0,182 | 1,300 | -1,006 | 0,18167 | 1,29993 | 1,00605 |
| | 4 | 0,12082 | -2,96285 | 5,37015 | 1,54853 | -2,9997 | 4,8863 | -1,428 | 0,037 | 0,484 | 1,42771 | 0,03685 | 0,48385 |
| | 5 | -0,54444 | -5,93395 | 1,73445 | 0,00553 | -5,80061 | -1,64166 | -0,550 | -0,133 | 3,376 | 0,54997 | 0,13334 | 3,37611 |
| | 6 | -0,17114 | -3,71351 | -1,08945 | -0,53961 | -4,81439 | 0,45702 | 0,368 | 1,101 | -1,546 | 0,36847 | 1,10088 | 1,54647 |
| | 7 | -0,12417 | -0,1186 | 1,34352 | -0,41378 | 1,00465 | 1,30317 | 0,290 | -1,123 | 0,040 | 0,28961 | 1,12325 | 0,04035 |
| | 8 | 0,12892 | -3,84073 | 3,57231 | -0,46462 | -3,01368 | 2,59643 | 0,594 | -0,827 | 0,976 | 0,59354 | 0,82705 | 0,97588 |
| | | | | | | | | | | | | | |
| ANS | 1 | 1,54363 | -5,37043 | -1,91891 | 1,05267 | -5,03391 | -0,01996 | 0,491 | -0,337 | -1,899 | 0,49096 | 0,33652 | 1,89895 |
| | 2 | -0,51137 | -3,62114 | 5,31625 | -0,21513 | -4,05351 | 2,8846 | -0,296 | 0,432 | 2,432 | 0,29624 | 0,43237 | 2,43165 |
| | 3 | -0,18609 | -5,32415 | -0,71444 | 0,11233 | -6,55277 | 0,31245 | -0,298 | 1,229 | -1,027 | 0,29842 | 1,22862 | 1,02689 |
| | 4 | 0,14664 | -2,83657 | 5,33472 | 1,6737 | -2,99798 | 4,83602 | -1,527 | 0,161 | 0,499 | 1,52706 | 0,16141 | 0,4987 |
| | 5 | -0,74519 | -6,00703 | 1,60006 | 0,00558 | -5,95103 | -1,88388 | -0,751 | -0,056 | 3,484 | 0,75077 | 0,056 | 3,48394 |
| | 6 | -0,22012 | -3,91353 | -1,17895 | -0,59257 | -4,98289 | 0,38173 | 0,372 | 1,069 | -1,561 | 0,37245 | 1,06936 | 1,56068 |
| | 7 | 0,03768 | 0,06105 | 1,79246 | -0,03239 | 1,61129 | 2,58254 | 0,070 | -1,550 | -0,790 | 0,07007 | 1,55024 | 0,79008 |
| | 8 | -0,16184 | -3,70974 | 3,64838 | -0,63653 | -3,02398 | 2,61252 | 0,475 | -0,686 | 1,036 | 0,47469 | 0,68576 | 1,03586 |
| | | | | | | | | | | | | | |
| U-Mid | 1 | 1,15035 | -4,14274 | -1,99481 | 1,68571 | -5,00758 | 0,00691 | -0,535 | 0,865 | -2,002 | 0,53536 | 0,86484 | 2,00172 |
| | 2 | 0,1898 | -6,64456 | 5,0577 | 1,04103 | -4,0887 | 2,87866 | -0,851 | -2,556 | 2,179 | 0,85123 | 2,55586 | 2,17904 |
| | 3 | 0,32983 | -2,63996 | -1,12804 | 0,07738 | -4,17702 | -0,08383 | 0,252 | 1,537 | -1,044 | 0,25245 | 1,53706 | 1,04421 |
| | 4 | -0,12524 | -4,31099 | 5,8455 | 0,06101 | -3,01818 | 4,97797 | -0,186 | -1,293 | 0,868 | 0,18625 | 1,29281 | 0,86753 |
| | 5 | -0,00914 | -5,44866 | 1,49554 | 0,00424 | -4,82053 | -2,1489 | -0,013 | -0,628 | 3,644 | 0,01338 | 0,62813 | 3,64444 |
| | 6 | 0,26053 | -1,64389 | -1,61484 | 0,01051 | -3,09208 | 0,00892 | 0,250 | 1,448 | -1,624 | 0,25002 | 1,44819 | 1,62376 |
| | 7 | 0,24348 | -1,85609 | 1,76363 | 0,00278 | -4,00046 | 2,87153 | 0,241 | 2,144 | -1,108 | 0,2407 | 2,14437 | 1,1079 |
| | 8 | 1,37928 | -4,82865 | 3,99102 | 0,05556 | -3,04546 | 2,60973 | 1,324 | -1,783 | 1,381 | 1,32372 | 1,78319 | 1,38129 |

Points A, ANS, U-Mid

| Point | | x | y | z | x | y | z | x | y | z | x | y | z |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| UL3 | 1 | 1,13176 | -4,08453 | -1,86717 | 1,50273 | -4,57064 | 0,44088 | -0,371 | 0,486 | -2,308 | 0,37097 | 0,48611 | 2,30805 |
| | 2 | 0,11944 | -6,46913 | 4,777 | 1,0156 | -4,09308 | 3,47865 | -0,896 | -2,376 | 1,298 | 0,89616 | 2,37605 | 1,29835 |
| | 3 | 0,24312 | -2,57359 | 0,18772 | 0,06023 | -4,18474 | 0,76306 | 0,183 | 1,611 | -0,575 | 0,18289 | 1,61115 | 0,57534 |
| | 4 | -0,29407 | -4,04745 | 5,04031 | 0,05084 | -3,01461 | 3,99581 | -0,345 | -1,033 | 1,045 | 0,34491 | 1,03284 | 1,0445 |
| | 5 | 0,20988 | -5,77808 | 2,48354 | 0,00437 | -4,74288 | -1,6668 | 0,206 | -1,035 | 4,150 | 0,20551 | 1,0352 | 4,15034 |
| | 6 | 0,31529 | -1,74386 | -0,12858 | 0,00758 | -3,06927 | 1,41833 | 0,308 | 1,325 | -1,547 | 0,30771 | 1,32541 | 1,54691 |
| | 7 | 0,0119 | -1,52085 | 1,28682 | -0,5236 | -3,48976 | 1,06514 | 0,536 | 1,969 | 0,222 | 0,5355 | 1,96891 | 0,22168 |
| | 8 | 1,71409 | -5,48433 | 4,79011 | 0,38083 | -3,66657 | 3,21 | 1,333 | -1,818 | 1,580 | 1,33326 | 1,81776 | 1,58011 |
| | | | | | | | | | | | | | |
| UR3 | 1 | 1,16243 | -4,17941 | -1,27301 | 1,48987 | -5,47181 | -0,4546 | -0,327 | 1,292 | -0,818 | 0,32744 | 1,2924 | 0,81841 |
| | 2 | 0,07721 | -6,62362 | 3,98607 | 0,9706 | -4,08199 | 2,31827 | -0,893 | -2,542 | 1,668 | 0,89339 | 2,54163 | 1,6678 |
| | 3 | 0,28117 | -2,6779 | -0,57075 | 0,06031 | -4,13794 | 0,71737 | 0,221 | 1,460 | -1,288 | 0,22086 | 1,46004 | 1,28812 |
| | 4 | -0,27155 | -4,6208 | 5,66002 | 0,05784 | -3,02201 | 5,98945 | -0,329 | -1,599 | -0,329 | 0,32939 | 1,59879 | 0,32943 |
| | 5 | 0,26179 | -5,03401 | 1,02702 | 0,00439 | -4,73877 | -1,62755 | 0,257 | -0,295 | 2,655 | 0,2574 | 0,29524 | 2,65457 |
| | 6 | 0,29893 | -1,61521 | -0,99581 | -0,01118 | -3,15229 | 0,3646 | 0,310 | 1,537 | -1,360 | 0,31011 | 1,53708 | 1,36041 |
| | 7 | 0,03099 | -2,26254 | 1,12655 | -0,43806 | -4,95467 | 1,40038 | 0,469 | 2,692 | -0,274 | 0,46905 | 2,69213 | 0,27383 |
| | 8 | 1,68599 | -4,0697 | 2,33517 | 0,33636 | -2,36553 | 1,93058 | 1,350 | -1,704 | 0,405 | 1,34963 | 1,70417 | 0,40459 |
| | | | | | | | | | | | | | |
| UL6 | 1 | 1,19564 | -4,28292 | -1,14616 | 0,97193 | -4,29959 | 0,70962 | 0,224 | 0,017 | -1,856 | 0,22371 | 0,01667 | 1,85578 |
| | 2 | -0,16035 | -5,96342 | 3,20116 | 0,79563 | -4,088 | 3,60794 | -0,956 | -1,875 | -0,407 | 0,95598 | 1,87542 | 0,40678 |
| | 3 | 0,02396 | -2,89083 | 2,34519 | 0,03053 | -4,49747 | 2,49532 | -0,007 | 1,607 | -0,150 | 0,00657 | 1,60664 | 0,15013 |
| | 4 | -0,55266 | -3,85939 | 4,01224 | 0,18488 | -3,01179 | 3,6796 | -0,738 | -0,848 | 0,333 | 0,73754 | 0,8476 | 0,33264 |
| | 5 | 0,49349 | -6,00596 | 3,35433 | 0,00497 | -4,86441 | -0,63887 | 0,489 | -1,142 | 3,993 | 0,48852 | 1,14155 | 3,9932 |
| | 6 | 0,29345 | -2,21233 | 1,45641 | -0,11154 | -3,41293 | 2,80418 | 0,405 | 1,201 | -1,348 | 0,40499 | 1,2006 | 1,34777 |
| | 7 | -0,46345 | -1,16966 | 0,2139 | -1,50008 | -2,80525 | -2,27797 | 1,037 | 1,636 | 2,492 | 1,03663 | 1,63559 | 2,49187 |
| | 8 | 2,28424 | -5,79151 | 4,72936 | 0,9782 | -4,05595 | 3,5727 | 1,306 | -1,736 | 1,157 | 1,30604 | 1,73556 | 1,15666 |
| | | | | | | | | | | | | | |
| UR6 | 1 | 1,25329 | -4,46142 | -0,12503 | 0,8855 | -5,6851 | -0,6672 | 0,368 | 1,224 | 0,542 | 0,36779 | 1,22368 | 0,54217 |
| | 2 | -0,20372 | -6,15949 | 2,29922 | 0,74679 | -4,07485 | 2,21672 | -0,951 | -2,085 | 0,083 | 0,95051 | 2,08464 | 0,0825 |
| | 3 | 0,09132 | -2,99844 | 1,18808 | 0,02776 | -4,36103 | 2,50996 | 0,064 | 1,363 | -1,322 | 0,06356 | 1,36259 | 1,32188 |
| | 4 | -0,52917 | -4,59983 | 4,79419 | 0,21255 | -3,02132 | 6,30851 | -0,742 | -1,579 | -1,514 | 0,74172 | 1,57851 | 1,51432 |
| | 5 | 0,48383 | -4,94671 | 1,16233 | 0,00502 | -4,92863 | -0,67327 | 0,479 | -0,018 | 1,836 | 0,47881 | 0,01808 | 1,8356 |
| | 6 | 0,30207 | -1,9068 | 0,31405 | -0,10304 | -3,41808 | 1,39877 | 0,405 | 1,511 | -1,085 | 0,40511 | 1,51128 | 1,08472 |
| | 7 | -0,45288 | -2,30028 | -0,07605 | -1,41018 | -5,05075 | -1,90435 | 0,957 | 2,750 | 1,828 | 0,9573 | 2,75047 | 1,8283 |
| | 8 | 2,35381 | -3,65347 | 0,90105 | 1,01386 | -2,09137 | 1,63723 | 1,340 | -1,562 | -0,736 | 1,33995 | 1,5621 | 0,73618 |

Points UL3, UR3, UL6, UR6

Fig.50 Raw data of the predicted and actual translation movement for all maxilla points of the splintless group, and the absolute error between prediction and actual movement.

| | | Predicted movement | | | Actual movement | | | average difference | | | absolute | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Point | case | x | y | z | x | y | z | x | y | z | x | y | z |
| A | 9 | 0,85763 | -0,61241 | 0,84401 | -0,01301 | -0,8524 | 1,70595 | 0,10806 | 0,23999 | -0,86194 | 0,10806 | 0,23999 | 0,86194 |
| | 10 | 0,9743 | -1,80366 | 1,60921 | 0,85057 | -1,34959 | 1,62754 | 0,12373 | -0,45407 | -0,01833 | 0,12373 | 0,45407 | 0,01833 |
| | 11 | -1,27576 | -5,00164 | 1,2393 | -1,04014 | -4,47856 | 0,38167 | -0,23562 | -0,52308 | 0,85763 | 0,23562 | 0,52308 | 0,85763 |
| | 12 | 1,49123 | -2,16839 | -0,11541 | 1,06325 | -2,56505 | -0,08057 | 0,42798 | 0,39666 | -0,03484 | 0,083825 | 0,638235 | 0,301635 |
| | | 1,63532 | -1,14272 | -0,85355 | 1,89565 | -2,02253 | -0,28512 | -0,26033 | 0,87981 | -0,56843 | | | |
| | 13 | 0,21811 | -5,03832 | 3,38354 | 0,05404 | -3,12567 | 1,98703 | 0,16407 | -1,91265 | 1,39651 | 0,16407 | 1,91265 | 1,39651 |
| | 14 | -1,47819 | -4,67606 | 1,85481 | 0,65398 | -5,38314 | 1,99167 | -2,13217 | 0,70708 | -0,13686 | 2,13217 | 0,70708 | 0,13686 |
| | 15 | -1,58223 | -3,242 | 0,17992 | 0,67903 | -5,65991 | 2,3787 | -2,26126 | 2,41791 | -2,19878 | 2,26126 | 2,41791 | 2,19878 |
| | 16 | -0,06719 | -2,69216 | 3,97945 | -0,86595 | -4,04017 | 2,11916 | 0,79876 | 1,34801 | 1,86029 | 0,79876 | 1,34801 | 1,86029 |
| | | | | | | | | | | | | | |
| ANS | 9 | 0,14298 | -0,49109 | 0,94053 | -0,01411 | -0,62285 | 1,87216 | 0,15709 | 0,13176 | -0,93163 | 0,15709 | 0,13176 | 0,93163 |
| | 10 | 1,18987 | -1,81316 | 1,5482 | 1,03486 | -1,58407 | 1,27019 | 0,15501 | -0,22909 | 0,27801 | 0,15501 | 0,22909 | 0,27801 |
| | 11 | -1,20102 | -4,91002 | 1,33073 | -1,04149 | -4,87145 | -0,00583 | -0,15953 | -0,03857 | 1,33656 | 0,15953 | 0,03857 | 1,33656 |
| | 12 | 1,91294 | -2,02194 | -0,11085 | 1,31092 | -2,47913 | -0,0681 | 0,60202 | 0,45719 | -0,04275 | 0,153155 | 0,621855 | 0,342945 |
| | | 1,60887 | -1,14643 | -0,85157 | 1,90458 | -1,93295 | -0,20843 | -0,29571 | 0,78652 | -0,64314 | | | |
| | 13 | 0,24401 | -4,19999 | 3,61952 | 0,05755 | -2,02951 | 2,27749 | 0,18646 | -2,17048 | 1,34203 | 0,18646 | 2,17048 | 1,34203 |
| | 14 | -1,08102 | -4,32178 | 2,28418 | 0,99953 | -4,90692 | 2,59753 | -2,08055 | 0,58514 | -0,31335 | 2,08055 | 0,58514 | 0,31335 |
| | 15 | -1,63919 | -3,08794 | 0,41811 | 0,6693 | -5,29361 | 2,87304 | -2,30849 | 2,20567 | -2,45493 | 2,30849 | 2,20567 | 2,45493 |
| | 16 | 0,08963 | -2,44145 | 4,71284 | -0,88199 | -3,75766 | 2,92669 | 0,97162 | 1,31621 | 1,78615 | 0,97162 | 1,31621 | 1,78615 |
| | | | | | | | | | | | | | |
| U-Mid | 9 | -0,06219 | -1,27804 | 1,11065 | -0,01747 | -2,07401 | 2,21564 | -0,04472 | 0,79597 | -1,10499 | 0,04472 | 0,79597 | 1,10499 |
| | 10 | 0,03253 | -1,73175 | 1,62055 | -0,092 | -0,04669 | 1,19607 | 0,12453 | -1,68506 | 0,42448 | 0,12453 | 1,68506 | 0,42448 |
| | 11 | -1,62409 | -5,35249 | 1,36434 | -1,02345 | -2,87481 | -0,20788 | -0,60064 | -2,47768 | 1,57222 | 0,60064 | 2,47768 | 1,57222 |
| | 12 | -0,24902 | -3,05008 | 0,27828 | 0,72548 | -2,95083 | 0,05237 | -0,9745 | -0,09925 | 0,22591 | 0,522425 | 0,77535 | 0,31012 |
| | | 0,68737 | -1,27192 | -0,77999 | 0,75772 | -2,92187 | 0,06616 | -0,07035 | 1,64995 | -0,84615 | | | |
| | 13 | 0,52675 | -8,50232 | 4,21717 | 0,09336 | -7,67812 | 3,20804 | 0,43339 | -0,8242 | 1,00913 | 0,43339 | 0,8242 | 1,00913 |
| | 14 | -2,06098 | -6,66506 | 2,11361 | -0,5209 | -8,28936 | 2,43164 | -1,54008 | 1,6243 | -0,31803 | 1,54008 | 1,6243 | 0,31803 |
| | 15 | -1,37996 | -5,3994 | 0,82018 | 0,4317 | -10,2926 | 3,96867 | -1,81166 | 4,89323 | -3,14849 | 1,81166 | 4,89323 | 3,14849 |
| | 16 | 0,03106 | -8,34876 | 5,82563 | -0,94029 | -10,2705 | 4,22657 | 0,97135 | 1,92178 | 1,59906 | 0,97135 | 1,92178 | 1,59906 |

Points A, ANS, U-Mid

| | | Predicted movement | | | Actual movement | | | average difference | | | absolute | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Point | case | x | y | z | x | y | z | x | y | z | x | y | z |
| UL3 | 9 | -0,11471 | -1,22888 | 0,60791 | -0,01277 | -2,12466 | 1,57584 | -0,10194 | 0,89578 | -0,96793 | 0,10194 | 0,89578 | 0,96793 |
| | 10 | 0,00092 | -1,62654 | 0,75875 | -0,08739 | -0,03489 | 0,80185 | 0,08831 | -1,59165 | -0,0431 | 0,08831 | 1,59165 | 0,0431 |
| | 11 | -1,59618 | -5,38084 | 0,94573 | -1,02778 | -2,943 | 0,51852 | -0,5684 | -2,43784 | 0,42721 | 0,5684 | 2,43784 | 0,42721 |
| | 12 | -0,97962 | -1,91427 | -1,79659 | 0,09856 | -1,8332 | -0,72466 | -1,07818 | -0,08107 | -1,07193 | 0,555675 | 0,75839 | 0,73046 |
| | | 1,05191 | -2,02299 | -1,34585 | 1,08508 | -3,62084 | -0,95686 | -0,03317 | 1,59785 | -0,38899 | | | |
| | 13 | 0,23808 | -8,11766 | 3,01759 | 0,05694 | -7,87356 | 1,54335 | 0,18114 | -0,2441 | 1,47424 | 0,18114 | 0,2441 | 1,47424 |
| | 14 | -2,56706 | -5,31375 | 0,47588 | -0,68641 | -7,37486 | -0,07782 | -1,88065 | 2,06111 | 0,5537 | 1,88065 | 2,06111 | 0,5537 |
| | 15 | -1,28083 | -5,53212 | 0,28071 | 0,51648 | -10,3279 | 2,14581 | -1,79731 | 4,79579 | -1,8651 | 1,79731 | 4,79579 | 1,8651 |
| | 16 | -0,39566 | -7,61924 | 3,49338 | -0,89036 | -10,3011 | 1,89782 | 0,4947 | 2,68185 | 1,59556 | 0,4947 | 2,68185 | 1,59556 |
| | | | | | | | | | | | | | |
| UR3 | 9 | -0,10661 | -1,36172 | 0,95849 | -0,01316 | -2,09295 | 1,63171 | -0,09345 | 0,73123 | -0,67322 | 0,09345 | 0,73123 | 0,67322 |
| | 10 | -0,10727 | -1,81632 | 2,42105 | -0,19065 | 0,03085 | 2,4336 | 0,08338 | -1,84717 | -0,01255 | 0,08338 | 1,84717 | 0,01255 |
| | 11 | -1,59916 | -5,31249 | 1,46308 | -1,0277 | -2,91774 | 0,54576 | -0,57146 | -2,39475 | 0,91732 | 0,57146 | 2,39475 | 0,91732 |
| | 12 | -1,00715 | -4,16098 | 1,53092 | 0,03076 | -4,00508 | 0,47143 | -1,03791 | -0,1559 | 1,05949 | 0,526215 | 0,797745 | 0,223305 |
| | | 1,1109 | -0,63342 | -0,42296 | 1,12542 | -2,38481 | 0,18992 | -0,01452 | 1,75139 | -0,61288 | | | |
| | 13 | 0,24502 | -8,97959 | 2,92104 | 0,05613 | -7,73338 | 1,52402 | 0,18889 | -1,24621 | 1,39702 | 0,18889 | 1,24621 | 1,39702 |
| | 14 | -2,69701 | -7,66582 | 1,68825 | -0,87804 | -8,84599 | 1,93059 | -1,81897 | 1,18017 | -0,24234 | 1,81897 | 1,18017 | 0,24234 |
| | 15 | -1,26128 | -5,27699 | -0,08533 | 0,49559 | -10,3863 | 2,5421 | -1,75687 | 5,10934 | -2,62743 | 1,75687 | 5,10934 | 2,62743 |
| | 16 | -0,42943 | -9,24184 | 3,70971 | -0,88597 | -10,4909 | 1,65263 | 0,45654 | 1,24907 | 2,05708 | 0,45654 | 1,24907 | 2,05708 |
| | | | | | | | | | | | | | |
| UL6 | 9 | -0,15584 | -1,15087 | 0,12805 | -0,00638 | -2,00509 | 0,72031 | -0,14946 | 0,85422 | -0,59226 | 0,14946 | 0,85422 | 0,59226 |
| | 10 | -0,00484 | -1,57876 | 0,36175 | -0,01443 | -0,16214 | 1,41118 | 0,00959 | -1,41662 | -1,04943 | 0,00959 | 1,41662 | 1,04943 |
| | 11 | -1,47505 | -5,31686 | 0,4824 | -1,03926 | -3,37958 | 2,02134 | -0,43579 | -1,93728 | -1,53894 | 0,43579 | 1,93728 | 1,53894 |
| | 12 | -1,75632 | -1,22286 | -3,23472 | -0,90583 | -1,25683 | -1,29163 | -0,85049 | 0,03397 | -1,94309 | 0,43009 | 0,71865 | 0,817805 |
| | | 1,95499 | -2,35144 | -1,71906 | 1,96468 | -3,75477 | -2,02654 | -0,00969 | 1,40333 | 0,30748 | | | |
| | 13 | -0,38161 | -7,25369 | 0,44808 | -0,02258 | -7,15076 | -1,95176 | -0,35903 | -0,10293 | 2,39984 | 0,35903 | 0,10293 | 2,39984 |
| | 14 | -3,46312 | -4,92135 | -1,21377 | -1,12002 | -7,08541 | -2,56101 | -2,3431 | 2,16406 | 1,34724 | 2,3431 | 2,16406 | 1,34724 |
| | 15 | -1,0784 | -5,05898 | -1,50779 | 0,77007 | -9,22349 | -2,35408 | -1,84847 | 4,16451 | 0,84629 | 1,84847 | 4,16451 | 0,84629 |
| | 16 | -1,16226 | -8,82397 | -0,09625 | -0,78865 | -9,6431 | -2,68944 | -0,37361 | 0,81913 | 2,59319 | 0,37361 | 0,81913 | 2,59319 |
| | | | | | | | | | | | | | |
| UR6 | 9 | -0,15856 | -1,3289 | 0,49564 | -0,00671 | -2,03567 | 0,76315 | -0,15185 | 0,70677 | -0,26751 | 0,15185 | 0,70677 | 0,26751 |
| | 10 | -0,12066 | -1,87102 | 2,88849 | -0,12511 | -0,12484 | 3,88372 | 0,00445 | -1,74618 | -0,99523 | 0,00445 | 1,74618 | 0,99523 |
| | 11 | -1,48309 | -5,2171 | 1,26572 | -1,03858 | -3,33431 | 1,96333 | -0,44451 | -1,88279 | -0,69761 | 0,44451 | 1,88279 | 0,69761 |
| | 12 | -1,95975 | -4,85619 | 2,06265 | -1,05213 | -4,72902 | 0,61132 | -0,90762 | -0,12717 | 1,45133 | 0,43543 | 0,79271 | 0,6929 |
| | | 1,97356 | -0,16253 | -0,25272 | 1,9368 | -1,87512 | -0,18719 | 0,03676 | 1,71259 | -0,06553 | | | |
| | 13 | -0,3373 | -8,69302 | 0,42922 | -0,0196 | -6,99473 | -1,79847 | -0,3177 | -1,69829 | 2,22769 | 0,3177 | 1,69829 | 2,22769 |
| | 14 | -3,37052 | -7,66081 | 0,59365 | -1,13839 | -8,63378 | 0,36508 | -2,23213 | 0,97297 | 0,22857 | 2,23213 | 0,97297 | 0,22857 |
| | 15 | -1,06561 | -4,29615 | -2,29719 | 0,76013 | -8,76235 | -1,78067 | -1,82574 | 4,4662 | -0,51652 | 1,82574 | 4,4662 | 0,51652 |
| | 16 | -1,16226 | -8,82397 | -0,09625 | -0,78865 | -9,6431 | -2,68944 | -0,37361 | 0,81913 | 2,59319 | 0,37361 | 0,81913 | 2,59319 |

Points UL3, UR3, UL6, UR6

| | A | ANS | U-MId | LL3 | LR3 | LL6 | LR6 |
|---|---|---|---|---|---|---|---|
| x | 0.008* | 0.045* | 0.682 | 0.569 | 0.569 | 0.214 | 0.153 |
| y | 1.00 | 0.153 | 0.808 | 0.808 | 0.808 | 0.933 | 0.808 |
| z | 0.072 | 0.109 | 0.109 | 0.072 | 0.153 | 0.808 | 0.214 |

Table 2: P values of the statistical difference for the translation movement of the maxillary points in all three axis, between splint and splintless group

| | | prediction | | | | actual | | | | absolute error | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | x | y | z | | | | | | | | |
| 1 | -3,13 | -1,00 | -0,03 | | 0,00 | 1,50 | -1,50 | | 3,15 | 2,50 | 1,48 |
| 2 | 0,68 | 2,88 | -1,34 | | -1,96 | 0,93 | -1,80 | | 2,64 | 1,95 | 0,46 |
| 3 | 4,80 | 1,13 | -0,54 | | 0,06 | 2,00 | 0,02 | | 4,74 | 0,87 | 0,55 |
| 4 | -5,63 | 1,03 | -0,37 | | -5,00 | -0,10 | -0,10 | | 0,63 | 1,12 | 0,27 |
| 5 | 2,70 | -0,80 | -0,80 | | 0,04 | -3,00 | -0,01 | | 2,65 | 2,20 | 0,79 |
| 6 | -1,56 | 2,22 | 1,11 | | -3,00 | 0,00 | 0,01 | | 1,44 | 2,22 | 1,11 |
| 7 | -5,98 | 1,30 | 0,37 | | -4,98 | 1,57 | 0,03 | | 1,00 | 0,28 | 0,34 |
| 8 | 2,22 | 3,88 | 2,11 | | 0,04 | 1,98 | 2,02 | | 2,18 | 1,89 | 0,10 |

Fig.51 Raw data of the predicted and actual rotation movement of maxilla in all three axes for the splint group, and the absolute error

| | | prediction | | | | actual | | | | absolute error | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 9 | 0,47854 | -1,73849 | 2,61934 | | 2,60916 | -2,25388 | 2,45346 | | 2,13 | 0,52 | 0,17 |
| 10 | 1,62867 | -0,47515 | -0,20975 | | 3,00129 | -0,00275 | 0,0219 | | 1,37 | 0,47 | 0,23 |
| 11 | 0,883 | -0,83419 | 0,12186 | | -3,99984 | 0,03139 | -0,01993 | | 4,88 | 0,87 | 0,14 |
| 12 | -0,20285 | -2,52364 | -0,30473 | | -3,30194 | -2,42115 | -0,18179 | | 3,10 | 0,10 | 0,12 |

Fig.52 Raw data of the predicted and actual rotation movement of maxilla in all three axes for the splintless group, and the absolute error

| | Splint | Splintless | p value |
|---|---|---|---|
| x | 2.30±1.31 | 2.87±1.52 | 0.68 |
| y | 1.62±0.78 | 0.49±0.31 | 0.04* |
| z | 0.63±0.45 | 0.17±0.05 | 0.04* |

Table 3. Mean absolute error and p values for rotation movement for maxilla between splint and splintless groups

| | | prediction | | | actual | | | difference | | | absolute | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| B | 1 | 2,51071 | 2,29321 | -0,55604 | 5,07378 | 2,54476 | 0,70583 | 2,56307 | 0,25155 | 1,26187 | 2,56307 | 0,25155 | 1,26187 |
| | 2 | 0,96614 | -3,55344 | 7,2545 | -2,81666 | -2,74122 | -6,65446 | -3,7828 | 0,81222 | -13,909 | 3,7828 | 0,81222 | 13,90896 |
| | 3 | -1,96566 | 6,44957 | 1,6384 | -0,01686 | 5,62461 | 1,94862 | 1,9488 | -0,82496 | 0,31022 | 1,9488 | 0,82496 | 0,31022 |
| | 4 | -1,66468 | -8,4336 | 3,0537 | -0,96614 | -7,16189 | 2,16302 | 0,69854 | 1,27171 | -0,89068 | 0,69854 | 1,27171 | 0,89068 |
| | 5 | 1,52468 | 1,05659 | 2,99427 | 3,50068 | 7,15998 | -2,48203 | 1,976 | 6,10339 | -5,4763 | 1,976 | 6,10339 | 5,4763 |
| | 6 | -0,75287 | 0,67739 | 0,51176 | -0,70555 | -1,3998 | 2,3902 | 0,04732 | -2,07719 | 1,87844 | 0,04732 | 2,07719 | 1,87844 |
| | 7 | 2,41264 | -8,33459 | -1,31499 | 0,43866 | -9,85226 | 0,861 | -1,97398 | -1,51767 | 2,17599 | 1,97398 | 1,51767 | 2,17599 |
| | 8 | 2,67466 | -2,85989 | 2,41713 | 1,8364 | -1,1904 | 4,28231 | -0,83826 | 1,66949 | 1,86518 | 0,83826 | 1,66949 | 1,86518 |
| Pog | 1 | 2,11284 | 2,57923 | -0,45656 | 5,17338 | 2,22178 | 0,65481 | 3,06054 | -0,35745 | 1,11137 | 3,06054 | 0,35745 | 1,11137 |
| | 2 | 1,72594 | -4,94347 | 7,41057 | -3,99265 | -3,11345 | -6,69269 | -5,71859 | 1,83002 | -14,1033 | 5,71859 | 1,83002 | 14,10326 |
| | 3 | -1,4179 | 6,58489 | 1,65473 | 0,03811 | 6,78423 | 1,79379 | 1,45601 | 0,19934 | 0,13906 | 1,45601 | 0,19934 | 0,13906 |
| | 4 | -1,53837 | -8,79332 | 3,0566 | -1,15853 | -5,39348 | 2,26085 | 0,37984 | 3,39984 | -0,79575 | 0,37984 | 3,39984 | 0,79575 |
| | 5 | 1,99395 | -0,37963 | 3,36161 | 3,83747 | 7,59547 | -2,55274 | 1,84352 | 7,9751 | -5,91435 | 1,84352 | 7,9751 | 5,91435 |
| | 6 | -0,76311 | 0,98693 | 0,42002 | -0,51494 | -1,03153 | 2,28344 | 0,24817 | -2,01846 | 1,86342 | 0,24817 | 2,01846 | 1,86342 |
| | 7 | 2,08531 | -11,6694 | -1,68257 | 0,52541 | -14,9373 | 0,48579 | -1,5599 | -3,2679 | 2,16836 | 1,5599 | 3,2679 | 2,16836 |
| | 8 | 3,75876 | -4,22978 | 2,40508 | 2,94398 | -2,46592 | 4,2644 | -0,81478 | 1,76386 | 1,85932 | 0,81478 | 1,76386 | 1,85932 |
| Me | 1 | 1,86608 | 2,65031 | -0,32155 | 4,99521 | 2,16656 | 0,56723 | 3,12913 | -0,48375 | 0,88878 | 3,12913 | 0,48375 | 0,88878 |
| | 2 | 1,87856 | -5,25506 | 7,0592 | -4,00619 | -3,16111 | -6,7462 | -5,88475 | 2,09395 | -13,8054 | 5,88475 | 2,09395 | 13,8054 |
| | 3 | -1,13507 | 6,63229 | 1,70954 | -0,0201 | 7,16485 | 2,12202 | 1,11497 | 0,53256 | 0,41248 | 1,11497 | 0,53256 | 0,41248 |
| | 4 | -1,36287 | -8,87663 | 2,96362 | -0,81048 | -4,99499 | 2,76289 | 0,55239 | 3,88164 | -0,20073 | 0,55239 | 3,88164 | 0,20073 |
| | 5 | 2,10983 | -0,65924 | 3,04272 | 3,44497 | 7,60935 | -2,46827 | 1,33514 | 8,26859 | -5,51099 | 1,33514 | 8,26859 | 5,51099 |
| | 6 | -0,72726 | 1,06195 | 0,51016 | -0,45077 | -0,93981 | 2,39718 | 0,27649 | -2,00176 | 1,88702 | 0,27649 | 2,00176 | 1,88702 |
| | 7 | 1,73489 | -12,0432 | -2,40301 | 0,50727 | -15,5458 | -0,591 | -1,22762 | -3,5026 | 1,81201 | 1,22762 | 3,5026 | 1,81201 |
| | 8 | 3,94149 | -4,58151 | 2,02948 | 3,00697 | -2,79398 | 3,91522 | -0,93452 | 1,78753 | 1,88574 | 0,93452 | 1,78753 | 1,88574 |
| L-mid | 1 | 2,89164 | 2,04746 | -0,67066 | 5,09741 | 2,75207 | 0,77394 | 2,20577 | 0,70461 | 1,4446 | 2,20577 | 0,70461 | 1,4446 |
| | 2 | 0,3309 | -2,32533 | 7,90367 | -2,27587 | -2,5132 | -6,56731 | -2,60677 | -0,18787 | -14,471 | 2,60677 | 0,18787 | 14,47098 |
| | 3 | -2,64522 | 6,30245 | 1,57529 | -0,01313 | 4,36527 | 1,80152 | 2,63209 | -1,93718 | 0,22623 | 2,63209 | 1,93718 | 0,22623 |
| | 4 | -1,90614 | -8,16314 | 3,14532 | -1,19584 | -8,58247 | 1,61321 | 0,7103 | -0,41933 | -1,53211 | 0,7103 | 0,41933 | 1,53211 |
| | 5 | 0,85861 | 2,99568 | 3,01581 | 3,67317 | 6,61686 | -2,52128 | 2,81456 | 3,62118 | -5,53709 | 2,81456 | 3,62118 | 5,53709 |
| | 6 | -0,78974 | 0,47549 | 0,44392 | -0,85057 | -1,64316 | 2,30047 | -0,06083 | -2,11865 | 1,85655 | 0,06083 | 2,11865 | 1,85655 |
| | 7 | 2,98581 | -5,67181 | -0,34642 | 0,40022 | -5,87202 | 2,22036 | -2,58559 | -0,20021 | 2,56678 | 2,58559 | 0,20021 | 2,56678 |
| | 8 | 1,7965 | -1,53176 | 3,10233 | 1,17122 | 0,03642 | 4,92092 | -0,62528 | 1,56818 | 1,81859 | 0,62528 | 1,56818 | 1,81859 |
| LL3 | 1 | 2,74952 | 2,44269 | -0,83724 | 4,91711 | 3,24018 | 0,83901 | 2,16759 | 0,79749 | 1,67625 | 2,16759 | 0,79749 | 1,67625 |
| | 2 | 0,28516 | -2,23757 | 7,94233 | -1,90175 | -3,32122 | -7,6889 | -2,18691 | -1,08365 | -15,6312 | 2,18691 | 1,08365 | 15,63123 |
| | 3 | -2,59613 | 6,04881 | 2,12548 | -0,09473 | 4,46828 | 2,21764 | 2,5014 | -1,58053 | 0,09216 | 2,5014 | 1,58053 | 0,09216 |
| | 4 | -1,85183 | -8,55722 | 3,20233 | -1,03596 | -9,86008 | 1,56814 | 0,81587 | -1,30286 | -1,63419 | 0,81587 | 1,30286 | 1,63419 |
| | 5 | 0,8372 | 3,06655 | 2,96978 | 3,11266 | 7,84598 | -2,39587 | 2,27546 | 4,77943 | -5,36565 | 2,27546 | 4,77943 | 5,36565 |
| | 6 | -0,76436 | 0,26 | 0,56131 | -0,89967 | -1,80692 | 2,64778 | -0,13531 | -2,06692 | 2,08647 | 0,13531 | 2,06692 | 2,08647 |
| | 7 | 2,58907 | -4,91884 | -1,28237 | 0,36632 | -5,82184 | 1,02898 | -2,22275 | -0,903 | 2,31135 | 2,22275 | 0,903 | 2,31135 |
| | 8 | 1,67206 | -1,22111 | 3,57804 | 0,94153 | 0,66291 | 5,41782 | -0,73053 | 1,88402 | 1,83978 | 0,73053 | 1,88402 | 1,83978 |
| LR3 | 1 | 2,77249 | 1,62785 | -0,29239 | 4,86243 | 2,34345 | 0,56357 | 2,08994 | 0,7156 | 0,85596 | 2,08994 | 0,7156 | 0,85596 |
| | 2 | 0,25494 | -2,2512 | 7,12209 | -1,96043 | -1,8032 | -5,81034 | -2,21537 | 0,448 | -12,9324 | 2,21537 | 0,448 | 12,93243 |
| | 3 | -2,54194 | 6,54631 | 1,12752 | -0,08784 | 4,1552 | 2,15142 | 2,4541 | -2,39111 | 1,0239 | 2,4541 | 2,39111 | 1,0239 |
| | 4 | -1,71834 | -7,69753 | 2,9166 | -0,54993 | -7,94783 | 2,52512 | 1,16841 | -0,2503 | -0,39148 | 1,16841 | 0,2503 | 0,39148 |
| | 5 | 0,87737 | 3,06449 | 2,34136 | 3,39896 | 5,21737 | -2,46785 | 2,52159 | 2,15288 | -4,80921 | 2,52159 | 2,15288 | 4,80921 |
| | 6 | -0,7649 | 0,45999 | 0,51983 | -0,90904 | -1,73354 | 2,22841 | -0,14414 | -2,19353 | 1,70858 | 0,14414 | 2,19353 | 1,70858 |
| | 7 | 2,74761 | -6,68553 | -0,75842 | 0,37987 | -6,13349 | 1,30349 | -2,36774 | 0,55204 | 2,06191 | 2,36774 | 0,55204 | 2,06191 |
| | 8 | 1,57569 | -1,61001 | 2,00013 | 0,84521 | -0,38204 | 3,84442 | -0,73048 | 1,22797 | 1,84429 | 0,73048 | 1,22797 | 1,84429 |
| LL6 | 1 | 2,35845 | 2,73974 | -0,75044 | 4,35482 | 3,69721 | 0,74097 | 1,99637 | 0,95747 | 1,49141 | 1,99637 | 0,95747 | 1,49141 |
| | 2 | 0,00675 | -1,85879 | 6,3428 | -0,38021 | -3,55815 | -8,51878 | -0,38696 | -1,69936 | -14,8616 | 0,38696 | 1,69936 | 14,86158 |
| | 3 | -2,18916 | 5,92977 | 2,59101 | -0,40541 | 4,55898 | 3,77123 | 1,78375 | -1,37079 | 1,18022 | 1,78375 | 1,37079 | 1,18022 |
| | 4 | -1,32941 | -8,9284 | 2,95425 | 0,36959 | -11,0442 | 3,06838 | 1,699 | -2,1158 | 0,11413 | 1,699 | 2,1158 | 0,11413 |
| | 5 | 0,93363 | 2,99992 | 1,79799 | 1,16789 | 9,03974 | -1,97286 | 0,23426 | 6,03982 | -3,77085 | 0,23426 | 6,03982 | 3,77085 |
| | 6 | -0,65925 | 0,14992 | 0,8914 | -0,89665 | -1,90304 | 3,11924 | -0,2374 | -2,05296 | 2,22784 | 0,2374 | 2,05296 | 2,22784 |
| | 7 | 1,46349 | -3,99778 | -3,81346 | 0,26645 | -5,77978 | -2,55578 | -1,19704 | -1,782 | 1,25768 | 1,19704 | 1,782 | 1,25768 |
| | 8 | 1,12256 | -0,86973 | 2,52369 | -0,13687 | 1,20347 | 4,47962 | -1,25943 | 2,0732 | 1,95593 | 1,25943 | 2,0732 | 1,95593 |
| LR6 | 1 | 2,34093 | 1,30893 | 0,24943 | 4,22933 | 2,07533 | 0,23205 | 1,8884 | 0,7664 | -0,01738 | 1,8884 | 0,7664 | 0,01738 |
| | 2 | -0,05766 | -1,85897 | 4,93514 | -0,3401 | -1,25381 | -5,71297 | -0,28244 | 0,60516 | -10,6481 | 0,28244 | 0,60516 | 10,64811 |
| | 3 | -2,20586 | 6,79217 | 0,80131 | -0,37808 | 3,8305 | 3,56095 | 1,82778 | -2,96167 | 2,75964 | 1,82778 | 2,96167 | 2,75964 |
| | 4 | -1,17955 | -7,46442 | 2,51729 | 0,90127 | -7,30638 | 4,42591 | 2,08082 | 0,15804 | 1,90862 | 2,08082 | 0,15804 | 1,90862 |
| | 5 | 1,00383 | 3,07126 | 0,2909 | 1,39735 | 3,85153 | -2,04277 | 0,39352 | 0,78027 | -2,33367 | 0,39352 | 0,78027 | 2,33367 |
| | 6 | -0,66144 | 0,49485 | 0,81621 | -0,89048 | -1,74863 | 2,45448 | -0,22904 | -2,24348 | 1,63827 | 0,22904 | 2,24348 | 1,63827 |
| | 7 | 1,64986 | -7,12121 | -3,09052 | 0,26654 | -5,75575 | -2,53594 | -1,38332 | 1,36546 | 0,55458 | 1,38332 | 1,36546 | 0,55458 |
| | 8 | 1,08554 | -1,63987 | -0,00175 | -0,18069 | -0,59373 | 1,96277 | -1,26623 | 1,04614 | 1,96452 | 1,26623 | 1,04614 | 1,96452 |

Fig.53 Raw data of the predicted and actual translation movement for all mandible points of the splint group, and the absolute error between prediction and actual movement

| | | prediction | | | actual | | | difference | | | absolute | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| B | 9 | -4,84707 | 0,9647 | 0,31289 | -5,45279 | -0,57911 | 0,63902 | -0,60572 | -1,54381 | 0,32613 | 0,60572 | 1,54381 | 0,32613 |
| | 10 | 0,09943 | -4,16036 | -1,10176 | 0,23209 | -5,37522 | 0,80283 | 0,13266 | -1,21486 | 1,90459 | 0,13266 | 1,21486 | 1,90459 |
| | 11 | -2,95246 | -11,4089 | 2,6451 | -2,35086 | -11,5641 | 1,23271 | 0,6016 | -0,15523 | -1,41239 | 0,6016 | 0,15523 | 1,41239 |
| | 12 | -0,38373 | -2,19831 | 5,85463 | 0,25226 | -5,28809 | 6,50071 | 0,63599 | -3,08978 | 0,64608 | 0,63599 | 3,08978 | 0,64608 |
| | 13 | 0,64174 | -11,1198 | 1,51577 | 0,47851 | -11,3094 | 1,56551 | -0,16323 | -0,1896 | 0,04974 | 0,16323 | 0,1896 | 0,04974 |
| | 14 | -3,97904 | 0,09493 | 4,23927 | -4,69673 | 2,16453 | 2,91672 | -0,71769 | 2,0696 | -1,32255 | 0,71769 | 2,0696 | 1,32255 |
| | 15 | -6,61914 | -9,14303 | -1,83251 | -4,81973 | -9,40944 | -0,54298 | 1,79941 | -0,26641 | 1,28953 | 1,79941 | 0,26641 | 1,28953 |
| | 16 | -0,88768 | -7,82421 | -1,87065 | 0,03807 | -13,0391 | 1,81433 | 0,92575 | -5,21485 | 3,68498 | 0,92575 | 5,21485 | 3,68498 |
| Pog | 9 | -6,88836 | 0,11851 | 0,25481 | -7,68455 | -1,79854 | 0,65967 | -0,79619 | -1,91705 | 0,40486 | 0,79619 | 1,91705 | 0,40486 |
| | 10 | -0,25695 | -4,40883 | -1,08771 | 0,23431 | -5,87179 | 0,86042 | 0,49126 | -1,46296 | 1,94813 | 0,49126 | 1,46296 | 1,94813 |
| | 11 | -3,66739 | -14,3515 | 2,73579 | -2,6748 | -13,9606 | 1,28895 | 0,99259 | 0,39095 | -1,44684 | 0,99259 | 0,39095 | 1,44684 |
| | 12 | -0,44643 | -4,55531 | 5,88102 | 0,22828 | -6,25166 | 6,4755 | 0,67471 | -1,69635 | 0,59448 | 0,67471 | 1,69635 | 0,59448 |
| | 13 | 0,84334 | -13,6602 | 1,4105 | 0,67046 | -14,6812 | 1,49762 | -0,17288 | -1,02096 | 0,08712 | 0,17288 | 1,02096 | 0,08712 |
| | 14 | -5,47419 | -1,63407 | 4,50092 | -6,1621 | 1,90057 | 2,77993 | -0,68791 | 3,53464 | -1,72099 | 0,68791 | 3,53464 | 1,72099 |
| | 15 | -7,3475 | -9,5803 | -1,87007 | -5,83715 | -10,5053 | -0,53486 | 1,51035 | -0,925 | 1,33521 | 1,51035 | 0,925 | 1,33521 |
| | 16 | -0,16227 | -9,19718 | -1,89211 | -0,13957 | -16,0606 | 1,83844 | 0,0227 | -6,86346 | 3,73055 | 0,0227 | 6,86346 | 3,73055 |
| Me | 9 | -7,14351 | -0,06232 | 0,03058 | -7,89584 | -2,06613 | 0,37074 | -0,75233 | -2,00381 | 0,34016 | 0,75233 | 2,00381 | 0,34016 |
| | 10 | -0,35491 | -4,47428 | -1,15116 | 0,07081 | -5,99018 | 0,7499 | 0,42572 | -1,5159 | 1,90106 | 0,42572 | 1,5159 | 1,90106 |
| | 11 | -4,00602 | -14,998 | 2,06451 | -2,70313 | -14,4861 | 0,75067 | 1,30289 | 0,51187 | -1,31384 | 1,30289 | 0,51187 | 1,31384 |
| | 12 | -0,50088 | -4,95485 | 5,03631 | 0,13714 | -6,40051 | 6,12359 | 0,63802 | -1,44566 | 1,08728 | 0,63802 | 1,44566 | 1,08728 |
| | 13 | 0,71011 | -14,1832 | 0,66821 | 0,65235 | -15,4106 | 0,52109 | -0,05776 | -1,22744 | -0,14712 | 0,05776 | 1,22744 | 0,14712 |
| | 14 | -5,51809 | -1,99522 | 4,09957 | -5,8442 | 1,85184 | 2,76034 | -0,32611 | 3,84706 | -1,33923 | 0,32611 | 3,84706 | 1,33923 |
| | 15 | -7,17912 | -9,73296 | -2,06461 | -5,59864 | -10,9101 | -1,03926 | 1,58048 | -1,17717 | 1,02535 | 1,58048 | 1,17717 | 1,02535 |
| | 16 | 0,14128 | -9,31628 | -2,29371 | -0,0077 | -16,3371 | 0,91067 | -0,14898 | -7,02079 | 3,20438 | 0,14898 | 7,02079 | 3,20438 |
| L-Mid | 9 | -3,43703 | 1,62393 | 0,569 | -4,02158 | 0,37494 | 0,95472 | -0,58455 | -1,24899 | 0,38572 | 0,58455 | 1,24899 | 0,38572 |
| | 10 | 0,46563 | -3,91023 | -0,99431 | 0,59857 | -4,84717 | 1,02098 | 0,13294 | -0,93694 | 2,01529 | 0,13294 | 0,93694 | 2,01529 |
| | 11 | -2,38889 | -9,78747 | 3,24092 | -2,21242 | -10,2447 | 1,71623 | 0,17647 | -0,45721 | -1,52469 | 0,17647 | 0,45721 | 1,52469 |
| | 12 | -0,29036 | 0,14524 | 6,42966 | 0,33746 | -4,35363 | 6,77166 | 0,62782 | -4,49887 | 0,342 | 0,62782 | 4,49887 | 0,342 |
| | 13 | -0,29036 | 0,14524 | 6,42966 | 0,33746 | -4,35363 | 6,77166 | 0,62782 | -4,49887 | 0,342 | 0,62782 | 4,49887 | 0,342 |
| | 14 | -3,11522 | 1,73985 | 4,93938 | -4,58355 | 2,43257 | 3,04239 | -1,46833 | 0,69272 | -1,89699 | 1,46833 | 0,69272 | 1,89699 |
| | 15 | -6,44154 | -8,8799 | -1,698 | -4,57446 | -8,71388 | -0,21737 | 1,86708 | 0,16602 | 1,48063 | 1,86708 | 0,16602 | 1,48063 |
| | 16 | -2,08045 | -6,44878 | -1,07495 | -0,04267 | -9,89683 | 3,45607 | 2,03778 | -3,44805 | 4,53102 | 2,03778 | 3,44805 | 4,53102 |

| | | actual | | | prediction | | | difference | | | absolute | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| LL3 | 9 | -3,06394 | 1,23785 | -0,98352 | -3,53971 | -0,2601 | -0,76741 | -0,47577 | -1,49795 | 0,21611 | 0,47577 | 1,49795 | 0,21611 |
| | 10 | 0,44532 | -3,90726 | -1,39644 | 0,3574 | -4,24339 | 0,77031 | -0,08792 | -0,33613 | 2,16675 | 0,08792 | 0,33613 | 2,16675 |
| | 11 | -2,37495 | -8,68895 | 2,24408 | -2,1134 | -9,84288 | 1,13033 | 0,26155 | -1,15393 | -1,11375 | 0,26155 | 1,15393 | 1,11375 |
| | 12 | -0,31701 | 0,36527 | 5,79728 | 0,27836 | -4,11115 | 6,51876 | 0,59537 | -4,47642 | 0,72148 | 0,59537 | 4,47642 | 0,72148 |
| | 13 | 0,55169 | -8,3909 | 2,15056 | 0,34043 | -8,16275 | 2,29109 | -0,21126 | 0,22815 | 0,14053 | 0,21126 | 0,22815 | 0,14053 |
| | 14 | -2,62875 | 1,20158 | 3,40361 | -3,7259 | 0,83798 | 2,3095 | -1,09715 | -0,3636 | -1,09411 | 1,09715 | 0,3636 | 1,09411 |
| | 15 | -5,80622 | -9,55039 | -2,50771 | -3,70667 | -9,52428 | -1,54946 | 2,09955 | 0,02611 | 0,95825 | 2,09955 | 0,02611 | 0,95825 |
| | 16 | -1,90693 | -7,03308 | -0,85949 | 0,07949 | -10,2502 | 2,5615 | 1,98642 | -3,21713 | 3,42099 | 1,98642 | 3,21713 | 3,42099 |
| LR3 | 9 | -3,40182 | 2,0841 | 1,85806 | -3,8923 | 1,11327 | 2,23021 | -0,49048 | -0,97083 | 0,37215 | 0,49048 | 0,97083 | 0,37215 |
| | 10 | 0,47551 | -3,91194 | -0,79235 | 0,34012 | -5,41906 | 0,8896 | -0,13539 | -1,50712 | 1,68195 | 0,13539 | 1,50712 | 1,68195 |
| | 11 | -2,36928 | -9,84954 | 3,37493 | -2,14197 | -9,77776 | 1,61078 | 0,22731 | 0,07178 | -1,76415 | 0,22731 | 0,07178 | 1,76415 |
| | 12 | -0,32265 | 0,08223 | 5,83709 | 0,27264 | -4,51481 | 6,52542 | 0,59529 | -4,59704 | 0,68833 | 0,59529 | 4,59704 | 0,68833 |
| | 13 | 0,55815 | -9,27754 | 1,8503 | 0,33893 | -8,45258 | 1,99486 | -0,21922 | 0,82496 | 0,14456 | 0,21922 | 0,82496 | 0,14456 |
| | 14 | -2,76938 | 2,55946 | 5,43193 | -3,83698 | 4,07819 | 3,81444 | -1,0676 | 1,51873 | -1,61749 | 1,0676 | 1,51873 | 1,61749 |
| | 15 | -5,88699 | -7,89994 | -1,1512 | -3,77309 | -7,21654 | 0,2578 | 2,1139 | 0,6834 | 1,409 | 2,1139 | 0,6834 | 1,409 |
| | 16 | -1,85859 | -5,94243 | -1,88002 | 0,052 | -9,70274 | 2,93176 | 1,91059 | -3,76031 | 4,81178 | 1,91059 | 3,76031 | 4,81178 |
| LL6 | 9 | -2,21916 | 1,00715 | -2,63878 | -2,26598 | -0,65861 | -2,87196 | -0,04682 | -1,66576 | -0,23318 | 0,04682 | 1,66576 | 0,23318 |
| | 10 | 0,45338 | -3,88472 | -1,79488 | -0,31097 | -3,91146 | 0,22663 | -0,76435 | -0,02674 | 2,02151 | 0,76435 | 0,02674 | 2,02151 |
| | 11 | -3,04412 | -7,78615 | -1,16625 | -1,86782 | -9,48722 | -1,42429 | 1,1763 | -1,70107 | -0,25804 | 1,1763 | 1,70107 | 0,25804 |
| | 12 | -0,44388 | 0,96755 | 3,02166 | 0,00288 | -3,71671 | 5,39357 | 0,44676 | -4,68426 | 2,37191 | 0,44676 | 4,68426 | 2,37191 |
| | 13 | -0,1233 | -7,72641 | -0,38815 | 0,10337 | -7,75483 | -1,14974 | 0,22667 | -0,02842 | -0,76159 | 0,22667 | 0,02842 | 0,76159 |
| | 14 | -1,48243 | 0,91053 | 1,07257 | -1,41072 | -0,348 | 1,78056 | 0,07171 | -1,25853 | 0,70799 | 0,07171 | 1,25853 | 0,70799 |
| | 15 | -4,6702 | -9,99168 | -3,34878 | -2,12569 | -10,1365 | -3,32007 | 2,54451 | -0,14483 | 0,02871 | 2,54451 | 0,14483 | 0,02871 |
| | 16 | -1,08982 | -7,27423 | -2,00898 | 0,73454 | -9,95151 | -1,44331 | 1,82436 | -2,67728 | 0,56567 | 1,82436 | 2,67728 | 0,56567 |
| LR6 | 9 | -2,63853 | 2,42301 | 1,94485 | -2,70493 | 1,62926 | 1,96533 | -0,0664 | -0,79375 | 0,02048 | 0,0664 | 0,79375 | 0,02048 |
| | 10 | 0,45045 | -3,92633 | -0,86367 | -0,28507 | -5,75184 | 0,45348 | -0,73552 | -1,82551 | 1,31715 | 0,73552 | 1,82551 | 1,31715 |
| | 11 | -3,00575 | -9,70288 | 0,81172 | -1,88833 | -9,17664 | -0,62608 | 1,11742 | 0,52624 | -1,4378 | 1,11742 | 0,52624 | 1,4378 |
| | 12 | -0,45579 | 0,45423 | 3,06113 | -0,00951 | -4,38985 | 5,39333 | 0,44628 | -4,84408 | 2,3322 | 0,44628 | 4,84408 | 2,3322 |
| | 13 | -0,19296 | -9,09501 | -1,18005 | 0,05379 | -7,81992 | -2,01051 | 0,24675 | 1,27509 | -0,83046 | 0,24675 | 1,27509 | 0,83046 |
| | 14 | -1,68478 | 3,34045 | 4,61848 | -1,45065 | 5,52705 | 4,51082 | 0,23413 | 2,1866 | -0,10766 | 0,23413 | 2,1866 | 0,10766 |
| | 15 | -4,68103 | -7,27256 | -1,16638 | -2,06436 | -6,31454 | -0,46849 | 2,61667 | 0,95802 | 0,69789 | 2,61667 | 0,95802 | 0,69789 |
| | 16 | -0,95587 | -4,81855 | -4,34849 | 0,76906 | -8,45332 | -1,11894 | 1,72493 | -3,63477 | 3,22955 | 1,72493 | 3,63477 | 3,22955 |

Fig.54 Raw data of the predicted and actual translation movement for all mandible points of the splintless group, and the absolute error between prediction and actual movement

| | B | Pog | Me | L-mid | LL3 | LR3 | LL6 | LR6 |
|---|---|---|---|---|---|---|---|---|
| x | 0.049* | 0.08 | 0.13 | 0.1 | 0.049* | 0.049* | 0.44 | 0.44 |
| y | 0.79 | 0.72 | 0.57 | 0.63 | 0.27 | 0.64 | 0.23 | 0.32 |
| z | 0.32 | 0.32 | 0.5 | 0.37 | 0.13 | 0.27 | 0.1 | 0.32 |

Table 4: p-values of the mean absolute error of translation for mandible points between splint and splintless

| | prediction | | | actual | | | absolute difference | | |
|---|---|---|---|---|---|---|---|---|---|
| 1 | -1,16991 | -1,05192 | -1,55915 | 0,76832 | 0,52102 | -1,89201 | 1,93823 | 1,57294 | 0,33286 |
| 2 | 4,29066 | 2,30484 | -0,28673 | 1,09997 | -3,46264 | 2,88971 | 3,19069 | 5,76748 | 3,17644 |
| 3 | -0,54919 | 2,04304 | 0,99954 | -3,91722 | 0,10187 | -0,78226 | 3,36803 | 1,94117 | 1,7818 |
| 4 | 1,05268 | 0,40113 | 1,65225 | -5,45277 | -1,0555 | 4,4215 | 6,50545 | 1,45663 | 2,76925 |
| 5 | 4,84179 | 1,68124 | 0,24844 | 4,84179 | 1,68124 | 0,24844 | 0 | 0 | 0 |
| 6 | -1,16249 | 0,07472 | 0,3969 | -1,38353 | 0,7606 | 0,17331 | 0,22104 | 0,68588 | 0,22359 |
| 7 | 8,06242 | -0,60801 | -3,69988 | 12,34693 | 0,29312 | -0,3837 | 4,28451 | 0,90113 | 3,31618 |
| 8 | 4,05988 | 3,16661 | -1,14924 | 3,76115 | 3,16559 | -2,48853 | 0,29873 | 0,00102 | 1,33929 |

Fig.55 Raw data of the predicted and actual rotation movement of mandible in all three axes for the splint group, and the absolute error

| | prediction | | | actual | | | absolute difference | | |
|---|---|---|---|---|---|---|---|---|---|
| 9 | 2,4896 | -5,82437 | 2,16952 | 3,59186 | -6,08295 | 3,44564 | 1,10226 | 0,25858 | 1,27612 |
| 10 | 0,84701 | -1,21821 | -0,04274 | 1,79268 | -0,30461 | -2,37479 | 0,94567 | 0,9136 | 2,33205 |
| 11 | 7,73797 | -2,10985 | -1,92274 | 6,2096 | -0,8167 | 0,51723 | 1,52837 | 1,29315 | 2,43997 |
| 12 | 7,23715 | -0,23076 | -0,36101 | 2,96361 | -0,07523 | -0,7432 | 4,27354 | 0,15553 | 0,38219 |
| 13 | 7,12752 | 0,54018 | -1,7682 | 9,51737 | 0,5246 | -0,64243 | 2,38985 | 0,01558 | 1,12577 |
| 14 | 5,08542 | -3,73615 | 3,10545 | 0,10966 | -3,02913 | 6,54833 | 4,97576 | 0,70702 | 3,44288 |
| 15 | 1,51603 | -2,64324 | 3,40374 | 4,10282 | -3,47131 | 4,94345 | 2,58679 | 0,82807 | 1,53971 |
| 16 | 3,95471 | 2,14583 | 2,32286 | 8,94166 | -0,43359 | 1,45377 | 4,98695 | 2,57942 | 0,86909 |

Fig.56 Raw data of the predicted and actual rotation movement of mandible in all three axes for the splintless group, and the absolute error

| | Splint | Splintless | p value |
|---|---|---|---|
| x | 2.48±2.30 | 2.85±1.68 | 0.64 |
| y | 1.54±1.85 | 0.84±0.82 | 0.64 |
| z | 1.62±1.36 | 1.68±1.00 | 0.87 |

Table 5: Mean absolute error of rotation for mandible for splint and Splintless, as well as p values of the statistical difference

## *Discussion*

In todays' orthognathic surgery practice, virtual planning is an applauded reality mainly because of the important advantages it offers when compared to the conventional planning(Ref). Nowadays, the most controversial argument in virtual planning for orthognathic surgery is determining the most reliable method of transferring the virtual plan into the operation room. The traditional splint has been used for many years, but because of the development of the virtual planning, it has been consistently substituted by the 3D CAD/CAM splint which is now one of the most common methods use for the transferring of the virtual plan. However, in the last few years, a new and promising transferring approach has been proposed. It consists of a combination of surgical guide, which helps the surgeon determine the exact location and direction of the osteotomy lines, and a fixation plate which stabilizes the osteotomized jaw in its new position. Both the surgical guide and fixation plate are customized for each case and are planned based on the 3D model of the virtual plan once it has been concluded. Along the series of publications on this argument, two characteristics are taken into account: The design of the system, and the accuracy analysis used to evaluate its reliability.

The first reports on systems that did not rely on teeth to reposition the osteotomized jaws were Li et al[55], Gander et al[30], and Mazzoni et al[31]. Li et al system included a resin surgical guide that needed to be adopted on the bone surface and a pencil needed to be used to draw the osteotomy lines. Then a resin fixation plate was fixed with screws in the anterior maxilla to stabilize the maxilla-mandible complex in the final position and conventional fixation plates were screwed in the lateral maxilla for final fixation. Even though this system was a step forward from surgical guides relying on teeth, to independent systems based solely on the outer bone surface of the maxilla, it was rather complicated to use and the fixation plate was not customized. On the other hand, Mazzoni et al and Garder et al were the first to proposed a fully customized surgical guide and fixation plate system. Garder et al was a case report on a customized system composed of a three-piece fixation plate only for maxilla, whereas Mazzoni et al was a case series of ten patients with a customized two-piece fixation plate only for maxilla. A similar concept and design was proposed by Kraime et al[32] in a case report, and by Suojanen et al[33] which constitutes one of the largest samples on this argument with a total of 32 patients. Both studies proposed a two-piece customized fixation plate only for maxilla repositioning.

At the same period, two other authors proposed a different design which included a customized fixation plate not only for maxilla but also for the mandible. Li et al[28] in his study with 10 patients and Burnso et al[34] reporting 6 patients, both proposed a two-piece fixation plate for maxilla, and a novel customized fixation plate for the mandible. The first study that reported a one-piece fixation plate was Heufelder et al[36], in his series of 22 patients. His customized plate was a continuous one-piece fixation plate based in the outer maxillary bone, with no fixation plate planned for the mandible bone.

In the present study, we propose a transferring system composed of a customized titanium surgical guide for maxilla and mandible, followed by a one-piece fixation plate for maxilla and two fixation plates for both sides of the mandible.

With the considerable amount of evidence regarding different transferring methods, the questions that followed were: Are these systems accurate? Which one is the most accurate?

Although many publications have addressed this issue, the answer is still difficult to formulate not only because of new transferring systems continuously being proposed, but also because there is confusion in terms of how to evaluate the accuracy of these methods.

An applausable attempt to answer to these questions was made by Bempt et al[24] in their systematic review of 2018. They concluded that the customized surgical guide and fixation plate system is very promising and shows at present the highest level of accuracy and reliability. However, the amount of evidence is very limited and, as it was also concluded by Haas et al[14] and Stokbro et al[38] in their respective systematic reviews on the accuracy of virtual planning, it is impossible to put the current publications together in a meta-analysis given the heterogeneity of the parameters and methods used to assess the accuracy.

Consequently, besides the different designs proposed for the customized fixation plate system, the method used for the accuracy was resulting very confusing. In order to clarify the present situation, a systematic review of Gaber et al[39] evaluated the different methods and concluded that it is impossible to compare the data available in the literature because of the variety of methods proposed. Moreover, Gaber concluded that in order to have a correct and reliable report on the accuracy of the virtual plan or the transferring methods, two processes must be followed: A voxel-based registration of the 3D pre and post dataset, and a landmark free analysis of the discrepancy.

Based on these recommendations, most of the studies do not qualify as reliable, mostly because the majority of them used a surface-based registration of the pre and post data. As explained in previous chapters, the surface-based registration carries some inaccuracies which compromise the overall reliability of the technique. The only studies that reported a voxel-based registration, were Baan et al and Sun et al but their studies were on the intermediate splint method of transferring. On the other hand, a landmark free registration means that there is no need to appoint the same landmarks at the pre and again at the post dataset, which inevitably carries a human error in it.

In the present study, we used a voxel-based registration for our pre and post dataset and a landmark free approach for the discrepancy analysis. Furthermore, we present the accuracy not only for the maxilla, but also for the mandible by doing a voxel-based registration of the mandible jaw as well, which, to our knowledge, was not previously reported in literature.

The two parameters that we reported for the accuracy of both the maxilla and the mandible are translation and rotation. The movement of each jaw can be precisely described by a total of six values: the translation and the rotation in the x, y and z axes. This means that we must only give the information of the rotation angle and the amount of displacement, and the new position of the jaw can be calculated. However, it is difficult to imagine this kind of movement based solely on numbers. In order to make it easier to quantify the amount of movement, we assigned some points at the pre-dicome dataset, and their position after the surgical movements were calculated based on the information on rotation and translation on each axe.

Among the many studies present in the literature, only two of them reported a comparative study between two different transferring method. Rucksloss at al were the first publication to compare the intermediate splint with the customized fixation plate as means of transferring the virtual plan. Their design included a two-piece fixation plate. They concluded that the customized fixation system was more accurate when compared to the CAD/CAM intermediate splint. However, they used a surface-based registration method, which, as mention above, is not reliable.

The second study which was recently published by Kraiem et al, used a voxel –based registration to compare the difference in accuracy between the intermediate splint and the customized fixation plate. However, they only reported for the accuracy of the maxilla and their system was a two-piece fixation plate.

In the present study, we use a voxel-based registration to compare the accuracy of intermediate CAD/CAM splint with the customized surgical guide and fixation plate. Based on our results, for the maxilla accuracy a significant difference was found for point A and ANS for the translation movement, with splintless group being more accurate. For the rotation movement, there was a significant difference of accuracy for the y (roll) and z (yaw) axes, with the splintless group being more accurate, but no significant difference was found for the x (pitch) group. Given that, for the splintless group, four of our cases were maxilla first surgery, and the other four were mandible first surgery, we used the maxilla first group to compare with the splint group. This was done in order to avoid adding additional inaccuracy based on the surgical approach, given that the mandible first approach, having little vertical control, can result more inaccurate (Ref, paskal). For the mandible accuracy, no significant difference was found between the two groups in terms of rotation, whereas for the translation movement only point B registered a significant difference in the x axe, with splintless group being more accurate.

Based on the result of our study we can formulate the following conclusions:

-Overall, the customized surgical guide and fixation plate resulted more accurate compared to the intermediate CAD/CAM splint.

-For the rotation accuracy of maxilla in the x-axe, even though no significant difference was found between the two groups, the splintless group had a larger margin of inaccuracy. We can hypothesize two causes:

a) the customized surgical guide and fixation plate are planned on the virtual 3D model of the patient once the virtual surgical plan has been decided. This model has been obtained after a segmentation process of the pre-surgery dicom dataset. Given that the segmentation process is a subjective one, it may inaccurately represent the surface of the maxilla bone. Consequently, if the decided maxilla surface during segmentation is different from the actual maxilla bone surface, the customized fixation plate will not perfectly fit, and the surgeon must perform slight intraoperative up or down movements of the fixation plate in order to find the best fitting location. This can produce small discrepancies in rotation.

b) the existence of a play between the screw and the hole not only on the surgical guide but also on the fixation plate, can contribute to the inaccuracy.

-For the translation movement, the fact that the splintless group is more accurate in anterior points such as point A, ANS, and B, might indicate that points that are closer to the fixation plates are more accurately positioned when compared to points further away.

Overall, the customized fixation plate is a reliable method for transferring the virtual plan in the operation theater. It has some limitations that are mainly related to the cost of fabrication and the presence of a third-party company capable of planning and producing such systems. Furthermore, this system lacks the flexibility of a second plan in case anything goes against the plan during the surgery. However, based on the results of our study, it offers a high level of accuracy and reliability.

## *Conclusions*

Among the many methods used for transferring the virtual plan into the operation room the two most common ones are: the CAD/CAM intermediate splint and the customized surgical guide and fixation plate. We compared these two methods, and found that overall the customized fixation plate system is more accurate than the intermediate CAD/CAM splint. Given the lack of significant studies in this argument, more investigations are encouraged in order to be able to put the data in a meta-analysis and have a more conclusive answer on the most reliable method for transferring the virtual plan.

## *Limitations and Future directions*

We consider the following as the limitations of our study:

-The small sample size, especially on the confrontation between maxilla-first and mandible-first surgical approach

-The quality of CBCT dataset is not very high, not just because of intrinsic limitations of the CBCT but also because of the presence of bracket in patients mouth. This way, the overall assessment becomes more difficult.

-The very specific accuracy analysis with an overload of technical information very difficult to comprehend for the clinical surgeon and orthodontist.

The future directions we suggest are the following:

. increase the amount of evidence that compare these two methods of transferring with an extended sample size

-Simplify the workflow of the accuracy analysis in order to make it easily accessible and replicable for the clinical surgeon and orthodontist

-compare the influence of the surgical approach (maxilla-first vs mandible-first) combined with different methods for transferring the virtual plan.

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