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"The Prediction Accuracy of Dolphin 3D Software for Facial Soft Tissue Changes after Bimaxillary Orthognathic Surgery"

Protocol submitted to the Faculty of Dentistry Ain-Shams University in partial fulfillment of the requirements for The Doctor Degree in Oral and Maxillofacial Surgery.

Introduction and Review of literature

During the last decades, there has been tremendous expansion in orthognathic surgery for the correction of dentofacial deformities. Increasingly sophisticated methods have been designed to improve the surgical outcome. At the same time the need to predict the end results has grown, and retrospective studies of treated patients have provided the clinician with guidelines for estimating the soft tissue response to the surgical movements of the osteotomy segments. (1,2)

Two dimensional planning and prediction methods:

The pre-operative planning of orthognathic surgery, and the prediction of the soft tissue changes became highly desirable(3). The early attempts to predict the postoperative profile of patients following orthognathic mandibular surgery is to cut a profile photograph to predict the postoperative appearance. (4,5)

The procedure of digitizing the cephalogram point using computer programs started in the eighties. The technique includes the digitization of the usual cephalometric landmarks by the operator followed by the repositioning of the different parts of the jaw bones using a specialized computer software programs (6,7). The method is more convenient and impresses the patient, but the provided information is no different from the first technique. (8)

However, these studies have focused on the soft-tissue profile as presented on lateral cephalogram, and they do not provide sufficient information to allow an accurate prediction of the postoperative appearance.(8) These Methods were focusing primarily on the lateral cephalogram,(9,10) which is certainly important but of a little direct concern to the patient. Because the patient is often interested in knowing the details of the expected facial appearance following surgery (10,11) video imaging has the potential to radically improve the nature and sophistication of the pretreatment communication between the patient and the doctor regarding the potential esthetic outcomes of the treatment alternatives being considered.(12,13)

Authors have used video imaging modalities for soft tissue prediction which provided a significant advance in the field of both orthodontic and orthognathic prediction(5,6). The basic difference lies in the additional step of superimposing the patient's lateral photograph onto the cephalogram (2D computerized prediction). (14,15) the main limitation of these systems is that the computerized prediction of the soft tissue changes following surgery is limited to the profile which is not suitable for the correction of facial asymmetry. It is important for patients to understand that the image produced is a simulation, which may be similar to but not identical with their final facial appearance.(6,16) In spite of its limitations, this latest method has two major advantages over previous techniques.(17) First, the tracing is digitally stored and can be altered more readily than with other methods. The second advantage of video imaging lies in the improvement of the doctor-patient communication(12,15), it promotes greater understanding and satisfaction with the outcome, as long as the patient recognizes that the prediction is only a goal and not a guarantee. Sarver et al (15) have found that 89% of a sample of patients judged video images to be realistic and thought that the goal was achieved. In addition, 83% of patients reported that the prediction helped them to take a decision regarding the proposed treatment modality. Finally, 72% felt that it also allowed them to be an integral part of the treatment process. Similarly, Kiyak and Bell(18) have shown that less than 45% of the patients who did not have video images as part of the treatment planning, were satisfied with the outcomes of their surgery. Because of the potential impact of video imaging on patient expectations is significant the accuracy of what is being shown becomes critical.(19)

3D Virtual planning and prediction:

The limitations of the Two-dimensional (2D) computer programs for cephalometric measurements and treatment prediction were widely used. Through the development of three-dimensional (3D) examination techniques and computerized analysis methods (Westermark et al. 2005)(20), the opportunity to make 3D computerized predictions of orthognathic treatments has arisen (Gateno et al. 2000, Gateno et al. 2003)(21,22) and authors started to compare the accuracy of both methods where the 3d virtual planning and prediction showed higher accuracy of the 3d than the 2d method. In 2017 Bengtsson et al conducted a prospective randomized blinded case controlled comparison study on Treatment outcome of orthognathic surgery comparing planning accuracy in computer-assisted two- and three dimensional planning techniques, the study showed a statistically significant difference between 3D and 2D prediction methods with an advantage for the 3D. There are several studies on accuracy of 3D planning techniques (Marchetti et al. 2006, Xia et al. 2007, Mazzoni et al. 2010, Tucker et al. 2010, Aboul-Hosn Centenero and Hernandez-Alfaro 2012, Zinser et al. 2012, Hsu et al. 2013)(23–29). The majority of these studies did not test the prediction only; they also assessed transference of planned movements to surgery (occlusal templates) (Xia et al. 2007, Tucker et al. 2010, Aboul-Hosn Centenero and Hernandez-Alfaro 2012, Zinser et al. 2012, Hsu et al. 2013)(24,26,28–30). Almost all of the comparable studies on 3D planning have set the level for linear success at <2 mm and showed high success rates (80%−100%) (*Marchetti et al.* 2006, *Xia et al.* 2007,*Mazzoni et al.* 2010, *Tucker et al.* 2010, *Hsu et al.*

2013)(23,24,26,29). Hsu et al (*Hsu et al.* 2013)(29) presented the largest number of studied subjects (n=65) and found a mean linear difference for the maxilla of 1.1 mm and for the mandible 1.0 mm so it stepped on the 2D limitations with proved higher accuracy.

Soft tissue analysis:

Facial soft tissue analysis is very useful and mandatory for pre-surgical planning, post-surgical evaluation, or for the evaluation and description of maxillofacial growth. Generally, cephalic radiographs have been used to analyze maxillofacial soft tissues (Lines et al., 1978; Ayoub et al.,1996)(31,32) , but these two-dimensional (2D) cephalic radiographs usually focus on the analysis of hard tissues thereby resulting in limitations in the analysis of soft tissues. There are difficulties in reconstructing the three-dimensional (3D) maxillofacial form and performing 3D maxillofacial analysis based on a 2D image. In addition, surgeons wish to demonstrate the facial changes and patients also desire to see the facial changes via 3D images before and after orthognathic surgery. The 2D analysis methods that are currently being used widely such as cephalometric analysis do not fulfill these requirements.

In order to address these shortcomings many studies and clinical applications regarding 3D analysis of the cranio-maxillofacial field are currently being conducted (Swennen et al., 2006)(33).

The ideal measurement method for facial morphological analysis should have the following characteristics: ability to record facial soft tissue data, good accuracy and precision, ability to produce 3D images, and reproducibility (Thomson, 1985)(34). It should also have a low technique sensitivity and be safe for the patients and the operator, noninvasive, quick and easy to perform, and not be too expensive (Miller et al., 2007)(35).

The methods of 3D facial soft tissue analysis that are currently being widely used in clinical practice include contact techniques represented by direct anthropometry (Allanson et al., 1993)(36),and digitizers (de Menezes et al., 2009)(37) and non contact techniques which are 3D laser scans (Moss et al., 1994; Bush and Antonyshyn, 1996)(38,39), stereoscopic camera (Ayoub et al., 1998; de Menezes et al., 2009)(32,37), and 3D computerized tomography (CT) (Moerenhout et al., 2009)(40). Clinicians should be aware of the advantages and disadvantages of each 3D facial soft tissue analysis method.

Contact measurements represented by direct anthropometry is the most common and easy 3D facial soft tissue measurement method. Facial measurement values are obtained by establishing a direct contact between the facial surface and the measurement tool such as vernier callipers. However, this method requires good patient cooperation since he or she needs to stay in a certain position and this is very difficult in children, the elderly, or the disabled. The digitizer method also acquires the measurement values via establishing a direct contact with the subject The reference points are placed in a 3D location of x, y, z coordinates, and the distance between two points is calculated to the nearest 0.000001 mm. This method is precise, but since there is an inevitable time interval between marking the landmarks, it is difficult to apply it in patients who have difficulty in staying still. It measures the fixed objects very accurately, and hence it is commonly used for performing standard measurements. The time taken by the method to perform the measurements is approximately the same as that taken by the direct anthropometry method (1 minute). Direct anthropometry and the digitizer method need to establish a contact with the object (contact measurement methods).

Noncontact measurement methods include 3D cephalometry using 3D CT, 3D laser scan, and stereoscopic camera. 3D CT is highly accurate and 3D facial reconstruction and recording are possible (Fourie et al., 2010)(41). Since CT basically provides sectional view of the object, 3D images of hard tissues and soft tissues are available in a single CT data set (Ono et al., 1992; Moerenhout et al., 2009)(40,42). There are disadvantages of this method such as: the cost is high, the equipment is generally not portable, and patients are exposed to radiation, the texture and colour of tissues cannot be visualized. Cone beam CT is often used because it is cheaper than the fan beam CT (conventional), and it can reduce exposure to radiation and acquire CT data quickly. The cone beam takes approximately 20 seconds to capture the facial image. 3D laser scan uses laser to capture the left and right side images at an interval and combines them into a 3D image. However, since there was an interval between the two scans; breathing motion, facial movement, and the characteristics of soft tissues such as the level of tension and fatigue can lead to errors in the measurements. Therefore, there can be an increased technical error of measurement when it is used in patients with facial problems or disabilities. Since a laser scan can demonstrate the texture of the object, but in monotone, patients might not identify with the 3D images. It takes approximately 30 seconds to capture a facial image by a laser scan.

The stereoscopic camera uses two or more cameras according to the principle of binocular vision. ,It takes two or more plain images of the subject at different angles and distances, and reconstructs a 3D image from plain images (Khambay et al., 2008; Winder et al., 2008; Fourie et al., 2011)(43–45). This method can capture an image in a short time, and demonstrate the colour of the surface. With the development of imaging technology, many different types of stereoscopic cameras have been introduced recently. The image capture time of approximately 1 second was very short. However, for this method the head has to be placed in an appropriate position and angle according to the manufacturer; and some time and effort on the part of the operator are needed to use it properly. Moreover, CT laser scan, and stereoscopic photography are used for providing 3D images and 3D facial measurement values. The other two methods such as direct anthropometry and digitizer scan measure the 3D facial values, but they cannot produce 3D images. Therefore, it needs to determine whether the former three methods provide accurate and reproducible measurement values compared to the latter two methods and to clarify whether 3D image reconstruction can be used as a diagnostic tool or should only be used as a patient consultation tool.

Kook et al, 2014 (46) compared all the five measurement methods and found a high coefficient of reliability, and a high accuracy with a TEM (Technical error of measurement) of less than 0.9 mm. These results are comparable with those in previous reports (Weinberg et al., 2006)(47) . Therefore, it can be stated that all these methods showed good accuracy and reproducibility and hence they can be used in research and in clinical practice. Although the stereo photogrammetry demonstrated a discrepancy compared to the other analysis methods, it was negligible; and therefore, 3D facial soft tissue analysis methods are expected to be appropriate and useful in research and clinical practice.

Comparing pre-operative and post-operative analyses:

Assessing the accuracy of 3D surgical predictions compared to the actual postoperative result relies on similar techniques of superimposition to 2D, but the method of measurement is potentially more complex. To date, several methods of analysis have been reported including: (1) differences in distance of specific landmarks,(48,49) (2) differences between all the 3D points of the two entire facial surface meshes,(50,51) and (3) differences between all the 3D points of the two facial surface meshes following division into predefined anatomical regions.(52) Quantitative analysis of each technique involves measuring the linear distances between specific landmarks or between all of the 3D points of the two 3D surface meshes. This can be performed taking into account the direction using the average distance difference, i.e. the signed difference, or irrespective of direction using the absolute Euclidean difference, and finally the root mean square (RMS) difference. The signed differences will cancel out positive and negative values, under-estimating the error; the absolute Euclidean difference will ignore the direction and only report the magnitude.

Analysis based on surface meshes

Pre and post-operative image registration for comparison:

The analysis of 3D surface polygonal meshes is one method of assessing topographical and positional surface changes in 3D. To assess the accuracy of the software-derived prediction compared to the actual final soft tissue image, registration or superimposition of the two images is required. This can be achieved using two methods. The first involves maintaining the existing hard and soft tissue relationship of each of patient's prediction and actual images and then superimposing the hard tissues on the anterior cranial base. As the hard and soft tissue relationship is 'locked', following hard tissue alignment, the soft tissues will also be aligned relative to their hard tissue position. The distance between the two soft tissue surfaces can then be analyzed. The second option is to ignore the underlying hard tissue and use the forehead region of the soft tissue only to align the two images. The results may be different, especially if the patient has lost adipose tissue from around the upper face region; this will be immediately apparent if the images are aligned on the skull but not if they are aligned on the soft tissue only. Alignment of the images relying on the soft tissue only may also be difficult as there is less surface topography for the images to reliably align on.

Following alignment of the images, the distance between the two surfaces can be determined. The current method is based on the distance between one point on one surface and the closest point to it on the second surface. Note that the measurement relies on the closest point, which may not necessarily be the corresponding anatomical point. Unless the surface meshes are identical, there will be some points on one mesh where the closest point on the second mesh is absent, but the algorithm finds an inappropriate point on the second mesh and produces a large incorrect reading. To overcome the effects of these 'outliers', some studies 'filter-out' the values by using the 95th and 90th percentiles.(50–52)

As the facial surface mesh is made up of thousands of points, an overall mean value for the error is often reported. If one facial surface mesh is totally in front of the other, all the distance measurements will be either positive or negative and therefore the mean is valid. If however some parts of one mesh lie behind and some in front of the other mesh, distance measurements for the whole face will be made up of positive and negative values. Any positive values will cancel out any negative values under-estimating the mean difference and so biasing the results. In order to overcome this problem, some studies use the absolute mean values or Euclidean distances, which ignore the sign (direction) and report on the magnitude of error or the RMS error. The RMS error is derived from all the points making up the surface mesh which makes it not clinically useful, as the site of the error remains unknown; however, dividing the face into anatomical regions and analyzing them separately immediately focuses on the areas of error. Many studies assess the accuracy of the prediction by comparing the differences in distance between the prediction and the actual surfaces using the entire face, including the areas that have been used for alignment, i.e. the areas with minimal change. Therefore a large percentage of the mesh has minimal or no change; this will bias the accuracy by reducing the impact of the error–the data will be skewed towards the smaller values. In order to overcome this, areas of the face used for alignment can be excluded and the remaining mesh divided into anatomically relevant regions this method highlights the true level of error in the predictive ability of the package.

Analysis based on landmarks

The use of landmarks to assess soft tissue is routine practice in orthodontics, especially when analyzing 2D images, i.e. radiographs and photographs. Therefore it seems logical to transfer this method from 2D to 3D. However, this method greatly under-utilizes the 3D data as the positional changes of these landmarks describe a change in an isolated point not a shape change. The associated error of landmark identification will also add to the overall error of this method of analysis and can be over 2 mm depending on the landmark.1If landmarks are going to be used, the data need to be analyzed correctly. To allow comparison, the distance between specific landmarks was recorded; the images were aligned to a common 3D origin and to one another. To analyze the difference, the anatomical point on one mesh is selected and the software calculates the distance 90 degrees to the tangent of the point on the second mesh. The analyzed point may not be the correct anatomical point on the second mesh, but the closest point; the horizontal and vertical components of the direction are also unknown.

Another option is to select the same anatomical landmark on both meshes, extract the 3D coordinates of both points, and use software to calculate the Euclidean distance between the points. This requires an extra step, but is clinically valid. Some software packages will allow direct measurement of the Euclidean distance between the two landmarks. (53)

Dense correspondences and generic conformed facial meshes with and without face division into predefined anatomical landmarks.

For long time, the analysis of three-dimensional (3D) facial images has generally been limited to linear and angular measurements between anatomical landmarks. The operator usually identifies and digitizes a set of landmarks that result in a 3D landmark configuration, which is then used for analysis. The limited number of accurately identifiable landmarks does not allow a comprehensive analysis of the facial morphology. To overcome this problem, the concept of a 'generic mesh' was introduced.(53) The presented innovative approach provides a useful tool for 3D analysis of the face; it provides comprehensive evaluation of the morphological characteristics, which is superior to assessment at a limited set of individual landmarks. A generic mesh can be thought of as a 'simplified symmetrized facial mask' that contains a known number and distribution of points or 'vertices'. The triangles or 'faces' formed by these vertices are indexed or ordered within the file structure. The generic mesh can be used to standardize the number and distribution of vertices for images of the same individual and between individuals. Using the process of 'conformation', the generic facial mesh can be 'wrapped' around any facial image depending on several anchoring landmarks, whilst the remaining points are mathematically fitted or elastically deformed to maintain the surface topography of the original 3D image. The conformation process on the preoperative and postoperative 3D facial images produces two meshes, which have the same number of vertices and triangles. Each vertex represents a corresponding point on the pre- and post-operative conformed meshes. The accuracy of the conformation process of the generic facial meshes will determine the precision in relating the corresponding facial points for the analysis.

Dense correspondence analysis has been reported as an efficient method of analyzing morphological changes, which may explain its broad applications in the medical field.(54) However, despite its accuracy and comprehensiveness in soft tissue analyses, this approach is largely dependent on '3D model elastic deformation', in which the generic facial mesh is elastically deformed to reproduce the individual's facial features. The initial step of the conformation process involved the translation of the corresponding landmarks to match their positions on the target image, followed by elastic deformation to minimize the bending energy. This process included both shape and positional changes. A total of 15 landmarks are used to execute the conformation procedure. To eliminate bias, these landmarks were excluded from the analysis of the accuracy of the conformation procedure. The accuracy of the conformation process has been previously reported.(55,56) In these studies, the accuracy was determined by measuring the inter-surface distance between the conformed mesh and the target models. The disadvantage of this approach is that the magnitude of error is measured as the distance between the closest points on the two surface meshes, namely the target model and the conformed mesh, and not the distances between the actual anatomical corresponding points. Measuring the closest distance between two meshes would not necessarily detect the potential sliding of the surface meshes over one another during the conformation process, which would provide a misleadingly low estimate of the conformation errors. However, the assessment of the accuracy of the conformation process based on specific landmarks also carries the risk of overestimating the accuracy of the conformation process as only a single point on the mesh is analyzed, whilst the remainder of the mesh is not assessed. The Euclidian distance between the actual landmarks on the non-conformed mesh and the landmarks on the conformed generic mesh was used as a measure of accuracy of the conformation process. Although this was not a comprehensive surface-based analysis, its robustness was maximized by carefully selecting the landmarks to represent various anatomical regions of the face, which was believed to be clinically relevant. The analysis was repeated using the classical intersurface distances based on the 90th percentile of the vertices of the two meshes and measuring the mean distances between the conformed mesh and original mesh for all facial expressions. This measure takes into account the direction of error and produces positive and negative values, which depend on the spatial location of the meshes relative to each other. Despite the fact that these measurements are descriptive to the magnitude and the direction of the conformation errors, the mean value of these measurements are underestimated as the positive and negative measurements would cancel each other. Moreover, the Euclidean distances measure the shortest distances between corresponding points on the two surface meshes, irrespective of the directionality of the mismatch between the two surface meshes; therefore, the arithmetic average value of these distances is more meaningful. As expected, the error based on the mean absolute distances is much smaller than those based on the Euclidian distances. Two main factors may contribute to the errors in the conformation process. First, and the most important, is the accuracy and reproducibility of the digitization of the landmarks, which are used in the initial conformation stage. This was minimized in the present study through pre- landmarking. The second source of errors depends on the deficiency in the algorithm of the conformation process.(55) to reduce the effect of landmarking errors, which affects the reliability of the conformation process, 2-mm-diameter round markers were pre-placed on 34 anatomical points on each participant's face. The use of pre-landmark placement significantly reduced the landmarking error and allowed the conformation process to be analyzed comprehensively by eliminating this potential source of error.(57) It can be applied for the evaluation of a sequence of 3D facial images (4D) for the analysis of the dynamics of facial expressions. We expect the method to be fully integrated as a clinical tool with various surgical specialties to improve the quality of diagnosis and prediction planning of corrective facial surgeries. The limitation associated with the visualisation of 3D facial model on a flat screen can be solved with the production of 3D objects using the innovation of 3D printing and rapid prototyping.(58) Then a distance color map can be generated for the visual illustration of the conformation process.

A generic facial mesh is a digitally constructed surface mesh that has the same shape as a typical human face. It consists of a known number of triangles and therefore a known number of points or vertices. (55,59) It is used to overcome the problem of two 3D surface meshes normally having broadly similar shapes but a different number of triangles; making it difficult to directly relate one point on one mesh to the same point on the other mesh. If the generic mesh is “wrapped” around two different 3D facial images, each new generic mesh will have the shape of each of the original 3D images and both new generic meshes will now have the same number of triangles and vertices. Since a point on one generic mesh is the same point on the other, direct anatomical correspondence can be achieved. The application of generic surface meshes allows comprehensive analysis using "dense correspondence analysis" of 3D human facial images using all the point making up the generic mesh pro- viding a comprehensive quantitative evaluation of the examined surfaces(60).

Softwares prediction different computational strategies

The orthognathic planning softwares use several computational strategies (models) to generate soft tissue predictions based on the bone-related planning. These four strategies are: a linear Finite Element Model (FEM), a non-linear Finite Element Model (NFEM), a Mass Spring Model (MSM) and a novel Mass Tensor Model (MTM) Molleman's et al For true validation of these four models we acquired a data set of 10 patients who underwent maxillofacial surgery, including pre-operative and post-operative CT data. For all patient data we compared in a quantitative validation the predicted facial outlook, obtained with one of the four computational models, with post-operative image data. During this quantitative validation distance measurements between corresponding points of the predicted and the actual post-operative facial skin surface, are quantified and visualized in 3D. The results showed that the MTM and linear FEM predictions achieve the highest accuracy. Furthermore, the MTM turned out to be the fastest model, with an average simulation time of only 10 s. Besides this quantitative validation, a qualitative validation study was carried out by eight maxillofacial surgeons, who scored the visualized predicted facial appearance by means of predefined statements. This study confirmed the positive results of the quantitative study, so we can conclude that fast and accurate predictions of the post-operative facial outcome are possible. Therefore, the usage of a maxillofacial soft tissue prediction system is relevant and suitable for daily clinical practice. Our results show that the MTM achieves the same accuracy as the linear FEM, but clearly beats MSM and the linear FEM in simulation time. No significant improvement of the simulation accuracy was found, when using the non- linear FEM. The validation study denotes moreover an acceptable error of the predictions for the MTM and linear FEM when quantitatively measuring distances between the predicted and real post-operative facial outlook. These positive results were confirmed by the qualitative validation study, so that we are able to conclude that maxillofacial soft tissue prediction systems can be used in daily clinical practice. (3)

The 3D color maps permit an objective analysis of the craniofacial structures. The method facilitated the evaluation of orthognathic surgery(61), reconstructive surgery(62),orthodontics(1), growth(63), and creation of facial templates(64). **A 3D color map** is a graphical qualitative and quantitative representation of the distance differences between 2 superimposed 3D images. Currently, most of the software compatible with 3D imaging data has the capability of generating color maps.(64) Color maps provide a qualitative methods of visualizing quantitative changes in skeletal position(63).

In the current study the research team try to formulate a complete surgical planning and prediction protocol that can pair the usage of recent methods of surgical planning, prediction, and assessment with the most reasonably priced service to allow treatment of patients with class II facial deformity in our developing country.

The Aim

The aim of the present study is to evaluate the accuracy of Dolphin 3D software in the prediction of facial soft tissue changes after bimaxillary orthognathic surgery.

Study Hypothesis

There will be no difference between actual soft tissue results and Dolphin 3D software soft tissue prediction.

Patients and Methods

This will be a retrospective study to investigate the accuracy of Dolphin 3d software for the prediction of post-operative soft tissue changes following bimaxillary orthognathic surgery to correct class III jaw defects through combined maxillary advancement and mandibular setback. The study will employ the pre-existing CBCT images routinely captured for orthognathic surgery patients in Glasgow dental hospital and school. Then difference between the pre-operative soft tissue prediction and the 6-month postoperative results will be analyzed. The study will be conducted in Glasgow dental school and hospital using patients pre-existing data after the ethical approval.

Sample size calculation

Based upon the assumption that we need to reach 90% accuracy, in light of the results of Resnick CM et al (2016), the computed effect size for the accuracy of linear measurements was found to be (1.05), using alpha (α) level of (5%) and Beta (β) level of (20%) i.e. power = 80%; the study will include 10 subjects. To compensate for 15% for the use of non-parametric tests; the final minimum estimated sample size will be 12 subjects. Sample size calculation was performed using G*Power Version 3.1.9.2.

Patients to be included:

a) Patients who have class III facial deformity to be corrected using bimaxillary orthognathic surgery.
b) No medical problems that might interfere with general anesthesia or interfere with bone and soft tissue healing.

Patients will be excluded if:

a) There are craniofacial anomalies including cleft lip/palate,
b) Patient have previous maxillofacial operations or facial scars,
c) Correction mandates multi-segment Le Fort I osteotomies,
d) There are orthodontic appliances in place at the time of T1 records.
e) Genioplasty is recommended for deformity correction.
f) There is facial Asymmetry.

All the patients are consented for using their data in research purposes. The CBCT scans of class III patients who undergone maxillary advancement with minimal or without impaction and mandibular setback will be identified. The preoperative and 6 months postoperative CBCT images will be anonymized and will be saved in a password protected computer. Only the research team members will have access to the research data.

In order to quantify the actual amount of surgical movement, the pre and post-operation CBCT voxel based super imposition using ONDEMAND 3d. The surgical movement will be quantified using direct slice land-marking.

Using the pre-operation CBCT to do the surgical mock up and the soft tissue simulation on dolphin 3D. Soft tissue surface models of the simulation and the actual postoperative images will be generated and exported as STLs.

Data Analysis

Superimposition of the predicted and the post-operative STLs and conformation of the generic meshes will be performed. Using VR mesh software, the mesh will be segmented into pre-identified anatomical regions. The distance between the corresponding vertices will be displayed as a colour scale in milli-meter and will be analyzed in the individual dimension of space (x, y and z) using in-house software developed for this purpose and each dimension will be displayed as a colour coded distance map. It will be generated to illustrate the magnitude and anatomical regions with prediction inaccuracies analysis. Using this software, the minimum, maximum, mean, standard deviation (SD), absolute maximum, absolute mean, and absolute SD of 90% of the points of each facial anatomical region will be measured.

Statistical analysis

Numerical data will be explored for normality by checking the distribution of data and using tests of normality (Kolmogorov-Smirnov and Shapiro-Wilk tests). Data will be presented as mean, median, standard deviation (SD), minimum, maximum and 95% Confidence Interval (95% CI) for the mean values. For parametric data, paired t-test will be used to compare between actual soft tissue measurement and software measurement. For non-parametric data, Wilcoxon signed-rank test will be used to compare between actual soft tissue measurement and software measurement. Inter- and intra-examiner reliability will be assessed using Cronbach's alpha and Intra-Class Correlation coefficients.

The significance level will be set at $P \leq 0.05$. Statistical analysis will be performed with IBM® SPSS® Statistics Version 20 for Windows.

® IBM Corporation, NY, USA.

® SPSS, Inc., an IBM Company.

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