Clinical evaluation of the Op-Track (maxillary repositioning) device

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Abstract

Introduction

In vitro analyses by means of imaging, software and model surgery have shown a high degree of precision in terms of the prediction of skeletal movement, but have proven impossible in transferring such strategies with similar accuracy to the patient intra-operatively. Hence, this study was designed to allow pre-operative maxillary assessment, monitor and guide the changes intra-operatively and analyse post-operative position with the help of Op-Track.

Materials and methods

Fifteen subjects were included in this study. Ten patients underwent pre-operative and post-operative measurements, which were subjected to analysis of changes in three axes by comparing them with the help of three methods (orthognathic planning using Erickson platform, Op-Track analysis and cephalometric analysis). Five patients were analysed intra-operatively. Unfortunately, 2 of 5 patients had to be excluded from the study because of procedural impediments and data of the remaining three were not subjected to statistical analysis. However, the intraoperative use of the repositioner detected a minute change of up to 0.1 mm.

Results

The results showed a significant difference in the p-value only in the y (anteroposterior)-axis when comparing method 1 with methods 2 and 3, but the latter two methods had similar outcomes.

Conclusion

Further modifications to the model, detailed discussions and planning with the surgeon would be necessary to facilitate improved results in the operating theatre.

Introduction

Many studies have attempted to use computerized techniques to overcome discrepancies when repositioning the maxilla. In the year 2000, Csaszar and Niederfellmann utilized three-dimensional (3D) orthognathic surgery simulation in reproducing planned patient treatment. Other procedures included virtual surgery on a computer-generated 3D head model simulated by a computer-assisted 3D virtual osteotomy system for orthognathic surgery, a complete system of model surgery and navigation (computerized operation simulation and model operation system), computer-assisted simulation system for orthognathic surgery 2001 software for hard tissue prediction of orthognathic surgical procedures, computer-assisted 3D virtual reality soft tissue planning and prediction for orthognathic surgery, 3D cephalometry and 3D imaging for virtual assessment and treatment planning.

Presently, there are no accurate techniques to determine the actual change in maxillary movement intra-operatively when compared with planned movements. Most surgeons have resorted to using internal reference points, which are of no use once the mucosa has been sutured. Most analytic procedures or software systems involve two-dimensional (2D) approaches (narrowing the spectrum of determining the position of the maxilla at a given time), require specialist expertise and may be cumbersome. Furthermore, other factors that contribute to errors are as follows: (a) error in facebow transfer, (b) difficulty in clinical data transfer, (c) the anaesthetized supine rest position of the mandible and (d) problems in assessing the orientation of bony fragments.

The aim of this study is to evaluate the accuracy of the maxillary repositioner when used pre-operatively and post-operatively and, more importantly, to intra-operatively assess the location of the maxilla throughout the surgery. The main objective would be realized if there are no significant differences between the values obtained from the three methods (orthognathic planning, maxillary repositioning device and cephalometric analysis) for any movement in the transverse (\(x\)), anteroposterior (\(y\)) and vertical (\(z\)) planes. Thus, the repositioner can be developed further to reduce the elaborate laboratory techniques and planning time.

Materials and methods

Subject selection criteria

Fifteen subjects were recruited for the entire study. All patients were undergoing orthognathic surgery (bimaxillary) in our hospital. Exclusion criteria included syndromic patients with deformities, patients undergoing mandibular procedures only and patients undergoing maxillary segmental or midline palatal split procedures. The study was explained to every patient 1 week before surgery.
Orthognathic planning (model surgery using Erickson platform)

One definitive set of alginate impression was taken, clearly defining the incisal and occlusal surfaces and also giving a 1 mm clearance margin around the buccal, palatal and lingual surfaces. Soft red wax was used for bite registration and Denar® facebow and Zhermack® Oculufast silicon impression material was used for facebow registration. A new set of working casts were then fabricated from the moulds. Facebow registration along with casts was transferred to the articulator. The maxillary cast was then mounted onto the Erickson mounting table. Markings are made on the tip of the upper left central incisor, upper left and right canines and upper left and right first molars as reference points. Maxillary midline was marked and the same line was registered at the posterior area of the cast. The advantage of using this model is that it allows visualization, movements and measurements in three planes while providing a stable base for the working cast. Various pre-operative measurements were taken in the x (vertical), y (anteroposterior) and z (transverse) planes for the upper left central incisor, upper left and right canines and upper left and right first molars using the mounted digital calipers and were recorded on the model surgery planning grid. The movements were then marked according to the planned movements (Figure 1). The maxillary cast was then removed and osteotomy cuts were made. The maxillary cast was then replaced back onto the articulator in relation to the mandibular cast with the help of the wax bite. The maxillary cast was then sealed into its new position using hard sticky wax. The palatal and lingual areas of both the casts were blocked off with silicon. The intermediate wafer was constructed using cold cure acrylic. Few holes were posteriorly made, which caters for the intermaxillary fixation (IMF) wires (Figure 2). The casts were replaced and guided into proper occlusion (the anterior teeth being in Class I relationship). The final wafer was constructed, thereby completing the entire procedure.

The Op-Track (a maxillary repositioning) system

The Op-Track system was validated in our department 6 months before the commencement of this study. This comprised of the following: (i) a modified and reprogrammed webcam to work along with the software designed to collect images from the camera and analyse them to determine the position of the target; (ii) the software that is able to provide the operator with the following data: (a) angle of the maxillary movements on the sagittal, coronal and axial planes; (b) distance of the maxilla from the camera in the x, y and z planes and (c) position of the left molar, right molar and central incisors in relation to the camera in the x-transverse, y-anteroposterior and z-vertical planes. The software can be set to give a mean reading of 10, 30, 50 and 100 image captures; the distances are given in millimetres and the angles in degrees. The software also gives the variance of the three angles and the three distances in separate columns; (iii) the target (light source) with a 15 mm probe designed to emit a precisely controlled pattern of light spots; (iv) occlusal wafer with ball-ended clasps specially constructed for every subject to retain the light source. A square stainless steel tube (30 mm in
length) was anteriorly fixed to the wafer, perpendicular to the mid-central incisor point and was used to accommodate the 15 mm probe of the light source; (v) modified plastic safety glasses with Velcro attachments for a secured fit; a screw on its middle is held by rapid cold cure resin to accommodate a webcam and (vi) polysiloxane material along with the safety glasses used to take an impression of the supraorbital ridges and nasal bridge.

Ten subjects were recruited and divided into two groups of fives. Measurements for the first group were taken while in a sitting position and the second group was assessed in a supine position on the dental chair. After connecting the camera to a computer, the safety glasses were placed on the subject’s head and secured in its place with Velcro straps. The wafer was then placed on the subject’s head and the impression material were then secured onto the patient (eyes closed) with the help of Velcro straps to record the supraorbital ridges and nasal bridge. It was recorded as accurately as possible, as the glasses had to be located back on the same place at the post-operative stage. After the material had set, the camera was fitted onto the glasses and the camera was connected to the laptop via a universal serial bus (USB) port. The modified occlusal wafer along with the target light was placed in the patient’s mouth and the target light was switched on. The software was then run and the data were automatically stored onto a file created on the hard drive. The patient was then seen 1 or 2 weeks post-operatively and depending on whether the patient had adequate mouth opening and the final wafer was taken out, post-operative measurements were taken. These measurements were then performed in the same manner as the protocol for the pre-operative measurements (Figure 3).

**Pre-operative/post-operative measurements**

The pre-operative measurements were taken when the patients were called for wafer try-in 1 week before the surgery. This set-up differs from the validation study with respect to the occlusal wafer. Ball-ended clasps were not used. However, to eliminate multiple wafers per patient, the intermediate wafer (with holes for IMF) constructed for use in the surgery was used in our study. The wafer was tried on in the clinic and confirmed to be satisfactory before any measurements were taken. In order for the software to locate the position of the molars and central incisors in relation to the camera, the system was provided with the dimensions of the wafer by measuring the distances of the upper left and right molars and mid-central incisor point in three dimensions from the light source; the three numbers of each point (mesiobuccal cusp of the upper left molar, mesiobuccal cusp of the upper right molar and mid-incisal edge of the left central incisor) were saved in a specific file on the hard disk before starting the program. The patient was then seated on the dental chair, which was adjusted to a complete supine position. The glasses along with the impression material were then secured onto the patient (eyes closed) with the help of Velcro straps to record the supraorbital ridges and nasal bridge. It was recorded as accurately as possible, as the glasses had to be located back on the same place at the post-operative stage. After the material had set, the camera was fitted onto the glasses and the camera was connected to the laptop via a universal serial bus (USB) port. The modified occlusal wafer along with the target light was placed in the patient’s mouth and the target light was switched on. The software was then run and the data were automatically stored onto a file created on the hard drive. The patient was then seen 1 or 2 weeks post-operatively and depending on whether the patient had adequate mouth opening and the final wafer was taken out, post-operative measurements were taken. These measurements were then performed in the same manner as the protocol for the pre-operative measurements (Figure 3).

**Figure 2:** The intermediate wafer with IMF wires
Intra-operative measurements

The whole process was tried on a mannequin before the repositioner was used on a patient in an operating theatre. An intra-operative situation was simulated using a nasopharyngeal tube in the mannequin (Figure 4) to make sure the system suited the theatre set-up. The tube was initially positioned underneath and subsequently over the glasses. The latter technique was found to be more convenient and acceptable by the anaesthetist and surgeon.

The basic mechanism of pre-operative measurements remained the same. The glasses were tried on the patient on the day of the wafer try-in and an impression was taken with the safety glasses and kept aside to make sure it had good stability and the soft tissues were recorded well. On the day of the surgery, after general anaesthesia had been induced, the glasses were placed back and the camera mounted onto position. The intermediate occlusal wafer with the target light source was then fitted onto the upper arch (Figure 5) and secured with inter-maxillary fixation to prevent any movement. Then the camera was connected to the personal computer via a USB port. All operating theatre lights were faced away from the target light. The target light was switched on and the software was run for about 15 s. Baseline data were recorded and saved. The target light and occlusal wafer were removed and replaced on further readings. The surgery was then in progress, and a second reading was taken before the maxilla was down-fractured to make sure that the manipulation during the surgery had not caused movements to the camera. The next reading was taken after the maxilla had been osteotomized to assess the position of the maxilla and its movement to the desired position.

Figure 3: Pre-operative measurements

Figure 4: Mannequin used for pre-operative simulation

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Once repositioning was complete, the maxilla was plated to its new position. The last reading was then taken to assess the minute movements of the maxilla while plating it. The intermediate wafer was then replaced by the final one. Several factors contributed to complications while obtaining the readings, thus leading to erroneous and repetitive measurements (Table 1). Because of these reasons, the measurements performed on the five patients were not included in the statistical analysis.

Although the data could not be subjected to statistical analysis, the system proved to be highly sensitive to the slightest movement of the maxilla in any given plane.

**Cephalometric measurements using Eastman analysis**

The cephalometric radiograph being a 2D representation provides only two working axes (\(x\)-anteroposterior and \(y\)-vertical). It is also assumed that the right and left sides of the patient are equal to each other in terms of measurements corresponding to the incisors and molars, unless any difference is clearly visible. The pre-operative and post-operative cephalometric radiographs were fed to the digitizer. The reference points were analysed and superimposed to evaluate the differences using

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**Table 1 Difficulties and possible solutions during intra-operative measurements**

<table>
<thead>
<tr>
<th>Difficulties</th>
<th>Solutions</th>
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<tbody>
<tr>
<td>Sterilization of the camera without damaging the lens</td>
<td>A protective covering can be used for the camera, so that it can be adequately sterilized.</td>
</tr>
<tr>
<td>Using different head rests in the theatre, resulting in difference to the fit of the glasses</td>
<td>Head rest discussed between the surgeon and operator prior to the procedures.</td>
</tr>
<tr>
<td>Pressure necrosis from the Velcro straps</td>
<td>Glasses along with the fastened Velcro straps have been kept on for about 2.5 h without any evidence of pressure necrosis.</td>
</tr>
<tr>
<td>Camera had to remain in position throughout the surgery, as the drapes covered the glasses for sterilization purposes, and hence, if removed would be outside the sterilization field</td>
<td>Changing the attachment joint of the camera to a click-on ball and socket joint, so that the camera can be removed during the surgery.</td>
</tr>
<tr>
<td>Manipulation of the instruments by the assistant standing at the top of the head led to movement of the camera</td>
<td>Maintain an external reference point, ideally use a screw inserted in the bony nasion to anchor the camera on it. The camera has to be of minimal bulk. Patients should consent for this and this should be part of a routine procedure practised by the orthognathic surgeon.</td>
</tr>
<tr>
<td>Vigorous movements during down-fracture of the maxilla led to movement of the entire set-up, hence repetitive readings were taken to correct the baseline measurements</td>
<td>Maintain an external reference point, ideally use a screw inserted in the bony nasion to anchor the camera on it. The camera has to be of minimal bulk. Patients should consent for this and this should be part of a routine procedure practised by the orthognathic surgeon.</td>
</tr>
<tr>
<td>Micro-movements were constantly in progression, although the silicon impression and the glasses were fitted and positioned as accurately as possible</td>
<td>Maintain an external reference point, ideally use a screw inserted in the bony nasion to anchor the camera on it. The camera has to be of minimal bulk. Patients should consent for this and this should be part of a routine procedure practised by the orthognathic surgeon.</td>
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**Figure 5:** The intermediate occlusal wafer with the target light source as shown intra-operatively.
Dolphin digitizer: The digitizer uses Eastman analysis. The only disadvantage of using this software is that there is a discrepancy of about 1.5 mm, which can be resolved by manual tracing using Eastman analysis (Figure 6).

For the purpose of statistical analysis and final outcome, a definitive frame of reference was used for the evaluation of all the three methods (Op-Track, standard orthognathic planning using Erickson analysis and cephalometric analysis), which originally corresponded with the frame of reference (Table 2) for the maxillary repositioner.

**Results**

All data were converted to SPSS format for statistical analysis. A three-way analysis was performed to observe the changes for three teeth (mesiobuccal cusp of the right molar, mid-incisal edge of the left central incisor and mesiobuccal cusp of the left molar) and three methods (as mentioned before) for all ten patients. If the result varied from the significant value, then Bonferroni’s post-hoc test was used to evaluate the results.

For the purpose of statistical analysis, the post-hoc test was performed for all the x, y- and z-axes changes. The assumptions of normality for changes in the x-axis were not so accurate, the p-value was very large for the method, and so the conclusion that there was no significant difference between the methods could still be assumed. However, the graph showing the ‘estimated marginal means of x’ (Figure 7) gave a symmetrical pattern for both the methods. Furthermore, a box plot diagram (Figure 7) of the means and medians could not be established in this case, which ideally should have an equal distribution. The zero value which signified no change in method 1 partly contributed to the large differences in value and inaccurate assumptions. To eliminate this problem, the data were transformed and a non-parametric test using Wilcoxon signed rank test was used. This showed that the p-value was not significant and there was not much difference in the means for each tooth between the two methods (Table 3).

**Analysis for changes in the x-axis (transverse)**

Univariate analysis was performed comparing only methods 1 and 2, as method 3 could not analyse the changes in the x-axis values. The results showed that the assumptions of normality for changes in the x-axis were inaccurate. The p-value was not significant (as p > 0.01 is significant) for the teeth when considering Bonferroni’s post-hoc tests for the dependent variable x. Although the assumptions of normality in changes between the methods for the x-axis were not so accurate, the p-value was very large for the method, and so the conclusion that there was no significant difference between the methods could still be assumed. However, the graph showing the ‘estimated marginal means of x’ (Figure 7) gave a symmetrical pattern for both the methods. Furthermore, a box plot diagram (Figure 7) of the means and medians could not be established in this case, which ideally should have an equal distribution. The zero value which signified no change in method 1 partly contributed to the large differences in value and inaccurate assumptions. To eliminate this problem, the data were transformed and a non-parametric test using Wilcoxon signed rank test was used. This showed that the p-value was insignificant and there was not much difference in the means for each tooth between the two methods (Table 3).

**Analysis for changes in the y-axis (anteroposterior)**

Univariate analysis was performed to monitor any changes in the y-axis for the given three methods. The p-value was significant, suggestive of differences in the methods. The post-hoc tests clearly showed no difference in the analysis of the teeth, but it showed differences between methods 1 and 2 and methods 1 and 3. However, methods 2 and 3 were similar. It is also well demon-

### Table 2 Frame of reference

<table>
<thead>
<tr>
<th>Operation (x)</th>
<th>Operation (y)</th>
<th>Operation (z)</th>
</tr>
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<tbody>
<tr>
<td>+x change moves the maxilla to the left</td>
<td>−y change moves the maxilla posteriorly</td>
<td>−z change is impaction of the maxilla</td>
</tr>
<tr>
<td>+y change moves the maxilla anteriorly</td>
<td>+y change moves the maxilla anteriorly</td>
<td>+y change moves the maxilla anteriorly</td>
</tr>
<tr>
<td>+z change lowers the maxilla</td>
<td>+z change lowers the maxilla</td>
<td>+z change lowers the maxilla</td>
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</table>
strated in the plot analysis (Figure 8). Even the box plot displaying the means and medians for each method clearly shows that methods 2 and 3 are at an equal range when compared with method 1 (Figure 8), thus confirming the difference in variation of measurements used in method 1.

Analysis for changes in the z-axis (vertical)

Changes in the z-axis were analysed in the same manner as changes in the y-axis. The p-value showed no significant difference in the methods for both univariate analysis and post-hoc tests. The only significant difference seen was between the teeth. But then again, the distribution of the data seemed to be quite proportional for each tooth using the different methods and no significant difference between the means and medians for each of the methods and tooth type (Figure 9).

Discussion

The only statistically significant discrepancy was seen in the process of advancement or pushback (y-axis) when method 1 was compared with the other two methods. In any case, the consistency in the other two methods showing overcorrection in the anteroposterior plane may actually have been contributed by discrepancy in the planning or transfer of treatment plan to the patient. The outcome of measurements showing discrepancies between the surgical outcome and the treatment plan is merely supported by previous results reported in the literature. The repositioner used in this study was designed with simple non-invasive attachments and an advanced tracking software program. The tracking device makes use of three teeth to track the position of the maxilla, which is coincidental and advantageous as these are part of the same teeth used in the model surgery with Erickson technique. This helps in relocating and assessing the maxillary position in a similar manner. The tracking system was able to make linear as well as angular measurements in the x, y and z planes. This makes the system far advantageous for assessing the position of the maxilla, which is difficult to relocate due to its intricate anatomical position. The method worked very well on static subjects (that is, pre-operative/post-operative positions). But when used intra-operatively on a patient undergoing orthognathic surgery, it was open to the elements of stress and strain produced during the procedure. The dynamic aspects were the cutting saw, constant exchange of instruments in the mouth, retraction provided by the assistants and the movements made during the repositioning itself. The tracking system being very sensitive was able to pick up any minute change or movement

Table 3 Test statistics for $x_2 - x_1$ for tooth a, b and c

<table>
<thead>
<tr>
<th></th>
<th>$x_2 - x_1$</th>
</tr>
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<tbody>
<tr>
<td>Z</td>
<td>0.980 (a)</td>
</tr>
<tr>
<td></td>
<td>1.548 (b)</td>
</tr>
<tr>
<td></td>
<td>0.841 (c)</td>
</tr>
<tr>
<td>Asymptotic significance (2-tailed)</td>
<td>0.327</td>
</tr>
</tbody>
</table>
and therefore the baseline recordings had to be taken and changed numerous times. But the one aspect that is certain is that the device can be easily used if the mount for the camera can be changed and the camera can be removed from the surgical field in a fixed position and replaced back for further measurements when necessary. The other option is to use a replacement for the glasses in such a way that the whole set-up comes off in between readings. The latter is obviously difficult, since the attachments were designed for the glasses and it seems to be the most stable material along with the silicon impression in locating external reference points such as the glabella and the nasion.

Conclusion
Further modifications to the model, detailed discussions and planning with the surgeon would be necessary to facilitate improved results in the operating theatre.

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Abbreviations list
2D, two-dimensional; 3D, three-dimensional; CR, coefficient of repeatability; USB, universal serial bus.

References

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