RESEARCH PROTOCOL

In partial fulfilment of the requirements for the degree of MDent(Orth).

TITLE

The sagittal soft tissue changes associated with autorotation of the mandible in response to surgical correction of lower anterior facial height excess.

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INTRODUCTION

Orthognathic surgery is a common treatment modality used in the correction of severe dentofacial deformities. The objective is to produce excellent functional, stable and aesthetic results. The aesthetic results are assessed in terms of facial balance and harmony. As such, it is vital that the orthodontist and the oral surgeon be able to accurately predict the soft tissue response to orthodontic and surgical movement of the jaws.

Considerable research has been undertaken regarding the soft tissue reactions to surgical maxillary advancement [1-16], maxillary elevation [2, 3, 4, 12, 14, 17-21], mandibular advancement [22-29], and mandibular setback [9-12, 30].

In the literature there are only three papers that discuss lower lip and chin changes as a consequence of mandibular autorotation following vertical maxillary impaction [19, 20, 21]. Schendel, Eisenfeld, Bell and Epker [21] investigated the soft tissue changes resulting from maxillary vertical impaction in fourteen adult patients and used a computer morphometric analysis. They reported that the soft tissue pogonion followed the skeletal pogonion in a 1:1 relationship. The lower lip fell lingual to the arc of mandibular autorotation in a 1:1 ratio with maxillary incisor retraction. When assessing this response, the lower lip changes in the horizontal and vertical planes were not related to the degree of mandibular autorotation. The relationship between the altered lower incisor position and the lower lip was not assessed. The interincisal gap was also not measured.

Radney and Jacobs [20] evaluated a group of ten non-growing patients who had undergone maxillary Le Fort I impaction procedures. Their results concurred with the results obtained by Schendel et al [21]. The soft tissues of the chin area responded in a 1:1 ratio with the autorotation of the mandible and the lip at labrale inferius fell within the arc of rotation. However, it responded in a less than 1:1 ratio with the lower incisor tip. The changes in the lower lip at labrale inferius were unpredictable and there was also a poor correlation between the anteroposterior movement of the upper incisors as the maxilla was impacted. It was speculated that this was due to inconsistent muscular tone of the lower lip and chin between pre- and post-operative radiographs, and errors in measurement and landmark location. No accurate prediction data was developed for the change in the lower lip.

Mansour, Burstone and Legan [19] studied the soft tissue profile changes in fourteen patients who underwent maxillary vertical impaction and consequent mandibular autorotation. They concurred that the soft tissue pogonion responded in a 1:1 ratio with the autorotation of the mandible. There was a good correlation between the horizontal change of the lower lip and the reduction in the interlabial gap. The lower lip was shown to follow 75% of the lower incisor movement in the horizontal plane and 93% in the vertical plane. In this study, the mean error value was large at approximately 22% due to the very small change evaluated. When the soft tissue changes are within the magnitude of 1.5 mm, the measurement error becomes more critical. These authors suggested that further investigations be undertaken using some of the independent variables proposed in their study so that it may be possible to increase the predictability of stepwise regression equations significantly.

None of the above mentioned studies had adequate sample size, nor were lip thickness and lip length measured. The highlighted lack of data describing the soft tissue response to mandibular autorotation as a result of maxillary impaction, underscores the necessity of continued research in this field.

OBJECTIVES

The purpose of this research is to retrospectively study the soft tissue changes of the lower lip and chin in the sagittal plane following autorotation of the mandible as a result of treatment for the correction of lower anterior facial height excess. It is hoped that in the future this data will enable clinicians to predict lower lip and soft tissue chin changes more accurately so as to improve treatment planning and to more adequately serve patient expectations.

METHOD

1. Sample size:

The cephalometric radiographs of 24 patients in whom growth had ceased have been selected from amongst the files of a private orthodontic practice. The criterion for subject selection is pure autorotation of the mandible as a consequence of correction of increased lower anterior facial height by maxillary impaction. Three of the 24 patients had additional genioplasty procedures. The sample excluded patients with congenital defects or developmental syndromes. Each patient received full fixed edgewise appliance orthodontic therapy prior to surgery. The incisor teeth were orthodontically decompensated and stabilised 6 weeks pre-surgery. Vertical maxillary impaction was accomplished by a maxillary osteotomy at the Le Fort 1 level by a number of different maxillofacial and oral surgeons. The sample comprises 15 females and 9 males with an average age at surgery of 26.6 years (range 14.9 to 45.0 years).

2. Experimental design:

All lateral cephalometric radiographs have been taken on the same machine by the same operator; using identical source-subject and subject-film distances. Soft tissues were in repose in all cephalograms and the teeth were in occlusion. Each radiograph is of a quality sufficient to enable accurate recording of the soft tissue profile and identification of pertinent hard tissue landmarks. The lateral radiographs for each case will include those taken (i) within a period of four weeks preceding surgery after which time no further orthodontic tooth movement would have occurred negating any further soft tissue changes (referred to hereafter as T1 radiographs)[20]; and (ii) between 4 and 32 months (mean 14.5 months) post-surgery at the time of completion of active post-surgical orthodontic treatment (referred to hereafter as T2 radiographs). T1-T2 will therefore indicate the changes that have taken place as a result of the orthognathic surgical treatment. For each time interval assessed, the data will be divided into two categories: (a) patients who have had maxillary intrusion and genioplasty with a T2 greater than 6 months (3 patients); and (b) patients who had maxillary intrusion only.

3. Measurements:

Cephalometric radiographs will be traced on Ozatex 0.05mm D/Matt drafting film paper (Ozalid SA Pty Ltd, Drawing Office Material, Spartan, Kempton Park, South Africa) using a 6H pencil. Two locating crosses will be scribed directly onto the radiographic film and copied onto each tracing paper after they have been secured onto the radiographs. The anatomic structures to be traced will include sella turcica, the floor of the anterior cranial fossa, superior orbital roof, the nasal bone, the mandible, the maxilla, and the soft tissue outline from glabella to the junction of the chin to the throat. The upper and lower most anteriorly placed incisors will be traced using a standard Unitek tracing template (3M – Unitek Co, Monrovia, California, U.S.A.) located accurately over the incisal tip and aligned along the long axis of the tooth. The following cephalometric landmarks will be identified and traced:

i)	Sella	(S)
ii)	Nasion	(N)
iii)	Lower Incisor Tip	(LIT)
iv)	Lower Incisor Anterius	(LIa)
v)	Infradentale	(In)
vi)	Supramentale	(B)
vii)	Hard Tissue Pogonion	(Pog)
viii)	Gnathion	(Gn)
ix)	Menton	(Me)
x)	Stomion Superius	(Stm-s)
xi)	Stomion Inferius	(Stm-i)
xii)	Labrale Inferius	(Li)
xiii)	Sulcus Inferius	(Si)
xiv)	Soft Tissue Pogonion	(Pog’)
xv)	Soft Tissue Gnathion	(Gn’)
xvi)	Soft Tissue Menton	(Me’)

Reference planes are to be constructed following the method of Phillips, Turvey and McMillian [25], and will include:

i) S-N Plane - Connecting points S and N

ii) X-axis - Constructed through point S at 6 degrees to S-N Plane

iii) Y-axis - Constructed through point S at 90 degrees to the X-axis

Through the use of these planes, a coordinate reference system with an origin at point S will be established. According to Baumrind and Frantz [31], the reproducibility of both sella and nasion rated extremely high.

Landmarks placed on anatomically-formed edges or creases are easy to identify, however, those placed on curves with wide radii show proportionally greater errors of measurement[31]. This was in agreement with an earlier study by Richardson [32], who also demonstrated that horizontal deviations rose towards higher margins of error when anatomical curves in the profile are involved, as is the case with points such as supramentale and menton. Therefore, in order to locate a particular landmark defined as 'most anterior' or 'most posterior' on a curved segment of the tracing, a perpendicular from the X-axis will be dropped to the most anterior or posterior part of the curvature in question and the midpoint of this linear contact area will be established by measuring its distance and then bisecting it [28]. Landmarks numbered iv, vi-ix, and xiii-xvi in the above list require this method of location.

Linear measurements to be investigated:

i) Lower lip thickness

Measured from (a) labrale inferius to lower incisor tip parallel to the X-axis, from (b) labrale inferius to lower incisor anterius, and from (c) labrale inferius to infradentale.

ii) Lower lip length

Measured from stomion inferius to soft tissue menton parallel to the Y-axis.

iii) Interlabial gap

Measured from stomion superius to stomion inferius parallel to Y-axis.

iv) Soft tissue chin thickness

Measured from (a) Pog’ to Pog along a line parallel to the X-axis, from (b) Me’ to Me, and from (c) Gn’ to Gn.

The T1 radiographs will be traced twice and the reference axes will be transferred from the first to the second pre-surgical tracing after superimposing the two tracings over the locating crosses. This will standardize the reference system for each set of tracings for each patient.

The reference axes constructed for each subject on the pre-surgical tracings will then be transferred to each of the post-surgical tracings after superimposing over the cranial base areas along sella tursica, De Costa’s line (line representing the sphenoid plane and the cribriform plate), superior orbital roof, orbit, and the frontonasal area as reference structures[33].

The co-ordinates of every landmark on each tracing will be sequentially computed using a digitizing programme on a Kontron MOP – Videoplan computer (Kontron Messgerate GMBH, Image-analysis-systems 8057 Eching/Munchen, Breslauer Street 2, Germany). The ‘X’ co-ordinates will represent the horizontal distance from the vertical axis, and the ‘Y’ co-ordinates the vertical distance from the horizontal axis, measured in millimetres to an accuracy of one decimal place. A positive value will be assigned to anterior or superior displacements, while a negative value will be assigned to posterior or inferior changes.

The parameters on all the pre-surgical radiographs will be measured twice, the values will be averaged to give a mean, thereby decreasing the error of variability. The error of variability will be further minimized by completing both sets of tracings for an individual patient at the same session[34].

The data that will be recorded on the Kontron computer, will then be organized and tabulated using Statistix version 4.1 software. This data will then be statistically analysed by Dr Piet Becker of the Medical Research Council, Centre for Epidemiological Research in Southern Africa, Pretoria.

4. Statistics:

A series of statistical analyses will be performed including descriptive and correlative procedures.

4.1 Error of method

This will include testing for accuracy of digitizing, intra-examiner repeatability of landmark identification, and inter-examiner accuracy of landmark identification.

4.1.1 Accuracy of digitizing

To test the proficiency of the operator in using the Kontron Videoplan digitizing system, one randomly chosen tracing will be redigitized on ten separate occasions, each at least twenty four hours apart. The coefficient of variation between the ten measurements of each landmark will be used to assess the accuracy of digitizing. A 5% or lower variation is chosen as a clinically acceptable level of accuracy.

a) Intra-examiner repeatability of landmark identification

The duplicate set of data from the pre-surgical tracings for each patient will be used to assess the accuracy of repeatability of landmark identification. A coefficient of repeatability, as utilized by the British Standards Institution[35], will be calculated for each landmark. Mitgard, Bjork and Linder-Aronson [36] reported the accuracy of repeatability of hard tissue landmarks to range from 0.42mm for point S to 2.08mm for orbitale, however, they found that the majority of landmarks were reproducible at an accuracy level of between 1.0 and 1.5mm. Moreover, Hillesund, Fjeld and Zachrisson [37] reported the accuracy of repeatability of soft tissue landmarks to also range from 1.0 to 1.5mm. Therefore, a level of repeatability of less than 1.5mm will be accepted for this study.

b) Inter-examiner accuracy of landmark location

A randomly chosen radiograph will be traced on separate occasions by ten different orthodontists. Each, using the described method, will locate the following six landmarks: Stm-s; Li; Pog'; LIT; In; and Pog. Each landmark on each tracing will then be digitized and the data subjected to statistical analysis to derive a coefficient of variation.

4.2. Statistics for the change from T1 to T2 time interval

Through the application of a Student t-test, it will be determined whether the three genioplasty patients differ significantly from the non-genioplasty patients with respect to the proportional changes between various hard and soft tissue landmarks. The results will then be adjusted for non-equal variances established from Levene's test [38] for equal variance. A finding of no significant difference will allow the two groups to be joined for the study, thereby increasing the sample size. The detection of significant differences between the two groups will exclude the genioplasty patients from the sample. A level of $P<0.05$ is chosen to represent significance.

Descriptive and comparative statistics will be calculated for the data from T1 to T2 time interval. A paired Student t-test will be used to evaluate the significance of the means of the differences between T1 and T2 values for each landmark, as measured in millimetres along both the horizontal and vertical reference planes. A level of $P<0.05$ is chosen to represent significance. The significant changes will then be further evaluated for their clinical relevance. A clinically relevant change is chosen to represent any change of greater than 1.5mm [31, 36, 37].

Those hard and soft tissue landmarks for which statistically significant and clinically relevant changes will be recorded, will be further analysed to assess the relationship between those changes. Correlation and regression analyses will be used in this statistical evaluation following the methodology of Radney and Jacobs [20]. Simple correlation analyses will involve a one-to-one comparison of changes in soft-tissue ratios to changes in hard-tissue ratios. Multiple correlations will be calculated in order to estimate the relative influence of each of two hard-tissue changes on the observed measurements of an associated soft-tissue point. Simple and multiple regression equations will be determined for the correlations that are statistically significant. The multiple regression analysis will assess the relationship of the hard and soft tissue changes, together with an additional factor, the pre-surgical tissue thickness. These calculations will then be used to develop tables of predicted movement.

ETHICAL CLEARANCE:

Application to the Committee for Research on Human Subjects to permit the use of practice records.

RISKS:

None

BENEFITS:

Identification of hard tissue predictors would enable pre-surgical forecasting of new positions for soft tissue landmarks in response to orthognathic surgery. This would assist the clinician in treatment planning with the view of achieving optimum balance and harmony of the face consistently.

BUDGET:

The budget should not exceed R2500. This will include all material costs and statistical services obtained.

TIME SCHEDULE:

Approximately 12 months

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