

Cephalometric soft tissue profile in unilateral cleft lip and palate patients

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SUMMARY Soft tissue profile analysis from cephalometric radiographs is recognized as an important part of the assessment of treatment outcome in cleft lip and palate (CLP), and has previously been found to discriminate between groups better than conventional hard tissue cephalometric analysis. Cephalometric radiographs of 182 12–14-year-old children from the UK with complete unilateral cleft lip and palate (UCLP) were available for this investigation, which aimed to describe the cephalometric soft tissue findings for this group of UK children. Seven soft tissue profile angular variables were measured using Dentofacial Planner Plus (DFP). Thirty films were re-measured two weeks later to assess the reliability of the method, which was acceptable for most of the variables, although use of landmarks related to the lips increased error. Mean nasolabial angle (97.44 degrees), facial convexity (138.02 degrees), and soft tissue ANB (2.99 degrees) compared unfavourably with previously reported data. These findings support the data given in the Clinical Standards Advisory Group study. Soft tissue profile assessment from cephalometric radiographs has acceptable reliability. The results of treatment show poor outcome in the UK compared with published data.

Introduction

Cephalometric analysis was embraced by the orthodontic profession as a method of measuring facial growth and assessing treatment effects in the first half of the twentieth century. Similarly clinicians involved in the care of children with cleft lip and palate (CLP) have found cephalometric radiographs and analysis a valuable tool for assessing facial growth and treatment outcome. There are, however, problems inherent in their use, ranging from difficulties in landmark identification to questions as to the validity of assessing three-dimensional (3D) structures in a two-dimensional projection. In children with CLP these difficulties are further compounded by the disruption of the normal anatomy of the maxilla, due to both the original defect and the surgical correction.

Analysis of the soft tissue profile has recently emerged as a measure that is more likely to be able to detect differences in outcome between groups than conventional skeletal analysis

(Molsted *et al.*, 1992). Soft tissue profile analysis also has the benefit of assessing the external appearance and so perhaps reflects an outcome closer to that perceived by an observer. Cephalometric soft tissue profile analysis, like its hard tissue equivalent, is based on a number of angular and linear variables to describe the soft tissue profile vertically and antero-posteriorly. The landmarks and variables commonly used are in many cases the soft tissue equivalent of conventional hard tissue points and variables with soft tissue ANB angle, nasolabial angle, and facial convexity (including nose) being frequently reported.

Subtelny (1961) was the first to publish longitudinal data on the analysis of the soft tissue profile, prompting other workers to report on soft tissue variables, including those looking at facial form in children with clefts. Coccaro and Pruzansky (1965) reported facial convexity to be flatter than Subtelny's normal population in children with unilateral cleft lip and palate (UCLP), suggesting that this may be due to

flattening of the nasal tip and a thin upper lip. Bishara *et al.* (1986) reported facial convexity and Holdaway angle, whereas Enemark *et al.* (1990) reported linear variables for adults with repaired UCLP, and Semb (1991a,b) gave mixed longitudinal data for skeletal and soft tissue variables for unilateral and bilateral CLP children.

The use of soft tissue variables increased in the early 1990s, with a number of reports that found they were valuable in comparative studies to discriminate between groups (Friede *et al.*, 1991; Brattström *et al.*, 1992; Molsted *et al.*, 1992; Tindlund and Rygh, 1993; Mackay *et al.*, 1994; Capelozza Filho *et al.*, 1996; Roberts-Harry *et al.*, 1996; Spyropoulos and Linder-Aronson, 1997; Da Silva Filho *et al.*, 1998; Leonard *et al.*, 1998; Smahel *et al.*, 1998, 1999). Table 1 summarizes these studies, and shows values for nasolabial angle, facial convexity (including nose), and soft tissue ANB where reported. Non-comparative studies reporting these values are also listed in Table 1 (Sadowsky *et al.*, 1973; Chen and So, 1997). The findings for these variables show values ranging from 98.5 to 119.8 degrees for nasolabial angle, 141.4 to 154.2 degrees for facial convexity, and 1.1 to 6.1 for ANB. Care must be taken in comparing these figures as they are at different ages and some are for mixed cleft types. However, it is interesting that soft tissue ANB has the smallest values for standard deviation, which may explain in part why this has proved to be a useful variable for detecting differences. Nasolabial angle in contrast has a large standard deviation in reported studies (8.6–17.4 degrees).

The aims of this investigation were to describe the soft tissue profile of UK children with UCLP as assessed on cephalometric radiographs, to determine the reliability of the methodology, and to make comparisons with previously published data.

Subjects and methods

Subjects

The subjects for this study were 182 children born in the UK with complete UCLP between the 1st April 1982 and 31st March 1984, aged

between 12 and 14 years at the time of data collection, who were examined as part of the UK Clinical Standards Advisory Group (CSAG) (1998) study. The method for identification of these children, and the inclusion and exclusion criteria, have been described previously (Williams *et al.*, 1998). For the purpose of this study children identified at the time of examination as non-Caucasian were excluded.

Method

Cephalometric radiographs of the 182 children were available. These were obtained in local centres according to local protocols. The films were digitized by a single operator (DRB) directly using a Numonics digipad backlit digitizing tablet (Numonics Accugrid, Numonics Corporation, Montgomeryville, Pennsylvania, USA) in a darkened room to allow the soft tissues to be clearly seen. The films were orientated with true vertical as determined by the film edge vertical. They were analysed using Dentofacial Planner Plus (DFP, v2.02, Dentofacial Software Inc., Toronto, Ontario, Canada), which allows customized analyses to be written. The landmarks digitized are shown in Figure 1 and the measurements calculated by the DFP programme in Table 2. Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS, v9.01, SPSS Inc., Chicago, Illinois, USA). Thirty films were redigitized after a period of two weeks under the same conditions to determine reliability.

Statistical methods

Reliability was assessed by calculating the 95 per cent confidence intervals and 95 per cent limits of agreement (Bland and Altman, 1986) and intra-class correlation coefficients (ICCs). The values for the 30 redigitized films were also analysed using Dahlberg's formula:

$$\text{Error of method}^2 = \Sigma d^2 / 2n$$

where d is the difference between two measurements and n is the number of double determinations. This formula equates to the

Table 1 Cephalometric studies reporting soft tissue parameters in cleft lip and palate subjects.

Authors	Year	Subjects	<i>n</i>	Soft tissue variables	NL angle (degrees)	Fac Conv (degrees)	ANB (degrees)	Comments
Coccaro and Pruzansky	1965	UCLP 6 m–7 yrs	21	Angular	–	142.5	–	Data for age 7 years
Sadowsky <i>et al.</i>	1973	UCLP 4–18 yrs	75	Angular, linear	–	145 (5.0)	–	Longitudinal. Data extrapolated from graphs, data at age 13 yrs
Bishara <i>et al.</i>	1986	Mixed 6–13 yrs	30	Facial convexity and Holdaway	–	149.9 (3.6)	–	Unoperated. 7 UCLP 6–13 yrs
Enemark <i>et al.</i>	1990	UCLP 5–21 yrs	57	Linear, angular	102.1 (8.6)	–	–	Data for age group 8–12 years
Friede <i>et al.</i>	1991	UCLP 7–10 yrs	60	2 angular, 7 linear	105.2–114.9 (11.5)	–	–	Four centre comparison
Semb	1991a,c	UCLP 1–18 yrs	257	Angular, linear	114.5 (10.4)	140.5 (5.3)	5.0 (2.5)	Data for age 13 years Nasolabial angle = PRN–SN–LS Facial convexity (Semb, 1991c)
Brattström <i>et al.</i>	1992	UCLP 16–18 yrs	85	Angular, linear	117.2–129.6* (12.0)	144.9–149.1 (5.0)	2.4–5.3 (2.6)	*ss–sn–prn four centre comparison
Molsted <i>et al.</i>	1992	UCLP 10 yrs	151	Angular, linear	98.5–106.8 (12.5)	148.8–154.2 (6.8)	2.5–6.1 (2.5)	Six centre Eurocleft study
Capelozza <i>et al.</i>	1993	UCLP	26	Linear to N–Pog	–	–	–	Adult unoperated subjects
Tindlund and Rygh	1993	Mixed 6 yrs	68 + 98	Angular, lips to E-plane	–	144.0 (4.89)	3.4 (3.24)	Expansion versus protraction
Mackay <i>et al.</i>	1994	UCLP 5 yrs	20	Angular, lips to E-plane	–	–	4.67 (4.10)	Manchester versus Oslo reference values
Capelozza Filho <i>et al.</i>	1996	UCLP Adults	93	Angular, lip prominence	91.2 (17.9)	–	–	Operated versus unoperated. Data are for operated group
Roberts-Harry <i>et al.</i>	1996	UCLP 10 yrs	32	Angular, linear	109.5 (15.5)	–	4.2 (1.9)	Bristol versus Oslo reference
Chen and So	1997	UCLP	10	Angular	86.8+ (6.17)	144.1 (1.6)	4.1 (1.2)	+PRN–SN–LS
Spyropoulos and Linder-Aronson	1997	BCLP + UCLP 4–19 yrs	43 × 2	Angular, upper lip thickness/length	106.8 (15.7)	–	–	Greeks versus Swedes
Da Silva <i>et al.</i>	1998	BCLP Adult	28	Nasolabial angle	119.8 (17.4) 132.8 (16.3)	–	–	Male unoperated Female unoperated
Leonard <i>et al.</i>	1998	UCLP 8–11 yrs	25	Angular, linear	103.82 (14.42)	149.46 (4.77)	5.98 (2.24)	Compared with Eurocleft centres
Smahel <i>et al.</i>	1998	UCLP Adult	84	Angular, linear	–	141.4–146.8 (1.75)	1.13–4.47 (0.73)	Four groups, historical comparison
Smahel <i>et al.</i>	1999	UCLP 15 yrs	62	Angular, linear	–	–	–	Two groups, historical comparison. Only gave data for variables showing significant differences

* $P < 0.01$, significantly different from zero.

+Intra-class correlation coefficient.

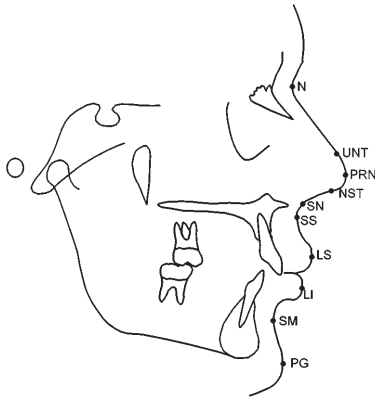


Figure 1 Landmarks used in soft tissue profile analysis (definitions after Molsted *et al.*, 1992). LI, labrale inferius, the most prominent point on the prolabium of the lower lip; LS, labrale superius, the most prominent point on the prolabium of the upper lip; N, soft tissue nasion, the deepest point in the frontonasal curve; NST, nasal septum tangent point, the anterior tangent point of the tangent through SN; PG, soft tissue pogonion, the most prominent point of the chin; PRN, pronasale, the most prominent point on the apex of the nose; SM, soft tissue supramentale, the point of greatest concavity of the lower lip between LS and PG; SN, subnasale, the deepest point on the nasolabial curvature; SS, soft tissue subspinale, the point of greatest concavity or convexity of the upper lip between SN and LS; UNT, upper nasal tangent point, the nasal tangent point of the nasofrontal line.

Table 2 Angular measurements calculated (see Figure 1 for location of landmarks).

Variable	Definition
Nasal projection	UNT–N–SS
Nasal tip angle	N–PRN–SN
Nasolabial angle	NST–SN–LS
Mental fold	LI–SM–PG
Soft tissue ANB	SS–N–SM
Maxillary prominence	SS–N–PG
Facial convexity	N–PRN–PG

reliability coefficient described by Bland and Altman (1986) but allows comparison with previously published data on measurement error. The assumption that the data were normally distributed was tested using the Kolmogorov–Smirnov test.

Results

Distribution

The Kolmogorov–Smirnov test for normality showed NST–SN–LS and SS–N–SM to be mildly skewed, but in view of the large sample size it was appropriate to use simple parametric statistical tests. All other variables were normally distributed.

Reliability

The data for the reliability of each of the measurements are shown in Table 3. The greatest error was related to the variables involving the lips on repeated measurement. The mean, range, and standard deviations for the angular measurements for the complete sample of 182 subjects are given in Table 4.

Discussion

Reliability of method

The use of 95 per cent confidence intervals and 95 per cent limits of agreement were preferred to using tests for significant differences between the means for repeated measurements, such as paired *t*-tests, as the latter will tend to find no significant difference if the power is low, and so falsely indicate reliability of the method (Bland and Altman, 1986). Limits of agreement, the mean difference $\pm 2 \times$ standard deviation, indicates the range that 95 per cent of observations would fall into if repeated for any one individual measurement. Inevitably this gives a greater range than the confidence interval (the mean difference $\pm 2 \times$ standard error), which indicates the range the mean difference would fall into in 95 per cent of cases if the 30 radiographs were measured again and the mean calculated. The ICC indicates the agreement between the first and second measurements. Bland and Altman (1986) also described the use of a reliability coefficient that is very similar to Dahlberg's formula, and in view of the widespread use of the latter in the orthodontic cephalometric literature Dahlberg's formula was used in this study.

Table 3 Paired differences, 95 per cent confidence intervals and limits of agreement, intra-class correlation coefficient, and Dahlberg's error of the method for repeatability of cephalometric angular variables ($n = 30$).

	Paired differences		95% Confidence interval of the difference		95% Limits of agreement		ICC ⁺	Error of the method
	Mean	SD	Lower	Upper	Lower	Upper		
UNT-N-SS	-0.02	0.97	-0.38	0.34	-1.96	1.92	0.94*	2.17
N-PRN-SN	1.13	2.85	0.07	2.19	-4.57	6.83	0.96*	0.68
NST-SN-LS	1.93	4.58	0.28	3.63	-7.23	11.09	0.96*	0.96
LI-SM-PG	0.33	3.32	-0.90	1.57	-6.31	6.97	0.97*	2.17
SS-N-SM	0.16	0.42	0.01	0.32	-0.68	1.00	>0.99*	2.35
SS-N-PG	0.14	0.45	-0.02	0.31	-0.76	1.04	>0.99*	0.33
N-PRN-PG	-0.20	0.75	-0.48	0.08	-1.70	1.30	>0.99*	0.54

⁺Intra-class correlation coefficient.

* $P < 0.01$, significantly different from zero.

Table 4 Descriptive statistics for the soft tissue variables ($n = 182$).

	Minimum	Maximum	Mean	SD
UNT-N-SS	16.10	35.50	25.53	3.27
N-PRN-SN	85.90	113.30	100.72	5.65
NST-SN-LS	49.40	127.20	97.44	14.64
LI-SM-PG	99.80	168.70	131.48	12.99
SS-N-SM	-8.90	11.40	2.99	3.72
SS-N-PG	-9.00	11.30	1.51	3.94
N-PRN-PG	122.30	156.20	138.02	6.56

The reliability varied between the different variables, with some having acceptably low error, but some showing a larger error than is clinically acceptable. Wisth and Bøe (1975) and Hillesund *et al.* (1978) studied the reliability of soft tissue measurements from cephalometric radiographs in non-cleft subjects. Wisth and Bøe (1975) found greater error for soft tissue measurements compared with hard tissue measurements and suggested that this may be due to less well defined anatomical structures and variations in facial expression between cephalometric radiographs (taken 3 weeks apart). They found significant differences in soft tissue facial heights, although they did conclude 'reliability of landmark identification seems comparable to that of hard tissue'. Hillesund *et al.* (1978)

confirmed this in finding the standard error for soft tissue landmark identification using Dahlberg's method to be 0.16–0.47 mm, which they viewed as 'acceptably low'. They concluded that all landmarks were reliable in the horizontal plane, but that errors could arise in identification of labrale inferioris, supramentale, and pogonion in the vertical plane.

The variables in this study with large random errors were: UNT-N-SS, LI-SM-PG, and SS-N-SM. Two of these include the lip points, LS and LI, and two contain point SS. This suggests that these points may be subject to landmark identification error on cephalometric radiographs.

It appears that soft tissue profile measurements from lateral cephalometric radiographs can be made with acceptable reliability; however, this does not mean that they are a valid measure of facial profile. The cephalometric radiograph is not primarily taken for soft tissue profile assessment and care must be taken in using them in this way. It may be more appropriate to use an analysis such as used in this study on profile photographs, and the reliability and validity of this is under investigation. Consideration should also be given to other methods of profile assessment, such as panel assessments (Asher-McDade *et al.*, 1991) and 3D scanning methods (Moss *et al.*, 1987), which may be able to detect other aspects of facial appearance.

Soft tissue profile analysis

The most striking feature of the results of the soft tissue angular analysis is the large range for all of the variables (Table 4). This is best demonstrated by the large values for the standard deviations for some variables, indicating the presence of long tails. This may be a reflection of the wide range of outcomes in facial profile found within this sample. Whilst this may represent the variability in outcome due to treatment factors, variability would be expected in a sample that contains both genders and an age range that may cover the pubertal growth spurt. Another possible cause of variability in the data is head positioning, which could not be standardized across all centres, and can lead to changes in landmark identification. Lip posture may also contribute to the variability in those measurements that included points LI and LS. It is possible that greater attention is placed on obtaining correct head posture and occlusion than correct lip posture during exposure. Subjective examination of radiographs would appear to show inappropriate lip posture on some films.

Comparison of means and standard deviation can be made with the values reported in previous studies and shown in Table 1 for nasolabial angle (NST-SN-LS in this investigation), facial convexity (N-PRN-PG), and soft tissue ANB (SS-N-SM). For nasolabial angle the mean value for this study of 97.4 degrees lies at the lower end of the previous studies, with only Capelozza Filho *et al.* (1996) in a historical group of adults from South America and Chaisrisookumporn *et al.* (1995) in a small sample of mixed ages reporting lower values. A decreased value for nasolabial angle may represent an improved outcome in terms of nose and lip relationship, and at 97.4 degrees is close to the normal value in the non-cleft population. However, examination of cases in this study with very low values for nasolabial angle shows the presence of 'hooked' noses, so it must be borne in mind that extremes at either end of this variable should be regarded as a poor result. In the light of this it is reassuring that the standard deviation for this measurement, while large at 14.6 degrees, is within the range of standard deviations in other work (12.5–17.9

degrees). It seems that while nasolabial angle is a good clinical outcome measure, in that achieving a value near the mean could be regarded as a good result, it does not lend itself to statistical analysis. This may explain why in the Eurocleft study (Molsted *et al.*, 1992) nasolabial angle did not discriminate statistically between groups. However, nasolabial angle is a widely reported variable and the establishment of an acceptable range could be clinically useful. Facial convexity (including the nose) had a mean value in this study of 146.9 degrees, which lies in the middle of the range of values previously reported (141.4–149.9 degrees), but the standard deviation at 7.1 degrees is larger than in other investigations. This would seem to indicate that whilst the mean facial convexity achieved in this group of patients is comparable to other reports there is wider variation in this outcome with more poor results. Soft tissue ANB angle was 2.99 degrees in this study, with a standard deviation of 3.72 degrees. This compares with previous values ranging from 1.2 to 6.1 degrees, with standard deviation ranging from 1.9 to 4.1 degrees. The mean value on this occasion is towards the lower end of the range with only two historical comparison groups (Smahel *et al.*, 1998) and one of the six Eurocleft centres (a UK centre) having worse results (Molsted *et al.*, 1992). The standard deviation is quite large, indicating that a considerable number of the children in this study have a poor outcome in terms of ANB and many had soft tissue ANB values of less than 1.0 degree.

The results of the soft tissue cephalometric findings are in agreement with those of the CSAG (1998) study, which reported poor outcome with regard to hard tissue ANB for this group, with 70 per cent having a value of less than 2 degrees. The CSAG report led to recommendations for changes in the delivery of cleft care in the UK and the data presented here strengthen the evidence in support of those recommendations.

Conclusions

1. Soft tissue profile measurements from lateral cephalometric radiographs can be made with

acceptable reliability, but care must be taken in their use.

2. The validity of soft tissue profile measurements from lateral cephalometric radiographs is unproven.
3. Soft tissue profile variables for a UK sample with UCLP presented here may indicate poorer skeletal growth but comparable nose and lip form to those found in previously published research.

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