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Velopharyngeal changes in a consecutive series of unilateral cleft lip and palate patients between the ages of 10 and 20

S.P. Van Eeden [a], M.J. Birch [b,*], B.C. Sommerlad [c]

[a] North West of England, Isle of Man & North Wales Cleft Lip and Palate Network, United Kingdom
[b] Barts and the London School of Medicine and Dentistry, United Kingdom
[c] North Thames Cleft Centre, United Kingdom

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Summary In the UK, cleft lip and/or palate affects approximately 1 in 700 babies, making it the most common facial birth defect. Approximately 150 (22%) of these will have a complete unilateral cleft of both the lip and palate (CUCLP). The purpose of this study was to establish if a particular surgical method, known as the Sommerlad technique, had over a 10 year period, impacted the growth and movement of the soft palate. The data required for the study was obtained from a retrospective analysis of standardised lateral video-fluoroscopic images. To quantify the changes in palate morphology and function, palatal extensibility, length, thickness, pharyngeal depth and palate velocity during phonation were measured. Measurements were taken at the ages of 10 and 20 years in a consecutive series of 20 CUCLP patients that had undergone palate repair by a single surgeon using the Sommerlad technique Outcome measures were assessed using descriptive statistics and the Students *t*-test was used to describe any significant differences of change with age. Intraclass correlation coefficient (ICC) was incorporated into the study design in order to assess intra- and inter-observer reliability. Palatal length, thickness extensibility and palate velocity increased in all patients between the ages of 10 and 20. The extensibility ratio showed no increase. Inter and intra observer reliability ranged respectively from 0.5 to 0.87 (moderate to good) and 0.67 to 0.91 (moderate to excellent). This study reveals that the soft palate continues to grow and palatal extensibility increases between the ages of 10 and 20 when primarily reconstructed using the Sommerlad technique (Sommerlad, 2003, 2015).

* Correspondence to: Barts and the London School of Medicine and Dentistry, Clinical Physics, Barts and the London NHS Trust, 56 Ashfield St, London E1 2BL, United Kingdom.
E-mail address: m.j.birch@qmul.ac.uk (M.J. Birch).

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Previous studies on palatal growth in cleft and non-cleft patients, carried out using lateral cephalograms, have shown that the soft palate continues to grow following primary surgical repair.[1-4] A further study on the influence of palatal length, nasopharyngeal depth and maxillary growth on speech resonance at different age groups found a correlation between soft palate length, pharyngeal depth and resonance.[5] As these studies used static lateral cephalograms to assess the velopharyngeal structures, it was not possible to assess dynamic velopharyngeal competence or the effect of growth on palatal extensibility. Furthermore, in patients who develop velopharyngeal incompetence between the ages of 10 and 20, it is not known whether this is owing to changes in pharyngeal architecture, adenoidal shrinkage or soft palate extensibility as static lateral cephalograms cannot be used to evaluate palatal movement and extensibility. However, the use of dynamic video-fluoroscopic imaging in this study allows the evaluation of palatal movement and extensibility.

The Sommerlad technique[6,7] is a radical muscle correction for creating a posterior levator sling. Some researchers argued that this radical muscle correction creates a dead space and potential scarring, but we hypothesised that the creation of a posterior levator sling would encourage soft palate lengthening with time.

The aim of this study was to establish if the Sommerlad technique had, over a 10-year period, negatively impacted the growth and dynamics of the soft palate.

Materials and methods

The materials and methods used in this study adhere to the STROBE guidelines.

The patients included in the study are a consecutive series (seen and imaged using standardised lateral video-fluoroscopy in cleft audit clinic at age 10 and then again at age 20) of patients with non-syndromic complete unilateral clefts of the lip and palate (CUCLP). Repair of CUCLP was undertaken by a single surgeon between November 1983 and September 1987 where the lip was repaired at the age of 3 months without closure of the alveolus, and the hard and soft palate were repaired at the age of 6 months with lateral releasing incisions in 17 of the 20 patients. There were 14 males and 6 females in the series and 12 had left-sided clefts and 8 had right-sided clefts. Three patients had Simonart's bands. Prior to the 20-year audit, 3 patients had undergone maxillary osteotomies and 2 had undergone Hynes pharyngoplasties.

Standardised lateral video-fluoroscopies were recorded, by an experienced radiographer with the cleft speech and language therapist and the cleft surgeon in attendance, using a 3D viewing device (View-Master©) fixed to the X-ray table to minimise movement and rotation of the head and to standardise magnification.[4] The radiation dose was minimised by the adherence to the following good practice: The cephalostat (head fixation viewing device) incorporated lead guards to completely shield the orbit of the eyes, the field of view was minimised at the outset of the examination to image only the speech articulators; the protocoled length of articulation was minimised to a very short speech sample typically lasting 10 s and only lateral views were taken. Specific radiological dose measurements were not undertaken; however, an in-depth video-fluoroscopic imaging X-ray dose assessment[8] of velopharyngeal function during speech confirmed that the technique involves a very low dose of radiation exposure.

Prior to each clinical measurement, a metal calibration ring with a known internal diameter, was temporarily attached to the cephostat in the centre of the lateral imaging plane. In this manner, the calibration ring was included in the initial lateral video-fluoroscopic recordings for each patient, to calibrate the magnification factors in each lateral plane. Based on this calibration, the absolute lengths and distances can be calculated.

The measurement errors, including an assessment of the inter/intra class coefficients between 3 operators, analysing images obtained from a similar imaging system have been previously described[9] and found to be reliable (ICC 0.8-0.9). On that basis, no pre-testing of operator observer reliability was carried out; however, reliability testing during the study is described and reported in Table 1.

Recordings were made at 10 and 20 years of age as part of routine cleft care. All recordings were edited onto SVHS tapes, digitised and then reviewed and analysed using Imagepro® software (Media Cybernetics, Inc. Rockville, MD 20850 USA). Measurements were made with the soft palate at rest in the nasal breathing position and at the point of maximal palatal closure during the production of the sound /i/ as previously described.[3] The following linear distances were measured, all of which are illustrated and summarised in Figure 1:

- The point B, located on the nasal surface with the soft palate at rest, is defined as the point from which the apex point C of the soft palate knee is derived. Point C is formed when the soft palate moves from the resting position to the position of maximum closure (soft palate excursion) (BC). Soft palate excursion has previously been referred to as soft palate reach.[4]
- Soft palate length at rest (resting length) (A-E = AB + BE): This is the total length of the soft palate measured from the hard/soft palate junction to the tip of the uvula
- Hard palate to knee at rest (A-B): This is the palatal length measured from the hard/soft palate junction to the knee at rest (point B)
- Soft palate thickness at rest—thickness between superior and inferior surfaces measured at point B
- Soft palate extensibility is defined as the functional length of the soft palate at closure (A-C). Based on these measurements, the following parameters were calculated:

- Closure velocity, the rate at which the soft palate knee moved from the resting position to the position of maximal closure (BC/time - measured as number of video frames).
- Extensibility ratio, a measure of the increase in soft palate length from the resting to extended position (AC:AB). An increase in the extended soft palate length relative to the resting length will give a ratio greater than 1, no change will yield a ratio equal to 1 and a decrease will result in a ration less than 1.

To assess the reliability of the image analysis method, 2 researchers independently carried out the measurements

Table 1 Intra- (repeated by the same measurer) and inter- (comparison between measurer) operator reliability of the measurement of absolute distance. Units are dimensionless. The ICC coefficient[10] is indicative of measurement reliability in the following bands: Less than 0.5, between 0.5 and 0.75, between 0.75 and 0.9 and greater than 0.9, where each band corresponds to poor, moderate, good and excellent reliability, respectively.

Length measured	Figure 1 ref	Intra-operator ICC	Inter-operator ICC
10-year palate length at rest	A-E	0.90	0.78
20-year palate length at rest	A-E	0.70	0.62
10-year hard palate to knee at rest	A-B	0.88	0.70
20-year hard palate to knee at rest	A-B	0.90	0.74
10-year palate thickness at rest	B	0.67	0.61
20-year palate thickness at rest	B	0.65	0.50
10-year palate extensibility	A-C	0.89	0.67
20-year palate extensibility	A-C	0.91	0.87
n, number of subjects	20		

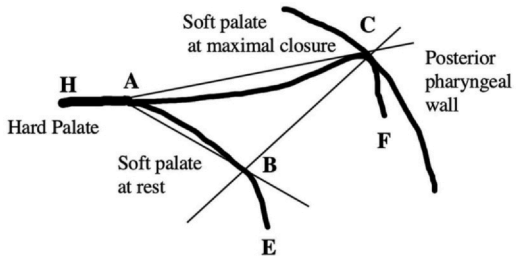

Figure 1 Landmarks used for the analysis of soft palate function. A. Posterior edge of the hard palate. B Point on the soft palate that forms the soft palate knee. C. Soft palate knee at the point of maximal closure on the pharyngeal wall. C. Line BC follows the line of levator action and identifies the point on the posterior pharyngeal wall at which closure/contact occurs.[9,10]

on all data sets and on all parameters shown in Figure 1. The researchers were a cleft surgeon (author SvE) and Clinical Scientist (author MB). Both researchers had extensive experience in measuring soft palate parameters using image analysis. Measurements were repeated after a time lapse of more than two weeks. The inter- (between researchers) and intra- (between repeats) correlation coefficients (ICC) were calculated using the ICC model[11] of 'two way random effects' (generalisable to any operators of similar experience to the researchers), a type of 'mean of two raters' and a definition of 'absolute agreement'. All reliability and general statistical analyses were carried out using the SPSS software version 26 (**IBM** Corp., Armonk, N.Y., USA).

Statistical difference between the 10-year and 20-year morphologies was tested using the Students *t*-test with the associated significance of the result indicated by the p value. Effect sizes were calculated for each of the parameter comparisons using the Cohen's D for *t*-test.

In addition, the study provides a set of descriptive data of palate morphology at the ages of 10 and 20 in a consecutive series of 20 treated patients with CUCLP. The reliability of the study methodology is also analysed.

Results

Results are summarised in Tables 1–3 below.

In all data sets (n=20), the data were found to be normally distributed.

Referring to Table 1, inter-observer reliability ranged from 0.5 to 0.87 (moderate to good) and intra-observer

Table 2 Morphological measurements of the palate in 20 patients at 10 and 20 years of age. Units are in mm, except for the velocity which is in mm/s and extensibility ratio which is dimensionless.

	Figure 1 ref	Mean	Range	Minimum	Maximum	Std. deviation
10-yr palate length at rest	A-E	22.9	10.8	17.4	28.2	3.2
20-yr palate length at rest	A-E	34.5	32.1	25.7	57.8	8.3
10-yr hard palate to knee at rest	A-B	10.4	7.6	6.6	14.2	2.0
20-yr hard palate to knee at rest	A-B	15.5	15.2	9.6	24.8	3.4
10-yr palate thickness at rest	B	9.6	7.1	6.6	13.7	1.6
20-yr palate thickness at rest	B	11.4	5.6	8.2	13.8	1.4
10-yr palate extensibility	A-C	13.8	5.9	9.8	15.7	1.7
20-yr palate extensibility	A-C	19.0	11.7	13.4	25.1	3.4
10-yr extensibility ratio	AC:AB	1.4	1.1	1.0	2.0	0.3
20-yr extensibility ratio	AC:AB	1.3	0.9	0.9	1.8	0.2
velocity@10 yr		149.9	132.5	95.8	228.3	35.4
velocity@20 yr		197.2	172.9	102.1	275.0	40.3
Number of subjects	20					

Table 3 Statistical analysis of the difference between palate morphologies of 20 patients measured at 10 and 20 years of age. Mean, standard deviation, standard error and 95% confidence interval are measured in mm. The Students *t*-test coefficient is *t* and the associated significance p value. Effect size from the Cohen's D test is shown as Effect.

				95% confidence interval of the difference				
Difference between 20 years and 10 years	Mean	Std. deviation	Std. error mean	Lower	Upper	t	p value	Effect
Palate length at rest	11.6	8.0	1.8	7.9	15.4	6.5	0.00	1.84
Hard palate to knee at rest	5.1	3.8	0.9	3.3	6.9	6.0	0.00	1.79
Palate thickness at rest	1.8	2.1	0.5	0.8	2.8	3.9	0.00	1.19
Palate extensibility	5.2	3.0	0.7	3.8	6.6	7.7	0.00	1.93
Extensibility ratio	−0.1	0.3	0.1	−0.2	0.1	−1.3	0.22	n/a
Palate velocity	47.3	40.0	8.9	28.5	66.0	5.3	0.00	1.24
Number of subjects	20.0				df	19.0		

reliability ranged from 0.65 to 0.91 (moderate to excellent).

Referring to Tables 2 and 3, the average soft palatal length (Figure 1: A-E) at rest in the 10 year cohort was 22.9 mm increasing to 34.5 mm among the 20 year olds resulting in an mean increase in length of 11.6 mm, ranging (95% CI) from 6.5 to 15.5 mm between 10 and 20 years. The mean length from the hard palate to the knee at rest (Figure 1: A-B) at 10 year was 10.4 mm increasing to 15.5 mm at 20 years, an average increase of 5.1 mm, ranging (95% CI) from 3.3 to 6.9 mm. Similarly, palatal extensibility (Figure 1: A-C) length during phonation of the sound /i/ increased from a mean length of 13.8 mm in the 10-year-olds to a mean length of 19.0 mm in the 20-year-olds resulting in an average increase in length by 5.2 mm, ranging (95% CI) from 3.8 to 6.6 mm. Soft palate thickness measured at rest at point B increased in all patients between the ages of 10 and 20 years with a mean increase of 1.8 mm (range, 0.8-2.8 mm). The extensibility ratio showed no mean increase between 10 and 20 years. The palate velocity showed a mean increase of 47.3 mm/s and a range of 28.5 to 66 mm/s.

Except for the extensibility ratio, all soft palate morphology measurements showed a statistically significant change ($p < 0.01$) between 10 and 20 years and the effect size of each comparison was consistently >1.

Discussion

The aim of cleft palate repair is to repair the cleft without residual fistulae and, more importantly, to provide a soft palate that is of adequate length and dynamism to effect velopharyngeal closure during speech and swallowing. Although speech assessment provides a proxy for velopharyngeal functioning, little is known about the changes that occur in the operated soft palate during growth, in terms of metrics at rest and during function. Previous studies have reported on soft palate length during growth. Coccaro et al. and Mazaheri et al. using lateral cephalograms showed that the length of the palate in cleft patients was shorter than that in non-cleft controls at 3 months and 6 months of age.[1,2] They also showed that the cleft soft palate grew and increased in length slightly more than non-cleft controls between the ages of 3 months, 7 years and 6 months and 6 years.[1,2] The Coccaro study did not specify or stratify patients according to cleft type or palate repair method.[1] Mazaheri et al. stratified patients according to cleft type and showed that the soft palate in all cleft subtypes grew more than the non-cleft controls during the time points measured. Growth inhibition or soft palate atrophy was not demonstrated in their cohort.[2] A more recent study demonstrated continued soft palate growth between childhood and adolescence following soft palate repair using the Furlow technique and delayed hard palate closure at 18 months. However, the increase in soft palate length in the palatoplasty cohort was less than the growth demonstrated in the cleft lip and alveolus control group.[4]

The dimensions of the nasopharynx are also important, as this will determine the distance the soft palate has to move to affect velopharyngeal closure. With growth, there is an increase in the height and depth of the nasopharynx and with the vertical growth of the maxilla the hard palate will descend and subsequently, the soft palate will move further away from the nasopharynx. Therefore, the soft palate will have to move further to reach the anterior wall of the nasopharynx as growth occurs.[5] Coccaro demonstrated that the nasopharynx does not increase as much in depth and length in children with cleft compared to normal controls. Initially, this appears advantageous; however, it has also been found that in some cleft children, the posterior aspect of the hard palate is forward relative to the location of the anterior aspect of the nasopharynx indicating that the soft palate would have to go further to effect nasopharyngeal closure.[1] Harada et al. found the opposite, in that the nasopharyngeal depth was greater in all age groups in the UCLP cohort compared to the UCLA cohort; however, this difference was not significant.[4] Mazaheri et al. found that the nasopharyngeal depth was greater in the non-cleft controls at 6 months and 6 years of age; however, the patients with UCLP and BCLP exhibited a greater increase in nasopharyngeal depth between the ages of 6 months and 6 years than non-cleft controls and patients with isolated cleft palate.[2] In childhood years, this increase in depth is offset by the adenoids and the soft palate will close against these implying that the soft palate has less distance to travel to closure.

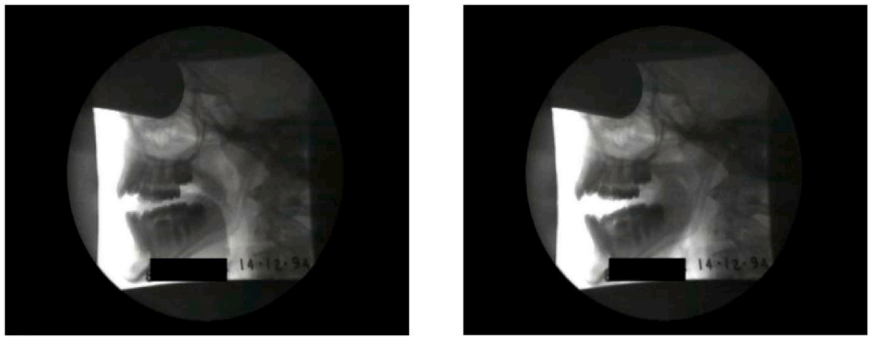

Image 1 Ten-year-old patient at rest and articulating the sound /i/ demonstrating extension to the posterior nasopharyngeal wall.

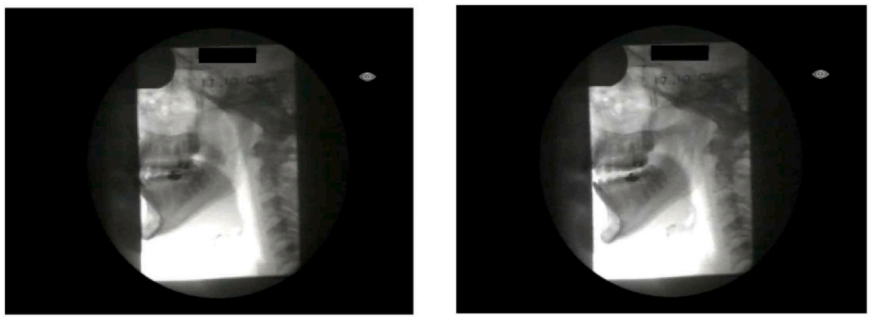

Image 2 Same patient at the age of 20 years at rest and articulating the sound /i/ demonstrating extension to the posterior nasopharyngeal wall.

As the adenoids involute, the soft palate will need to extend further if velopharyngeal insufficiency is to be avoided.[5]

An investigation of palatal growth between the ages of 4 and 17 years in UCLPs following Veau-Wardill-Kilner palatal repair compared to non-cleft controls showed that palatal growth in the control group was significantly more than that in the UCLP group.[3] This study also measured nasopharyngeal depth and calculated an 'adequate ratio' by comparing soft palatal length with nasopharyngeal depth; however, we did not correlate this ratio with speech outcome or measure dynamic palatal function.[3] Similarly, Harada et al. measured 'adequate ratio' and showed that the adequate ratio decreased in the UCLP cohort from childhood to adolescence compared to the UCLA cohort and speculated that this could worsen velopharyngeal competence with age; they did not directly correlate the 'adequate ratio' with speech outcome in this study.[4] Stellzig-Eisenhauer correlated palatal length and nasopharyngeal depth in 3 patient age groups with speech resonance and found a relationship between both parameters and speech in that patients with shorter palates and a deeper nasopharynx did have a significant negative influence on speech outcome.[5] However, this study though did not directly assess the effect of growth on palatal extensibility and velopharyngeal closure.

Our study, the first of its kind to report on dynamic changes with growth, demonstrated that soft palate length at rest and during speech increases between the ages of 10 and 20 years. There is also an increase in extensibility and this together with the increases in length indicate that the soft palate can respond to the increase in nasopharyngeal depth that occurs with growth and adenoidal involution and thereby maintains velopharyngeal sufficiency. Although nasopharyngeal depth was not specifically measured in this study, palatal extensibility is a proxy for measuring pharyngeal depth in this cohort of patients because all their palates reached the posterior wall with no patients at either age having a velopharyngeal gap during speech. Therefore, velopharyngeal sufficiency is partly accomplished by an overall increase in length and thickness as the soft palate grows and partly by an increase in extensibility; in the 2 patients who required surgery for velopharyngeal insufficiency between the ages of 10 and 20, an anterior bulge was also created on the posterior pharyngeal wall in the form of a posterior pharyngeal wall (Hynes) pharyngoplasty. Although 3 patients required maxillary osteotomies for deficient maxillary growth prior to 20 years, all patients had velopharyngeal sufficiency at the 20-year audit without needing speech surgery.

Thus, in all the patients in this study, the soft palate made contact with the nasopharyngeal wall indicating that the length of the soft palate at closure is equivalent to the nasopharyngeal depth.

The soft palate velocity during the /i/ phonation has shown to systematically increase between the ages of 10 and 20 years. This appears to be consistent with the increase in pharyngeal depth with age; hence, the commensurate increase in absolute distance that the soft palate must travel to achieve closure—this is important as velopharyngeal closure and consequently velopharyngeal competence during speech closure has to be achieved at the correct time to avoid nasal air escape. Therefore, functional length and timely closure are necessary to achieve velopharyngeal closure. Closure is normally achieved in a minimum of 100 ms.

However, the extensibility ratio showed no significant difference between the age groups. This is owing to the length of the palate at rest and extended length increasing between 10 and 20 years; hence, the increase in 'extended length' per unit 'at rest length' remains unchanged. It is unclear if these changes in velocity and extensibility ratio are related to the technique of palate repair and especially the method of muscle reconstruction used or if they are simply normal features of age-related change. The patients with CUCLP in the Harada study,[5] after undergoing Furlow double opposing Z-plasty repair in infancy, did not achieve adequate soft palatal growth to close the velopharyngeal gap as evidenced by the decrease in soft palate length to pharyngeal depth ratio; this may be owing to the surgical technique used and would suggest that the Sommerlad technique results in better growth, extensibility and velopharyngeal competence in this group of patients.

In summary, this study showed that the soft palate repaired in patients with UCLP using the Sommerlad technique, continues to increase in length at rest and during function between the ages of 10 and 20 years. It is reasonable to conclude that radical muscle reconstruction in this group of patients did not produce damaging scarring that interfered with soft palate function and growth, and adequate velopharyngeal closure during speech was achieved.

The findings support the hypothesis that the Sommerlad technique for repairing the soft palate in patients with UCLP does not adversely affect the soft palate's growth or its functional dynamics, such as length, thickness and extensibility.

The limited number of patients, who were operated on by a single surgeon, included in this study is a clear limitation on how far the conclusion can be generalised to the wider surgical outcomes for CUCLP repair. Broadening the study to examine the outcomes from a number of surgeons who use the Sommerlad technique would enable the variability between surgeons to be assessed and increase the statistical confidence in the data owing to greater patient numbers.Images 1 and 2.

Ethical approval

Not required.

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Declaration of Competing Interest

None.

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