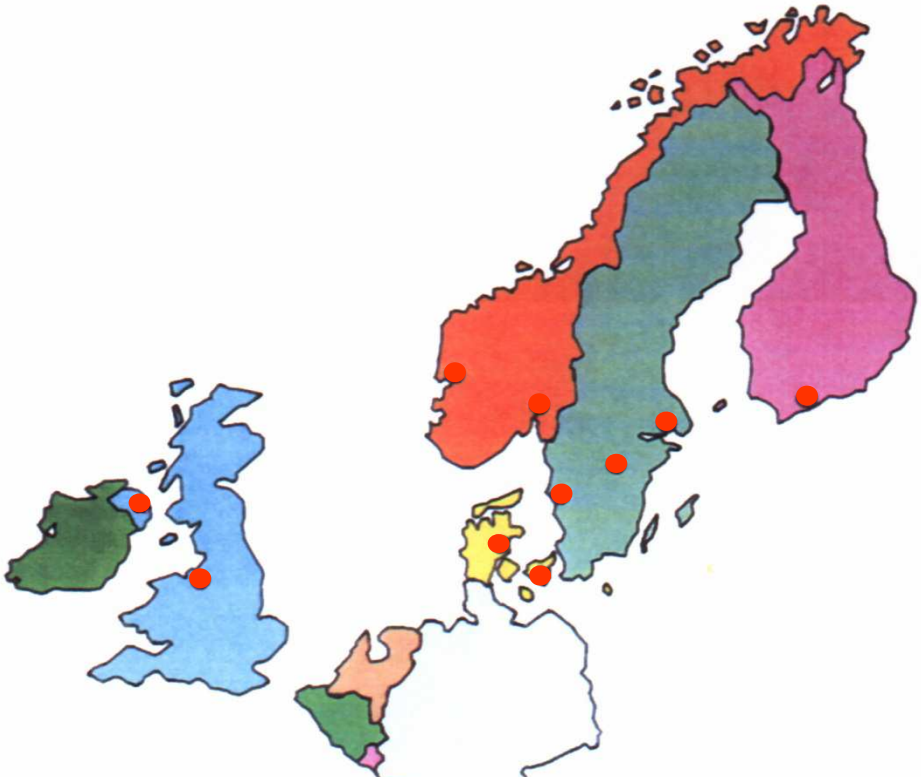
Scandcleft

Scandcleft Project

initiated March 27th, 1997



Randomised Trials of Primary Surgery in Unilateral Cleft Lip and Palate

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RANDOMISED TRIALS OF UNILATERAL CLEFT LIP AND PALATE SURGERY

Background

Clefts of the lip and palate, occurring with an incidence of about 1 per 500 births, are among the commonest birth anomalies affecting humans. The anatomical location of the defect creates problems in feeding, speech, hearing, dental development and facial growth. Communication disability and the distorted facial appearance represent serious barriers to social integration. The success of primary surgery in the early months of life is crucial in determining outcome for the above functions, and the subsequent cost of secondary surgery and remedial care.

The scientific basis of the cleft lip and palate discipline is weak since virtually no elements of treatment have been subjected to the rigours of contemporary clinical trial design (Roberts et al., 1991). Thus highly complex and varied protocols of care and a bewildering diversity of surgical technique, timing, and sequencing is practised by teams.

Cleft care generally constitutes only a minor part of the clinical load of the disciplines involved - nursing, plastic surgery, maxillofacial surgery, otolaryngology, speech therapy, audiology, counselling psychology, genetics, orthodontics, dentistry. Cleft surgery is almost completely devoid of a sound evidence base. A review of 25 years of the Cleft Palate-Craniofacial Journal identified only 3 randomised control trials, and none of these involved primary surgery (Roberts et al., 1991).

In the Cochrane Collaboration Controlled Trial Register only two randomised control trials of primary surgery are listed: Two small randomised control trials of primary surgery were conducted by Robertson and Jolleys and published in 1968 and 1974. In the first study a sample was randomised in respect of alveolar bone grafting at the time of lip repair. Follow-up revealed a detrimental effect on facial growth in the grafted group (Robertson and Jolleys, 1968). The second study involved two groups of 20 cases where one group's anterior palate closure was delayed until age 5. No benefit for dentofacial growth was found in delaying hard palate closure (Robertson and Jolleys, 1974). A follow up study when the children were 11 years of age reached the same conclusion (Robertson and Jolleys, 1990).

Marsh et al. (1989) alternated palate repair with or without intravelar veloplasty (IVV) in 51 subjects with a broad range of palatal cleft types. Speech evaluations were made at a two year follow-up. No difference in outcome was detected, but the procedure including IVV required a significantly longer operating time. This negative finding has frequently been challenged in British circles because the trialists' technique for IVV was not considered to be sufficiently radical.

All other available research reports have been retrospective, frequently at case series level. An extensive review of these has been undertaken with the conclusion that comparison between reported outcomes is unreliable because of the invariable presence of bias (Semb and Shaw, 1996). A principal source of bias inevitably, is surgical skill.

There are many controversies that would be appropriate to randomised control trials. For combined clefts of the lip and palate, important points of dispute at present are the surgical sequencing of repair and use or non-use of vomerine flaps in closure of the anterior palate. The principal outcome in relation to these choices is the extent to which the potential for good facial growth can be realised, i.e. unsuccessful surgery causes a disturbance of facial growth associated with progressive disfigurement throughout the childhood and teenage years, usually requiring a major corrective procedure in the late teens (maxillary osteotomy). The quality of initial surgery is also important for speech and language development (Grunwell et al., in press).

Preliminary work

Since 1986 members of the trial consortium have been developing a concerted programme of multidisciplinary intercentre research in cleft lip and palate. These include a comparison of surgical outcome in four Scandinavian centres (Friede et al., 1991; Enemark et al.,1993) and six European centres (Shaw et al.,1992a; Mølsted et al.,1992; Mars et al.,1992; Asher-McDade et al.,1992; Shaw et al., 1992b; Shaw et al.,1992c).

This experience provides compelling stimulus for the establishment of randomised control trials in surgery of clefts, though the professional community involved in cleft care has, in the past, rehearsed many arguments against randomised control trials regarding them as unmanageable or unethical (Berkowitz, 1995; Shaw, 1995). These objections have largely been refuted by the initiation of the first multicentre randomised control trial of secondary cleft surgery in 1992 involving centres in the US, Norway, and the North West of England (Sloan et al., 1996).

The British Association of Plastic Surgeons (Cleft Group) has also declared a strong commitment to participation in randomised control trials of primary surgery and a proposal for a multicentre trial in the UK has received ethical approval in 1996.

The Proposed Study

Null hypothesis

The study will test the null hypothesis that variations in surgical technique and staging are not associated with difference in outcome.

Study design

The study will be conducted as a parallel series of three randomised control trials of primary surgery for complete unilateral cleft lip and palate.

Each team will initially register newly born patients at birth with the study co-ordinator. The patient's name, gender and date of birth will be given.

A full description of the proposed study will be presented to the parents and they will be given written information (Appendix 4).

The team will inform the study co-ordinator before 3 months, whether the child is to be entered into the study or not, along with the consent form or the reason for exclusion.

For children entered into the study, the study co-ordinator will provide an envelope just before the first surgery containing the group allocation for the child. The envelope will be opened on the morning of the surgical operation.

Surgical variations

- Variation A. 'The common arm. Short delay hard palate closure':

  Lip and soft palate closure at 3-4 months.
  Hard palate closure at 12 months.

- Variation B. 'Long delay hard palate closure':

  Lip and soft palate closure at 3-4 months (as variation A).
  Hard palate closure at 36 months.

- Variation C. 'Simultaneous hard and soft palate closure':

  Lip closure at 3-4 months.
  Hard and soft palate closure at 12 months.

- Variation D. 'Early hard palate closure with vomer flap':

  Lip closure at 3-4 months combined with a single layer closure of the hard palate using a vomer flap.
  Soft palate closure at 12 months.

(See appendix 2 for detailed surgical protocols).

Participating Teams

The seven Nordic teams will participate in the trials according to the following scheme. (Two UK teams co-ordinated by Manchester will also participate in Trial 3):

Table 1. Participating teams and surgical variations.

Trial	1	2	3
Teams	Aarhus Copenhagen Gothenburg	Helsinki Linköping Stockholm	Belfast Bergen Manchester Oslo
1st arm	A	A	A
2nd arm	B	C	D

Inclusion/exclusion criteria

The trial will include Caucasian infants with non-syndromic complete unilateral cleft lip and palate, who are otherwise healthy. A soft tissue bridge of 5 mm or less will be accepted.

Proposed outcome measures

Outcome measures are speech and language development, dentofacial development, nasolabial appearance, hearing, perioperative complication rate, symptomatic fistulae and operation and hospitalisation time, (Appendix 1, 2 and 3).

Proposed sample size

Sample size calculations have been based on data for equivalent outcomes in the previous multicentre comparisons. We have also used the data from the previous controlled trial of intravelar veloplasty published by Marsh et al., (1989). Detectable differences between groups have been set at a level of sufficient clinical importance to persuade most clinicians that a change in practices would be worthwhile. These have been derived from the levels of difference apparent between the better centres of our previous multicentre studies. We will use dental arch relationship as our principal indicator of dentofacial development as this has been shown to discriminate better than any other measure between groups (Friede et al., 1991, Shaw et al., 1992c). Although the previous measuring instrument was developed for UCLP in the early permanent dentition (Mars et al., 1987), a similar instrument has been validated for 5 year olds (Hathorn et al., 1996; Atack et al., 1997).

Speech Assessment

Using the study by Marsh et al., (1989): The sample size is calculated for changes in the proportion of children falling into the VPC (velopharyngeal competency) * and type I categories compared with those falling into the type II & III categories. A two group continuity corrected χ^2 test with a 0.05 two-sided significance level will have 90% power to detect the difference between a Group 1 proportion of 0.600 and a Group 2 proportion of 0.300 (odds ratio of 0.286) when the sample size in each group is 63.

Dental Arch Relationship

Taking an intermediate difference between the centres of 0.4, a sample size of 66 in each group will have 90% power to detect a difference in means of -0.400 assuming that the common standard deviation is 0.700 using a two group t-test with a 0.05 two-sided significance level.

The largest difference between centres in the six centre study was 0.87 (Shaw et al., 1992c, Table 1.9).

Using the GOAL yardstick (Friede et al., 1991, Fig. 4), to detect a 30% difference between two groups for the proportion of cases rated 1 or 2 of 65 per group would be required (with alpha=0.05, beta=0.10).

* VPC (velopharyngeal competency) comprises VPI (velopharyngeal insufficiency) WNL (within normal limits)

Naso-labial appearance

The proposed sample for determining this outcome is based on the overall appearance of the upper lip (L1 in Morrant and Shaw, (1996)). The mean and standard deviation for English patients were used. A sample size of 55 in each group will have 90% power to detect a difference in means of 0.320 (the difference between a Group 1 mean of 2.720 and a Group 2 mean, of 2.400), assuming that the common standard deviation is 0.510 using a two group t-test with a 0.05 two-sided significance level.

If the vermilion border from Table 1 of Asher-McDade et al., (1992) is used as the outcome, a sample size of 60 in each group will have 90% power to detect a difference in means of -0.300 (the difference between a Group 1 mean, of 2.800 and a Group 2 mean, of 3.100) assuming that the common standard deviation is 0.500 using a two group t-test with a 0.05 two-sided significance level.

Using the data from Enemark et al., (1993, Table 3) the mean basal view for centre D was 2.26 (SD=1.11), assuming that the mean difference between the measurements was 0.70 (SD=1.11), then a sample size of 65 per group would be required (with alpha=0.05, beta=0.10).

Ethical approval

A full description of the proposed study will be presented to parents and they will be given written information (Appendix 1). Each team will seek ethical approval from the appropriate authorities.

Planned recruitment rate

The above estimates indicate that we will need minimum group sizes between 55 and 66 subjects per group. We propose to recruit 75 cases to each group to compensate for potential drop-out.

On the basis of the present annual numbers of patients born with UCLP, table 2 demonstrates likely recruitment rate:

Table 2. Recruitment Rates

Trial	1	2	3
Teams	Aarhus Copenhagen Gothenburg	Helsinki Linköping Stockholm	Belfast Bergen Manchester Oslo
New UCLP cases per year	40	31	65
Period required for sample of 150 cases per trial	3.75 years	4.8 years	2.31

Randomisation

Random assignment will be in sealed envelopes which will be given to each team and kept in the operating theatre, and should be opened just prior to surgery.

Proposed frequency/duration of follow-up

Existing patterns and traditions of follow-up at respective teams will not be interfered with. The additional records agreed upon for judgement of outcomes are listed in Appendix 3 and 4. The proposed 60 month period of the project will allow definite conclusions to be reached on perioperative complications and their costs, direct surgical costs, speech and audiological outcome, scar healing, the size of the residual hard palate cleft prior to closure and nasolabial appearance. The first attempt to measure dentofacial growth outcome will be carried out on study casts and cephalograms obtained at age 5 years.

Measurements of outcome and statistical analysis

Analysis of the records will be performed by blinded panels using standardised rating schemes. Repeatability tests will be performed. Appropriate multiple comparison tests will be performed.

Publications and presentations

A minimum of one member from each team will be on every publication. Each team will decide who has done most of the work and determine authorship. The first author should be the person doing most of the work.

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Appendix 1

Parental Information and Informed Consent

Enrolment and Informed Consent

Parents of eligible children were invited to consider taking part in the project. Information concerning the trial being undertaken at the centre was provided directly by staff and written information was issued for consideration at home. An example of the wording of information for Trial 3 and a consent form are presented below.

INFORMATION ON A STUDY OF TREATMENT FOR UNILATERAL CLEFT LIP AND PALATE

One common sequence is to close the cleft lip and the cleft in the hard palate at a first operation around age 3-4 months. The soft palate cleft is then closed at a second operation around age 12 months.

Another common sequence is to close the lip and the soft palate cleft around age 3-4 months, and then the hard palate around 12 months.

As yet, there is no clear evidence to help surgeons decide whether one way is better than the other. The surgeons taking part in this study believe the only way to find out is to make a careful comparison of the results of each sequence of operating.

Babies taking part in the study will be divided into two equal groups, one group getting the first sequence and the second group the other sequence. The sequence that any baby gets will be decided at random by throwing a dice. In all other respects the treatment and follow-up will be the same. The records used to make the comparison are the standard follow-up records and checks that all babies with cleft lip and palate should have, except that extra photographs and longer recordings of speech will be taken.

You are under no obligation to take part in this study. Joining is strictly optional and if you decide not to participate you will still receive all necessary treatment from the cleft team.

If you would like more information about the study please contact

……

……

……

CONSENT TO TAKE PART IN STUDY OF TREATMENT OF UNILATERAL CLEFT LIP AND PALATE

This study has been described to me by

……..... on

……

……

I understand that my baby does not have to take part in this study.

I agree/do not agree to my baby taking part in this study.

Signed: …… Date: .....

Address:

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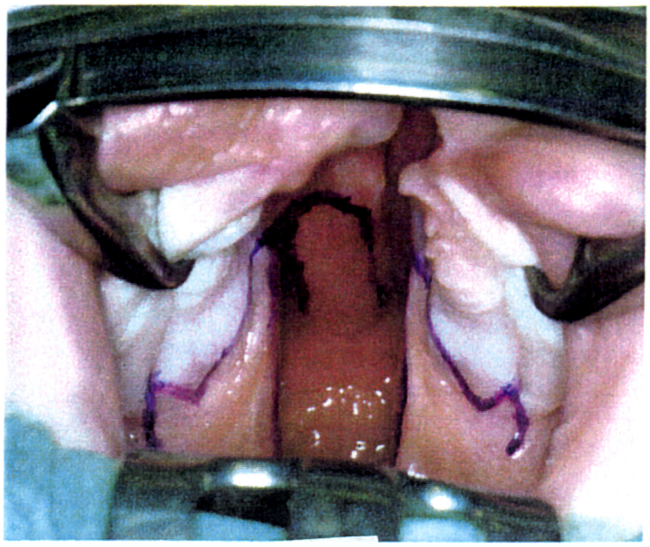
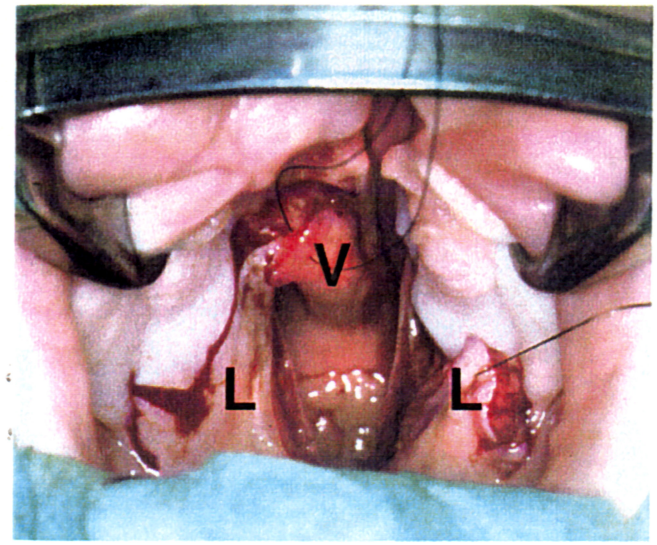


Picture series 1 Fig 1



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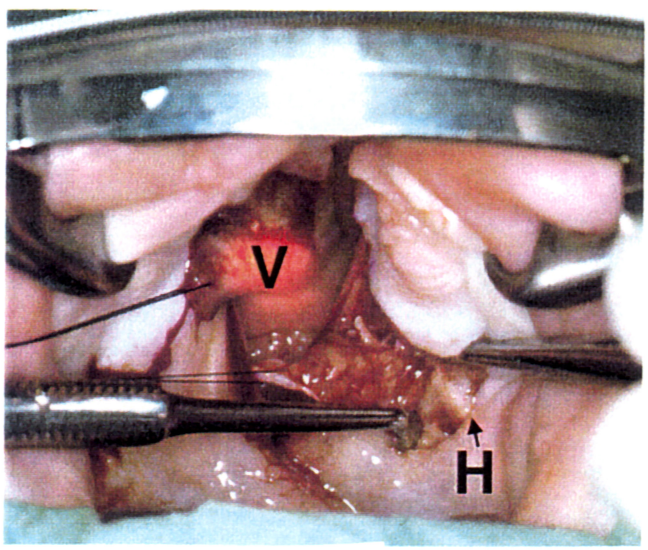

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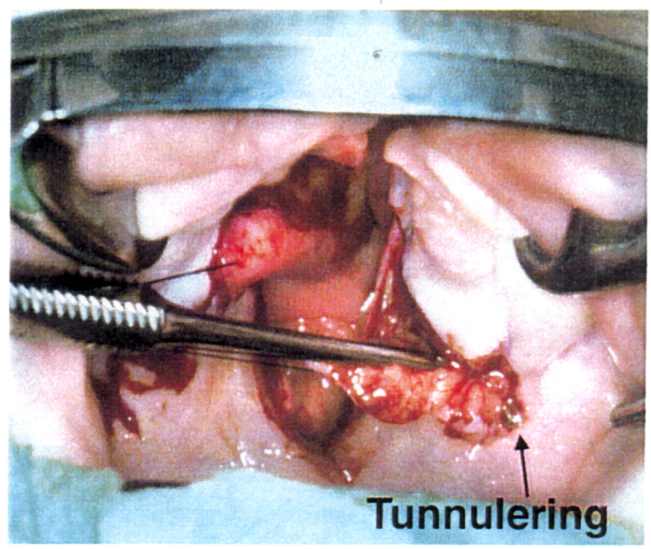

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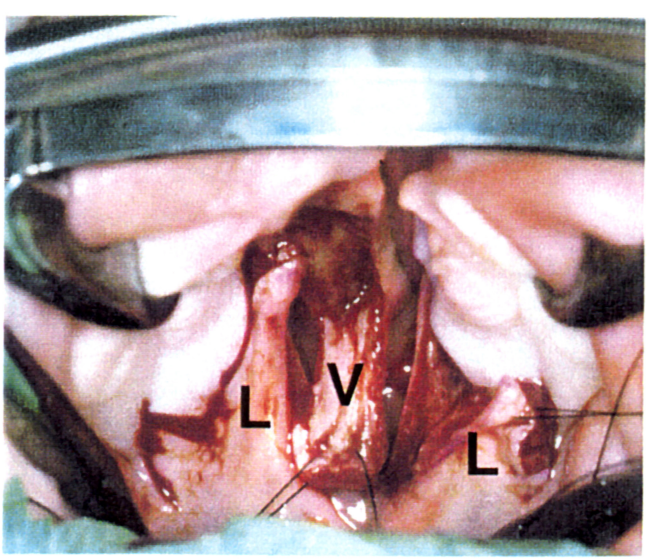

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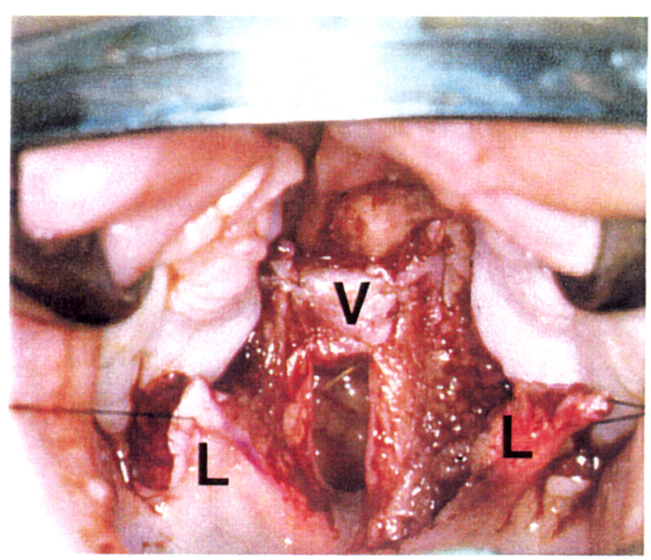

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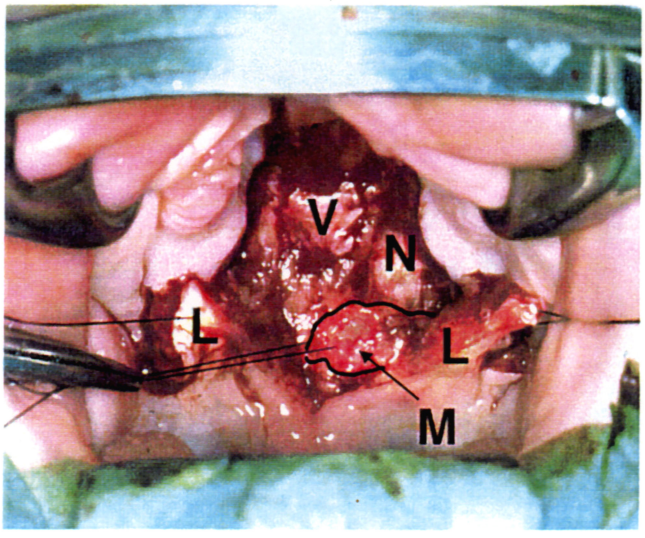
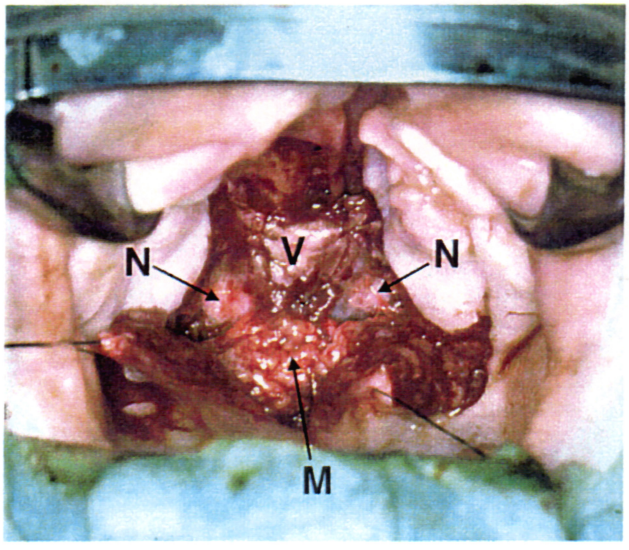
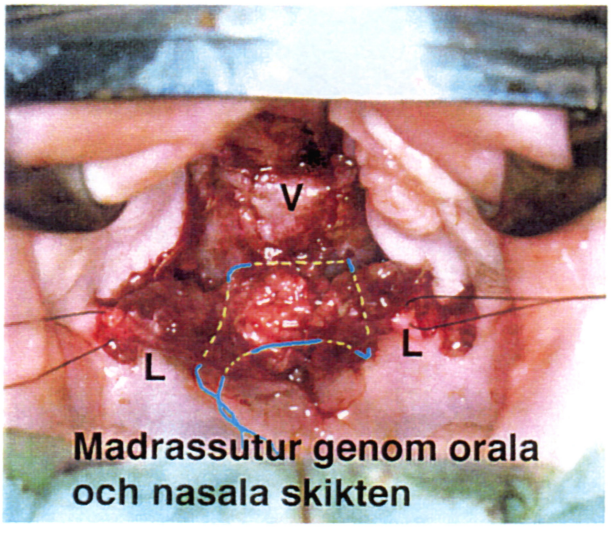


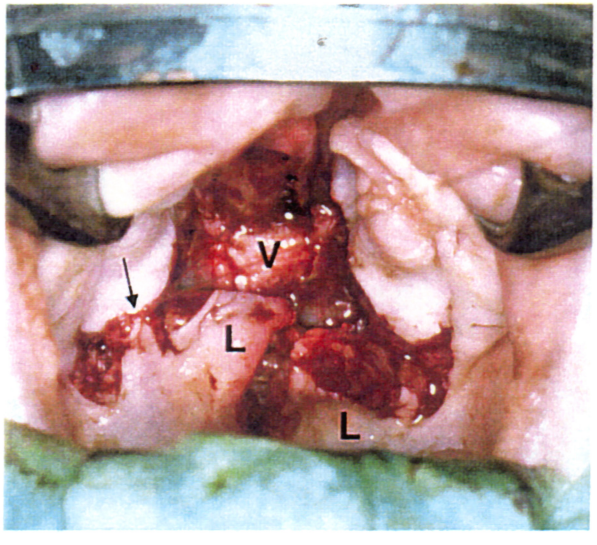
Picture series 1 Fig 7



Picture series 1 Fig 8



Picture series 1 Fig 9



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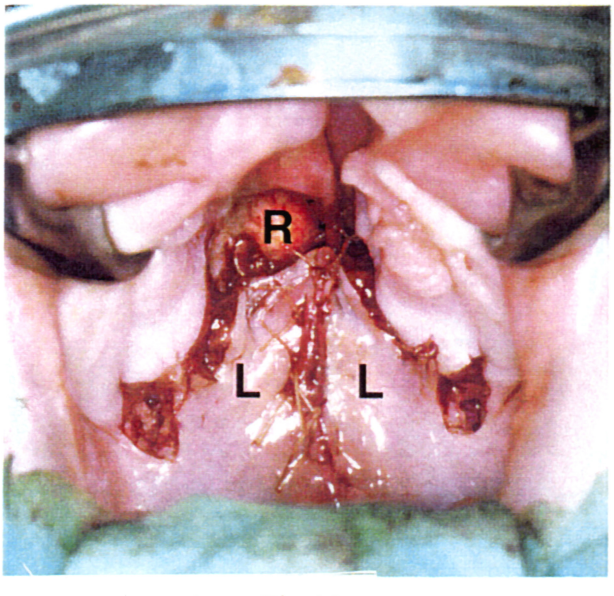
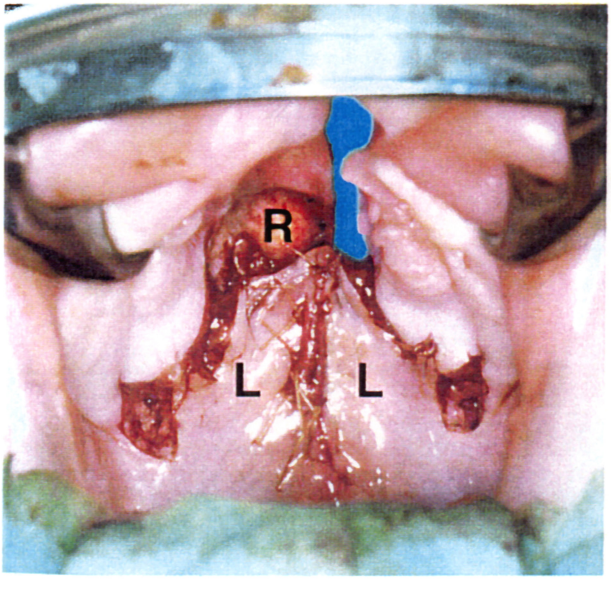


Picture series 1 Fig 11



Picture series 1 Fig 12

Appendix 2

Surgical Techniques

Variation A:
The common arm: Short delay in hard palate closure.

Timing of surgery:

The lip and soft palate will be closed at 3-4 months.
The hard palate will be closed at 12 months.

Lip closure:

The technique for lip closure that is presently used in the respective teams will be performed. For description, see Variation B, C and D.

Posterior palatoplasty with a posteriorly based vomer flap

Drawing

A line is drawn in a zig-zag fashion along the border between the hard and the soft palate. Start in the hamulus region and from there anteriorly to the tuber. The line is then continuing in a medial-anterior direction for about 5 mm and then 90 degrees medial-posteriorly for another 5 mm, from there turning medial-anteriorly again and 1 cm lateral to the cleft border, creating a triangular mucoperiosteal flap in the medial part of the hard palate.

The triangular vomer flap is drawn posteriorly based as wide and long as needed to cover the defect in the nasal mucosa. (The flap is planned to reach about 5mm posterior to the vomero-premaxillary suture, Picture series 1, Fig. 1).

Local anaesthesia

Local anaesthesia with adrenaline is used in the soft and hard palate and in the vomer.

Incisions

Starting laterally, the mucosa is incised superficially along the drawn lines. Medial to the palatine vessel, the incision is going deeper down to the bone. The vomer flap is raised subperiostally as shown in the drawing. At the cleft border in the soft palate, an incision is made along the border between the nasal and oral mucosa, dividing the soft palate into two layers (Picture series 1, Fig. 2. V= vomer flap, L= lateral flaps with mucoperiost in their anterior part from the hard palate).

Dissection

The oral mucosa is dissected subperiostally in the anterior part from the hard palate. The incision above hamulus is deepened by blunt dissection and the hamulus is identified, but

not broken (Picture series 1, Fig. 3. V = vomerflap, H = hamulus). Using blunt and sharp dissection, the oral mucosa of the soft palate is mobilised posteriorly. A tunnel is made by blunt dissection from the hamulus, going medially at the border of the hard palate to the incision of the cleft edge (Picture series 1, Fig.4).

The vomer flap is raised long enough to reach the nasal layer of the soft palate (Picture series 1, Fig. 5. V = vomer flap, L = lateral flaps with mucoperiost in their anterior part from the hard palate). The oral flap should now be mobile enough to reach its counterpart without tension in the midline where it later will be sutured. Occasional tethering fibres should be released by sharp dissection.

Suturing

The vomer flap is raised and is turned posteriorly and sutured into the nasal layer for about 10 mm with resorbable suture material; 4-0, 5-0, (using mattress sutures) (Picture series 1, Fig. 6. V = vomer flap, L = lateral flaps with mucoperiost in their anterior part from the hard palate). The nasal layer is then sutured by mattress sutures back to the uvula.

Muscle dissection

After suturing the nasal layer, it is possible to incise the muscular fibres on both sides of the suture line. The muscular insertions to the posterior border of the hard palate are then cut. The muscles can then be dissected from both the oral and the nasal mucosa and then mobilised medial-posteriorly. The muscle flaps are then sutured in the midline. Describe in the surgical report how the muscle reconstruction was performed (Picture series 1, Fig. 7. V = vomer flap, L = lateral flaps with mucoperiost in their anterior part from the hard palate, M = muscle, N = nasal mucosa dissected free from musculature).

Muscle suture

The muscles are sutured by 2-3 mattress sutures using 5-0 resorbable suture (Picture series 1, Fig. 8. V = vomer flap, N = nasal mucosa dissected free from musculature, M = muscle).

Suturing

The oral mucosa is sutured from the uvula and anteriorly, 4-0 or 5-0 resorbable sutures. A pull through suture is passed as a mattress suture anterior to the muscle reconstruction, keeping the oral and nasal layers together, reducing dead-space and keeping the muscles in a posterior position (Picture series 1, Fig. 9. V = vomer flap, L = lateral flaps with mucoperiost in their anterior part from the hard palate).

The muscles in the oral layer should now be posteriorly moved almost 1cm. The small anteriorly pointing flap from the oral mucosa in the soft palate medially to the hamululs is brought medially-posteriorly and sutured with 5-0 dexon or Vicryl (Picture series 1, Fig.10. arrow), and a raw surface is then left without cover laterally (Picture series 1, Fig. 10. V = vomer flap, L = lateral flaps with mucoperiost in their anterior part from the hard palate.

The lateral flaps with mucoperiost in their anterior part are then sutured all the way to the tips, covering the raw surface of the vomer flap. The raw bony surface of the vomer is left without coverage (important to cauterise the cut edges where the flaps were raised), (Picture series 1, Fig. 11. R= raw bony surface, L= lateral flaps with mucoperiost in their anterior part from the hard palate).

If the edges of the oral layer are mobile, sutures are put to anchor them without anterior pull. A remaining residual cleft is left open in the hard palate (Picture series 1, Fig. 12. R= raw bony surface, L= lateral flaps with mucoperiost in their anterior parts from the hard palate, Blue colour = residual cleft).

Closing the residual cleft in the hard palate at age 12 months

Drawing

The incision line is drawn on the palatal shelf on the non-cleft side, starting at the cleft border at the area of incisive foramen, going posterior to the cleft for about 5 mm making a sharp angle and then back on the cleft side at the border between the nasal and oral layer. The width of the flap should be calculated to reach the opposite side of the cleft with the possibility to be tucked under the palatal flap raised on that side (Picture series 2, Fig. 1).

The vomer flap

On the non-cleft side the vomer flap including a suitable part of the oral layer on the palatal shelf is raised by subperiosteal dissection. In the posterior part, the dissection should be performed carefully, dividing the mucosa without entering the nasal cavity (Picture series 2, Fig. 2).

The palatal mucoperiosteum on the cleft side

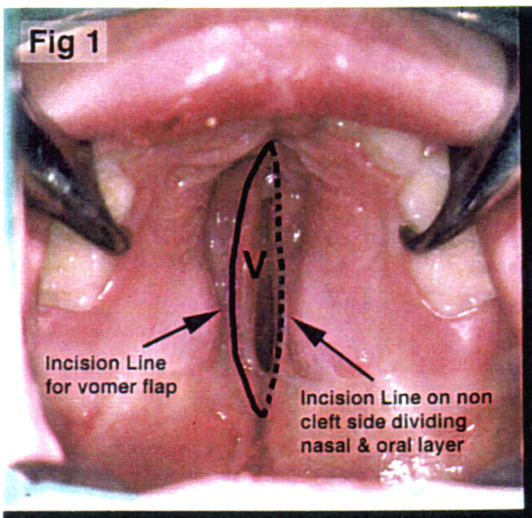
The incision is continued at the border between the oral and the nasal layers on the edge of the palatal shelf on the cleft side, preferably with an angled Beaver knife (Picture series 2, Fig. 3 a & b). The oral layer on the palatal shelf on the cleft side is then raised subperiostally creating a pocket above the bone of the palate about 5mm wide (Picture series 2, Fig. 4).

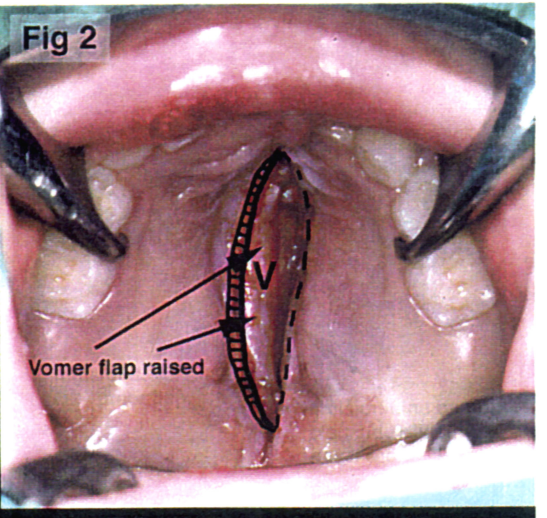
Suturing

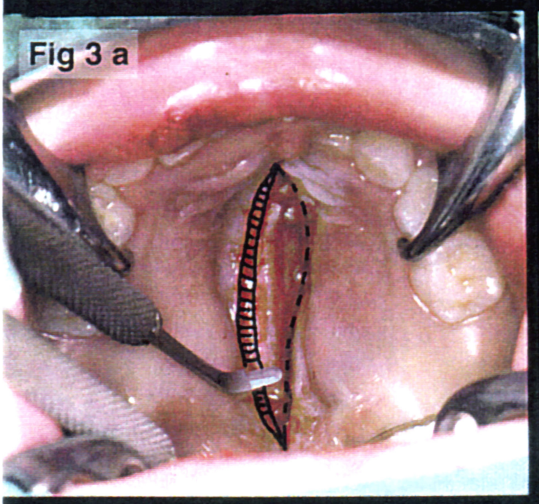
Starting orally on the cleft side a 4-0 resorbable suture is put through the mucoperiosteal layer, entering the created pocket, going out and catching the edge of the vomer flap from the raw surface. Then the suture is put back into the pocket and through the mucoperiosteal layer (Picture series 2, Fig.5). The suture can now be tied and then the vomer flap will be tucked into the created pocket on the cleft side where the raw surfaces will come together without tension giving good healing conditions (Picture series 2, Fig. 6).

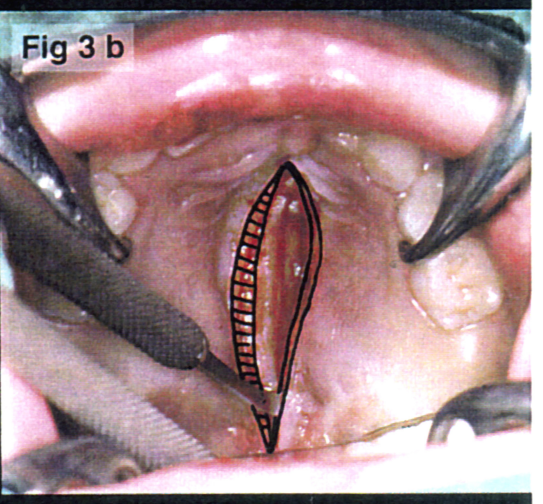
The above procedure should be possible to perform in most cases. However, sometimes, in wide clefts, the nasal layer may be sutured as a separate layer. The oral layer can then be mobilised, preferably by subperiosteal dissection, on both sides, the flaps then brought together and sutured without tension.

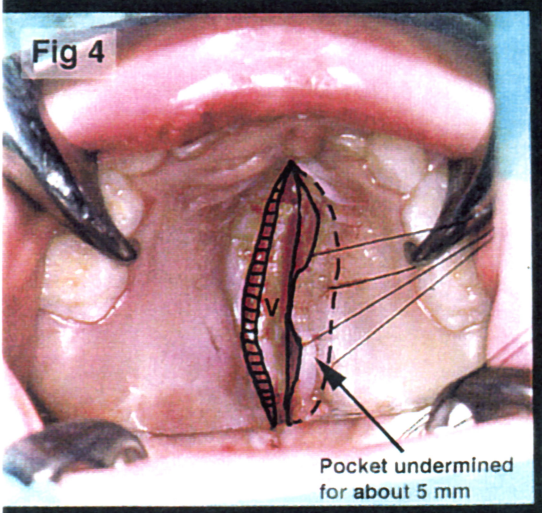
The procedure for closure of the residual cleft should be carefully noted in the surgical report.

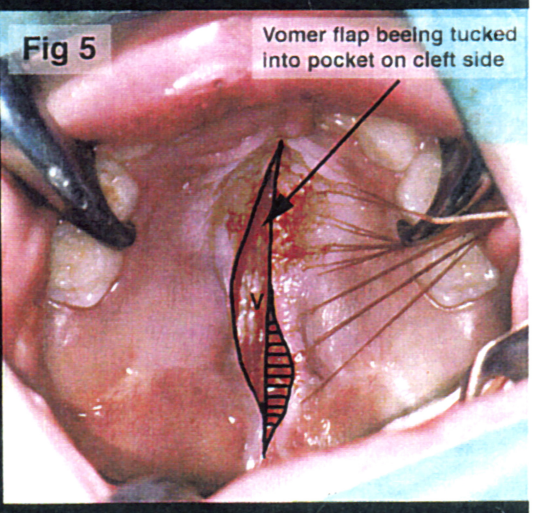


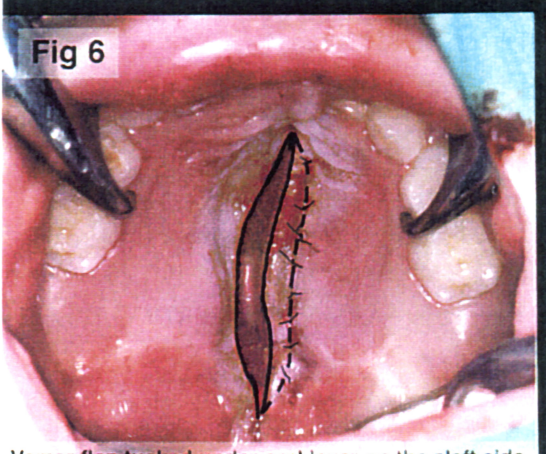












Vomer flap tucked under oral layer on the cleft side.
Sutured in place (4,0 Dexon)

Variation B: Long delay in hard palate closure.

Timing of surgery:

The lip and soft palate will be closed at 3-4 months.
The hard palate will be closed at 36 months.

Lip closure techniques:

Lip closure including primary nose correction.

When planning the definitive lip closure, the length of one half of the Cupid's bow is used as a yardstick. After definition of half a Cupid's bow on the non-cleft side, this measurement is used to define the position of the Cupid's bow close to the cleft.

From this point the distance measuring half a Cupid's bow is kept in a pair of callipers and is set off along the planned future philtrum ridge. From the calculated point of the Cupid's bow nearest to the cleft on the medial side an incision line is made along the vermilion border closest to the cleft, where the white skin roll can still be identified. From this point an incision line, measuring half a Cupid's bow is marked anteriorly to the muscle bulge on the lip on the cleft side. At the cranial endpoint of this line, the same distance is marked laterally at a right angle (90°). Incisions are then made along the planned lines through the whole lip. The medial lip frenulum is trimmed and the sulcus line is brought up to the same depth as on the non cleft stage, but the alar wing often needs further mobilisation between the cartilage and the skin. Subdermal dissection over the alar cartilages is performed ad modum McComb. Any excessive lip and scar tissue in the cleft area is then excised or used for augmentation of the columella base on the cleft side. The lip is approximated and sutured on the oral side. In the next step the musculature is closed where the incision, following the incision line 90° to the incision from the vermilion, is dividing the musculature in the lip into two parts, one downwards, representing the orbicularis oris muscle, and one upwards, representing muscles coming from the zygomatic and nasal musculature. These muscles are sutured separately where the upper part brings the alar wing into position and the lower part is reconstructing the freely moving orbicularis oris muscle. The skin can then be sutured without tension, and sutures tied over cotton wool bolsters according to McComb are placed through the alar wing on the cleft side to lift the cartilage in the dome area, stabilise the position and to prevent haematoma. Finally, the nostrils are packed with gauze.

Posterior palatoplasty:

Posterior palatoplasty with a posteriorly based vomer flap will be performed together with lip closure as described on page 9-10.

Hard palate closure:

Closing of the residual cleft in the hard palate will be done at 36 months. The technique used will be identical to the one described on page 11.

Variation C: Simultaneous hard and soft palate closure.

Timing of surgery:

The lip will be closed at 3-4 months.
The hard and soft palate will be closed at 12 months.

Lip closure techniques:

Primary lip closure according to Millard and primary rhinoplasty according to McComb.

The operation starts with careful planning and drawing of the incision lines. A lateral advancement flap and a medial rotation flap is performed. A small C-flap is prepared and this flap is rotated medially into the columella.

At the vermilion border a small white roll flap is prepared and at the border between the wet and dry red lip, a vermilion flap is also prepared.

The lateral advancement flap is going partly around the alar rim. A supraperiostal dissection is performed on the maxilla sometimes up to the infraorbital nerve.

The orbicularis oris muscle is dissected free both on the medial and on the lateral side. On the medial side the muscle is dissected into the middle of the philtrum. The muscle ends are sutured in one layer end-to-side according to Park or end to end with vertical madras sutures (5/0 PDS).

The musoca is sutured with 5/0 Vicryl rapid and the skin is closed with 6/0 and 7/0 Prolene.

If the nose is not perfectly symmetrical a rhinoplasty according to McComb is performed where half of the nose on the cleft side is undermined through the incision at the alar rim and through the columella. Two holding sutures with 5/0 Dermalon are usually used to keep the cartilage in its new upright position. These sutures are kept for 7-10 days.

Primary lip closure according to Tennison-Randall and primary rhinoplasty according to McComb.

After careful planning with calliper the incision lines are marked according to Randall where the measurements of the non cleft side are used as yard stick. The vermillion border is tattooed.

A 0,5% Xylocain-lidocain adrenaline solution is infiltrated in the lip and in the nose. The lip is incised according to the markings. A vestibular incision in the sulcus is done and a supraperiosteal dissection is performed on the maxilla. The orbicularis oris muscle and the levator labii muscles are dissected free. On the medial side the dissection is done into the middle of the filtrum and on the lateral side as far laterally as necessary to achieve good muscle contact in the midline. Subdermal dissection of the nose on the cleft side according to McComb is done laterally through the incisions in the lip and medially through the columella. Two holding sutures with 5-0 Ethilon are usually used to keep the alar cartilage in the new upright position. The sutures are kept for 7 days.

Suturing of the mucosa is done with 5-0 Vicryl. Suturing of the muscles is done with 5-0 Vicryl. The first most cranial suture is sutured to the region of the anterior nasal spine. Suture of the skin is done with 6-0 Novafil.

All three teams will use the following method for hard and soft palate closure:

Palatoplasty with incisions along the cleft margin and behind the maxillary tuberosities.

Local anaesthesia

0,5 % lidocain with adrenalin is infiltrated in the soft and hard palate and in the vomer

Incisions

The cleft margins are incised in the soft palate. In the hard palate, the incision line is on the lesser maxillary segment made down to bone and about 1 mm in on the oral side. On the larger maxillary segment the incision line is, if necessary, made on the vomer to get enough tissue for suturing of the nasal and oral layers. A minor angular incision of 5-7 mm is made down to bone behind the maxillary tuberosities.

Dissection

Soft palate: from the incisions behind the tuberosities the hamulus is identified through blunt dissection. Going medially along the posterior border of the hard palate the muscle is released. From the incision along the cleft margin the palatal aponeurosis is divided and the levator muscle elevated until it can be moved medially.

The hard palate

On the lesser maxillary segment the mucoperiosteum is elevated from the nasal and oral sides of the palate plate with elevators. On the larger maxillary segment the mucoperiosteum of the vomer is elevated sufficiently to reach the mucoperiosteum on the nasal side of the lesser segment. On the oral side the mucoperiosteum underneath the vomer and on the palatal plate is elevated enough to reach the oral mucoperiosteum of the lesser segment. The undermining is carried on laterally as far as necessary. The greater palatine vessels are when necessary carefully dissected free to mobilize the oral mucoperiosteum around the posterior border of the hard palate.

Suturing

All suturing is done with 5-0 Vicryl. Interrupted sutures are used for the nasal layer - mattress sutures for the oral layer. The levator muscle is sutured with deeply put mattress sutures from the oral side and when necessary with separate sutures in the muscle.

Variation D: Early hard palate closure with vomer flap.

Timing of surgery:
The lip and hard palate will be closed at 3-4 months.
The soft palate will be closed at 12 months.

Lip and hard palate closure.

The lip and anterior palate are closed at the age of 3-4 months. No form of presurgical orthopaedics is employed to assist the repair.

On the operating table, detailed close-up photographs of the cleft are taken, as are impressions of the maxilla. These are part of the permanent records. For closure of the lip, a Millard rotation-advancement procedure is utilised. In complete clefts, closure of the anterior palate with a single-layer vomer flap is performed simultaneously. With this procedure, a nasal floor is constructed from the nostrils into the hard palate.

The incisions are marked with Bonnies blue dye in the usual manner. Local anaesthetic (0,5% lidocain, with 1:50 000 epinephrine) is infiltrated into all layers of both lip segments and under the planned vomer flap and palatal flap. This reduces the bleeding, and blood transfusions are never required. The maximal blood loss that is tolerated is 10% of the child's estimated blood volume.

The incisions for the lip dissection are made to, but not through, the periosteum on the anterior aspect of the maxillary segments. On the lateral side of the cleft, an incision is made in the sulcus to the periosteum. The lateral labial muscle is freed from its abnormal insertion at the pyriform margin and mobilised. The labial muscle is isolated on each side of the cleft and dissected free for at least 5mm.

The incisions for the vomer flap are made to bone or cartilage, because this dissection is possible only subperiosteally. On the medial side of the lateral segment, the incision follows the border between the oral and nasal mucosa. The oral mucoperiosteum on the hard palate on the cleft side is bluntly undermined. The dissection of the vomer flap is carefully performed over the premaxillary-vomerine suture to avoid tearing the tissue in this area. The cleft side of the premaxilla must also be handled with great care, because it is easy to interfere with the developing tooth buds.

The vomer flap is mobilised sufficiently to allow the flap to be turned, like a book page, across the cleft and sutured beneath the mucoperiosteal palatal flap, raw side against raw side.

The suturing begins posteriorly and moves forward. Either 4-0 or 5-0 polyglactin (Dexon) suture is used. From the anterior part of the palate and forward, the nasal floor is reconstructed by direct everting mattress sutures that connect the anterior part of the vomer flap to the nasal wound edge of the lateral side. This terminates in the nostril sill.

The labial muscle is then reconstructed across the cleft with 4-0 polyglactin sutures (Dexon). The lower third of the labial muscle is directed horizontally, if necessary, by making a horizontal cut between the lower and middle third of the labial muscle.

The skin incision is closed, with 6-0 polypropylene sutures. On the vestibular side of the lip, a Z-plasty is performed to avoid a whistling deformity.

Primary nasal correction is not routinely performed. If a severe alar cartilage deformity is observed when the alar base is brought medially to its normal position, a modified McComb procedure is performed. The skin is dissected free from the alar cartilage on the cleft side, and the alar cartilage is elevated with traction sutures that are looped over bolsters within the vestibule and tied over bolsters on the nasal dorsum. This also raises the nostril rim. Traction on this suture during closure of the anterior nasal floor makes it easier to achieve alar base symmetry.

Posterior palate closure

The palatal repair is based on von Langenbeck's principles. The incisions and flap thickness are similar, but unlike the von Langenbeck procedure, the oral mucoperiosteal layer as well as the nasal layer is closed. In addition, the levator muscle sling is reconstructed. For speech and hearing considerations, palatal closure at the age of 12 months is currently performed.

A self-retaining mouth gag (the Dott gag) is inserted and the operating field is infiltrated with local anaesthetic (0,5% lidocaine) and with epinephrine (1:50 000) to reduce bleeding.

The incisions are made along the cleft at the junction between the oral and nasal mucosa. The dissection begins anteriorly, and the mucoperiosteal flaps are bluntly dissected free from the bony palatal shelves. The difficult point during the dissection is at the junction between the soft and hard palate, where the mucosa is firmly attached to the bone. Careful dissection of the soft tissue from the bone and definition of the nasal layer allows visualisation of the anterior attachment of the levator muscle at the posterior medial edge of the hard palate. The muscle is cut and moved to a posterior position. A lateral longitudinal palatal incision is then made along the alveolar ridge on the borderline between the oral mucoperiosteum and the gingiva on both sides. The incision is carried to bone anteriorly; posterior to the hard palate, however, the incision is superficial through mucosa and submucosa only. The mucoperiosteal flaps are then completely undermined. The neurovascular palatine bundle is identified and is preserved. All connective tissue surrounding the bundles must be removed in order to achieve the necessary mobility of the flaps.

Suturing is initiated with the nasal layer. The first suture is placed in the soft palate area, where it is easy to approximate the nasal layer without tension before proceeding in an anterior direction. If the cleft is very broad in the anterior part, bilateral vomer flaps can be used in this area to close the nasal layer. The nasal layer is everted with sutures, and the knots are left on the nasal side. The levator veli palatini muscle sling is then reconstructed by suturing the two muscles together in the midline with separate sutures. Finally, the oral layer is closed with everting mattress sutures starting anteriorly. In the soft palate, the sutures are full thickness through the velar muscle and mucosa. Absorbable 4-0 polyglactin (Dexon) suture is used.

The lateral incisions are left open for secondary healing, which occurs in the 3 to 4 days, and it is never necessary to pack the denuded bone regions.

ID Number

SURGICAL PROTOCOL

Team: ……

Date of Birth: …….

Gender: …….

Date of Surgery: ……..

Surgeon: …….

Procedure: …….

…….

Type of Lip Repair: ……...

Type of Nose Repair: ……..

Side of cleft: …….

Soft Tissue Bridge: …… mm

	Step 1	Step 2
Arm A	☐	☐
Arm B	☐	☐
Arm C	☐	☐
Arm D	☐	☐

Deviation from described operation: ……...

……

Prophylactic Antibiotics	Yes	No
Pre-Op	☐	☐
Inter-Op	☐	☐
Transfusion (op day)	☐	☐

Surgical blood loss ……. ml

Operating Time …… min

Length of time in hospital … nights

Suture material in skin

Resorbable ☐

Non resorbable ☐

Early Complications	Yes	No
At surgery	☐	☐
Anaesthetic complication	☐	☐
Post op airway problems	☐	☐
Bleeding	☐	☐
Other complications	☐	☐

Details: ……..

……..

Late Complications	Yes	No
Minor dehiscence (< ¼)	☐	☐
Major dehiscence (> ¼)	☐	☐
Infection	☐	☐

Details: ……

……..

Minor dehiscence (< ¼)

ID Number

Nurses, Post-Operative Questionnaire.
Scandcleft Data Collection

Date of Birth …… Expected Date of Delivery…..……
Date of surgery:…….. Nude weight ……..
Gestational age at repair…… Primary Surgery: Tick box 1st ☐ or 2nd ☐

Where infant nursed following surgery

Recovery Room……... Length of stay…….
Intensive Care Unit……. Length of stay…….
High Dependency …….. Length of stay ……..
Ward (special nurse)…….. Length of time …….
Ward (normal staff ratio)……. Length of time…….

Observations monitored in 1st 48 hrs : Please underline if undertaken

- Arterial blood gasses, Carbon dioxide & Oxygen, Oxygen Saturation levels,
- Heart rate, Respiration, Body Temperature,
- Child restless, crying, calm, satisfied
- Others……..

Abnormal observations noted with above:…….

…….

Post operative blood loss: Ooze, Haemorrhage, None.
Treatment for above: Iron supplement, Blood transfusion, None.

Drugs used in first 0-24 hours:

	Name	Frequency	How administered
Pain relief:			
Anti–inflammatory:			
Antibiotics:			
Others:			

ID Number

Nurses, Post-Operative Questionnaire.
Scandcleft Data Collection

Drugs used 24 – 48 hours

	Name	Frequency	How administered
Pain relief:			
Anti–inflammatory:			
Antibiotics:			
Others:			

Method of feeding: Please underline as appropriate:

Oral: 0 – 6 hours, 6 – 12 hours, 12 – 48 hours, 48+ hours
Intravenous: 0 – 12 hours, 12 – 48 hours, 48+ hours
Nasogastric: 0 – 12 hours, 12 – 48 hours, 48+ hours

Additional comments …….

…….

Telephone contact at least 1 week later

Parents perception of stay in hospital on a scale of 0 – 5

Please underline one number, eg. very stressful = 5, no stress = 0

5 4 3 2 1 0

Additional comments: …….

…….

…….

Appendix 3
Protocol for the Speech Pathologists

Age	Method	Analysis	Action
1. 12 months	Observation Audio recording	Preference of place of articulation and occurrence of pressure consonants Evaluation of “babbling” stage	Send completed 12 month speech assessment and copy of audio tape recordings to project co-ordinator
2. 18 months	Audio and video recording	Evaluation of place and manner of articulation Perceptual evaluation of hypernasality	Send completed 18 month speech assessment and copy of audio and video tape recordings to project project co-ordinator
3. 3 years	Audio and video recording Repetition / naming Spontaneous speech	Transcription and perceptual analysis of speech variables	Send completed 3 year speech assessment, part of resonance form, copy of audio and video recordings and copy of audiogram to project co-ordinator
4. 5 years	Audio and video recording Repetition / naming Spontaneous speech / retelling Nasometer	Transcription and perceptual analysis of speech variables Acoustic analysis of hypernasality	speech assessment, part of resonance form, copy of audio and video recordings and copy of audiogram to project co-ordinator
5. 10 years	Audio and video recording Repetition / naming Spontaneous speech Nasometer	Transcription and perceptual analysis of speech variables Acoustic analysis of hypernasality	speech assessment, part of resonance form, copy of audio and video recordings and copy of audiogram to project co-ordinator
6. 18-22 years *	Audio and video recording Repetition / naming Spontaneous speech Nasometer	Transcription and perceptual analysis of speech variables Acoustic analysis of hypernasality	speech assessment, part of resonance form, copy of audio and video recordings and copy of audiogram to project co-ordinator

* Final assessment is work in progress and not yet decided upon

SCANDCLEFT SPEECH ASSESSMENT

INSTRUCTIONS FOR THE SPEECH PATHOLOGIST / THERAPIST
0 – 12 MONTHS

BACKGROUND INFORMATION

Feeding

A local speech pathologist or a specially trained nurse visits the *new-born* baby with UCLP during the first days and inform the parents about *feeding*. The information should be given according to the actual routines at each hospital/centre.

Ear Status

During the *first weeks* the family will visit the cleft centre for information about the treatment plan. Information about the status at 12 months of age should be entered on to the protocol. Grommets mean that ear status is not normal.

OBSERVATION

In centres where the evaluation is not done in connection with the palatal surgery the evaluation should be done at the age of 12 months +/-two weeks but always pre-operatively.

Babbling

At *12 months of age*, all children in the project will be seen by a speech pathologist in the Cleft Palate Team. The pre-speech vocalisations and early speech is evaluated during a one hour observation at the clinic. The evaluation should always be made pre-operatively. A protocol should be filled in during or immediately after the observation which should be audio tape recorded with a good digital technique. Indicate by ticking the boxes whether the information was observed by the speech pathologist / therapist or reported by the parents. A determination of “babbling stage” is performed as well as an evaluation of the presence/absence of pressure consonants and an evaluation of articulatory place. An estimation of the predominant place of articulation should, if possible, also be filled in.

One or more squares in the assessment form can be filled in depending on the child’s’ use of articulatory places, that is, whenever present mark a square.

Irrespective of language, the evaluation focuses on the child’s ability to produce consonant sounds at different places in the mouth and to build up enough intraoral pressure for production of pressure consonants. Thus, it will not be possible to perform comparisons between the single sounds produced by the children at the different centres.

In order to get the child to speak we recommend the following:

- Ask the parents to bring some of the child's own toys.
- Leave the observation room with the tape recorder switched on.

Some space is left for comments. It might be used for extra information e.g. usage of one word utterances at 12 months of age, apico-labial articulation of dentals or alveolars etc.

Finally, indicate whether the parents feel the speech production is representative for the child or not i.e. if the child uses the same speech sounds, words etc as at home (even though the frequency might be lower).

12 month speech assessments are not used for the main outcome in the Scandcleft trial.

ID Number

SCANDCLEFT SPEECH ASSESSMENT

12 MONTHS ASSESSMENT (preoperatively)

Speech and language Pathologist/Therapist: ……..

Centre: …… Community/County: ……..…

Date of Birth: …… (year) …… (month) …… (day) Date of recording: …… (year) …… (month) …… (day) Language: …….

BACKGROUND INFORMATION

Feeding

Breast Feeding: ☐ yes, completely ☐ yes, partially ☐ no

If yes, how long …….

Bottle feeding : ☐ yes ☐ no Type of bottle:……. Type of Nipple:……..

Comments: (for ex other feeding methods)…….

……

Ear status

Status normal	Left ear	☐ yes	☐ no	☐ not studied
	Right ear	☐ yes	☐ no	☐ not studied
Grommets	Left ear	☐ yes	☐ no	☐ not studied
	Right ear	☐ yes	☐ no	☐ not studied

OBSERVATION (audio recording)

Type of Babbling	Vocalisation:	☐ yes	☐ no	☐ not evaluated	☐ reported	☐ observed
	Repetitive babbling:	☐ yes	☐ no	☐ not evaluated	☐ reported	☐ observed
	Variegated babbling:	☐ yes	☐ no	☐ not evaluated	☐ reported	☐ observed
	Pressure consonants:	☐ yes	☐ no	☐ not evaluated	☐ reported	☐ observed
Place of Articula-tion	Labial:	☐ yes	☐ no	☐ not evaluated	☐ predominant	
	Alveolar/dental:	☐ yes	☐ no	☐ not evaluated	☐ predominant	
	Palatal/velar/uvular:	☐ yes	☐ no	☐ not evaluated	☐ predominant	
	Glottal:	☐ yes	☐ no	☐ not evaluated	☐ predominant	

Comments:…….

……

Do the parents feel that the babbling is representative : ☐ yes ☐ no ☐ do not know

SCANDCLEFT SPEECH ASSESSMENT

INSTRUCTIONS FOR THE SPEECH PATHOLOGIST / THERAPIST
18 MONTHS

At *18 months of age* all children are seen by a speech pathologist in the Cleft Palate Team at the clinic. The visit will be audio and video recorded. All audio recordings should be performed with a digital technique and all recordings with Super VHS video. An assessment form should be filled in after the visit.

BACKGROUND INFORMATION

Ear Status

Please refer to the 12 month speech assessment form. Grommets indicate that ear status is not normal.

Fistula

For children who have had palatal surgery before 18 months of age indicate whether there is a fistula in the palate.

Language

Indicate whether the child used single words (how many), two-word utterances and whether the child can follow simple instructions. For the language related information the Reel 2 material (the Bzoch-League Receptive-Expressive Emergent Language Scale) should be used. Enter the score of the Reel 2 on the assessment form and indicate whether the score relates to normal or delayed language development.

OBSERVATION

Presence/absence of hypernasality should be filled in on the assessment form.

The consonant repertoire for the child and the predominance of articulatory place/-s and manner/-s should be noted. One or more squares can be filled in depending on the child's' repertoire, that is, whenever present mark a square. If distortion such as nasal emission is heard, diacritics should be added.

Irrespective of language, the evaluations focus on the child's ability to produce consonant sounds at different places in the mouth and to build up enough intraoral pressure for production of pressure consonants. Thus, it will not be possible to perform comparisons between the single sounds produced by the children at the different centres.

In order to get the child to speak we recommend the following:

- Ask the parents to bring some of the child's own toys.
- Leave the observation room with the tape recorder switched on.

Some space is left for comments. It might be used for extra information e.g apico-labial articulation of dentals or alveolars etc.

Finally, indicate whether the parents feel the speech production is representative for the child or not i.e. if the child uses the same speech sounds, words etc. as at home (even though the frequency might be lower).

18 month speech assessments are not used for the main outcome in the Scandcleft trial.

ID Number

SCANDCLEFT SPEECH ASSESSMENT

18 MONTHS ASSESSMENT

Speech and language Pathologist/Therapist: ……..

Centre: …… Community/County: ……

Date of Birth: …… (year) …… (month) …… (day) Date of recording: …… (year) …… (month) …… (day) Language: ……

BACKGROUND INFORMATION

Ear status

Status normal	Left ear	☐ yes	☐ no	☐ not studied
	Right ear	☐ yes	☐ no	☐ not studied
Grommets	Left ear	☐ yes	☐ no	☐ not studied
	Right ear	☐ yes	☐ no	☐ not studied

Fistula

yes ☐ no ☐

Language

Single words	yes ☐	no ☐	not evaluated ☐	reported ☐	observed ☐
If yes, how many ☐					
2 word utterances:	yes ☐	no ☐	not evaluated ☐	reported ☐	observed ☐
Follows simple commands: (e.g. “Give me the ball”)	yes ☐	no ☐	not evaluated ☐	reported ☐	observed ☐

Score of “Reel 2”	R ☐	normal ☐
		delayed ☐
	E ☐	normal ☐
		delayed ☐

ID Number

SCANDCLEFT SPEECH ASSESSMENT

18 MONTHS ASSESSMENT

OBSERVATION (audio and video recording)

Hypernasality: yes ☐ no ☐ not evaluated ☐

Articu-lation/ sounds:	p/b	t/d	k/g	[ ]	[ ]
	s-like fricative	f/v	[ ]	[ ]	[ ]
	m	n	ŋ		

Put a circle around the sound your hear eg (p) / (b) or (t) / (d)

If you hear additional sounds, add them between the solidus.
Add diacritics

(eg p̃ for nasal escape on p).

Predominant articulatory place:

☐ Labial ☐ alveolar/dental ☐ palatal/velar/uvular ☐ glottal

Predominant articulatory manner:

☐ Plosive ☐ Fricative ☐ Approximant ☐ Nasal ☐ Other

Comments: ……

……

……

Do the parents feel that the speech is representative : ☐ yes ☐ no ☐ do not know

SCANDCLEFT SPEECH ASSESSMENT

INSTRUCTIONS FOR THE SPEECH PATHOLOGIST/THERAPIST 3 YEARS

At 3 years of age the children will be both audio and video tape recorded during the visit at the speech therapist. Important background information should be collected on a proforma and sent with copies of the recordings and audiogram to the coordinator. The speech analysis will be performed by a blinded procedure at a later moment.

BACKGROUND INFORMATION

Fistula

For children who have had palatal surgery before 3 years of age indicate if there is a fistula in the palate.

Ear and hearing

Status should be taken care of by an ENT-doctor. Audiogram should be taken by the professional who usually does it and a copy should be sent to the coordinator in Manchester.

Language

Use the REEL screening and give the scores in the proforma.

Speech therapy

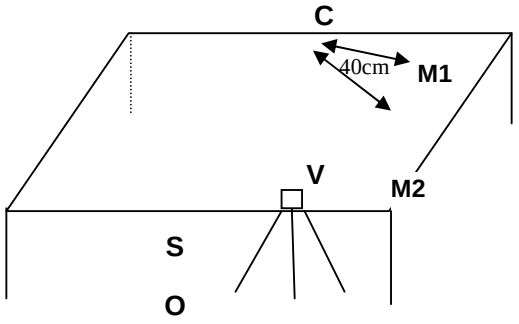
The total number of visits and the type of management counted from 0 - 3 years of age should be filled in the proforma including information from the local therapist. Do **not** count any sessions related to early intervention feeding. Comments on other types of speech intervention i e speech plates, oral motor training etc. should be filled under the box "other(s)".

SPEECH DOCUMENTATION

Equipment

A DAT tape recorder (SONY TCD-D8) with a condensator microphone (AKG C407/B) and a super-VHS video camera with external microphone of excellent quality.

Setting: Set–up for Video & Audio Recording of Speech



Key
C = child
S = speech therapist
O = camera operator
V = video recorder on tripod at child's level
M1 = microphone 1 (audio)
M2 = microphone 2 (video)

All three year assessments should be both tape and video recorded needing two persons to be involved. The examiner should be placed in front of the child with the camera man just behind so the camera is placed en face. The two microphones should be placed at a distance of about 40 cm from the edge of the table in front of the child and on the same side as the camera (please see the drawing). Use a neutral background and a distance that shows the head and the shoulders of the child with some space on both sides in the TV screen. The test pictures should be presented so the child could look at them in a straight forward position.

Material
30 pictures made in the computer software "BoardMaker". Two dummies will be presented for the child in order to get started. Minimal pairs for auditory discrimination; for example of dental/alveolar and velar.

Elicitation
See to that the parents do not interfere with the child's production. *Naming* should be used in the first place if this fails *semantic prompting* should be used and finally *repetition* if necessary. **No phonetic prompting** should be used. The examiner should repeat after the child in order to identify the words. Two minutes of spontaneous speech should be collected as well as counting to five. The spontaneous speech should be recorded on an audio tape. Try to do the spontaneous speech in the same setting as during the picture naming. If this is not possible try to do the best and indicate how it was done on the proforma. The spontaneous speech could be elicited in different ways.

- Naming 30 pictures and 2 dummies
- Counting to 5
- Two minutes spontaneous speech (accumulated time)

Analysis
The **single words** are both used for analysis of consonant articulation and nasal resonance: hypernasality on high vowels and hyponasality on nasal consonants. The **counting** and the **spontaneous speech** are used for overall judgement of resonance and perceived velopharyngeal function. (please, see separate proformas with a manual for the documentation and analysis).

3 year speech assessments are not used for the main outcome in the Scandcleft trial.

ID Number

SCANDCLEFT SPEECH ASSESSMENT

3 YEAR ASSESSMENT

Speech and language Pathologist/Therapist: ……..

Centre: …… Community/County: ……

Date of Birth: …… (year) …… (month) …… (day) Date of recording: …… (year) …… (month) …… (day) Language: ……

BACKGROUND INFORMATION
Ear status

Status normal	Left ear	☐ yes	☐ no	☐ not studied
	Right ear	☐ yes	☐ no	☐ not studied
Grommets	Left ear	☐ yes	☐ no	☐ not studied
	Right ear	☐ yes	☐ no	☐ not studied
Audiogram		☐ yes	☐ no	

Fistula

Yes ☐ no ☐

Language

Score of "Reel 2"

R ☐ normal ☐ delayed ☐

E ☐ normal ☐ delayed ☐

Speech therapy (from 0-3 years)

Total number of visits (Team & Local SLT) ☐

Team speech therapist (number) ☐

Local speech therapist (number) ☐

Type of management

Routine (number) ☐

Review (number) ☐

Counselling parents (tick) ☐

Counselling others (tick) ☐

Treatment (number) ☐

Reason for intervention

Language delay ☐

Phonological problems ☐

Articulation problems ☐

Resonance problems ☐

Voice problems ☐

Other(s) ☐

If you have ticked more than one box, please indicate the main focus of intervention (circle).

OBSERVATION /ANALYSIS

On separate proformas for blinded consonant and resonance analyses

Comments ……

SCANDCLEFT SPEECH ASSESSMENT

INSTRUCTIONS FOR THE SPEECH PATHOLOGIST/THERAPIST 5 YEARS

At 5 years of age all the children will be seen by the speech therapist at the unit for both digital audio and videotape recordings and measurement on the Nasometer. Important background information should be collected on a proforma and sent with copies of the recordings and the audiogram to the project coordinator. The speech analysis will be performed using a blinded procedure at a later date.

BACKGROUND INFORMATION

Ear and hearing
Status should be taken care of by an ENT-doctor. Audiogram should be taken by the professional who usually performs the assessment and a copy should be sent to the coordinator in Manchester.

Fistula
Indicate if there is a fistula in the palate.

Tonsilectomy	)	
Adenoidectomy	)	Indicate with a tick in the appropriate box if the
V-P Investigation	)	child has had any of these procedures
Secondary surgery for VPI	)	

The investigation of VP-dysfunction is an additional speech assessment.

Language
The “Bus story” should be used to elicit spontaneous speech and as a screening assessment of ‘language level’. A number of statements about language performance should be ticked (see separate sheet). A full analysis of the ‘bus story’ need not be performed within the Scandcleft project. Record the ‘bus story’ on DAT and video.

Speech therapy
The total number of contacts since birth with both the cleft team speech therapist and the local speech therapist should be filled in using a number. Numbers should also be used to fill in the *routine*, *review*, and the *treatment* boxes. The two *counselling* boxes can be ticked. The reason for intervention should be indicated with a tick in one or more of the boxes. If more than one is ticked you should circle the main focus of intervention. Comments on other types of speech intervention i.e. speech plates, oral motor training etc. should be entered into the box "other(s)".

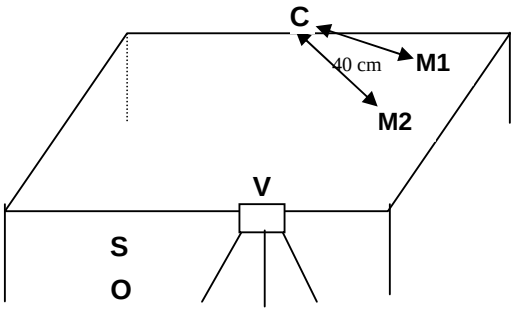
SPEECH DOCUMENTATION

Equipment
The following equipment should be used:-

- A DAT tape recorder (SONY TCD-D8) or one of comparable quality with a condensor microphone (AKG C407/B) or one of comparable quality.
- A Super-VHS or digital video camera with external microphone of excellent quality.

- Nasometer (Key Elemetrics Corp.) (The DAT with a good quality microphone will be used to record this session).

Setting



Key
C = child
S = speech therapist
O = camera operator
V = video recorder on tripod at child's level
M1 = microphone 1 (audio)
M2 = microphone 2 (video)

All 5 year assessments should be both audiotape and video recorded and undertaken by two clinicians. The examiner should sit opposite the child with the camera operator just behind so that the camera lens is directly facing the child. The two microphones should be placed at a distance of about 40 cm from the edge of the table in front of the child and on the same side as the camera (please see the drawing). Use a neutral background and focus in on the child so that their head and the shoulders are in the centre of the viewer with some space on either side. The test pictures should be presented in such a way that the child is able to look straight ahead into the camera.

Points to remember
* use external microphones
* minimize external noise
* check recordings to avoid reoccurrence of same problem
* use camera person
* repeat word after child

The assessment with the Nasometer should be audiotape recorded. This will enable the child's speech production and cooperation during the data collection session to be reviewed at a later date.

Material

The following material should be used:

- 33 colour pictures created using the computer software "BoardMaker".
  (This includes the 30 original pictures + the 3 pictures with initial /s/).
  The nine high vowel pictures (randomised) should be presented initially followed by the rest of the pictures (also randomised). There is a standard procedure for randomisation.

- Two dummy pictures should be presented to the child at the very start.

- The Bus story - language screen (Winslow Press Limited, Telford Road, Bicester, Oxon OX6 0TS, UK)

- Minimal pair pictures for auditory discrimination e.g. dental/alveolar and velar contrasts should be available.
- Pictures for nasometry – 9 high vowels

- Ma-ma-ma-ma-ma-string

- Each centre is recommended to add language specific sentences to the nasometry protocol to allow intra- and intercentre comparisons within language.

  Three types of sentences are recommended:
1) oral sounds only
2) one nasal consonant
3) several nasal consonants

Elicitation

Speech
Ensure the parents do not interfere with the child's production. ***Naming*** should be used in the first instance, if this fails ***semantic prompting*** should be used. Finally if all else fails, the child should ***repeat*** the word. **No phonetic prompting** should be used. **The examiner should repeat the target word after the child** in order to identify the words. A short pause between child's production and adult's is preferred.
Spontaneous speech should be elicited using the Bus story.

Nasometer
The 9 high vowel pictures should be named by the child in a sequence. This should be repeated 5 times with the pictures in the same order each time. The pictures from the naming test should be used to elicit this data. The pictures should be held up for the child one at a time and they should name them. To test **hyponasality** ask the child to repeat "ma ma ma ma ma" 5 times – calculating the percentage nasalance score each time so you end up with 5 scores. Language specific sentences should be repeated by the child and scores recorded.

The nasometer scores for each sequence of the 9 high vowel words and the 'ma ma ma' strings should be noted on the proforma and saved on the computer for analysis at a later date.

Note on the proforma under comments if the child has a cold or blocked nose.

Order of assessment

*

1) Naming test - (and do discrimination test if needed) – 33 pictures and 2 dummy pictures
2) Bus story
3) Counting 1-10 and repetition of "ma ma ma ma ma" syllable string twice
4) Nasometry (9 high vowel words and ma-ma-ma-ma-ma string)

* Conversational speech can be elicited at the beginning or end of the session (accumulated time = 2 minutes).

Analysis

The **single words** are used for both analysis of consonant articulation and nasal resonance: hypernasality on high vowels and hyponasality on nasal consonants. The **counting** and the **spontaneous speech** are used for overall judgement of resonance and perceived velopharyngeal function (see separate proformas plus the manual for the documentation and analysis).

SCANDCLEFT SPEECH ASSESSMENT

ID Number

5 YEAR ASSESSMENT

Speech and Language Pathologist/Therapist: ……

Centre: …….. Community/County: ……

Date of Birth: …… …….. ……. (year) (month) (day) Date of recording: …… …….. …….. (year) (month) (day) Language: ……

BACKGROUND INFORMATION

Ear status

Status normal	Left ear	☐ yes	☐ no	☐ not studied
	Right ear	☐ yes	☐ no	☐ not studied
Grommets	Left ear	☐ yes	☐ no	☐ not studied
	Right ear	☐ yes	☐ no	☐ not studied
	Audiogram	☐ yes	☐ no	

Fistula

yes ☐ no ☐

Tonsilectomy

yes ☐ no ☐

Adenoidectomy

yes ☐ no ☐

V-P Investigation

yes ☐ no ☐

Secondary surgery for V.P.I.

yes ☐ no ☐

Language

Screening (Bus story) ☐

normal ☐

suspected delay ☐

Speech therapy (from 0-5 years)

Total number of visits (Team & Local SLT) ☐

Type of management

Team speech therapist (number) ☐

Local speech therapist (number) ☐

Routine (number) ☐

Review (number) ☐

Counselling parents (tick) ☐

Counselling others (tick) ☐

Treatment (number) ☐

Reason for intervention - If you have ticked more than one box, please indicate the main focus of intervention (circle).

Language delay ☐

Phonological problems ☐

Articulation problems ☐

Resonance problems ☐

Voice problems ☐

Other(s) ☐

SCANDCLEFT SPEECH ASSESSMENT

5 YEAR ASSESSMENT

ID Number

OBSERVATION /ANALYSIS

Nasalance

Score on 9 high vowel word string

Score on “ma ma ma ma” string

Speech

On separate proformas for blinded consonant and resonance analyses

Material completed YES NO

Comments …….

…….

…….

SCANDCLEFT SPEECH ASSESSMENT

INSTRUCTIONS FOR THE SPEECH PATHOLOGIST/THERAPIST 10 YEARS

At 10 years of age all the children will be seen by the speech therapist at the unit for both digital audio and videotape recordings and measurement on the Nasometer. Important background information should be collected on a proforma and sent with copies of the recordings and the audiogram to the project coordinator. The speech analysis will be performed using a blinded procedure at a later date.

BACKGROUND INFORMATION

Ear and hearing
Status should be taken care of by an ENT-doctor. Audiogram should be taken by the professional who usually performs the assessment and a copy should be sent to the coordinator in Manchester.

Fistula
Indicate if there is a fistula in the palate.

Tonsilectomy	)	
Adenoidectomy	)	Indicate with a tick in the appropriate box if the
V-P Investigation	)	child has had any of these procedures
Secondary surgery for VPI	)	

The investigation of VP-dysfunction is an additional speech assessment.

Language
The “Bus story” should be used to elicit spontaneous speech. Record the ‘bus story’ on DAT and video.

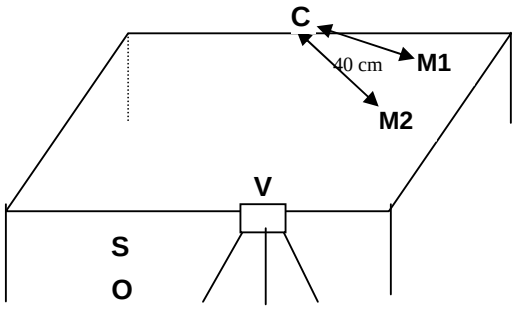
Speech therapy
The total number of contacts between 5 and 10 years of age with both the cleft team speech and language therapist and the local one should be filled in using a number. Numbers should also be used to fill in the *routine*, *review*, and the *treatment* boxes. The two *counselling* boxes can be ticked. The reason for intervention should be indicated with a tick in one or more of the boxes. If more than one is ticked you should circle the main focus of intervention. Comments on other types of speech intervention i.e. speech plates, oral motor training etc. should be entered into the box "other(s)".

SPEECH DOCUMENTATION

Equipment
The following equipment should be used:-

- A DAT tape recorder (SONY TCD-D8) or one digital of comparable quality with a condensor microphone (AKG C407/B) or one of comparable quality.
- A digital video camera with external microphone of excellent quality.
- Nasometer (Key Elemetrics Corp.) (The DAT with a good quality microphone will be used to record this session).

Setting



Key
C = child
S = speech therapist
O = camera operator
V = video recorder on tripod at child's level
M1 = microphone 1 (audio)
M2 = microphone 2 (video)

All 10 year assessments should be both audiotape and video recorded and undertaken by two clinicians. The examiner should sit opposite the child with the camera operator just behind so that the camera lens is directly facing the child. The two microphones should be placed at a distance of about 40 cm from the edge of the table in front of the child and on the same side as the camera (please see the drawing). Use a neutral background and focus in on the child so that their head and the shoulders are in the centre of the viewer with some space on either side. The test pictures should be presented in such a way that the child is able to look straight ahead into the camera.

Points to remember
* use external microphones
* minimize external noise
* check recordings to avoid reoccurrence of same problem
* use camera person
* repeat word after child

The assessment with the Nasometer should be audiotape recorded. This will enable the child's speech production and cooperation during the data collection session to be reviewed at a later date.

Material

The following material should be used:

- 33 colour pictures created using the computer software "BoardMaker". (This includes the 30 original pictures + the 3 pictures with initial /s/). All pictures should have the words written on for reading.
  The nine high vowel pictures (randomised) should be presented initially followed by the rest of the pictures (also randomised). There is a standard procedure for randomisation.

- Two dummy pictures should be presented to the child at the very start.

- Composite picture or 'The Bus Story' – connected speech sample (Winslow Press Limited, Telford Road, Bicester, Oxon OX6 0TS, UK)

- Sentences

- Pictures for nasometry – 9 high vowels

- Ma-ma-ma-ma-ma-string

- Each centre is recommended to add language specific sentences to the nasometry protocol to allow intra- and intercentre comparisons within language.

  Three types of sentences are recommended:

1) oral sounds only
2) one nasal consonant
3) several nasal consonants

Elicitation

Speech

Ensure the parents do not interfere with the child's production. ***Reading*** should be used in the first instance, if this fails **naming** should be used. Semantic prompting can be used. Finally if all else fails, the child should ***repeat*** the word. **No phonetic prompting** should be used. **The examiner should repeat the target word after the child** in order to identify the words. A short pause between child's production and adult's is preferred. Spontaneous speech should be elicited using the Bus story.

Nasometer

The 9 high vowel pictures should be named by the child in a sequence. This should be repeated 5 times with the pictures in the same order each time. The pictures from the naming test should be used to elicit this data. The pictures should be held up for the child one at a time and they should name them. To test **hyponasality** ask the child to repeat "ma ma ma ma ma" 5 times – calculating the percentage nasalance score each time so you end up with 5 scores. Language specific sentences should be repeated by the child and scores recorded.

The nasometer scores for each sequence of the 9 high vowel words and the 'ma ma ma' strings should be noted on the proforma and saved on the computer for analysis at a later date.

Nb. Note on the proforma under comments if the child has a cold or blocked nose.

Order of assessment

*

1) Naming test - (and do discrimination test if needed) – 33 pictures and 2 dummy pictures
2) Bus story
3) Counting 1-20 in native language and 1-10 in English
4) Repetition of "ma ma ma ma ma" syllable string twice
5) Repetition of sentences
6) Nasometry (9 high vowel words and ma-ma-ma-ma-ma string)

* Conversational speech can be elicited at the beginning or end of the session (accumulated time = 2 minutes).

Analysis

The **single words** are used for both analysis of consonant articulation and nasal resonance: hypernasality on high vowels and hyponasality on nasal consonants. The **counting** and the **spontaneous speech** are used for overall judgement of resonance and perceived velopharyngeal function (see separate proformas plus the manual for the documentation and analysis).

SCANDCLEFT SPEECH ASSESSMENT

10 YEAR ASSESSMENT

ID Number

Speech and Language Pathologist/Therapist: ……

Centre: …….. Community/County: ……

Date of Birth: …… …….. ……. Date of recording: ……. ……. ……. Language: ……
(year) (month) (day) (year) (month) (day)

BACKGROUND INFORMATION

Ear status

Status normal	Left ear	☐ yes	☐ no	☐ not studied
	Right ear	☐ yes	☐ no	☐ not studied
Grommets	Left ear	☐ yes	☐ no	☐ not studied
	Right ear	☐ yes	☐ no	☐ not studied
	Audiogram	☐ yes	☐ no	

Fistula

yes ☐ no ☐

Tonsilectomy

yes ☐ no ☐

Adenoidectomy

yes ☐ no ☐

V-P Investigation

yes ☐ no ☐

Secondary surgery for V.P.I.

yes ☐ no ☐

Speech Sample

Bus story yes ☐ no ☐

Conversational speech yes ☐ no ☐

Speech therapy (from 5-10 years)

Total number of visits (Team & Local SLT) ☐

Team speech therapist (number) ☐

Local speech therapist (number) ☐

Type of management

Routine (number) ☐

Review (number) ☐

Counselling parents (tick) ☐

Counselling others (tick) ☐

Treatment (number) ☐

Reason for intervention - If you have ticked more than one box, please indicate the main focus of intervention (circle).

Language delay ☐

Phonological problems ☐

Articulation problems ☐

Resonance problems ☐

Voice problems ☐

Other(s) ☐

SCANDCLEFT SPEECH ASSESSMENT
10 YEAR ASSESSMENT

ID Number

OBSERVATION /ANALYSIS

Nasalance

Score on 9 high vowel word string

Score on “ma ma ma ma” string

Speech

On separate proformas for blinded consonant and resonance analyses

Material completed YES NO

Comments …….

…….

…….

SCANDCLEFT PROJECT

Therapy Questionnaire

To be completed by the local speech therapist

Date of birth:……...

1. How many times has the above child been seen by a local speech therapist since birth?
…….

2. What type of management has been carried out? (you can tick more than 1 box)

☐ review/monitor

☐ counselling/advice to parents

☐ counselling/advice to others

☐ treatment – speech therapy

how many treatment sessions? ☐

3. Reasons for intervention with this child? (you can tick more than 1 box)
Please circle main focus of therapy

☐ Language delay

☐ Phonology delay

☐ Articulation problems

☐ Resonance problems

☐ Voice problems

☐ Other (s)…….

Signed:……..……..

Date:…….

ID Number

SCANDCLEFT

Investigation of V-P dysfunction

	Yes	No	Date of Recording
Extra Speech assessment			/ /
Videofluroscopy : frontal			/ /
lateral			/ /
Nasendoscopy			/ /
Nasometry			/ /
Other instrumental analysis			/ /

Give details

……

……

Appendix 4

Protocol for Orthodontists

Documentation as regards to dental study models, radiographs and photographs.

On the following page is an overview of the timing for record taking.

The first comprehensive analysis will be done at age 5 years. The orthodontists plan to follow the patients until age 18-21 years.

In principle: study models, photos and cephalograms will be analysed according to the protocols of the Scandcleft (Friede et al., 1991; Enemark et al., 1993) and Eurocleft (Shaw et al., 1992, Mølsted et al., 1992, Mars et al., 1992, Asher-McDade et al., 1992) studies (and future refinements of these that are currently being developed within the study groups). Soft tissue measurements have shown to be a sensitive outcome measure (Friede et al., 1991; Mølsted et al., 1992; Mackay et al., 1994). A new 5-year model analysis for dental arch relationship has been developed and is undergoing further validation (Hathorn et al., 1996, Atack et al., 1997).

DOCUMENTATION AS REGARDS TO DENTAL STUDY MODELS, RADIOGRAPHS AND PHOTOGRAPHS

	PHOTOGRAPHS			MODELS			X-RAYS		
	Por-trait x 3	Lip-nose x 2	Occlu sion x 4		Den-tal casts		Lat ceph	Occlu sal X-ray cleft side	OPG
PRE-SURG 1									
PRE-SURG 2									
5 YEARS									
8 YEARS									
10 YEARS									
PRE-ORTHO 11-13 YEARS									
POST-ORTHO 14-16 YEARS									
ADULT 18-21 YEARS									

Photographic documentation:

1. Pretreatment photos.

- Frontal and worms-eye view (Figs. 1a and b). The extra-oral slides should be taken with a standardised magnification of ¼. If this exact magnification adjustment is not available, please take a second slide adding a ruler in the measurement plane (nose/lip) to allow calibration for computer analysis.
- Close-up photos at magnification ½ if the patient is co-operative (Figs. 1c and d).
- A photo of the preoperative study cast (magnification ½) (Fig. 1e). If the proper magnification is not possible, please add a ruler.

2. Immediate preoperative and immediate postoperative photos.

- Close-up photos of the lip and worms-eye view are required (same projection and magnification as Figs. 1c and d).
- Pre- and postoperative photos of the palate are required. These should be taken while the patient is still on the operating table as a documentation of the performed surgery.
  (Please note there are no illustrations provided for these photos).

3. Photos before the second operation at 12 months of age (leg A, C and D) or 3 years of age (leg B).

- Extra-oral photos; en face and worms-eye view are taken. The same standard as 1 (Figs. 2a, b).
- A photo of the dental cast made just before this second operation, magnification ½ (Fig. 2c).
- Photos of the palate are also taken pre- and postoperatively (see 3j).

4. Photos at 5 years of age.

- Full face portrait photos; en face, ¾ and profile of the cleft side (Figs. 3a, b, c).
- A ¼ magnification photo is taken including the eyes, nose, lip and mouth (Fig. 3d).
- A similar photograph is taken with the patient biting on a spatula to detect any tilting of the occlusal plane (Fig. 3f).
- Worms-eye view (Fig. 3e).
- Intraoral photos of the occlusion: right and left side front and palatal view (Figs. 3g, h, i, j)

Instructions

Profile photo: Let the patient stand up with relaxed, closed lips and look directly at him or her self in the eyes in a mirror. The picture is not taken straight from the lateral but slightly forward compared to the patient. At the ¾ picture observe that the nose is just inside the cheek. Another important point is that the photographer is at the same vertical level as the patient.

Antero-posterior close-up view: The patient can be placed in the dental chair with the interpupillary line horizontal. The patient is asked to look into the camera and the face is symmetrically orientated with no turning sideways and the distance from the outer cantos equal on both sides. The sagittal tilting of the face is then orientated with the interpupillary line just above the ears. The patient is asked to look into the camera with the pupils visible and the mouth relaxed.

Worms-eye view: The same standard lighting and enlargement conditions are used. The patient is asked to tilt the head backwards until the tip of the nose is seen between the eyes in the glabella area, but without the upper lip overshadowing the nasal alar base, and again the patient is asked to have a relaxed mouth.

5. Photos at age 8, 12, 16 and 19-21 years of age.

- Standardised extra and intraoral photos are taken as described at 4 (Figs. 4a-j).

6. Photos before orthodontic treatment.

- In the early mixed dentition intraoral photos are taken of the occlusion: right and left side, frontal and palatal view (Figs. 4g-j).

7. Photos before, during and after the final orthodontic treatment.

- The same photos as in 6 are taken. A few illustrations are given in Figs. 5a-b and Figs. 6a-c.

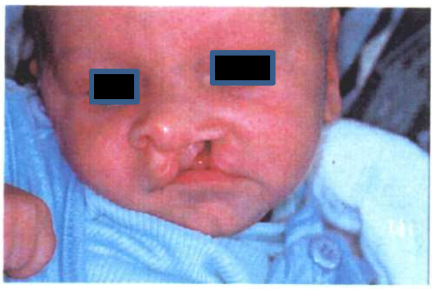


Fig 1(a)

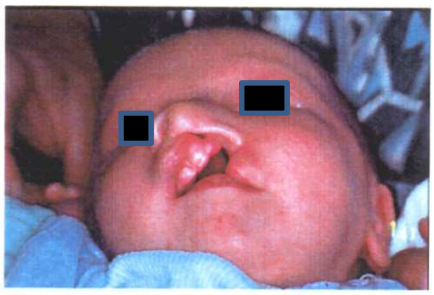


Fig 1(b)

Fig 1(c)

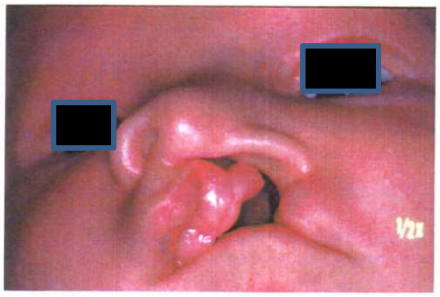


Fig 1(d)

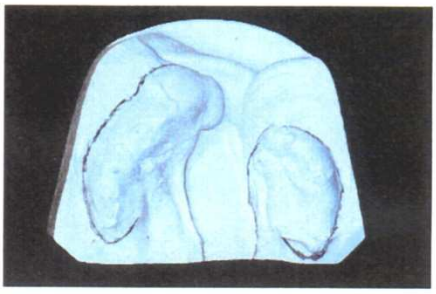


Fig 1(e)

Fig 2(a)

Fig 2(b)

Fig 2(c)

Fig 3(a)

Fig 3(b)

Fig 3(c)

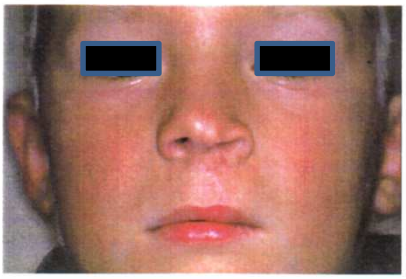


Fig 3(d)

Fig 3(e)

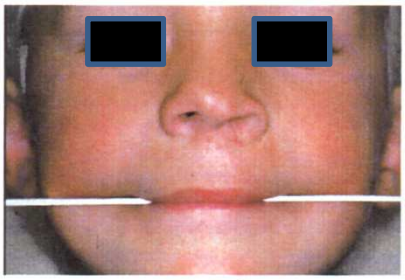


Fig 3(f)

Fig 3(g)

Fig 3(h)

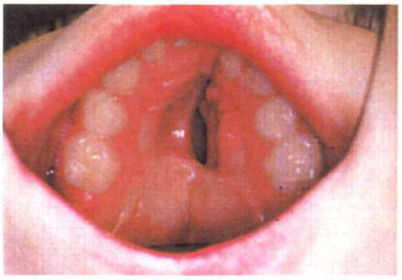


Fig 3(i)

Fig 4(a)

Fig 4(b)

Fig 4(c)

Fig 4(d)

Fig 4(e)

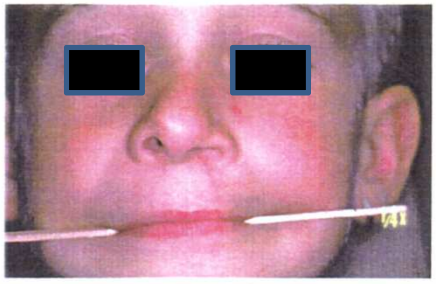


Fig 4(f)

Fig 4(g)

Fig 4(h)

Fig 4(i)

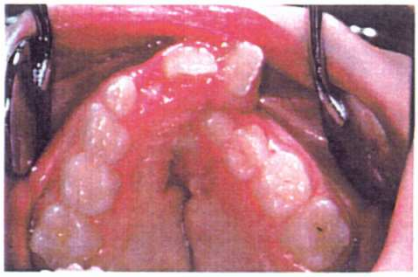


Fig 4(j)

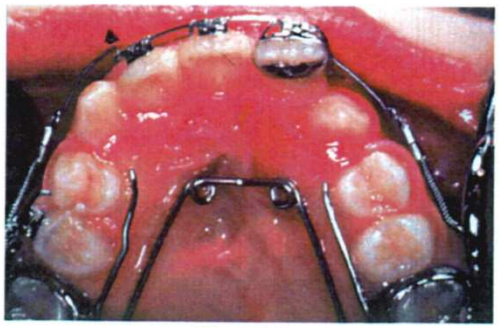


Fig 5(a)

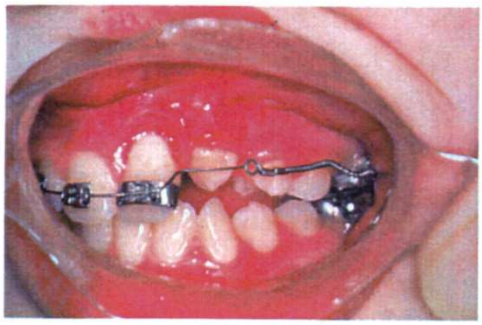


Fig 5(b)

Fig 5(c)

Fig 5(d)

Fig 5(e)

Appendix 5

Parent satisfaction questionnaire

SCANDCLEFT

QUESTIONNAIRE for PARENTS
+
CLEFT EVALUATION PROFILE

Dear Parent,

As you know, your child is participating in a project called 'Scandcleft' in order to look at the results of cleft lip and palate treatment. We believe that it is very important to understand the psychological and social outcomes for you and your child.

Therefore, we would be very grateful if you could take the time to complete these questionnaires before returning to your next appointment. **There are no right or wrong answers, just answer it in the way that seems right to you**. Please bring the completed questionnaires with you to the clinic. If you are unsure how to complete the questionnaires, then somebody will go through them with you at the clinic.

We do feel it is important to have this information which will help us provide the best care for the children we treat.

Thank you very much for your time and effort – it is much appreciated.

Yours sincerely

SCANDCLEFT

QUESTIONNAIRE for PARENTS

Section 1: Background

Age of child …….. Gender ……..

Occupation of parents

……

……

……

Are there any other brothers and / or sisters in the family? YES ☐ NO ☐

If yes, what are their ages?

…….....

……

Any other family members with a cleft? YES ☐ NO ☐

If yes, which family members? ……..

……

Section 2: Responses to treatment (use Cleft Evaluation Profile)

This is a way of assessing the results of the treatment. Please complete the measure following the instructions at the top.

Section 3: Responses to the cleft

Did you have an ante-natal diagnosis? YES ☐ NO ☐

If yes, at what stage of pregnancy? ….……...

……

……..……

Did you get support from your family? YES ☐ NO ☐

If yes, what type of support?……

……

……

……

Did you get support from your friends? YES ☐ NO ☐

If yes, what type of support? ……

……

……

Were any of your family or friends unsupportive of you? YES ☐ NO ☐

If yes, in what way?……..

……

……

……

Did you get support from the professionals treating your child? YES ☐ NO ☐

If yes, from whom? ……...

……

……

……

Did you have any comments from strangers when you took your baby out before the lip surgery? YES ☐ NO ☐

If so, what sorts of comments? ……

……

……

……

How did you react at the time? ……..….

……..……..……..

……..……..……..……

……..……..……..…..

How do you feel now? ……...

……..……..……..…

……..……..……..……

……..……..……..…

Are there any differences between the parents in how you feel? YES ☐ NO ☐

If so, then describe…… ……

……..……..……..……

……..……..……..……

……..……..……..……

Section 4: Responses of the child to the cleft

Has your child asked any questions or made any comments about anything relating to the cleft? YES ☐ NO ☐

What has he/she asked or said?..……

……..……..……..……

……..……..……..……

……..……..……..……

……..……..……..……

……..……..……..……

……..……..……..……

Has your child shown any signs of being upset about anything relating to the cleft? YES ☐ NO ☐

If so, then describe and say at what age ……

……

……

……

Have any other children commented or teased your child because of the cleft? YES ☐ NO ☐

If so, then describe who by and say at what age your child was teased

……

……

……

……

How has your child coped with attending:

a) Speech therapy?……

……

……

b) Surgery?……

……

……

c) Other? (please specify) ……

……

……

Do you have any worries about your child's future? YES ☐ NO ☐

If so, then describe ……

……

……

……

Has the experience of having a child with a cleft affected decisions about having further children? YES ☐ NO ☐

If so, then describe ……

……

……

Any further comments you would like to make?

……

……

……

……

……

……

……

……

……

Questionnaire completed by :

☐ Mother

☐ Father

☐ Both

☐ Other (please specify)

……

CLEFT EVALUATION PROFILE

In each case below, please circle 1 to 7 to indicate how you feel about different aspects of your child's cleft lip and palate. 1 indicates that you are very satisfied, 7 that you are very dissatisfied.

SPEECH

1 2 3 4 5 6 7
very satisfactory very unsatisfactory

HEARING

1 2 3 4 5 6 7
very satisfactory very unsatisfactory

APPEARANCE OF THE TEETH

1 2 3 4 5 6 7
very satisfactory very unsatisfactory

BITE

1 2 3 4 5 6 7
very satisfactory very unsatisfactory

APPEARANCE OF THE LIP

1 2 3 4 5 6 7
very satisfactory very unsatisfactory

APPEARANCE OF THE NOSE

1 2 3 4 5 6 7
very satisfactory very unsatisfactory

BREATHING

1 2 3 4 5 6 7
very satisfactory very unsatisfactory

PROFILE OF THE FACE

1 2 3 4 5 6 7
very satisfactory very unsatisfactory

Scandcleft