

The design of cleft lip and palate surgery pathways in Wales

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Key points

This article details the rationale for surgical pathway decisions, made at the start of a cleft surgical career and categorised by cleft phenotype.

The Welsh Centre for Cleft Lip and Palate is relatively unusual among centralised UK cleft teams as being a single-surgeon service.

Early open declaration of surgical intent helps to pave the way for transparent outcome reporting.

Abstract

This article describes the decisions made relating to cleft surgery pathway design in a single-surgeon cleft service in the United Kingdom at the start of a cleft surgeon's consultant career. Pathways are described according to cleft phenotype and detail aspects of surgical technique, sequence and timing. Transparency is vital to ensure clinical governance and external analysis, especially in the setting of a single-surgeon service. This early declaration of surgical intent aims to lead the way for ongoing reflection, so that future changes to practice can be identified and outcomes monitored.

Introduction

Cleft surgeons are united globally by a common desire to provide the highest quality care for their patients and yet there is a striking diversity of surgical pathways in common use with a paucity of scientific evidence to support them.^{1,2} Cleft surgeons have typically published their chosen surgical pathways towards the end of their career, when they are established and have earned their reputation. High-profile examples of this include Roberto Brusati³ and Jean Claude Talmant.⁴ While it is undoubtedly incredibly valuable to learn from experienced clinicians, publishing at the end of a career, in isolation, could potentially be problematic due to recall bias.

Centralised cleft services in the United Kingdom (UK) match their number of surgeons to their caseload, to ensure surgeons operate on at least 30 new babies born with cleft lip and/or palate per year, as stipulated in the national service specification.⁵ The Welsh Centre for Cleft Lip and Palate is relatively unusual in that

it is a single-surgeon UK cleft service (Fig. 1). Having been appointed as the Welsh Cleft Surgeon September 2024, I had the opportunity to design bespoke cleft surgery pathways at the start of my cleft surgery career with the multidisciplinary cleft team.

The aim of this opinion article is to document my chosen paediatric cleft surgical pathways (for patients aged 0–16 years) in the hope that an open declaration of surgical intent and associated reasoning would set the scene for transparent and accurate outcome reporting in the future.

Training to be a cleft surgeon and designing cleft pathways

My surgical training was, for the most part, carried out within the UK National Health Service (see online Supplementary Information).⁶ I trained in the plastic and reconstructive surgery parent specialty and undertook two years of dedicated cleft fellowship training (Cleft and Craniofacial Fellowship at the Royal Children's Hospital in Melbourne, Australia and the Training Interface Group Fellowship in Cleft Lip and Palate at the Spires Cleft Centre in Oxford and Salisbury, UK), before being appointed as an independent consultant cleft surgeon. Cleft surgery pathway decisions were initially proposed by me, based on my personal training experiences and interpretation of evidence in the literature.

Modifications were made following discussion with cleft care professionals within the Welsh cleft multidisciplinary team and presentation to global cleft professionals at a dedicated Circle of Cleft Professionals online forum.⁷

This article details the agreed surgical pathways by cleft phenotype (see the online Supplementary Information for accompanying peri-operative care, operative kardex and operative steps).

Unilateral and bilateral cleft lip +/- alveolar cleft

Single-stage reconstruction of the unilateral cleft lip will be scheduled at 4–5 months, aiming to improve maternal bonding in infancy.^{5,8,9}

The markings for unilateral lip reconstruction are influenced by the anatomical subunit approximation technique described by David Fisher¹⁰ and modifications described by Marc Swan¹¹ and David Chong.¹² Subperiosteal dissection is chosen to reorientate the facial envelope⁴ because of limited evidence to suggest a detrimental impact on maxillary growth outcomes compared to supra-periosteal dissection.¹³ The primary rhinoplasty is a closed technique aiming to address the anatomical differences associated with the unilateral cleft nose, in order to reduce stigma during childhood, while minimising the risk for secondary deformity.^{14,15} Elements of the

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primary rhinoplasty include caudal septal dissection and repositioning without suture fixation, closed nasal tip dissection, internal nasal valve plication, and alar transfixion stitches. Silicone nasal stents, stitched in place for six weeks, aim to improve alar shape and reduce risk of nostril stenosis.¹⁶

The markings for bilateral cleft lip reconstruction follow the principle of recruiting white roll and vermillion tissue from the lateral lip elements, as described by David Chong¹⁷ (technique influenced by John Mulliken and David Fisher).^{18,19} The strategy for asymmetric bilateral cleft lip reconstruction is to favour a complete primary bilateral lip reconstruction in infancy, with the aim of achieving tissue balance, as influenced by David Fisher.²⁰ The approach to primary rhinoplasty mirrors the principles described for the unilateral phenotype, with the exclusion of septal dissection/repositioning and with the addition of an alar cinch stitch to set the alar bases.

If an alveolar cleft is present, reconstruction with an autologous alveolar bone graft (ABG) will usually be performed at 8–11 years of age, based on dental development during mixed dentition.²¹ Patients will be jointly assessed at 7–8 years of age by the cleft surgeon, orthodontist and paediatric dentist to determine the ideal timing for the ABG. Pre-operative orthodontic expansion will be used if surgical access is required or to improve arch alignment.^{22,23} The extraction of erupted cleft-adjacent teeth will occur intra-operatively at the time of alveolar bone grafting due to weak evidence to suggest a clinical benefit for extraction in advance and to reduce the burden of additional anaesthetic episodes.^{24,25} Bilateral clefts of the alveolus will preferentially be reconstructed in a single stage; however, if palatal fistulae are present (typically Pittsburgh 5/6 fistulae), bilateral alveolar clefts will be reconstructed in two stages to increase the likelihood of definitive fistulae closure and reduce the risk of premaxillary necrosis.

Cleft palate only

Single-stage reconstruction of a cleft palate at eight months of age aims to achieve a balance of promoting optimal speech outcomes before the onset of babble,²⁶ while minimising harm to maxillary growth.^{5,8} The intravelar veloplasty technique using the operating microscope, as described by Brian Sommerlad,^{27,28} will incorporate the palatal portion of tensor aponeurosis with the en bloc velar muscle

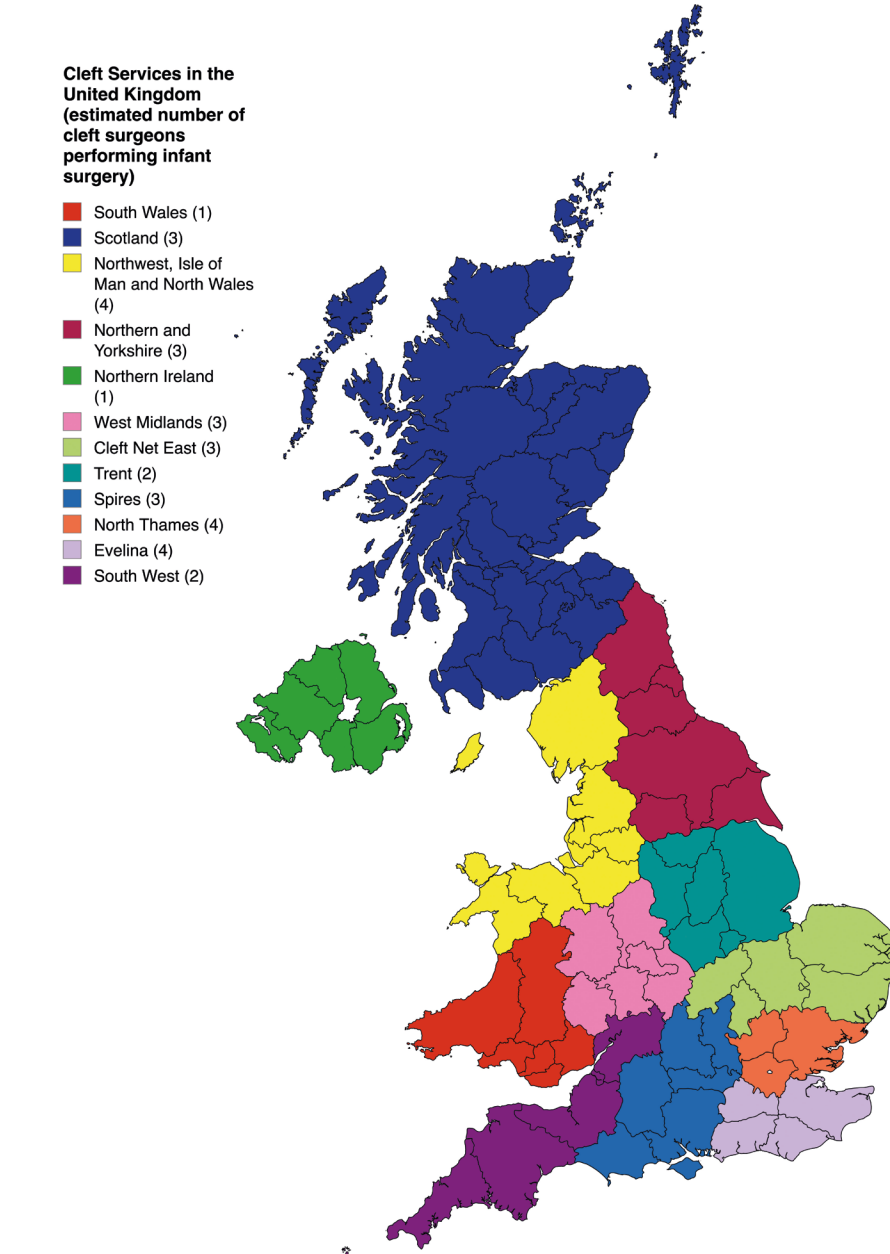


Fig. 1 A map to show the 12 cleft services in the United Kingdom and the estimated number of cleft surgeons performing infant surgery in each service. Created with mapchart.net

dissection to provide fibrous tissue bulk for muscle approximation. Emphasis will be placed on radical muscle repositioning, leaving the levator sheath in place on the nasal mucosal layer. There will be a low threshold for lateral relieving incisions where the cleft distance at the hard-soft junction is more than or equal to 10 mm, and buccal fat pads will be used if the nasal mucosa has been inadvertently perforated or lateral relieving incisions have been used.²⁹ In wide clefts involving the hard palate, the hard palate will be closed in two layers, using vomer flaps anteriorly and sphenoid flaps posteriorly to assist with closure of the nasal layer.³⁰

Submucous cleft palate

The decision to operate will be based on multidisciplinary assessment and the presence of velopharyngeal symptoms. The presence of an overt submucous cleft palate may warrant surgical reconstruction before the development of velopharyngeal symptoms, judged on a benefit-risk profile for each patient, carefully discussed with parents. The surgical technique will incorporate an intravelar veloplasty in association with double opposing Z-plasties in both the oral and nasal layers, with an aim of achieving both velar muscle repositioning and palatal lengthening.³¹

Table 1 Operative sequence for babies born with unilateral cleft lip and palate in the first year of life

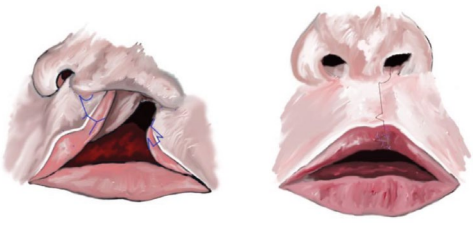
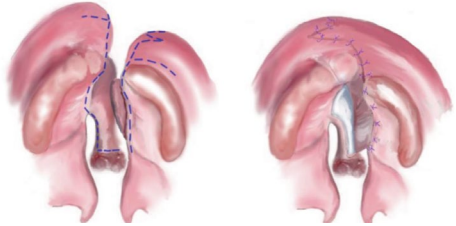
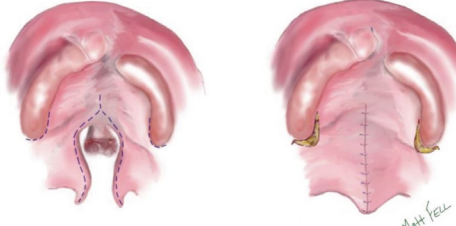
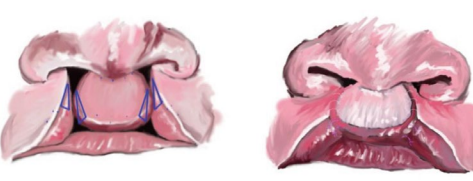
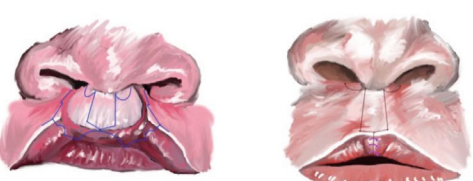
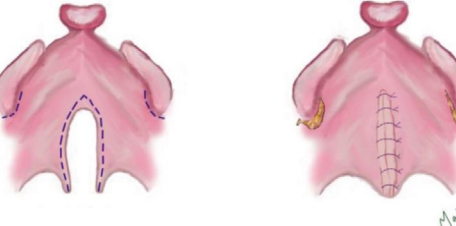
Stage	Lip	Palate
1) Lip reconstruction and vomer flap		
2) Palate reconstruction		

Table 2 Operative sequence for babies born with bilateral cleft lip and palate in the first year of life

Stage	Lip	Palate
1) Lip adhesion and vomer flap		
2) Lip reconstruction and vomer flap		
3) Palate reconstruction		

Unilateral cleft lip and palate

In line with the widely adopted surgical approach for unilateral cleft lip and palate in the UK, a sequence of two stages for primary closure of the cleft lip and palate in infancy will be used (see Table 1), followed by ABG in the mixed dentition.^{32,33} The first stage at four months of age will consist of unilateral cleft lip reconstruction with complete

nasal floor closure and vomer flap.^{34,35} The aim of the vomer flap is to make the soft palate reconstruction easier, reducing the prevalence of symptomatic fistulae and to provide a good foundation for mixed dentition ABG.^{36,37} The second stage, at eight months of age, will consist of a completion palatoplasty with the intravelar veloplasty technique, as described for the cleft palate-only phenotype. The third planned stage of

ABG will occur during mixed dentition at 8–11 years of age.

Bilateral cleft lip and palate

In the absence of a national consensus of surgical sequence for bilateral cleft lip and palate,³⁸ a three-stage approach for the primary closure of cleft lip and palate will be used in the first year of life (see Table 2),

followed by ABG in mixed dentition. The first stage at three months will be a lip adhesion and unilateral vomer flap.³⁹ This stage will allow the dissection, release and repositioning of the orbicularis oris muscle to the edge of the prolabium without overstretching the myofibrils across the premaxilla. The unilateral vomer approach is safe and minimises vascular compromise to the premaxilla and the development of complex Pittsburgh 5 fistulae, which are common in BCLP.^{40,41} The second stage, at five months, will be a definitive bilateral lip reconstruction and contralateral vomer flap. The 'delayed' orbicularis muscle can now be brought across the pre-maxilla with minimal tension. The third stage, at eight months, will consist of a completion palatoplasty, with the intravelar veloplasty technique, as described for the cleft palate-only phenotype. ABG will occur in one or two stages during mixed dentition at 8–11 years of age, dependent on the status of tissue healing following infant surgery.

Velopharyngeal dysfunction surgery

Patients with velopharyngeal dysfunction (VPD) will be assessed in a multidisciplinary setting and undergo both perceptual speech assessment and instrumental assessment (lateral videofluoroscopy and/or nasendoscopy). There will be an open acknowledgement of complexity and lack of consensus regarding optimal surgical options in VPD⁴² (both cleft and non-cleft VPD), with unreliable outcomes, potential to cause harm (i.e., sleep apnoea, mixed hypo/hypernasality, decreased clearance of secretions) and need to consider non-surgical options. There will be an overarching principle of first doing no harm (*primum non nocere*).

If surgical intervention is indicated, a palate-first strategy, incorporating radical muscle repositioning and double opposing Z-plasties,³¹ will be advocated for mobile palates with an anterior velar muscle position and a small gap. A sphincter-type pharyngoplasty, using bilateral superiorly based myomucosal flaps inset side-to-side into the posterior pharyngeal wall, will be considered for mobile palates and a moderate gap.^{43,44} Bilateral buccinator myomucosal flaps will be considered for short mobile palates with a large gap.^{45,46,47} A posterior pharyngeal flap⁴⁸ will be considered

as a first-line strategy for VPD in the setting of an immobile palate and for patients born with 22Q1.1 deletion.⁴⁹ Pre- and post-operative sleep studies will be arranged for patients undergoing potentially obstructing pharyngeal surgery.

Peri-operative pathways

A single antibiotic dose on induction will be used as per the national guidance of cleft surgery being categorised a clean-contaminated procedure.⁵⁰ Three post-operative intravenous doses of antibiotics will be given following ABG procedures, due to the most common risk of bone graft failure being wound dehiscence and infection.⁵¹ Post-operative antibiotic prophylaxis will not be planned for any other elective cleft procedure.^{52,53,54,55,56,57} A single airway dose of dexamethasone 250 micrograms/kg on induction will aim to reduce airway swelling. For palatal and pharyngeal procedures, three post-operative doses of dexamethasone will be administered.^{58,59,60} A single dose of tranexamic acid 10 mg/kg on induction will aim to reduce intra- and post-operative bleeding.^{61,62,63} As part of an enhanced recovery pathway strategy,⁶⁴ pre-incisional regional nerve blocks will be used, including the infra-orbital nerve block for lip and alveolar procedures,⁶⁵ and the suprazygomatic maxillary nerve block for palatal procedures.^{65,66}

Discussion

The opportunity to design a cleft surgery pathway at the start of a surgical career is a privilege; however, the multitude of decisions to be made can be overwhelming, especially because the outcomes of the pathway will only be realised many years later. Early outcomes at five years of age are a useful indicator, but only at the end of facial growth at approximately 20 years of age will results be fully appreciated. It is incumbent upon cleft surgeons to have a clear rationale for the surgical pathway decisions they have decided upon and a strategy of how to assess the effectiveness of decisions made.

Working within a single-surgeon service, it will be imperative to adhere to a robust strategy of outcome evaluation and both internal and external validation (see online Supplementary Information). In the UK, the national Cleft Registry and

Audit Network (CRANE) provides quality assured benchmarking of outcomes at a cleft service level, but due to a limited number of multidisciplinary outcomes reported, the CRANE database is currently not sufficient alone for comprehensive outcome evaluation at an individual surgeon level. Consecutive evaluation of surgical outcomes over time is required, with notable examples in the literature acting as an inspiration to aspire to.^{67,68} For internal validation, I will use cumulative summation techniques for performance monitoring⁶⁹ and will engage with audit and quality improvement processes. For external validation, I will seek structured, supportive peer review through engagement with the Surgical Clinical Excellence Network mentoring and coaching schemes, complex case discussion forums and annual visits to external (national and international) cleft units.

I am extremely grateful for the support I have received from colleagues, patients and my family to reach this long-standing dream position of becoming a cleft surgeon. I hope my decisions for the cleft surgery pathways described will serve my patients, their families and the Welsh Cleft Team well. Furthermore, it is the hope that this contribution will ignite debate and encourage open publishing of cleft surgery pathways and outcomes going forward.

Ethics declaration

The author declares no conflicts of interest.

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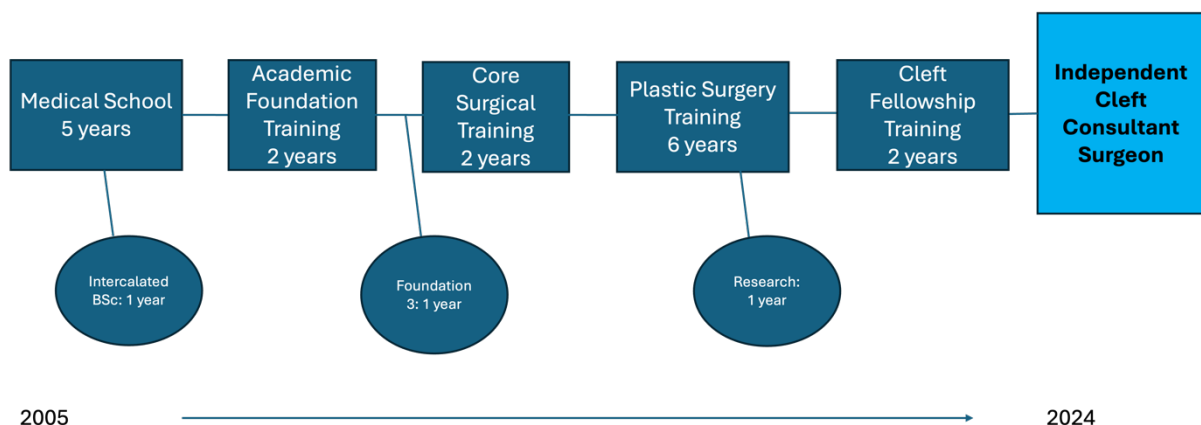
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Supplementary Material

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3. Cleft Surgical Kardex
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 - b. Bilateral lip adhesion +/- vomer flap
 - c. Bilateral lip reconstruction +/- vomer flap
 - d. Palate reconstruction
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 - f. Furlow palatoplasty for SMCP, Speech or Fistula
 - g. Sphincter-type pharyngoplasty
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Supplementary 1: Matthew Fell's Cleft Surgery Training Pathway



Supplementary 2:

Protocols for the Care of Infants and Children Undergoing Cleft Lip and Palate Surgery

Inpatient care for children undergoing cleft surgery

Cleft patients are admitted under the name of the Cleft Surgeon, to a Maxillofacial Surgery bed card, with joint care from Paediatrics.

Babies and children under 5 years of age undergoing cleft lip, palatal or pharyngeal surgery should be nursed in the Paediatric Surgical High Observation Unit post-operatively for the first night. This is because of the risk of critical haemorrhage and airway difficulties.

The High Observation Unit has a nurse-to-patient ratio of 1:2, day and night, with a nurse in the room at all times. The unit must be staffed by personnel with expertise in managing paediatric airways and post-operative care for cleft surgery. Patients are observed on continuous cardiac monitoring and observations are recorded on the High Dependency Observation Charts, initially every 30 minutes and then hourly. The High Observation Unit should be equipped to handle and manage potential complications that arise after surgery. These include the management of an obstructed airway (with nasopharyngeal airway and oxygen delivery), hypovolaemia (with fluid and blood replacement) and pain (with analgesia).

The High Observation Unit is not equipped to provide interventions such as high flow oxygen, non-invasive ventilation (CPAP, PCA's), intubation or medications that require additional monitoring. Patients with known co-morbidities that require a level of care beyond that of the High Observation Unit, should have surgery planned in a surgical HDU or ICU setting (i.e. Cardiff or Bristol). It is not appropriate to plan elective cleft surgery for care within the medical HDU environment, due to the co-existence of respiratory viruses increasing the risk of significant post-operative complications.

Cleft education sessions, led by members of the Cleft MDT, should be organised at least annually for nurses staffing the High Observation Unit, to aid in communication and to help ensure knowledge and skills are up to date. This should include simulation sessions for cleft post-operative emergencies.

Pre-Operative Clerking on the Day of Surgery

This will involve a review by the anaesthetic team (Consultant Anaesthetist +- Registrar), the cleft surgical team (Consultant Cleft Surgeon +- Registrar / SHO) and a Doctor from the Paediatric Team.

The patient is to be admitted on the day of surgery, usually at 07:30.

Pre-Operative Fasting

- Formula milk feed/ food up to 6 hours pre-operatively
- Breast milk up to 4 hours pre-operatively
- Clear fluids sips to send.

Post-operative analgesia: -

Regular pain relief post-operatively:

- Paracetamol 15mg/kg QDS
- Ibuprofen 7.5mg/kg QDS
 - Alternating times of paracetamol and ibuprofen will allow analgesia to be given every 3 hours
- Benzydamine (Diffлам) spray 0.15% - 1 spray/4kg every 2 hours (max. 4 sprays/dose). Not required for cleft lip reconstruction only

PRN breakthrough pain relief post-operatively:

- Morphine sulphate 10mg/5ml – 100-200micrograms/kg 4 hourly PRN

****CLEFT EMERGENCIES****

Airway Obstruction

Any patient having lip or palate surgery is at risk of airway problems, especially if they have Pierre Robin Sequence (PRS) or they are having a pharyngoplasty or pharyngeal flap.

Signs and Symptoms

- Baby/child distressed and restless
- Sitting up, still and drooling
- Stridor (noises on breathing in and out)
- Sucking in of lower lip
- Increasing respiratory rate
- Look at the chest for recession, use of accessory muscles and tracheal tug
- Decreasing pO₂ (<93% on air or 95% on oxygen is very low)
- Tachycardia

Later may become drowsy and cyanosed.

Actions

- Nurse in upright position
- High flow oxygen via face mask or nasal cannula
- Gentle oral suction if there is a collection of fluid or blood exacerbating airway obstruction
- The insertion of a nasopharyngeal airway may help to alleviate upper airway obstruction but can potentially damage the cleft operative repair site. If possible, post-operative nasopharyngeal airway insertion should be performed by the cleft surgeon and anaesthetist.

CLEFT BLEEDING PROTOCOL

Post-Palatoplasty/Pharyngoplasty Haemorrhage

Blood stained mucous or saliva coming from the child's nose or mouth is common in the first few days after the operation but should settle.

Active or profuse bleeding following any form of intra-oral surgery in a child (i.e. cleft palate reconstruction or pharyngoplasty) is post-operative haemorrhage and potentially life threatening due to the risk of airway obstruction. In the event of a post-operative bleed, it is important that the medical team can assess the patient and instigate effective management to achieve rapid cessation of the bleed.

Haemorrhage following palate or pharyngeal surgery can be categorised as:

1. **Primary haemorrhage** if occurring within 24 hours post op. Usually caused by a bleeding vessel that has not been controlled during the operation.
2. **Secondary haemorrhage** if occurring more than 24 hours post op. Usually caused by infection or inflammation that has led to bleeding within the traumatised tissues.

Identifying a post-op bleed:

- Obvious – fresh blood from the nose or mouth
- Concealed – if in the palate or pharynx (throat) – may be swallowed or absorbed into dead space and soft tissue. May only become apparent when patient vomits. If associated with evolving increased work of breathing or respiratory obstruction consider expanding palatal hematoma.

Signs and Symptoms due to bleeding:

- Tachycardia – Check HR trend on chart as rising pulse is the most important
- Baby agitated
- Increased capillary refill time (sternal)
- Decreased urine output (dry nappies)
- Widening core versus peripheral temperature gradients – if baby is cool peripherally consider hypovolaemia
- Falling BP is a serious late sign

Actions: APLS/ALS approach

GET HELP!

**Immediately call the Anaesthetic Registrar and OMFS Registrar
AND
Immediately call the Cleft Surgeon and Consultant Paediatric Anaesthetist
AND
The Consultant Paediatrician**

If the patient has significant active bleeding, they will need to return to theatre as a Cat1 on CEPOD.

Contact theatre to make immediate arrangements.

Airway

- Nurse upright and keep parents' calm
- Consider Suction:
 - If fresh blood in mouth and affecting airway then consider using gentle suction away from the surgical wound site
 - If a blood clot is present but stable and is not affecting the airway then **leave alone, suction may dislodge and re-start bleeding**

Breathing

- Oxygen via facemask or nasal cannula

Circulation

- Secure IV access – FBC/U+E and cross match bloods
- Fluid bolus 10ml/kg 0.9% NaCl, reassess and if required give further 10ml/kg 0.9% NaCl bolus.
- Consider resuscitation with blood in boluses of 10mg/kg: The blood bank at Morriston Hospital always aims to have 4 x Paedipaks (each of which contains 35mls of CMV negative blood) available, blood group O Negative, that is a total of 140mls.
- IV Tranexamic Acid (10mg/kg)

- If profuse bleeding, consider applying direct pressure to the bleeding area using a swab (can soak in 1:1000 adrenaline vial from crash trolley)
- Consider starting IV Augmentin (clarithromycin in penicillin allergy) in secondary haemorrhage

Infection

Significant post-operative infections are very rare in cleft lip and palate babies but if they occur they can have serious consequences. Certain patients will be prescribed post-operative prophylactic antibiotics in theatre.

Post-Operatively

Monitor the temperature, it is very common for cleft babies, especially palate repairs, to have a transient pyrexia. If the temperature is raised on 2 readings, it is probably reactive but discuss this with the Surgeon/look for possible causes of pyrexia in:-

- The wound
- The chest
- The ears/tonsils
- The urinary track

Assume a patient with a persistent raised temperature must have an infection and may therefore require antibiotics.

Escalation strategy

If a cleft patient deteriorates whilst in the High Observation Unit there are **3 potential scenarios**:

1. **The patient is stabilised** following successful intervention performed in the High Observation Unit (i.e. insertion of NPA for identified airway obstruction).
 - **Outcome:** Care can be continued in the High Observation Unit.

2. **A decision is made to return to theatre** (ie identification of post-op bleed)
 - **Outcome:** Patient to be transferred immediately to theatre as CAT1 priority

3. **The patient remains unstable** (i.e. haemodynamic or respiratory instability despite intervention started in High Observation Unit)
 - **Outcome:** Patient to be transferred to Medical HDU for stabilisation and consideration for transfer to Surgical HDU (via ambulance transfer) or ICU (via WATch transfer) in Cardiff

Discharge

- Patient to be discharged once eating and drinking near normally and observations are within normal parameters for their age.

Medication for discharge:

Lip Recon	• Paracetamol 15mg/kg QDS • Ibuprofen 7.5mg/kg QDS • Sterimar nasal spray (If parents have not previously acquired Sterimar Baby) • Soft White Paraffin for vermillion • If Vomer Flap: Benzydamine (Diffлам) spray 0.15% - 1 spray/4kg every 2 hours (max. 4 sprays/dose)
Palate Recon	• Paracetamol 15mg/kg QDS • Ibuprofen 7.5mg/kg QDS • Benzydamine (Diffлам) spray 0.15% - 1 spray/4kg every 2 hours (max. 4 sprays/dose)
ABG	• Paracetamol 15mg/kg QDS • Ibuprofen 7.5mg/kg QDS • Chlorhexidine 0.2% mouthwash 10ml BD for 1 week • Benzydamine (Diffлам) spray 0.15% - 1 spray/4kg every 2 hours (max. 4 sprays/dose)
Speech Surgery	• Paracetamol 15mg/kg QDS • Ibuprofen 7.5mg/kg QDS • Benzydamine (Diffлам) spray 0.15% - 1 spray/4kg every 2 hours (max. 4 sprays/dose) • Oral Morphine 100 micrograms per kg for breakthrough pain. Maximum 4 doses per day. 12 doses overall

Supplementary 3: Cleft Surgery Kardex in the Welsh Centre for Cleft Lip and Palate

Cleft Local Anaesthetic Infiltration Formula (Modified Oxford Formula)

For Children < 12.5 kg

Scrub nurse to use a sterile 10 ml Leur lock syringe to draw up a fresh mixture of:

- 4.5 ml of 0.25 % bupivacaine
- 4.5 ml of 0.9 % saline
- 1.0 ml of 1:10,000 adrenaline

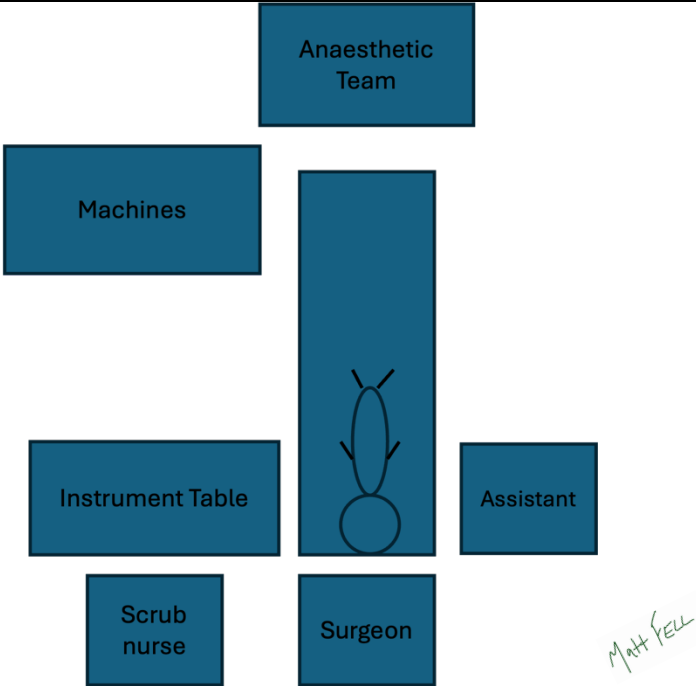
Creates a mixture of 1:100,000 adrenaline with 0.125 % bupivacaine. Maximum dose (volume): 1.6 ml per kg.

For Children/Adults > 12.5 kg

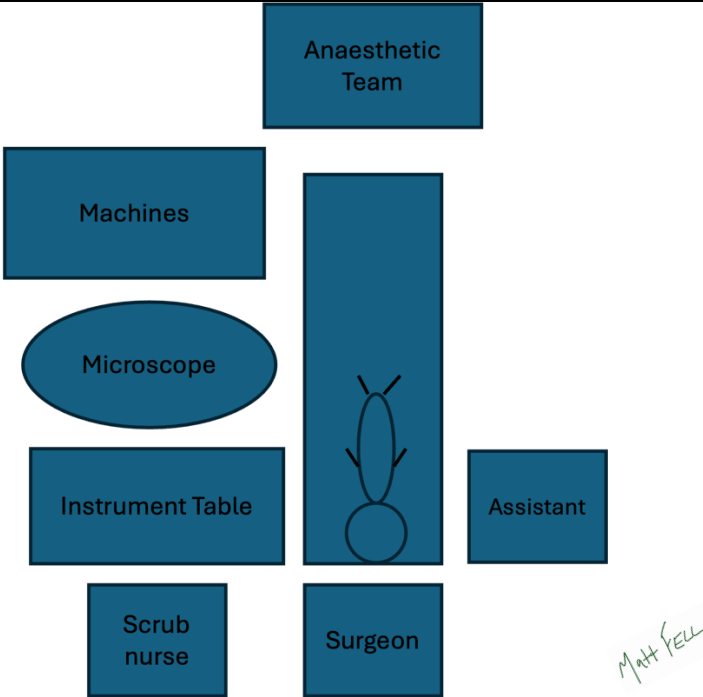
Scrub nurse to use a sterile 10 ml Leur lock syringe to draw up a fresh mixture of:

- 9.0 ml of 0.25 % bupivacaine
- 1.0 ml of 1:10,000 adrenaline

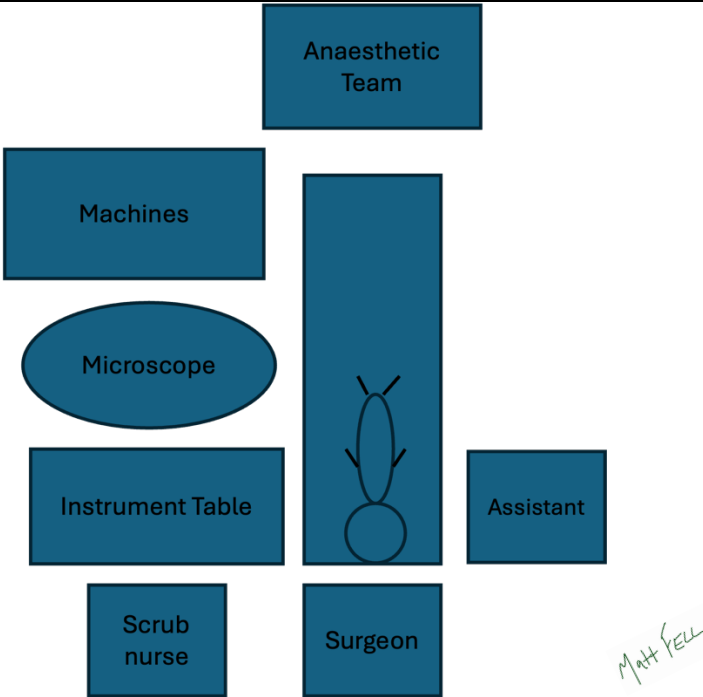
This creates a mixture of 1:100,000 adrenaline with 0.25 % bupivacaine. Maximum dose (volume): 0.8 ml per kg.

Procedure	Cleft lip reconstruction +- vomer flap Cleft lip revisions
Date	September 2024
Description	An operation to reshape the lip and nose. May be combined with a vomerine flap to reconstruct the anterior hard palate.
Position of patient	Supine with head at end of the bed
Position of theatre	
Aids to positioning	Shoulder roll Horseshoe head ring
Special equipment	Nasal stents (for paediatric primary definitive lip reconstructions only)
Prep	Pre-prep betadine for nose with cotton wool sticks Non-alcoholic clear chlorhexidine for face Mouth Wash for intra-oral
Trays	Cleft Lip and Palate Tray
Pack/Drapes	½ inch Steristrips cut in half for eyes Throat pack Head drape Body drape
Blades	15 Beaver Orange BEAVER6700
Sutures	Vomer: 4-0 Monocryl Round Bodied MCP3435G Alar cinch stitch (BCL only): 4-0 Clear Prolene Reverse Cutting F2861

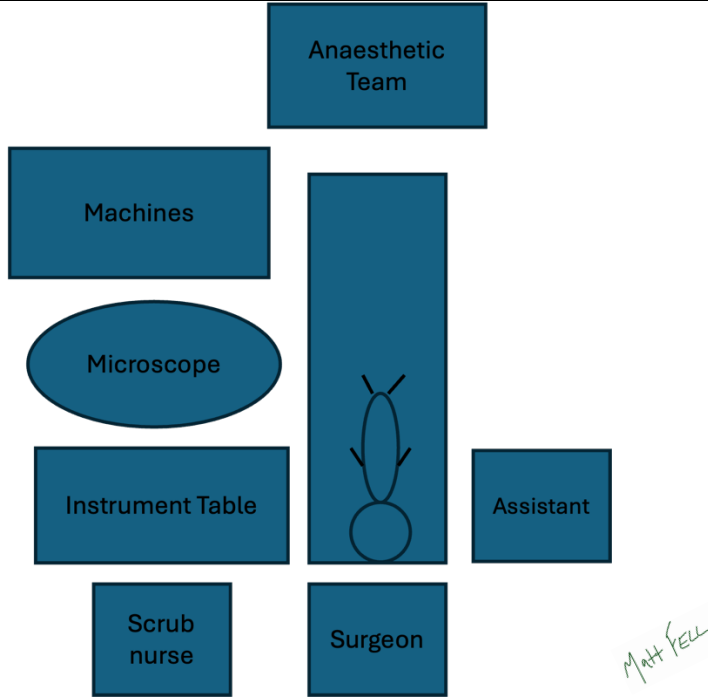
	Mucosa and Vermillion: 5-0 Vicryl Rapide W9915 and 6-0 Vicryl Rapide W9913 Muscle: 5-0 Prolene Round Bodied W8710 Nasal floor: 6-0 Vicryl Rapide W9913 Skin: 7-0 PDS W9095T Nose: 4-0 Monocryl clear MCP496H and 6-0 Vicryl Rapide Stents: 5-0 Prolene W8710
Infiltration	Cleft Local anaesthetic mixture by child weight for local infiltration and ION block
Extras	27G Grey needle for infiltration Orange needle for tattooing Bonney's Blue ink Alcohol wipe 10ml syringe for local 1ml syringe for tattoo Mastoid swabs
Dressing	Dermabond skin glue Paraffin for lips
Other comments	Anthropometric measurements to be recorded on laminated sheet at the start of the procedure Please soak all Vicryl and Vicryl Rapide Stitches in Saline Place nasal stent sizers in kidney dish with chlorhexidine

Procedure	Cleft palate reconstruction or revisional cleft palate reconstruction
Date	September 2024
Description	An operation to close the gap in the roof of the mouth, to facilitate speech development and reduce nasal regurgitation.
Position of patient	Supine with head at end of the bed
Position of theatre	 The diagram illustrates the theatre layout. At the top is the 'Anaesthetic Team'. Below them, on the left, are the 'Machines', 'Microscope', and 'Instrument Table'. At the bottom left is the 'Scrub nurse', and at the bottom center is the 'Surgeon'. To the right of the surgeon is the 'Assistant'. A signature 'MATT FELL' is written in the bottom right corner of the diagram area.
Aids to positioning	Shoulder roll Horseshoe head ring
Special equipment	Microscope
Prep	Pre-prep betadine for nose with cotton wool sticks Non-alcoholic clear chlorhexidine for face Mouth Wash for intra-oral
Trays	Cleft lip and palate
Pack/Drapes	½ inch Steristrips cut in half for eyes Throat pack Head drape Body drape
Blades	15 Blade Beaver Green Blade BEAVER6400
Sutures	Stay stitch: 3-0 Prolene W8770G Nasal layer: 4-0 Monocryl MCP3435G and 5-0 Monocryl MCP2131H Muscle: 4-0 Prolene 8557H Oral layer: 4-0 Monocryl MCP3435G and 5-0 Monocryl MCP2131H

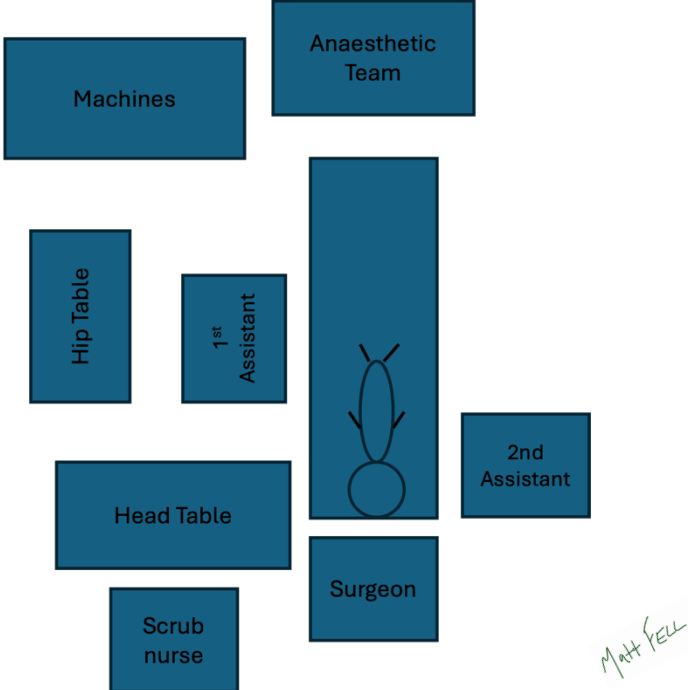
Infiltration	4mls 0.2% Ropivacaine for Suprazygomatic Maxillary Nerve Block – Green needle 40mm length Cleft Local anaesthetic mixture by child weight for local infiltration
Extras	27G Grey needle for infiltration Bonney's Blue ink 10ml syringe for local Neurosurgical patties x3 1ml 1:1000 Adrenaline for topical Mastoid swabs Microscope handles
Standby	Beaver Angled Blade BEAVER660
Dressing	Paraffin for lips
Other comments	Place mirror in kidney dish with chlorhexidine at the beginning of the procedure Anthropometric measurements to be recorded on laminated sheet at the start of the procedure Assistant to move to left of patient for first half of muscle dissection if microscope set up with two assistant ports.

Procedure	Buccinator Flap
Date	September 2024
Description	A bilateral myomucosal buccinator flap is an operation to lengthen the palate by interposing two flaps from the inside of the cheek into an incision between the hard and soft palate.
Position of patient	Supine with head at end of the bed
Position of theatre	
Aids to positioning	Shoulder roll Horseshoe head ring
Special equipment	Microscope
Prep	Pre-prep betadine for nose with cotton wool sticks Tisept
Trays	Cleft lip and palate
Pack/Drapes	½ inch Steristrips cut in half for eyes Throat pack Head drape Body drape
Blades	15 Blade
Sutures	Stay Stitch: 3-0 Prolene W8770G for commissures, 4-0 Prolene 8557H for flaps Donor site: 4-0 Monocryl MCP3435G Flap Inset nasal layer: 4-0 Vicryl 5/8 th Curve W9820 Flap Inset oral layer: 4-0 Monocryl MCP3435G and 5-0 Monocryl MCP2131H

Infiltration	4mls 0.2% Ropivacaine for Suprazygomatic Maxillary Nerve Block and Cleft Local anaesthetic mixture by child weight for local infiltration
Extras	27G Grey needle for infiltration Bonney's Blue ink 10ml syringe for local Neurosurgical patties x3 1ml 1:1000 Adrenaline for topical Mastoid swabs Microscope handles Ketac Cem Radiopaque Glass Lonomer Luting Cement
Standby	4-0 Monocryl Compound Curve NP0126
Dressing	Paraffin for lips
Other comments	May use bite blocks if 2 nd and 3 rd erupted molar teeth threaten pedicle of flaps – either pre-made removable bite blocks from orthodontist or non-removal cement bite blocks made in theatre

Procedure	Pharyngoplasty or posterior pharyngeal flap
Date	March 2024
Description	An operation to assist with speech by changing the shape and function of the back of the throat (pharynx) and soft palate. This is done by raising two longitudinal flaps on the posterior pharyngeal wall and inseting them within a horizontal incision
Position of patient	Supine with head at end of the bed
Position of theatre	
Aids to positioning	Shoulder roll Horseshoe head ring
Special equipment	Microscope
Prep	Pre-prep betadine for nose with cotton wool sticks Tisept
Trays	Cleft lip and palate
Pack/Drapes	½ inch Steristrips cut in half for eyes Throat pack Head drape Body drape
Blades	15 blades
Sutures	4-0 Vicryl 5/8 th Curve W9820 4-0 Vicryl Compound Curve W9437 4-0 Monocryl MCP3435G 4-0 Monocryl Compound Curve NP0126
Infiltration	Cleft Local anaesthetic mixture by child weight for local infiltration

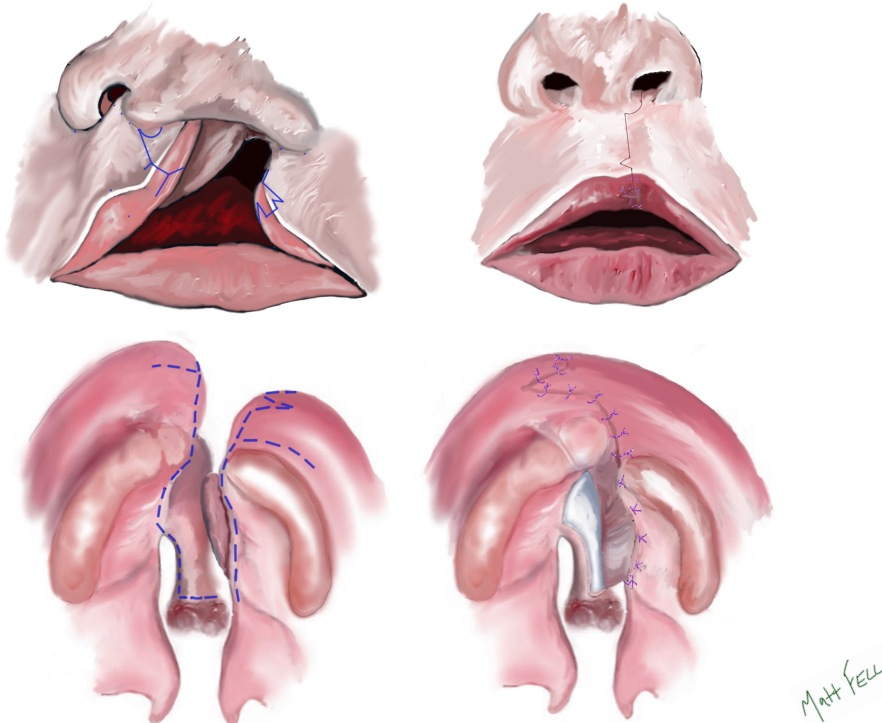
Extras	27G Grey needle for infiltration Jakes catheter Copper malleable Peanut swabs Bonney's Blue ink 10ml syringe for local Mastoid swabs Microscope handles
Standby	Neurosurgical patties x3 1ml 1:1000 Adrenaline for topical
Dressing	Paraffin for lips
Other comments	Place mirror in kidney dish with chlorhexidine at the beginning of the procedure

Procedure	Alveolar Bone Graft	
Date	September 2024	
Description	An operation to reconstruct the gap in the gum (alveolus) with bone taken from the hip (iliac crest). The aim of this operation is to provide support for the adult teeth, foundational support for the nose and stability to the alveolar arch. There may be a fistula to repair at the same time.	
Position of patient	Supine with head at end of the bed	
Position of theatre		
Aids to positioning	Head	Hip
	Shoulder roll	Sand bag
	Head ring	
Special equipment		
Prep	Head	Hip
	Pre-prep betadine for nose with cotton wool sticks	Chlorhexidine 2%
	Clear chlorhexidine	
	Mouthwash	
Trays	Head	Hip
	Cleft lip and palate	Bone graft tray
Pack/Drapes	Head	Hip
	Head drape	Square drapes
	Body drape	
	½ inch Steristrips cut in half for eyes	

	Throat pack	
Blades	Head	Hip
	15 Blade	10 Blade
		15 Blade
Sutures	Head	Hip
	4-0 Monocryl MCP3435G	3-0 Vicryl Round Bodied W9114
	4-0 Vicryl Round Bodied W9113	4-0 PDS Cutting 8557H
	4-0 Vicryl 5/8 th Curve W9820	5-0 Monocryl Cutting W3204
	5-0 Monocryl MCP2131H	
Infiltration	Cleft Local anaesthetic mixture by child weight for local infiltration. Need 10mls for head and 10mls for hip. Grey needle 27G long for head and orange needle for hip	
Extras	Head	Hip
	Mastoid swabs	Coupland
	Mouth props	Volkman spoon
	Spandex check retractor	Gallipot
	Toothbrush	West self-retractor
	Catspaw	Orange needle for infiltration
	Curved Iris Scissors	
	Bulb irrigation syringe	
Standby	Head	Hip
	4-0 Vicryl Compound Curve NP0126	
	Bone nibbler	
Dressing	Head	Hip
	Paraffin for lips	Dermabond
		Opsite dressing
Other comments	Place the mirror and toothbrush in chlorhexidine at the start of the case. Hip is a clean procedure whereas Head is a clean-contaminated procedure. Hip and Head surgical sites must remain separated throughout the case.	

Supplementary 4: Operative steps for Core Cleft Surgery Procedures

1. Unilateral cleft lip reconstruction +/- Vomer

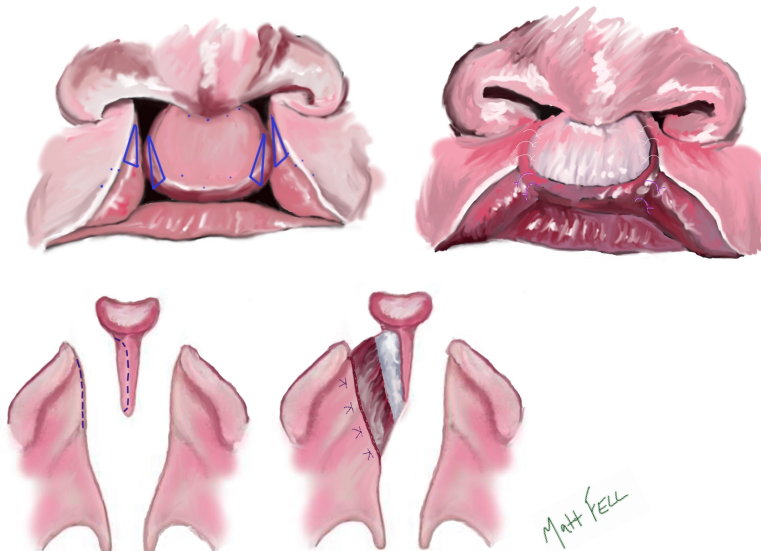


Operative steps:

- If vomer flaps: Bilateral suprazygomatic maxillary nerve blocks before prepping.
- Lip marking and photos:
 - Markings for complete unilateral cleft lips influenced by the anatomical subunit approximation technique described by David Fisher and modifications made by Marc Swan (<https://www.youtube.com/watch?v=qbjOVHbD5xE>).
 - Markings for incomplete cleft lip reconstruction influenced by the preservation modification of the anatomical subunit approximation described by David Chong.
- Local anaesthetic infiltration into lip (not into vermillion)
- Examination of palate, photos, measurement and insertion of throat pack
- Lip incisions and dissection:
 - Subperiosteal over maxilla to zygomatic arch, around anterior nasal spine medially and piriform aperture laterally
- Approach to nose: Primary rhinoplasty technique influenced by the foundation approach described by Raymond Tse. Use of nasal stents to improve alar shape and reduce risk of stenosis.
 - Subperiosteal alar base release

- Lateral piriform release of lateral accessory cartilage complex
- Caudal septal reposition if the columella base of the caudal septum is visible in the non-cleft side airway. No stitching of the caudal septum to the anterior nasal spine.
- Tip dissection only if lower lateral cartilage is not in a satisfactory position following previous manoeuvres
- Internal nasal valve plication with horizontal mattress suture of lower lateral cartilage to upper lateral cartilage to recreate scroll (Skoog stitch)
- Lasso stitch in septum to reduce dead space following dissection and to project tip
- Alar transfixion stitch to lateralise caudal rotation of lateral crus if required
- In cases of wide cleft lip and alveolus, raise inferior turbinate flap to assist with nasal floor closure
- Raise Vomer flap
 - Mark
 - Local anaesthetic infiltration
 - Raise vomer flap. Pay special attention to haemostasis at base of flap and along free edge of flap.
 - Lesser segment incision and raise oral mucoperiosteum margin
- ****Sterile cockpit**** Has sufficient dissection occurred for the lip to be reconstructed without tension and with lip and nose structures in balance? Is the vomer flap donor site dry?
- Inset Vomer flap
 - Inset flap with imbrication mattress sutures 4-0 Monocryl
- Nasal floor closure: 4-0/5-0 Vicryl
 - Single layer closure of lateral sidewall tissue sutured to medial vomer/septal mucosa.
 - Consider use of turbinate flap if lacking tissue
 - Minimal dissection around alveolar region and adjacent growth centres.
- Mucosal and vermillion reconstruction: 5-0 Vicryl/6-0 Vicryl Rapide
 - Attempt to get precise volume matching to avoid a bulge with careful haemostasis to reduce risk of haematoma and scar
- Muscle reconstruction: 5-0 Prolene and 6-0 Prolene
 - Rotation advancement of the muscle
 - Apposition with simple interrupted stitches rather than an imbrication
- Skin closure
 - 7-0 PDS subcutaneous
 - 8-0 Vicryl for key stitches if required
 - Glue
- Nasal stents sutured in place with single 5-0 Prolene stitch for 6 weeks
- Removal of throat pack

2. Bilateral lip adhesion + vomer flap

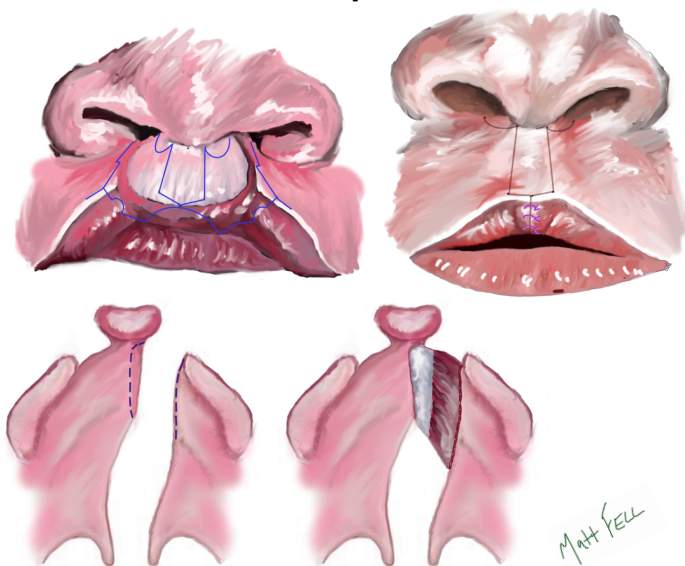


Operative steps:

1. Lip marking and measurements
 - Lip measurements
 - Mark definitive bilateral lip markings (see definitive bilateral lip guide)
 - Mark lip adhesion incision in the vermillion cutaneous border
 - Tattoo adhesion excision
 - Local anaesthetic infiltration
2. Palate markings
 - Palatal measurements
 - Mark vomer flap
 - Local anaesthetic infiltration
3. Lip and nose dissection
 - Incise vermillion-cutaneous border and buccal extension on lateral elements
 - Prolabium
 - Dissect down to premaxilla so that the prolabium is freed and can come down
 - Lateral lip elements
 - Define muscle
 - Subperiosteal undermining to allow advancement of lateral lips and release of alar base around piriform aperture
 - ****Sterile cockpit**** Has sufficient dissection occurred for lip adhesion to occur with minimal tension
4. Vomer flap
 - Raise vomer flap. Pay special attention to haemostasis at base of flap and along free edge of flap.
 - Lesser segment incision and raise oral mucoperiosteum margin

- Inset flap with imbrication mattress sutures
5. Consider Closing nostril floor
 - Continuous with vomer flap incision medially to go into septum. Suture onto lateral vestibular tissue mucosa - extended incision from upper buccal sulcus incision from lateral lip.
 - May use turbinate flap or Muir flap if missing tissue
 6. Close lip
 - Mucosal reconstruction
 - 6-0/5-0 Vicryl
 - Muscle reconstruction
 - 5-0 Prolene x 3 through prolabium
 - Skin reconstruction
 - 5-0 vicryl Rapide

3. Bilateral cleft lip reconstruction +/- vomer



Operative steps:

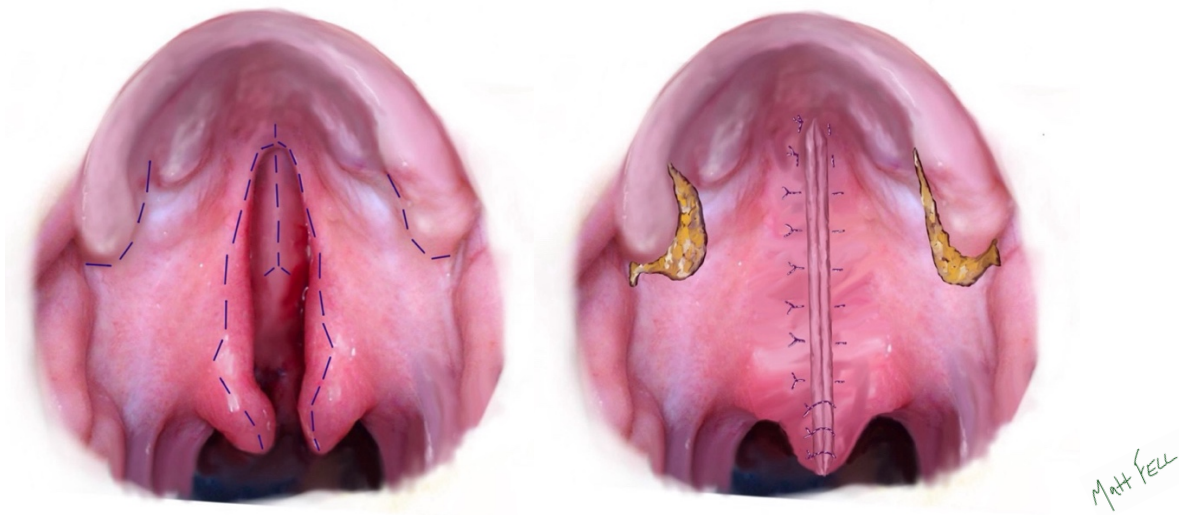
1. Lip marking and measurements
 - Lip measurements
 - Prolabial marking
 - Midline lip-columellar junction. 2-3mm at base of tie
 - Use full length of prolabium without going on to white roll. Length of tie 6-8mm
 - The tip of the tie determines cupid's bow: 2mm lengths. All above white roll. Mark at right angle to mid-point to achieve cupid's bow

- Lateral lip element marking
 - Just medial to Norrdhofs point (red dot)
 - Local anaesthetic infiltration
2. Palate markings
 - Palatal measurements
 - Mark vomer flap
 - Local anaesthetic infiltration
 3. Lip and nose dissection
 - Prolabium
 - Raise philtral tie and c flaps.
 - Raise and inset the mucosal sulcus flap
 - Lateral lip elements
 - Incise markings. Over the vermillion, do a curve to get fullness. Avoid whistle notch deformity by preserving lateral mucosa when incising.
 - Dissect in sub periosteal plane. Need to get far out – all way to zygoma and around the infraorbital nerve.
 - Nose
 - Alar base release
 - Lateral piriform release of lateral accessory cartilage
 - Tip dissection
 4. Primary rhinoplasty
 - a. Internal nasal valve plication with horizontal mattress suture of lower lateral cartilage to upper lateral cartilage to recreate scroll (Skoog stitch) 5-0 PDS
 - b. 2x PDS 5-0 in septum whilst elevating fibrofatty tissue to project tip
 - c. Alar base cinch stitch 4-0 Clear prolene or PDS anchored to premaxilla
 - d. 5-0 PDS Alar transfixion stitch to lateralise caudal rotation if required
 5. Vomer flap
 - Raise vomer flap. Pay special attention to haemostasis at base of flap and along free edge of flap.
 - Lesser segment incision and raise oral mucoperiosteum margin
 - Inset flap with imbrication mattress sutures
 6. Close nostril floor
 - Continuous with vomer flap incision medially to go into septum. Suture onto lateral vestibular tissue mucosa - extended incision from upper buccal sulcus incision from lateral lip.
 - May use turbinate flap or Muir flap if missing tissue
 7. Close lip

- Mucosal reconstruction
 - 6-0/5-0 Vicryl
- Muscle reconstruction
 - 5-0 Prolene and 6-0 PDS
- Skin reconstruction
 - 7-0 PDS, 8-0 Vicryl Rapide
 - Glue

8. Insert nasal stent – secure with 5-0 prolene

4. Cleft palate Reconstruction



Operative steps:

- Suprazygomatic maxillary nerve block: 2mls 0.2% Ropivacaine bilaterally
- Microscope in. scrub to left, assistant to right
- Photo (pre-op)
- Measure
 - Hard soft palate junction width
 - Intertuberosity width
 - Palatal shelf width right and left
 - Base of hemi-uvula width
 - Randall length
- Mark marginal incision
- Local anaesthetic infiltration
- Marginal incision at junction of oral and nasal mucosa
- Lateral access incisions if cleft at hard-soft palate junction >10 mm wide
- Raise oral mucoperiosteum off the bony hard palate, define back of hard palate shelf and get into plane between oral mucosa and the velar musculature in the

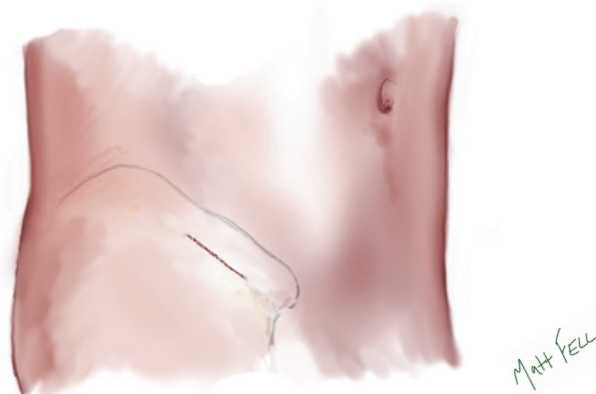
soft palate. View the greater palatine artery as it emerges from its foramen, medial to the maxillary alveolar tuberosity.

- Raise nasal layer off bony hard palate
- Nasal layer repair: 4-0 Monocryl
- Neuro patties and 1mg Adrenaline. **GAG DOWN**. Stay stitches in mucous glands to retract oral layer
- Velar muscle dissection, retro positioning and approximation 4-0 Prolene
- Buccal fat pad if required
- ****STERILE COCKPIT**** to ensure no bleeding and Photo
- Oral layer repair 4-0/5-0 Monocryl with vertical mattress sutures
- Photo

5. Alveolar Bone graft

Operative steps:

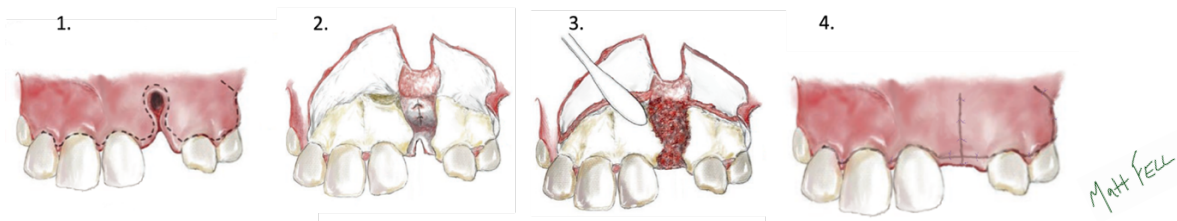
Hip donor site (Clean)



- a. Sandbag under hip
- b. Marking – 3cm in length, 2cm lateral to ASIC (prevents injury to lateral femoral cutaneous nerve (L2-L3) which lies medially). Mark with cranial skin traction to leave scar away from bony prominence of iliac crest.
- c. Prep with Chlorhexidine and square drape
- d. Local anaesthetic infiltration along incision line with needle perpendicular down to bone
- e. Approach
 - i. Through skin and subcutaneous fat down to fascia with outside 10 blade
 - ii. Self retainer in
 - iii. Incise through external oblique fascia onto cartilage cap with inside 15 blade, avoiding muscle fibres

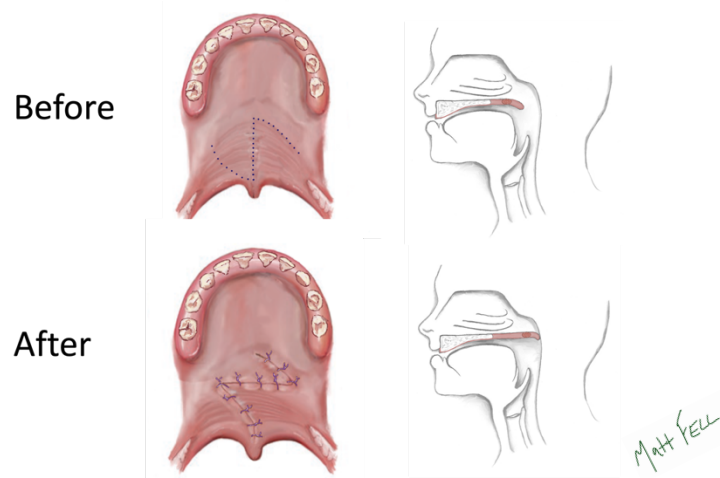
- iv. Design superior based treasure chest hinge incision on lip of iliac crest
- v. Incise down to bone and raise cartilaginous lid with osteotome
- f. Cancellous bone Harvest with coupland and curette:
 - i. Always need more than you think.
 - ii. Use non dominant hand to palpate inner and outer table of the ilium to prevent inadvertent structural damage.
- g. Closes in 4 layers
 - i. Cartilage: 3-0 Vicryl
 - ii. Deep fascia: 3-0 Vicryl
 - iii. Deep dermal: 4-0 PDS
 - iv. Subcuticular: 5-0 Monocryl
- h. Glue and Opsite dressing

Alveolar recipient site (Clean-contaminated)



- i. South facing tube. ****Throat pack in ****
- j. Prep inside and out
- k. Probe – understand extent of fistula. Pressure test with bulb syringe.
- l. Mark
 - i. Buccal mucosa medial and lateral to the cleft with lateral sliding flap on lesser segment
 - ii. Palatal mucosa medial and lateral to the cleft
- m. LA infiltration and ION blocks
- n. Gingival incision and raise buccal mucoperiosteal flaps
 - i. Lateral buccal flap will need back cut and scoring of periosteum to ensure adequate advancement.
- o. Gingival incision and raise palatal mucoperiosteal flaps
 - i. Artificial separation of nasal floor and palatal tissue
- p. Close nasal floor if fistula present 4-0/5-0 Vicryl. ****Sterile Cockpit****
Check watertight with nasal flush.
- q. Palatal closure – 3-0/4-0 Vicryl
- r. Pack in cancellous bone graft
- s. Buccal closure with 4-0/5-0 Vicryl
- t. ****Throat pack out****

6. Furlow Palatoplasty for Submucous Cleft Palate or Cleft Palate Re-Repair

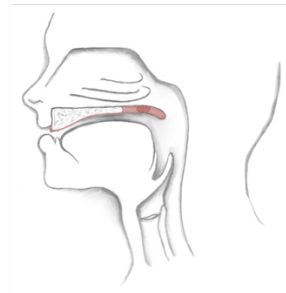
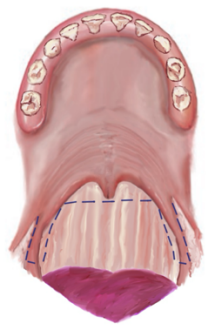


Operative steps:

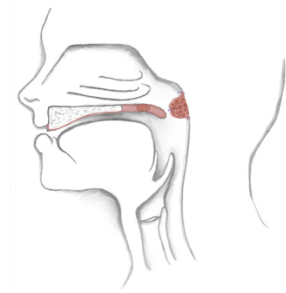
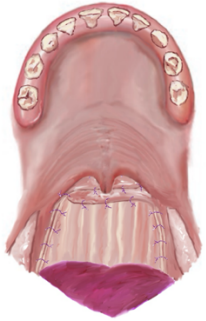
- Suprazygomatic maxillary nerve block: 2mls 0.2% Ropivacaine bilaterally
- Microscope in. scrub to left, assistant to right
- Photo (pre-op)
- Measure
 - Length of soft palate
 - Length from uvula to posterior pharyngeal wall
 - Randall length
- Marking
- Local anaesthetic infiltration
- Raise oral Z flaps
 - Left side flap is myomucosal
 - Right side flap is mucosa only.
- Incise opposing nasal Z flaps. Muscle is raised separately from the nasal mucosa on the right side
- Lateral releasing incisions may be required to allow flaps to re-orientate
- ****Sterile cockpit**** to ensure adequate release and haemostasis
- Closure
 - Right then left nasal flaps
 - Muscle approximation
 - Left then right oral flaps
 - Lateral releasing incisions

7. Sphincter-type Pharyngoplasty

Before



After

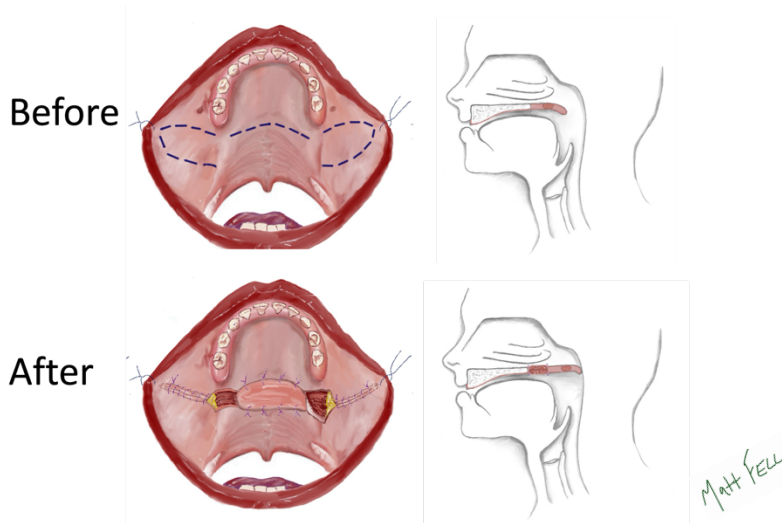


Operative steps:

- Microscope
- Elevate palate with Jakes Catheter and stay stitch through uvula – 3-0 prolene
- Palpate
 - For medialised carotid arteries
 - Arch of atlas
- Mark
 - Arch of atlas
 - Transverse incision positioned high at the estimated velopharyngeal sphincter closure point (as seen on pre-op lateral videofluoroscopy investigation)
 - Superiorly based flaps in lateral pharyngeal recess. Lateral vertical incisions at border of posterior tonsillar pillar (can involve some of lateral posterior pharyngeal wall especially if larger gap). Flaps marked approximately 15mm wide, as long as possible with tapered tip. Aim to leave 15-20cm in middle.
- Local anaesthetic infiltration with care make sure wheal is made (so that you are not in vessel)
- Raise flaps
 - Malleable retractor to clear posterior tonsillar pillar. lateral vertical incision into muscle. Then medial vertical incision. Ensure incisions extend through the muscle to the white pre-vertebral fascia.
 - Use blunt scissors and peanut to get behind muscle along the length of the flap.
 - Finally, the inferior border of flap is incised and the flap is raised completely.
- Transverse incision - needs to be wide enough to accommodate two flaps but not too wide so that the flaps flatten out

- ****Sterile Cockpit**** Ensure complete haemostasis
- Close donor sites 4-0 Vicryl
- Inset flaps
 - Need to overlap the flaps – 1 above the other (should not be short flaps that meet in the midline), raw surface to raw surface to create a shelf.
 - Left sided flap used as **superior flap** – stitch (F) through the medial edge of the flap in the midline – this will become the superior edge.
 - Right sided flap used as **inferior flap** – medial margin at centre is sutured to the left sided flap (already in position). Then stitch in inferior border of the inferior flap.

8. Buccinator myomucosal flaps

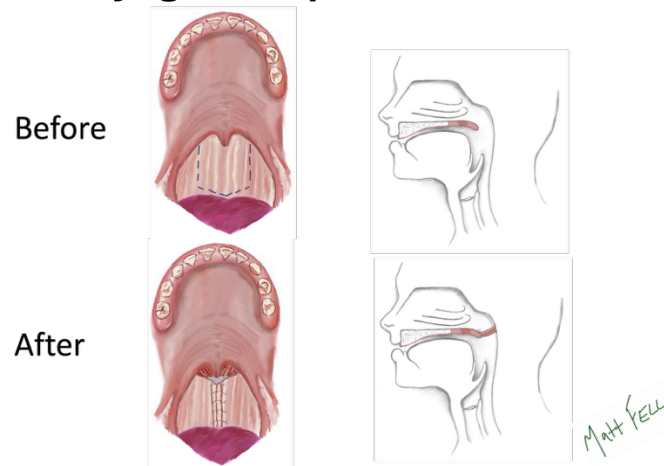


Operative steps:

- Suprazygomatic maxillary nerve block: 2mls 0.2% Ropivacaine bilaterally
- Microscope in. scrub to left, assistant to right
- Photo (pre-op)
- Measure
 - Length of soft palate
 - Length from uvula to posterior pharyngeal wall
 - Randall length
- Marking
 - Transverse incision 2-3mm behind the hard-soft palate junction
 - Opening of Stenson's duct adjacent to maxillary second molar
 - Bilateral buccal flaps with base at retromolar trigone (respecting retromolar space) and extending to commissure (leaving 1-2mm to commissure). Width 10-15mm.
- Local anaesthetic infiltration
- Stay stitches to commissure and flap
- Palatal incision and dissection / retro-positioning of velar musculature
- Raise buccinator flaps and close cheek donor sites
- ****Sterile cockpit**** to ensure adequate release of both palate and buccinator flaps and haemostasis

- Closure – flap inset
 - Nasal flap
 - Oral flap

9. Posterior Pharyngeal Flap



Operative steps:

- Microscope in
- Palpate
 - For medialised carotid arteries
 - Arch of atlas
- Mark
 - Arch of atlas
 - Flap
 - Tip of flap at level of uvula
 - Base of flap usually at start of adenoids
 - Palatal incision
- Local anaesthetic infiltration with care make sure wheal is made (so that you are not in vessel)
- Raise flap
 - Malleable retractor to clear posterior tonsillar pillar. Vertical incisions to prevertebral fascia. Then raise flap superiorly
- Create palatal pocket
 - Retract palate with forceps on uvula and skin hooks at either end for traction
 - Incise palate transversely
 - Dissect with scissors between muscle and nasal mucosa
- ****Sterile Cockpit**** Ensure complete haemostasis
- Partial closure of donor site – may need back cuts superiorly. 4-0 Vicryl
- Inset flap – with 5 parachute stitches 4-0 Vicryl

Supplementary 5: Cleft Surgery Outcome Reporting Strategy

The Welsh Centre for Cleft Lip and Palate submits data nationally to the NHS Dashboard and to the Cleft Registry and Audit NEtwork (CRANE).

In addition to this national data submission, the following data will be collected for patients undergoing cleft surgery:

- 1. Cleft Surgery Database:** All cleft operations to be recorded in a cleft surgery database, stored securely within the IT systems at the Welsh Centre for Cleft Lip and Palate
- 2. 2D Photos:** for all cleft operations will be taken according to Guidance published by the Institute of Medical Illustrators. Photos will be taken pre-operatively, intraoperatively and at each post-operative clinic visit
- 3. LAHSHAL classification:** will be used to document cleft phenotype.
- 4. Intra-operative anthropometric measurements**
 - a. Unilateral Lip
 - i. Total Lip Height
 - ii. Greater Lip Height
 - iii. Lesser Lip Height
 - iv. Third Height
 - b. Bilateral lip
 - i. Premaxilla symmetry
 - ii. Premaxilla inclination
 - iii. Prolabial height
 - iv. Prolabial width
 - v. Columella length
 - c. Alveolar clefts
 - i. Transverse distance
 - ii. AP distance
 - d. Palate
 - i. Hard Soft Junction width at mucosa
 - ii. Right palatal shelf width
 - iii. Left palatal shelf width
 - iv. Inter-tuberosity width
 - v. Base of uvula
 - vi. Randall classification of palatal position to posterior pharyngeal wall
 - vii. Levator bulk
- 5. Oronasal fistula**
 - a. Evidence of early wound dehiscence at 1 week: dichotomous outcome based on parental report at phone review
 - b. Evidence of fistula at 6 weeks using Pittsburgh anatomical classification: dichotomous outcome based on joint surgeon and cleft nurse specialist clinic review
- 6. Speech outcomes**

- a. Early perceptual speech outcomes at 18 months where 2 or more oral sounds would be expected if the velopharyngeal sphincter was competent.
- b. Perceptual speech outcomes at 5 years of age by specialist cleft speech and language therapists according to national standards using GOS.SP.ASS Speech assessment and CAPS-A audit outcomes.

7. Facial growth

- a. Intra-operative dental mould impressions to be taken for all babies with cleft lip and/or palate at their first operation
- b. Dental mould impressions to be taken at 5 years of age according to national standards. Analysis with 5 Year Old's index
- c. Dental mould impressions to be taken at 10 years of age

8. Alveolar bone graft outcomes

- a. Kindelan score at 6 months of age using upper occlusal Xray analysed by Consultant Orthodontist
- b. Canine eruption – dichotomous outcome (no upper limit of time post-op)
- c. Fistula recurrence - dichotomous outcome (no upper limit of time post-op)
- d. Re-operation - dichotomous outcome (no upper limit of time post-op)

9. Internal Validation Strategy - in keeping with annual appraisal process and engage with quality improvement, audit and outcomes monitoring. Statistical process control to be utilised to monitor surgical outcomes and identify if surgical processes go out of control using Cumulative Summation (CUSUM) charts.

10. External Validation Strategy - through structured peer review. This will take the form of mentoring and coaching schemes, complex case discussion forums and visits to external cleft units.

11. Publishing strategy: Aim to publish outcomes of surgical pathways every 5 years in a peer reviewed scientific journal