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TITLE

Exploring the relationship between palatal cleft type and width with the use of relieving incisions in primary repair.

ABSTRACT

Objective: The mainstay of palatal repair in the United Kingdom is the intravelar veloplasty. It is not always possible to align the oral mucosa in the midline to achieve tension free repair. The addition of lateral relieving incisions may aid transposition of the oral mucosa to allow closure. The aim of this study was to explore cleft features that may predispose to a requirement for relieving incisions in order to allow palate closure.

Design: We performed a national multi-institutional retrospective study using data from the United Kingdom's Cleft Collective cohort study.

Patients: The study sample consisted of 474 patients who had undergone intravelar veloplasty at the time of palatal closure across all 16 of the United Kingdom's cleft units.

Results: We found strong evidence for the requirement for relieving incisions in patients with an increased degree of clefting per the Veau classification ($p<0.001$), increasing palatal soft-edge width ($p<0.001$) and moderate evidence of an associated use in patients with Pierre Robin sequence ($p=0.015$). Insufficient data were available to explore the relationship between intertuberosity distance, and the presence of fistula formation with the use of relieving incisions.

Conclusions: The results of this study identify cleft features that increase the likelihood for requiring lateral relieving incisions to allow palatal closure. The degree to which the addition of relieving incisions to intravelar veloplasty affects maxillary growth and speech outcomes is unknown. Further study is required to answer this important question.

Key Words: Cleft Collective, cleft palate, intravelar veloplasty, palatoplasty, cleft palate repair, relieving incision, relaxing incision, releasing incision, Pierre Robin sequence

MANUSCRIPT

Introduction

In the United Kingdom, primary repair of a cleft palate is usually undertaken using the intravelar veloplasty (IVVP) technique (Sommerlad, 2003). This involves incising the cleft margin, performing repair of the nasal mucosa, dissection and retro-positioning of the palatal muscles across the posterior aspect of the velum, then repair of the oral mucosa. Where possible a direct side-to-side closure of the oral mucosa is preferred. However it is not always possible to align the oral mucosa in the cleft midline in order to achieve a tension free repair. Repairing the oral mucosa under tension may lead to relative hypoperfusion of the tissues, wound breakdown and eventual fistula formation.

In cases where it is not possible to perform a direct side-to-side repair, wide undermining of mucoperiosteal flaps of oral mucosa from the cleft margin to the alveolus and incision around the posterior palatal alveolar margin allows the oral mucosa to be elevated as a bipedicled flap and transposed to the midline in order to aid cleft closure. This can be performed unilaterally or bilaterally and is a well-established adjunct to palatal closure and follows the principles of von Langenbeck's palatoplasty (Langenbeck, 1986).

There is however concern that the addition of relieving incisions and raising of oral mucoperiosteal flaps to IVVP may cause abnormal palatal/maxillary growth (Ross, 1987; Chate et al., 1997). Studies of alternative cleft palate repair techniques performed worldwide have demonstrated that wide elevation of oral mucosa can be deleterious to palatal growth (Schweckendiek and Doz, 1978; Bardach et al., 1998; Ysunza et al., 1998). It is thought that this leads to damage or devascularisation of the palatal growth centres. In

order to reduce the risk of scarring to palatal growth centres, incisions used as an adjunct to IVVP are often much shorter than those originally described by von Langenbeck (Figure 1). The effect of this however has not been investigated in the IVVP technique.

The primary endpoint of this initial study was to investigate and report the association between cleft phenotype and the use of relieving incisions. As a secondary endpoint, we aimed to determine the rate of postoperative fistula formation in patients who had relieving incisions used as an adjunct to IVVP compared to those who did not. At this stage data were insufficient to report this (see Discussion).

We used data from the Cleft Collective, based at the University of Bristol, in order to explore these associations (Project Number CC016). The Cleft Collective is a national longitudinal cohort study investigating the biological and environmental causes of cleft lip and palate, the best treatments and the psychological impact on those affected and their families. The study comprises two separate cohorts, a Birth Cohort and a 5-year-old Cohort. Recruitment to these two cohorts is ongoing across the UK via the 16 cleft surgical sites. Data collected are available as a resource for researchers and clinicians to answer their own cleft related research questions (http://www.bristol.ac.uk/cleft-collective/professionals/access/).

Children recruited to the Cleft Collective cohorts will be followed up into adulthood with data collected at a number of waypoints during their growth. Data is submitted from surgical teams during each surgical intervention. Furthermore, outcome data, to include speech, growth, surgical and psychological outcomes, will be collected throughout the course of the study. At the time of analysis, the study had recruited 7700 participants from 2735 families. This includes unaffected family members to aid in the determination of

genetic and environmental factors that may cause clefting, as well as influence outcomes of cleft care. A number of different methods are used to collect data for the cohorts, these include questionnaires completed by parents, children and clinicians, clinical data, biological samples (cord blood, blood, tissue, saliva), speech recordings and data through linkage to externally held records. Nested within the main study are a number of substudies investigating specific aspects of cleft care. The Cleft Collective Speech and Language Study was investigated to provide data on fistula rates.

In this paper we set out to investigate the following research questions:

1) Is there an association between Veau classification of cleft and the use of relieving incisions with IVVP when repairing a cleft palate?
2) Is there an association between the pre-operative soft tissue margin width of the palatal cleft at the hard/soft palate junction and the use of relieving incisions with IVVP when repairing a cleft palate?
3) Is there an association between the presence of Pierre Robin Sequence (PRS) and the use of relieving incisions with IVVP when repairing a cleft palate?

Patients and Methods

The analyses in this study used data collected through a short one-page surgical questionnaire completed by surgeons following operations related to cleft. Data collected on these forms include, but are not limited to, the classification of cleft using LAHSHAL (Kriens, 1989; McBride et al., 2016), date of procedure, type of procedure, surgical technique, syndrome and cleft measurements.

At the point of analysis the Cleft Collective data revealed 1401 surgical procedures on 1222 children of which 749 were primary palatoplasties. Of those, 474 included IVVP (as described by Sommerlad) as the repair technique. Techniques other than those described by Sommerlad, that may, nonetheless, include a muscular repair as part of the technique, were excluded so as to avoid the impact of any adjuvant manoeuvres employed by the surgeon. Data on these 474 participants have been provided by all 16 cleft surgical sites across the United Kingdom.

Following the Eurocleft (Shaw et al, 2005) and United Kingdom's Clinical Standards Advisory Group (CSAG) (Sandy et al, 1998) studies, best practice protocols were put in place in the UK for the management of patients with cleft lip and palate. For patients with cleft lip and palate, lip repair is ideally performed between 3-6 months and accompanied by vomer flap reconstruction of the anterior hard palate. Neither primary alveolar bone grafting, nor gingivoperiosteoplasty is performed. Repair of the soft palate (with IVVP) and posterior hard palate is then performed between 6-12 months of age. Patients in this study were reviewed for deviations from this protocol in order to attempt to ensure uniformity in the study group, and prevent undue influences from differing surgical technique. Patients with submucous cleft palate, wherein relieving incisions should not be required, were not included in the study.

In addition to the surgical data forms, assessment forms from the nested Speech and Language sub-study, completed by speech and language therapists during routine clinical assessments when the child is 18-24 months, were used to determine the fistula rate amongst our sample size of 474 patients, when available. These forms record the presence

and location of fistula as determined by direct visualisation of the palate at the time of data collection.

Statistical Analysis

Data used in our analyses were initially explored using descriptive statistics. To address our first question a chi square test was used to determine if an association was present between the classification of cleft and the use of relieving incisions. A Wilcoxon rank-sum test was used to explore question 2 due to the non-parametric distribution of the soft tissue margin width of the palatal cleft. Chi-square tests were used to explore question number 3. Further descriptive analysis was also performed on the pre-operative width of the palate at the tuberosity and post-operative fistula rate. Associations were not explored between presence of fistula or intertuberosity width with relieving incisions due to small numbers and suspected lack of reliability in this data.

All analysis was performed using STATA/IC v15.1 (StataCorp, Texas, US).

Results

Data received on the short surgical form differed in completeness. Sample size therefore differed for each study question. Surgeons detailed if relieving incisions were used in 414 of the 474 cases (87%). Data completeness for the 414 cases varied from 86-99 per cent for the variables including cleft type, cleft measurements and the diagnosis of PRS. Further analysis was undertaken to identify outliers within the cleft measurements, 13 measurements were

classed as outliers and therefore removed from the analysis. This resulted in a sample size of 395 for question 1, 343 for question 2 and 411 for question 3 (Figure 2).

1. *Is there an association between classification of cleft and the use of relieving incisions with IVVP when repairing a cleft palate?*

For ease of understanding, cleft classification was translated from the LAHSHAL classification into four groups according to the Veau classification (Veau, 1931);

1. cleft of the soft palate only (with or without clefting of the lip and alveolus),
2. cleft of the hard and soft palate (without clefting of the alveolus),
3. unilateral cleft of the soft palate, hard palate and alveolus (with or without clefting to the lip).
4. bilateral cleft of the soft palate, hard palate and alveolus (with or without clefting to the lip).

Data on cleft type were available for 395 participants (Table 1). A chi-square test demonstrated a strong association between cleft type and the use of relieving incisions (χ^2=55.8; p<0.001). The more extensive the Veau classification, the more likely a surgeon was to use relieving incisions with an IVVP repair. It is important to note that we have only tested for an association with an increasing trend and a causal effect has not been found.

2. *Is there an association between the pre-operative soft tissue margin width of the palatal cleft at the hard/soft palate junction and the use of relieving incisions with IVVP when repairing a cleft palate?*

Data on soft tissue margin width of the palatal cleft and relieving incisions were available for 356 participants. Measurements were taken from the free edge of the palatal shelf just posterior to the hard/soft palate junction to the contralateral palatal shelf. The measurements formed a positively skewed distribution with a median of 9mm, minimum of 0mm, maximum of 75mm and an interquartile range of 6mm – 12mm (6mm) for the 356 participants. Some of the larger measurements were deemed questionable and therefore the available measurements were tested for "boxplot outliers" (Tukey, 1977). Outliers were identified as measurements that were 1.5 times the interquartile range greater than the upper quartile or 1.5 times the interquartile range less than the lower quartile. This resulted in 13 measurements being classed as outliers. The remaining 343 cases were used within our analysis and collectively formed a positively skewed distribution with a median of 9mm, minimum of 0mm, maximum of 21mm and an interquartile range of 5mm – 12mm (Table 2; Figure 3). Using the sample of 343 cases, with the outliers removed, a Wilcoxon Rank-Sum test demonstrated strong evidence ($z=-10.3$; $p<0.001$) of an association between the soft tissue margin width and the use of relieving incisions with an IVVP repair. The larger the soft tissue margin width the more likely it is that relieving incisions will be used with an IVVP repair. A sensitivity analysis was conducted by repeating a Wilcoxon Rank-Sum test on the larger sample of 356 cases, which included the outliers. The results concluded the same outcome with strong evidence of an association between the pre-operative palatal cleft width and the use of relieving incisions with an IVVP repair ($z=-9.9$; $p<0.001$).

3. *Is there an association between the presence of Pierre Robin Sequence and the use of relieving incisions with IVVP when repairing a cleft palate?*

Data on PRS and the use of relieving incisions were available for 411 participants, of these 70 were identified as having PRS (Table 3). Five of the 70 participants with PRS had a Veau I cleft and the remaining 65 PRS participants had a Veau II cleft. There was moderate evidence (χ^2=5.9; p=0.015) to suggest an association between PRS and the use of relieving incisions when performing an IVVP repair. Our data would suggest that patients with PRS are more likely to receive relieving incisions than those that do not have PRS.

4. *Descriptive analysis of Fistula rate and intertuberosity measurements*

Fistula rate

Data on the presence of fistula were obtained through data forms completed for the speech and language sub-study, following direct visualisation of the palate, at the 18/24 month or 36-month assessment. Forms were only collected for those participants who were enrolled in the Cleft Collective Speech and Language sub-study and had reached a minimum of 18/24 months. Of our original sample, 83 questionnaires had been completed and returned at the time of analysis. This demonstrated an 11 per cent (N=9) fistula rate, with no fistula in 75 per cent (N=62), leaving 14 per cent (N=12) where it had not been possible to accurately examine the palate. Data on the use of relieving incisions were available for 70 participants, of which 12.86 per cent (N=9) had a diagnosed or suspected fistula. Half of the sample had received relieving incisions.

Due to the small sample no further analysis was performed on these data. Plans are in place to try to obtain richer fistula data once sufficient children in our original sample have reached the 18/24 month waypoint. Once these data are available full analysis will be

performed, and reported, to determine the effect of relieving incisions on the rate of fistula formation in IVVP repair in our cohort.

Intertuberosity width

Preoperative width of the palate at the tuberosity was recorded for 308 cases of cleft palate repaired with an IVVP. Only descriptive statistics for the measurement were calculated as it was felt some of the measurements were unreliable. The minimum value recorded was 0mm and the maximum was 49mm. These extreme values represent measurements that are incompatible with development of the palate. Attempts to statistically determine outliers failed to provide meaningful measurements. The lack of clear alignment of the data with significant outliers brought this dataset into question and therefore no further analysis was performed.

Discussion

The primary endpoint of this study was to explore the use of relieving incisions in patients undergoing intravelar veloplasty. By utilising nationally collected data from across the United Kingdom as part of the Cleft Collective study, we have identified that there is strong evidence to suggest an increasing Veau classification increases the need for relieving incisions. Strong evidence of an association between palatal cleft width and the need for relieving incisions was also found. Our analysis suggested that relieving incisions were more likely to be used with a wider palatal cleft width. In addition, the presence of Pierre Robin sequence shows moderate evidence for the requirement of relieving incisions. It is likely

that the more extensive clefts seen within these groups necessitate greater transposition of the oral mucosa to the midline in order to affect palatal closure; therefore relieving incisions are required in order to allow such movement and relieve tension on the repair.

Studies of patients with unoperated clefts indicate that there is normal potential for maxillary growth (Shetye, 2004). It has been demonstrated that the choice of palatoplasty technique as well as timing of the surgery affects palatal growth (Farronato et al., 2014; Shi and Losee, 2015). The use of bilateral bipedicled mucoperiosteal flaps for palatoplasty were first described by von Langenbeck (1862). As well as cleft marginal incisions he described the addition of lateral relieving incisions at the junction of the palatal and gingival mucosa allowing for medial transposition of the oral mucosa to the midline to affect cleft closure. The denuded palatal shelves are then left to granulate and re-epithelialise.

In recognition of the need to obtain palatal lengthening in an effort to aid velopharyngeal closure, Veau (1931), Kilner (1937) and Wardill (1937) developed von Langenbeck's technique with the addition of V-Y closure at the anterior hard palate. Whilst the Veau-Kilner-Wardill pushback palatoplasty theoretically improves positioning of the levator the technique has not been proven to improve speech. In addition, the more extensive denuding of the palatal shelves and the anterior hard palate results in more pronounced failure of maxillary growth. Addressing this failure Bardach advocated returning the flaps to their original position after exposure of the velar musculature (Bardach and Salyer, 1991). However such extensive undermining may lead to excessive fibrosis and thus deleterious palatal growth (Cronin, 1957).

Even in the more limited dissection of the von Langenbeck palatoplasty, relieving incisions are often extensive, leaving large areas of denuded lateral palatal shelves. This in itself is felt to have an adverse effect on maxillary growth by damaging palatal growth centres.

Furlow (1986) described his double opposing z-palatoplasty to achieve palatal closure and levator repositioning, but advocated against the use of relieving incisions to prevent excess scarring. Notwithstanding many surgeons have found it necessary to add limited relieving incisions to this technique to achieve tension free closure. Such modifications include the Children's Hospital of Philadelphia technique (LaRossa et al., 2004). The Philadelphia cohort demonstrated no adverse effects on midfacial growth (Wang et al., 1999), nor the development of posterior crossbite (Mayro et al., 1997). It would seem that limited relieving incisions are a safe addition to Furlow palatoplasty and may help to reduce the risk of fistula from closing under tension (Baker et al., 2000).

Following the description of abnormal velar musculature by Veau (1931) attention was turned to repositioning of the aberrantly placed muscles, and Braithwaite and Maurice (1968) and Kriens (1969) promoted restoration of the levator sling in order to improve palatal function and speech outcomes. This eventually resulted in Kriens (1970) proposing the concept of intravelar veloplasty, the techniques of which were elucidated further by Cutting et al (1995) and Sommerlad (2003).

To reduce the potential growth-limiting effects of denuding the palatal shelves, Sommerlad described the use of the "drawbridge" effect to achieve closure of the oral mucosa without resorting to the lateral relieving incisions described by von Langenbeck. This effect relies on the high-arched oral mucoperiosteum being mobilised into a horizontal position at the time of repair. This movement often brings the two sides of the oral mucosal layer into

approximation allowing for direct closure. Adjunctive manoeuvres such as unfolding of the flaps and division of the oral component of the tensor palatini insertion and periosteal sleeve of the greater palatine neurovascular bundle allow easier horizontal positioning of the oral flaps.

Sommerlad's technique can be applied to a wide range of cleft palates, however, as many a cleft surgeon can attest, despite these manoeuvres it is not always possible to achieve tension free closure of the oral mucosa in the midline. In such situations the addition of lateral relieving incisions allows for the relief of lateral tension in the oral mucosa and thus transposition of the flaps to the midline. In IVVP the degree of release is often smaller than the incisions required in a formal von Langenbeck palatoplasty (Figure 1).

From this study we can conclude that relieving incisions are more likely to be required when performing IVVP in patients with increasing severity of clefting per the Veau classification, those with wider palatal cleft widths, and in patients with Pierre Robin sequence. These data provide surgeons with information to provide to parents on the likely need for relieving incisions in their child.

Faced with a case of a wide palate and inability to close the midline defect the surgeon may consider the surgery would not be successful without the use of relieving incisions. The patient would have a definitive fistula due to failure of primary repair to close the defect and speech would likely be negatively affected as well. It would, therefore, seem that the risk/benefit argument of relieving incisions would fall in favour of their use, even if large incisions are necessitated and extensive mucoperiosteal undermining needed in order to close both hard and soft palate in one operation. This may be mandated to ensure tension free closure.

An alternative approach is to move from the use of large relieving incisions to close wide clefts, to a staged approach. If large relieving incisions are used and the palate closed in one procedure, most of the time it should work, but there is the potential for scar tissue to form laterally on the hard palate, possibly hampering antero-posterior growth. But if this procedure fails then the surgeon is faced with a fistula with accompanying scar tissue, which may be more difficult to close. In a staged approach, the soft palate is closed first – with or without muscle repair (IVVP versus velar adhesion, respectively). As this heals, the large "o" shaped residual hard palate cleft becomes longer and narrower, tapering towards the ends (spindle shaped) and so easier to close three to six months later. It is felt by some authors that, despite intrinsic tissue deficiency in the palatal shelves at birth, catch-up growth is seen prior to palatal repair (Ye et al., 2012; Latief B et al., 2012). Berkowitz (1999) has suggested that further accelerations in growth may continue until six years of age. Such capacity for growth of the palatal shelves can potentially be harnessed in a two-stage repair technique.

Such a two-staged approach would not be expected to have a negative impact on speech as both stages should be complete well before 18 months old. This differs from previously described two-staged protocols whereby the second stage is performed a significant number of months, sometimes years, following the first. It is suspected that delaying the second stage negatively impacts speech outcomes (Bardach et al., 1998; Kappen et al., 2017), although satisfactory results have been reported (Lohmander et al., 2012). In their randomised controlled study, Reddy et al. (2018) reported no difference in fistula rate between patients undergoing a one-stage Bardach palatoplasty compared to those undergoing soft palate repair with levator repair followed by delayed hard palate repair. They reported a slightly higher nasalance rate in those who had undergone a one-stage

repair, although this was not clinically significant. Although compelling for a single-stage repair, further data on the effect on mid-facial growth and long term speech outcomes are awaited.

The evidence for either a single-stage approach with relieving incisions versus a two-staged repair is insufficient to firmly advocate for either approach. Within the Cleft Collective cohort, surgical teams are free to choose their preferred approach. It is hoped that outcome data from the approaches has the potential to provide a glimpse into the correct approach that may then be used to drive further randomised controlled trials.

Following IVVP, the degree to which oral mucoperiosteal undermining alone, as advocated by Sommerlad, compared to the addition of relieving incisions effects maxillary growth remains unknown. Studies of minimal relieving incisions are limited. Maluf et al. (2014) demonstrated in their porcine study that mucoperiosteal elevation without relieving incisions reduced the incidence of maxillary underdevelopment at four months compared to those who received relieving incisions. It should be noted that these animals did not themselves have cleft palates.

In their retrospective analysis of minimal incision palatoplasty, Parikakis et al. (2019) compared patients undergoing muscle reconstruction with simple straight-line repair. Both groups received limited relieving incisions. It was demonstrated that the additional dissection required for IVVP caused only minor differences in craniofacial morphology at five and ten years. This study however was limited by small sample size at a single centre, and did not directly compare with those children not requiring relieving incisions.

The effect of relieving incisions as an adjunct to IVVP thus remains unknown and an important study question to be resolved in order to ensure the least deleterious effect on

facial growth and dental alignment. Our dataset suggests that 45% of palate repairs utilised relieving incisions, of which the effect on fistula formation, maxillary growth and speech remains unknown at this stage. Whilst it was hoped that the cohort would provide sufficient data on the effect on fistula formation, we concede that the study is currently underpowered to provide meaningful statistical analysis of this secondary endpoint (see Limitations). Children recruited to the Cleft Collective birth cohort at the start of the study are, at the time of writing, beginning to approach five years of age. Further time is needed for the rest of our sample to reach this waypoint. At this time measurements will be undertaken on initial speech outcomes (GOSPASS, CAPS-A) and, through linkage with the UK's Cleft Registry and Audit Network (CRANE) database, it is hoped data can be collected on maxillary and facial growth outcomes (5 year index). This will provide us with the first data on the effect of relieving incisions on these important outcomes in cleft palate surgery.

Limitations

The Cleft Collective cohort is a growing dataset and whilst it was not possible to address our secondary endpoint of fistula rate following the use of relieving incisions, we intend to report our analysis once the data are available. It is recognised that such a national multicentre study brings with it the challenge of ensuring consistency in the measurements collected. However, of the analyses performed, consistency was demonstrated in the data as shown by a low outlier rate of four per cent.

Accurate and sufficient records for the presence of fistula were essential for facilitating analysis between the use of relieving incisions and the development of fistula. Presence was determined using the Cleft Collective Speech and Language sub-study data as it was felt this

method of prospective data collection would prove to be most reliable. Previous systemic reviews of fistula incidence, whilst suggesting no significant difference between palate repair techniques, have been hampered by retrospective data collection with the authors advocating prospective examination and reporting using a standardised classification scheme (Hardwicke et al., 2014).

Furthermore, evidence from the United Kingdom's national Cleft Care Study, suggests that the incidence of fistula may be higher than previously reported (Yang et al., 2020). The authors found that when including data from speech and language therapy notes, incidence increased compared to surgeon-reported data. Again the study authors call for prospective collection of fistula occurrence. Retrospective collection of fistula occurrence may be confounded by the non-reporting of small, asymptomatic fistula that may be left for closure at the time of alveolar bone grafting. They conclude that perhaps only those larger fistula requiring repair are being routinely reported by surgeons.

As such, at this time, there were insufficient data from the Cleft Collective cohort to determine a relationship between fistula formation and relieving incision use due to the limited number of patients that had reached their speech and language assessment waypoint at 18/24 months. However we support the call for internationally standardised reporting of fistula data.

At the 2019 Craniofacial Society of Great Britain and Ireland annual scientific meeting the Cleft Collective asked surgeons to clarify how they measure intertuberosity distance in practice. This ranged from simple straight-line vector between the tuberosities, measurement of straight-line vectors around the palatal shelves and cleft, to measurement of the exact curvature of the palatal shelves and cleft. It was felt that this variability in how

surgeons were measuring intertuberosity distances may be responsible for the unreliable data values seen and therefore no meaningful statistical inferences could be made.

There also remains much discussion about whether to measure from the buccal, midpoint or palatal aspect of the tuberosity. The latter would provide the width of the potential transposable soft tissue flap. It would appear that most surgeons are now moving to this latter definition but earlier measurements would not have been taken uniformly.

There was consensus regarding the measurement of palatal soft tissue margin width, with all surgeons reporting that measurements were taken from just posterior to the hard/soft palate junction. In clefts isolated to the soft palate, where palatal fusion had occurred at the level of the hard/soft palate junction, there was consensus that the width at this level should be recorded as zero. We therefore had confidence that this measurement has been taken as intended.

Patients with Pierre Robin sequence often have wider u-shaped clefts compared to those patients in which the sequence is not present. We recognise that in dealing with such clefts, where the width is maintained even in the anterior portion of the cleft, the operating surgeon may need to perform relieving incisions that also extend more anteriorly into the hard palate, rather than just at the level of the tuberosity. Such extensive incisions may be more akin to those described by von Langenbeck. Whilst we excluded those patients who had their palatoplasty procedure formally recorded as a von Langenbeck repair, we do not currently have the granularity of data to determine if more extensive relieving incisions are required in PRS patients compared to non-PRS patients. However, our data would suggest that relieving incisions, of any length, are more likely to be required in PRS patients. We are looking at ways to investigate the length of relieving incisions used, as the potential for

increased scarring with longer incisions may have implications for later end-point analyses of palatal growth.

The findings in this study would benefit from further validation by nationalised prospective studies using methods of performing palatal measurements and standardised reporting of fistulae that has international consensus. However, our large dataset is likely to be a representative sample of the cleft population as a whole in the United Kingdom demonstrating greater generalizability than single-centre studies.

Conclusion

Our study is the first national cohort utilising data from across the United Kingdom to identify key risk factors for the likely requirement of relieving incisions in IVVP. Whilst this study benefits from data supplied from all the cleft units across the country, thus removing variability in individual surgical team practice, there appears at this stage to be a lack of robustness in some of the measurement data. This is evidenced in the multiple techniques used by surgeons in order to measure intertuberosity distance. However, it remains likely that increasing palatal cleft width, and degree of clefting per Veau requires the utilisation of relieving incisions in order to effect palatal repair. In order to address this in future research the authors seek a plea for consensus amongst surgeons about which method to use for measurements to ensure consistency in data collection.

Our study demonstrates cleft phenotypes that increase the requirement for lateral relieving incisions in order to achieve palatal closure during primary repair. It remains uncertain if the additional scarring incurred from the use of relieving incisions negatively impacts fistula

rate, palatal growth and speech development compared to simple undermining of the oral mucoperiosteum alone. It is hoped that the ongoing data collection of the United Kingdom's two longitudinal cleft cohorts, namely the Cleft Collective and CRANE, will provide answers to this question.

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FIGURE LEGENDS

Figure 1. Short type relieving incision used as an adjunct to intravelar veloplasty in order to reduce the risk of scarring to palatal growth centres (A), compared to the more extensive incision originally described for von Langenbeck's palatoplasty (B)

Figure 2. Consort diagram of surgical data available at point of analysis

Figure 3. Box plot detailing the pre op soft edge width of the palatal cleft at the hard/soft palate junction (mm) by use of relieving incisions