

# Investigation of the breadth of surgical techniques and timing used in primary cleft lip and palate repair in the CCUK study

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## Scientific outline

### Summary

The CCUK study shows that overall outcomes following treatment of cUCLP in the UK have improved since reorganisation of services. Reorganisation of cleft care in the UK created a centralised multi-disciplinary audited service with designated cleft surgeons performing at least ~40 primary cleft operations per year. Individual surgical practice in the UK remains variable, however, and differences between surgeons are poorly described.

Primary surgery is mentioned in publications as a factor affecting outcomes, although it is not clear in what way primary surgery affects outcome. Evidence for the effects of technique, timing or surgeon skill or experience is lacking.

Since primary surgery to repair cleft lip and palate in the UK is not standardised, the CCUK study provides an excellent opportunity to undertake an initial description of the range of primary surgical procedures used, the range of timing of primary surgery, and the consistency with which individual surgeons use a particular protocol. Examination of the information in the surgical forms will allow an assessment of where details of surgery may vary between surgeons but not be described in sufficient detail or consistency to understand whether these differences are important. It will also allow consideration of other surgeon factors such as grade, training, level of experience, and numbers of cases per year. If such a descriptive study shows that detail is missing, it will provide the basis for further investigation of aspects of primary surgery that may impact on clinical outcomes.

With this data it may also be possible to assess whether technique, timing, surgeon or centre are important components in explaining differences in outcome.

### Key words

Primary cleft surgery, cleft outcomes, surgical technique, timing of surgery

## Background

There are many different outcomes that may be measured to assess the success of treatment of UCLP. There are, however, fewer valid, reliable outcome measures. The CCUK study looked at a number of outcomes at the age of 5 years including facial growth, speech, dmft and oral health, and facial appearance.

Facial growth and speech are the most frequently used outcomes to assess quality of care following treatment for UCLP. In the literature the quality of these outcomes varies widely both between centres and surgeons and many factors have been implicated in these differences in outcome. These include both non-modifiable factors such as genetics or the severity of the cleft, and modifiable factors such as primary surgery. Evidence for the importance of any of these factors is weak. A RCT comparing 4 different surgical technique/ timing arms did not find a strong/significant association between surgical technique and outcomes (facial growth).

Despite a lack of evidence, it is still felt that the initial surgery is important in determining outcomes. More recently, as a result of the failure to identify a specific surgical technique that gives better outcomes, many have suggested that any effects of primary surgery are the result of differences between individual surgeons such as skill.

However, single centre audit in the West Midlands Cleft Centre has shown that two experienced surgeons using different protocols of care over a period of 10 years have differing outcomes in facial growth. Moreover, despite very different outcomes in facial growth, these two surgeons have very similar speech outcomes over a similar period of time. Further study is required to understand whether this is a chance finding or whether it indicates that speech and facial growth outcomes are influenced by different aspects related to surgery.

Reorganisation of cleft services in the UK has resulted in improvements overall in facial growth and speech outcomes at age 5 years. Reorganisation created a centralised multi-disciplinary audited service with designated surgeons performing at least ~40 operations per year. It also introduced specialised training in cleft surgery. This in turn means that all cleft surgeons in the UK have higher training in cleft surgery and carry out a higher volume of cases than prior to reorganisation. However, neither surgical techniques nor timing of primary surgery have been standardised. There are still different techniques used and some differences in the timing of surgery. Furthermore, when discussing their own surgical techniques, UK cleft surgeons have found it surprisingly difficult to accurately and effectively describe their techniques to their colleagues.

If the effects of surgery and surgeon on outcomes are to be understood better, the differences in primary surgery need to be clearly described, and associations of surgeon, surgical technique and outcome explored further.

#### Aims of this study

1 to describe the range of surgical techniques and timings used to repair the lip and palate in infancy in the UK using information from the surgical form in the CCUK study, and to see if surgeons consistently use the same technique/timing in cUCLP.

2 to determine if there are differences in outcomes associated with surgical techniques and timing in primary surgical repair of cleft lip and cleft palate (there may not be power to achieve this)

3 To determine if the surgeon or surgeon related differences are an important component in explaining observed differences in facial growth

4 to determine if surgeon or surgeon related differences explain the variation in speech outcomes found between centres

#### Information needed for each patient:

Gender

Ethnicity

Date of birth

Socioeconomic status

Gestational age at birth

Corrected age at lip repair

Corrected age at palate repair

Presurgical orthodontics (or not)

Details of surgical history from surgical form anonymised for surgeon and centre

5 year index scores

Facial growth scores from photos

Speech outcomes – nasality scores