

Profile photographs as a measure of outcome for CSAG and CCUK

Principle Applicant: Emma McCartin

Scientific outline

In this study I intend to find out how the facial appearance of children with UCLP treated post the 1998 reorganisation of cleft services compare with the appearance of children with UCLP treated pre 1998. The results of this study will be important in contributing to the CCUK study evaluation of the impact of cleft service centralisation on the standard of care and the outcomes achieved in children with cleft lip and palate in the UK.

The specific objectives of this research project are:

- 1) To describe and compare the facial appearance outcomes in five year old children with UCLP from the original CSAG survey with those since the centralisation of the cleft services
- 2) To ascertain and compare the level of concurrence among raters' assessments of profile, frontal and worm's eye views of the CCUK photographs.

Participants: All left lateral photographs of five year old children with non-syndromic complete UCLP gathered as part of the 1998 CSAG study and the left lateral photographs from the CCUK 2012 study.

Main outcome measures: An aesthetic rating using a categorical five point Likert scale rating of the profile photographs.

Methods: Using a web-based aesthetic scoring tool the photographs will be scored by 6 raters using a categorical 5-point Likert type scale over a 3 week period. Repeat rater scoring will then allow analysis of inter and intra-rater reliability. Two of the raters in my study (Consultant Orthodontist and Orthodontic FTTA) will also be participating in another DDS study where they are rating 180 frontal and WEV views of UCLP children from the CCUK study. I will compare my scores of the lateral views with those of the frontal and WEV views of the same patient to assess the level of concurrence.

Data Collection, Storage and cropping/anonymisation of the data set

The photographs from both the CSAG study and CCUK study had previously been collected for research purposes and saved on an encrypted NHS laptop and external hard-drive (Al-Ghatam *et al.* 2014). The photographs will be cropped and anonymised.

Analysis of the photographs

Many outcome measure rating systems exist for facial aesthetics in cleft lip and palate yet there is no one internationally accepted system (Sharma *et al.* 2012). In this study we will use a recently developed web-based aesthetic outcome scoring tool developed by the Birmingham Institute of Paediatric Plastic Surgery (BIPPS). This tool has been standardised and validated and had been piloted in a tri-centre aesthetic outcome audit and also recently used in a study assessing aesthetic outcomes for CSAG and CCUK using frontal images of patients with UCLP (Al-Ghatam *et al.* 2014). The study by Al-Ghatam *et al.* (2014) found this tool to be advantageous as it provided a secure system which was simple to use and allowed images to be scored by assessors at a convenient time over a period of time.

The cropped and coded images will be arranged on the BIPPS scoring system in a randomised fashion using a random number generator provided through Stat Trek (<http://stattrek.com/statistics/random-number-generator.aspx>).

The assessment panel will comprise of:

- A lay person
- An orthodontic FTTA
- Four cleft professional assessors from the Cleft Unit at UH Bristol namely:
 - A consultant orthodontist
 - A speech and language therapist
 - A maxillofacial surgeon
 - A clinical psychologist

An invitation letter will be emailed to each assessor detailing the nature of the study and inviting them to participate. Confirmed assessors will be sent an email with a personalised Token enabling them to access the scoring website and will also receive instructions on how to use the tool.

Statistical analysis will be undertaken using Stata version 12 statistical software package.

Agreement between the following will be assessed

- Between raters (inter-examiner agreement)
- Within raters (intra- examiner agreement)
- Between views agreement (frontal, profile and worm's eye views)

Summary

The primary *aim* of this study, and as part of the 2012 Cleft Care UK study into the effect of this reorganisation, is to investigate the facial appearance of children that have been treated following the 1998 reorganisation, and to compare this with the appearance of children treated pre 1998.

Specific objectives:

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