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The use and reliability of SymNose for quantitative measurement of the nose and lip in unilateral cleft lip and palate patients☆

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ABSTRACT

Introduction: It is essential to have a reliable assessment method in order to compare the results of cleft lip and palate surgery. In this study the computer-based program SymNose, a method for quantitative assessment of the nose and lip, will be assessed on usability and reliability.
Methods: The symmetry of the nose and lip was measured twice in 50 six-year-old complete and incomplete unilateral cleft lip and palate patients by four observers. For the frontal view the asymmetry level of the nose and upper lip were evaluated and for the basal view the asymmetry level of the nose and nostrils were evaluated.
Results: A mean inter-observer reliability when tracing each image once or twice was 0.70 and 0.75, respectively. Tracing the photographs with 2 observers and 4 observers gave a mean inter-observer score of 0.86 and 0.92, respectively. The mean intra-observer reliability varied between 0.80 and 0.84.
Conclusions: SymNose is a practical and reliable tool for the retrospective assessment of large caseloads of 2D photographs of cleft patients for research purposes. Moderate to high single inter-observer reliability was found. For future research with SymNose reliable outcomes can be achieved by using the average outcomes of single tracings of two observers.

1. Introduction

Cleft lip and palate are a common facial and oral malformation that occurs in early pregnancy. It affects about 1–2 per 1000 births in the developed world (Watkins et al., 2014). There is no internationally agreed-upon objective method for assessing cleft-related deformities. It is essential to have a reliable and precise assessment method in order to compare the results of surgical techniques, of cleft lip and palate teams or individual surgeons, and to determine the optimal timing for primary lip repair (Al-Omari et al., 2005; Sharma et al., 2012; Mosmuller et al., 2013).

Orthodontists use the generally accepted Goslon Yardstick to assess the dental arch relationships in cleft lip and palate patients (Mars et al., 1987). For the assessment of the nasolabial appearance, several methods have been proposed: direct clinical assessment, assessments based on two- or three-dimensional photographs combined with ordinal scales, measurements and video assessments. None of these methods have been generally accepted (Al-Omari et al., 2005; Sharma et al., 2012; Mosmuller et al., 2013).

Assessment of two-dimensional (2D) photographs combined with a five-point ordinal scale is used most frequently. For example, the Asher-McDade Aesthetic index (Asher-McDade et al., 1991) uses a five-point scale to rate nasolabial appearance on frontal and profile photographs. Several objective 2D techniques are currently in use. Most of these methods involve the placement of facial landmarks and use Photoshop® for facial symmetry assessment (Al-Omari et al., 2005; Sharma et al., 2012; Mosmuller et al., 2013). A more recent objective method that employs specially designed software is ASYMNOS. This program automatically

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calculates nine characteristic features of the nostrils and will give an objective estimation of the symmetry (Daelemans et al., 2006; Baeyens et al., 2006). However, a great variation in intra- and inter-observer reliability scores was found.

Three-dimensional (3D) imaging is a more recent technique, which is precise and reliable in comparing cleft outcome (Al-Omari et al., 2005; Sharma et al., 2012; Mosmuller et al., 2013). In most cleft lip and palate centers, however, this technique is not readily available. Moreover, since all cleft patients are photographed during their treatment period at predetermined intervals, 2D assessment is more applicable in daily practice (Mosmuller et al., 2013).

In 2010, Pigott and Pigott presented SymNose. The objective of this system is to measure asymmetry in cleft lip and palate patients based on two-dimensional photographs (Pigott and Pigott, 2010). This program enables researchers to quantify asymmetry of the nose and lip from the front view, in addition to the asymmetry of the nose from the basal view, by using the area of mismatch on the affected (left) side of the photograph reflected over the unaffected (right) side (Pigott and Pigott, 2010). According to the original authors, SymNose is a quick and simple-to-use objective method in the assessment of cleft lip and palate patients. However, it is preferable to have independent observers make tracings because observers may do this differently (Pigott and Pigott, 2010). Other studies have shown that the program is easy to use and that it takes less than three minutes for an observer to trace a photograph and for the system to calculate the outcomes for all the variables. The program also allows the observer to assess the nostrils from the basal view independently, which in other studies were reported to be a difficult and cumbersome task. Still, their method has not been generally accepted as a method of choice to evaluate nasolabial appearance in cleft lip patients. The accuracy and reliability of the SymNose method has already been investigated and significant variations in the accuracy and reliability were found (Pigott and Pigott, 2010; McKearney et al., 2013; Freeman et al., 2013; Russell et al., 2014). For example, the intra-observer reliability varies in these studies between 0.76 and 0.92. The inter-observer reliability scores varied between 0.67 and 0.94. Moreover, in the previous studies only one or two observers were involved in the positioning of the roundels and were performing the tracings. Also, it was concluded that multiple observers should perform at least two tracings to have reliable outcomes (Pigott and Pigott, 2010; McKearney et al., 2013; Freeman et al., 2013; Russell et al., 2014).

The first objective is to test the usability of the SymNose method for quantitative assessment of the nose and lip after complete and incomplete unilateral cleft lip repair. The second objective is to quantify intra- and inter-observer reliability and document measurement errors, the third objective is to determine how many observers and number of tests is necessary to achieve reliable outcomes.

2. Material and methods

For the preparation of this study the following equipment was used:

- SymNose© Brian Pigott 2009, version 6.18 (2014)
- Apple Macintosh OSX 10.4 or later on a 15 inch screen
- Digitizing pad: Wacom BAMBOO CTH-470

Photographs of 50 patients at the age of six years with complete or incomplete unilateral cleft lip and palate were obtained from the Academic Centre for Dentistry Amsterdam. Both frontal and basal view photographs were used. All the right-sided clefts were mirrored using Photoshop and presented as being left-sided.

The images met the following criteria: the head had to fill the complete image to avoid pixilation if magnified for use. Images had to be sharp and not rotated in the sagittal plane. The patients' lips had to be touching but not smiling, grimacing or compressed. Patients with a history of facial trauma or with a bilateral cleft lip were excluded. A standard protocol has been used to make the frontal and basal photographs (distance and head orientation); the photographs have all been taken with the same camera and with similar lighting. Also the angle of the photographs was semi-standardized. Non-Caucasian patients were also excluded, since the norm values of SymNose are based on a control group of 90 five-year-old children from South West England (Pigott and Pigott, 2010).

All the original photographs were stored in an archive in a dedicated folder on a single MacBook laptop, which was passed onto the four observers. The photographs were traced using the computer program SymNose and the digitizing pad in accordance with the enclosed user manual files and the new guidelines acquired during test sessions with the program's developers. Each photograph was traced two times by each observer consecutively as advised by the developers. This was repeated after a two-week interval. Thus, four observers traced both frontal and basal view photographs a total of four times: twice on two different occasions.

A two-week interval is a common period of time in a study to calculate the inter-observer reliability in order to prevent any influence from the previous assessments (de Vet et al., 2011).

2.1. Testing SymNose

Before conducting this study, two of the authors read the earlier articles on SymNose and the user manual incorporated into the system. Following this, 5 photographs were used to test the system. Pigott and Pigott (2010) advise that the roundels be placed in each photograph prior to the tracings by a single observer. However, in this study each observer placed the roundels themselves on each single photograph since this is might be a source of variation and therefore a part of the reliability study.

Non-cropped photographs were used in this study, as the MacBook that was used was able to handle the large files without any problems. However it is recommended to crop the photographs, since cropping will reduce the large files, making it easier to run future batches.

In previous studies SymNose was used on MacBooks that were 20″ or larger. In this study we examined whether the tracings could be done on a 15″ MacBook. Therefore multiple photographs were traced on different sized screens (15″ and 20″).

Every assessment started with uploading a photograph into SymNose, placing the roundels on both medial canthi of the eyes and placing the normal side marker as seen in Fig. 1B and D. Subsequently, the image scale was set between 500 and 600 for the frontal view and between 650 and 750 for the basal view. Thus, each observer was tracing similarly sized images.

The photographs were traced as seen in Fig. 1A (frontal view) and C (basal view).

SymNose compares the left side of the face with the right side and calculates the percentage of mismatch between these two sides. This percentage of mismatch is a proxy for asymmetry, the greater the mismatch, the less symmetry there is.

SymNose shows a total of 22 parameters in the result panel (Pigott and Pigott, 2010). Relevant parameters used for the frontal view were: the nose parameter (FNP), which represents the percentage of asymmetry of the nose, and the lip parameter (FLP), which represents the percentage of asymmetry of the upper lip. For the basal view (worm's eye view), the basal nose parameter (BNP) and nostrils parameter (NP) were relevant.

Two observers (observer 1 and 4) were well instructed and extensively trained before they started the experimental sessions.