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ORIGINAL ARTICLE

# Dental arch relationship in children with complete unilateral cleft lip and palate following one-stage and three-stage surgical protocols

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**Abstract** The objective of this study is to compare dental arch relationship following one-stage and three-stage surgical protocols of unilateral cleft lip and palate. Dental casts of 61 children (mean age, 11.2 years; SD, 1.7), consecutively treated in one center with one-stage closure of the complete cleft at 9.2 months (SD, 2.0), were compared with a sample of 97 patients (mean age, 8.7 years; SD, 0.9), consecutively treated with a three-stage protocol including delayed hard palate closure in another center. The dental casts were assigned random numbers to blind their origin. Four raters graded dental arch relationship and palatal morphology using the EUROCRAN index. The strength of agreement of rating was assessed with kappa statistics. Independent *t* tests were run to compare the EUROCRAN scores between one-stage and three-stage samples, and Fisher's exact tests were performed to evaluate differences of distribution of the EUROCRAN grades. The intra- and inter-rater agreement was moderate to very good. Dental arch relationship in the one-stage sample was less favorable than in three-stage group (mean scores, 2.58 and 1.97 for one-stage and three-stage samples, respectively; $p < 0.000$). Palatal morphology in the one-stage sample was more favorable than in the three-stage group (mean scores, 1.79 and 1.96 for one-stage and three-stage samples, respectively; $p = 0.047$). The dental arch relationship following one-stage repair was less favorable than the outcome of three-stage repair. The palatal morphology following one-stage repair, however, was more favorable than the outcome of three-stage repair.

**Keywords** Cleft palate · Orthodontics · Treatment outcome · Delayed hard palate closure · Dental arch relationship · EUROCRAN index · One-stage repair · Unilateral cleft lip and palate

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## Introduction

Incomplete understanding of factors affecting outcome of treatment in children with unilateral cleft lip and palate (UCLP) has resulted in large variety of protocols and surgical techniques employed by various cleft teams worldwide. A survey of European cleft centers [1] demonstrated

that 201 cleft teams practiced 194 different protocols. Although approximately 43% of them were two-stage, in which lip closure was followed by simultaneous repair of hard and soft palate, the number of primary surgeries ranged from 1 (when all cleft structures are repaired simultaneously) to 4 (when cleft structures are closed at different timings).

Comparison of treatment outcome of several European cleft centers—the Eurocleft studies—showed that one of the best treatment outcomes was achieved by a center practicing a three-stage treatment protocol with hard palate closure delayed until 8–11 years of age [2]. Nollet et al. [3], who examined dental arch relationship in a sample of 9-year-olds treated at the Radboud University Nijmegen Medical Centre according to three-stage protocol with delayed hard palate closure (DHPC), also found a very good treatment outcome compared to the Eurocleft study. Also, studies by Lilja et al. [4] and Sinko et al. [5] revealed favorable dental arch relationships following protocols including DHPC. Lilja et al. reviewed treatment results in a sample of 104 patients treated consecutively by the Gothenburg cleft team, Sweden, and found that 85% of them were rated as having good or very good outcome. Sinko et al. examined dental arch relationship in 123 9-year-olds treated according to the *Vienna concept*—four-stage protocol including DHPC at 6 years—and found that 71.5% of the patients were assessed as having good or very good outcome.

Few studies have so far examined the long-term results following one-stage repair of UCLP. In a cephalometric study, Corbo et al. [6] compared two small samples of preadolescent children with complete UCLP that were operated according to the Malek procedure. In 11 children, the complete cleft was closed in one operation at 3 months of age, and in ten children, a two-stage repair was used where the soft palate was closed at 3 months and lip and hard palate closed at 6 months of age. No difference between the two protocols was observed. Savaci et al. [7] reported cephalometric findings of two groups of children with UCLP and a non-cleft control group. In the children with clefts, 19 subjects had had a one-stage cleft closure at 10.2 months of age, and the second group consisted of 22 subjects who had lip closure at a mean age of 4.8 months and palate closure at a mean age of 14.6 months. The authors did not find any differences in cephalometric measurements between the two cleft groups at a mean age of 6.3 years. De Mey et al. [8] in a historical control study compared 18 patients with UCLP whose cleft was closed in one operation at 3 months of age with 26 patients operated according to the Malek procedure (soft palate closure at 3 months and lip and hard palate closure at 6 months). No significant difference in antero–posterior mid-facial growth was found in the two cleft groups, but the one-stage procedure resulted in less downward inclination of the maxillary plane relative to the anterior cranial base compared to the Malek cohort.

Fudalej et al. [9] evaluated in a single-center report dental arch relationship in a sample of 10-year-olds treated consecutively with one-stage approach at the Warsaw Institute of Mother and Child, Poland, and found that the outcome obtained by the Warsaw cleft team was comparable with the results of the best cleft teams. Comparison with published data, however, decreases value of evidence due to susceptibility to potential biases [10]. Intercenter comparisons offer greater transparency, hence, minimization of occurrence of some types of bias. Although intercenter studies have also their limitations, i.e., they cannot distinguish the influence of individual treatment components on the outcome, they can demonstrate the quality of the treatment outcome achieved in a particular center in comparison to others. Therefore, the purpose of this study was to perform an intercenter comparison of dental arch relationship in patients with UCLP who were treated with one-stage versus three-stage surgical treatment regimens.

## Materials and methods

### Subjects

The Warsaw sample consisted of 61 children (42 males and 19 females) with a non-syndromic complete UCLP, with and without Simonart's bands, consecutively treated at the Warsaw Institute of Mother and Child, Poland. All subjects were born between May 1992 and January 1996 and were operated on by the same high-volume operator (ZD) between May 1993 and August 1996. The mean age at which dental casts were made was 11.2 years (SD, 1.6; range, 9.1–14.7).

The Nijmegen sample comprised 97 consecutively treated patients with a non-syndromic complete UCLP without Simnart's bands. All patients (74 boys and 23 girls) were born between April 1976 and December 1995. The mean age at which the dental casts were made was 8.7 years (SD, 0.9; range, 7.1–11.0).

### Surgical management

*Warsaw sample* No infant orthopedic (IO) treatment was carried out. During one operation, lip, hard, and soft palate were closed according to the following protocol: lip closure was undertaken using a triangular flap; for hard palate repair, an extended vomer flap with a tight closure of the anterior palate was performed. During the soft palate repair, all abnormal muscle insertions were dissected from the posterior edge of the hard palate up to the hamuli, which were always fractured; subsequently, the palatal muscles were reconstructed and sutured in the midline. No primary nose surgery was performed at the time of operation. The mean age at surgery was 9.2 months (SD, 2.0; range, 6.0 to

15.8 months). Alveolar bone grafting was performed between 9 and 12 years.

*Nijmegen sample* All patients underwent IO treatment with passive plates composed of soft and hard acrylic, which were maintained until soft palate closure. No primary nose surgery was performed at the time of lip surgery. In Nijmegen, the soft palate was closed at 12–14 months of age, whereas the hard palate has been left open to be closed at the age of 9–11 years at the time of the alveolar bone-grafting procedure. For patients born before 1985, timing of hard palatal closure was variable. For this study, only patients with closure of the hard palate after the age of 4 years were included. Summary of the Warsaw and Nijmegen protocols is shown in Table 1.

### Orthodontic treatment

Simple orthodontic treatment, mostly with removable appliances, was performed in some children. If a subject was treated orthodontically, this was reflected in the assigned score (Table 2).

### Methods

The EUROCRAN index [11] was used to rate dental arch relationship. According to the index, two components are rated separately: (1) *dental arch relationship* (grades from 1 to 4, when 1 means a very good treatment outcome and 4 corresponds to a poor outcome and necessity for orthognathic surgery) and (2) *palatal morphology* (from 1, meaning very good morphology, to 3, meaning poor morphology). Anchor models were available to illustrate the grades. A detailed description of the EUROCRAN index is given in Table 2.

**Table 1** Summary of treatment protocols used in Warsaw and Nijmegen groups

| Age | Warsaw | Nijmegen |
|---|---|---|
| 0–6 months | | Infant orthopedics |
| 6–12 months | Lip, soft, and hard palate closure (one-stage) | Lip closure (Millard) |
| 12–18 months | | Soft palate closure (modified von Langenbeck); at 12–14-month |
| 9–11 years | Bone grafting | Bone grafting and hard palate closure (Boyne and Sands' procedure) |

The 158 models were coded and placed in random order. Four raters (PF, CK, CB, and AK) scored the models. After calibration exercises, the *dental arch relationship* was evaluated first. The anchor models were available throughout the calibration and the rating sessions as a reference. To evaluate intra-rater agreement, 20 randomly selected models were reassessed.

### Statistical analysis

Reliability of the scorings was evaluated by calculating the intra- and inter-rater agreement with proportionally weighted kappa statistics [12]. Strength of agreement was defined according to Landis and Koch [13]: poor (kappa<0.20), fair (0.21–0.40), moderate (0.41–0.60), good (0.61–0.80), and very good (0.81–1.00).

Independent *t* tests were run to compare the EUROCRAN scores between Warsaw and Nijmegen samples, and Fisher's exact tests were performed to evaluate difference of distribution of the EUROCRAN grades. The level of significance was set at $p<0.05$.

## Results

### Reliability of the EUROCRAN index

Both intra- and inter-rater agreement was moderate to very good according to Landis and Koch (1977)—Tables 3 and 4. Higher values of *kappa*, corresponding to better agreement, were observed for the *dental arch relationship* component than for the *palatal morphology* component of the EUROCRAN index.

### Treatment outcome

Tables 5 and 6 show the mean EUROCRAN scores for the Warsaw and Nijmegen samples. *Dental arch relationship* in the Warsaw group was less favorable than in the Nijmegen group (mean, 2.58 and 1.97, respectively; $p<0.000$). On the contrary, *palatal morphology* in the Warsaw group was more favorable than in the Nijmegen group (mean, 1.79 and 1.96, respectively; $p=0.047$).

Distribution of the EUROCRAN grades in both samples is demonstrated in Fig. 1a, b. Fisher's exact tests showed statistically significant differences between samples ($p<0.01$).

## Discussion

Over the last two decades, the GOSLON yardstick [14] has usually been chosen as outcome measure in studies evaluating dental arch relationship in patients with UCLP

**Table 2** Grade allocation according to the EUROCRAN index

| Grades | |
|---|---|
| Dental arch relationship | |
| 1 | (a) Apical base relationship skeletal class I or class II |
| | Both central incisors positive overjet and overbite |
| | Note: If both incisors have a positive overjet and overbite but the incisor relationship was achieved by obvious dental compensation/orthodontic treatment, the case is grade 2 |
| | (b) Apical base relationship skeletal class I or class II |
| | No overbite but overjet markedly increased |
| | Note: If there is no overbite and the overjet is not markedly increased, the case is grade 2 |
| 2 | Apical base relationship skeletal class I |
| | Non-cleft incisor in positive overjet and overbite |
| | Tilting or derotation would achieve stable positive overjet and overbite of the incisor on the cleft side |
| | Note: the case is grade 3 if there is a moderate open bite |
| 3 | (a) Apical base relationship edge-to-edge or mild class III |
| | One or both central incisors edge-to-edge or in anterior cross-bite |
| | Tilting or derotation would not achieve a stable positive overjet and overbite (i.e., the proclined tooth would relapse). May include moderate open bite |
| | Note: if both incisors have an edge-to-edge relationship but the skeletal class is III (i.e., incisor relationship was achieved by dental compensation/orthodontic treatment), the case is grade 4 |
| 4 | (a) Apical base relationship class III |
| | Both centrals in anterior cross-bite or one in anterior cross-bite with the other edge-to-edge |
| | Central incisors may or may not be in contact with the lower incisors |
| | (b) As grade 3 but with a marked open bite |
| Palatal morphology* | |
| 1 | Good anterior and posterior height; minor surface irregularities (bumps and crevices); no or minor deviation of arch form |
| 2 | Moderate anterior and posterior height; moderate surface irregularities (bumps and crevices); moderate deviation of arch form (e.g., segmental displacement) |
| 3 | Severe reduction in palate height; severe surface irregularities (bumps and crevices); severe deviation in arch form (e.g., "hourglass" constriction) |

*The worst feature of the three suggests the initial score. This may be modified up or down depending on how good the other features are. If good arch form was achieved by means of orthodontic treatment, the case is graded lower

**Table 3** Intra-rater agreement

| Raters | kappa | SE | 95% CI |
|---|---|---|---|
| Dental arch relationship | | | |
| 1 | 0.86 | 0.10 | 0.66–1.00 |
| 2 | 0.90 | 0.07 | 0.76–1.00 |
| 3 | 0.96 | 0.04 | 0.88–1.00 |
| 4 | 0.89 | 0.07 | 0.77–1.00 |
| Palatal morphology | | | |
| 1 | 0.56 | 0.16 | 0.25–0.86 |
| 2 | 0.91 | 0.09 | 0.72–1.00 |
| 3 | 0.89 | 0.11 | 0.69–1.00 |
| 4 | 0.64 | 0.17 | 0.30–0.97 |

*SE* standard error, *CI* confidence interval

[2,4,5,15]. Since then, increasing understanding of factors adversely affecting treatment outcome resulted in an improvement of therapeutical protocols. Consequentially, differences between cleft centers became subtler, and these small differences are difficult to detect with the original GOSLON Yardstick. In response to the need for a system capable of discriminating fine differences in treatment outcomes, the EUROCRAN index was developed [11]. The index has a separate grading for *dental arch relationship* and *palatal morphology* to increase its discriminating power. Overall, the EUROCRAN index employs more detailed and nuanced guidelines for categorization of treatment outcome in comparison with the GOSLON yardstick.

The validity of the EUROCRAN index, i.e., whether the treatment outcome assessed at pre-puberty reflects the final results after completion of growth, has not been tested. However, it is recognized that a formal validation of both the EUROCRAN index and the GOSLON yardstick is not possible because it requires a sample of adults with UCLP

**Table 4** Inter-rater agreement

| Raters | kappa | SE | 95% CI |
|---|---|---|---|
| Dental arch relationship | | | |
| 1 vs. 2 | 0.73 | 0.04 | 0.65–0.80 |
| 1 vs. 3 | 0.73 | 0.04 | 0.66–0.80 |
| 1 vs. 4 | 0.77 | 0.03 | 0.71–0.84 |
| 2 vs. 3 | 0.73 | 0.03 | 0.66–0.79 |
| 2 vs. 4 | 0.81 | 0.03 | 0.75–0.87 |
| 3 vs. 4 | 0.70 | 0.04 | 0.63–0.77 |
| Palatal morphology | | | |
| 1 vs. 2 | 0.53 | 0.06 | 0.41–0.64 |
| 1 vs. 3 | 0.53 | 0.06 | 0.40–0.65 |
| 1 vs. 4 | 0.49 | 0.06 | 0.37–0.62 |
| 2 vs. 3 | 0.54 | 0.06 | 0.42–0.66 |
| 2 vs. 4 | 0.55 | 0.06 | 0.44–0.67 |
| 3 vs. 4 | 0.52 | 0.07 | 0.39–0.64 |

*SE* standard error, *CI* confidence interval

treated only with primary surgery, for whom the dental casts made at the age of 10 years are also available [15]. Such a group likely does not exist as most patients undergo orthodontic, restorative, and bone-grafting procedures, which mask the effects of the primary surgery. Therefore, the power of the EUROCRAN index is in its face validity, which is said when the relevance of a measurement appears obvious to the investigator [16].

Moderate to very good reliability of the EUROCRAN index, defined as the combined level of intra- and inter-rater agreement, can only be compared with reliability of the GOSLON yardstick since no studies employing the index have been published yet. The *dental arch relationship* component of the EUROCRAN system demonstrated satisfactory reliability—intra-rater agreement was very good, and more experienced raters (No. 1 and 2, Table 3) demonstrated similar intra-rater agreement as less experienced colleagues—and comparable with that for the GOSLON yardstick [2,4,5]. The *palatal morphology* component of the EUROCRAN index demonstrated a lower intra- and inter-rater agreement than the *dental arch relationship* component. Although values of *kappa* ranged from 0.49 to 0.91 (moderate to very good agreement), the lower limit of 95% confidence interval implies that agreement might have been poorer. The lower level of intra- and inter-rater agreement for *palatal morphology* might result from the method of scoring—among three judged elements (Table 2), the worst feature was suggestive of the final score, and this might be modified up or down depending on how good the other features were. The difference between moderate and *severe* deviation of arch form or *minor*, *moderate*, and *severe* surface irregularities is difficult to make, and therefore, anchor models need to be used as well when scoring the cleft sample. Moreover, when various features of palatal morphology showed a different degree of deviation as, for example, in the case of a severe reduction of palatal height but normal arch form, grading the case was even more difficult likely leading to the lower intra- and inter-rater agreement. It is possible that when more experience in using the EUROCRAN index will be gained, intra- and inter-rater agreement will improve, as occurred with the GOSLON yardstick in the Eurocleft study [2,17]. Overall reliability of the EUROCRAN index, however, appears acceptable.

The Warsaw one-stage and Nijmegen three-stage groups were not perfectly matched regarding age when records were taken. The Polish sample was slightly older. Since the Eurocleft studies [2] demonstrated the dental arch relationship might deteriorate with growth, it is possible that this influenced the scores. Also, inclusion of children with Simonart's bands only into the Warsaw sample might have increased inequivalence of the groups. However, long-term effects of the Simonart's band on facial development are unclear. Semb and Shaw [18] demonstrated that children with bands required fewer secondary revisions of the nose and lip. On the other hand, Johnson et al. [19] detected no relationship between the width of the cleft and dental arch relationship.

*Dental arch relationship* in the Warsaw group was less favorable in comparison with the Nijmegen sample, and mean difference between the groups was 0.61 EUROCRAN points on a four-grade scale. There were striking differences between the two treatment protocols. IO treatment was used only in the Nijmegen sample. Effects of IO on different aspects of facial growth and development have been recently evaluated through the randomized prospective clinical study *Dutchcleft* [20–25]. Findings of *Dutchcleft* do not substantiate claims that normalization of feeding and tongue posture with IO permits favorable growth of the maxillary segments. Conversely, it has been demonstrated that effects of IO are minimal—maxillary

**Table 5** The mean scores for the *dental arch relationship* component of the EUROCRAN index

| Group | Number | Mean | SD | SE | 95% CI | *p* value |
|---|---|---|---|---|---|---|
| Warsaw | 61 | 2.58 | 0.92 | 0.12 | 2.25–2.82 | 0.000 |
| Nijmegen | 97 | 1.97 | 0.88 | 0.09 | 1.79–2.15 | |

*SD* standard deviation, *SE* standard error, *CI* confidence interval

**Table 6** The mean scores for the *palatal morphology* component of the EUROCRAN index

| Group | Number | Mean | SD | SE | 95% CI | *p* value |
|---|---|---|---|---|---|---|
| Warsaw | 61 | 1.79 | 0.43 | 0.06 | 1.68–1.90 | 0.047 |
| Nijmegen | 97 | 1.96 | 0.55 | 0.06 | 1.85–2.07 | |

*SD* standard deviation, *SE* standard error, *CI* confidence interval

growth, development of occlusion, feeding, and satisfaction in motherhood were similar irrespective of use of IO. Therefore, it seems that IO was not associated with development of better dental arch relationship in the Nijmegen group in comparison with the Warsaw sample. It should be mentioned, however, that some studies [26–28], although not using a rigorous methodology of the Dutchcleft, demonstrated a positive association between favorable facial growth and IO treatment.

Closure of a hard palate was postponed in the Nijmegen group until 8–10 years of age, whereas in the Warsaw group, the hard palate was repaired at 9 months. DHPC has been a subject of much dispute over the last decades. Although main controversy has been focused on its postulated favorable effect on maxillary growth [29,30] versus deleterious influence on speech development [31,32], facial growth following DHPC has also been widely debated. Better facial growth after hard palate repair postponed until *past-puberty* was observed in the *Marburg* sample by Ross [29]. In the Eurocleft study, one of the three best growth and occlusal results was found in the center using DHPC [2]. Favorable dental arch relationship was also found in other cleft centers practicing DHPC—Gothenburg [4] and Vienna [5]. Also, the results of the meta-analysis [33] suggest that dental arch relationship in children, whose hard palate was repaired after the age of 3, was substantially better. However, Noverraz et al. [34] and Friede et al. [35] found no difference in dental arch relationships or growth between groups of patients with different timing of hard palate repair. In a recent systematic review, Liao and Mars [36] concluded that reviewed articles did not provide firm evidence confirming favorable facial growth following DHPC. Liao and Mars implied that heterogeneity of the studies and methodological deficiencies might result in conflicting findings. Nevertheless, uncertainty of the effects of DHPC does not rule out that advantageous growth following DHPC is possible but could not have been detected due to methodological limitations. It is conceivable then that DHPC contributed to more favorable dental arch relationship found in Nijmegen three-stage group in comparison with Warsaw one-stage sample.

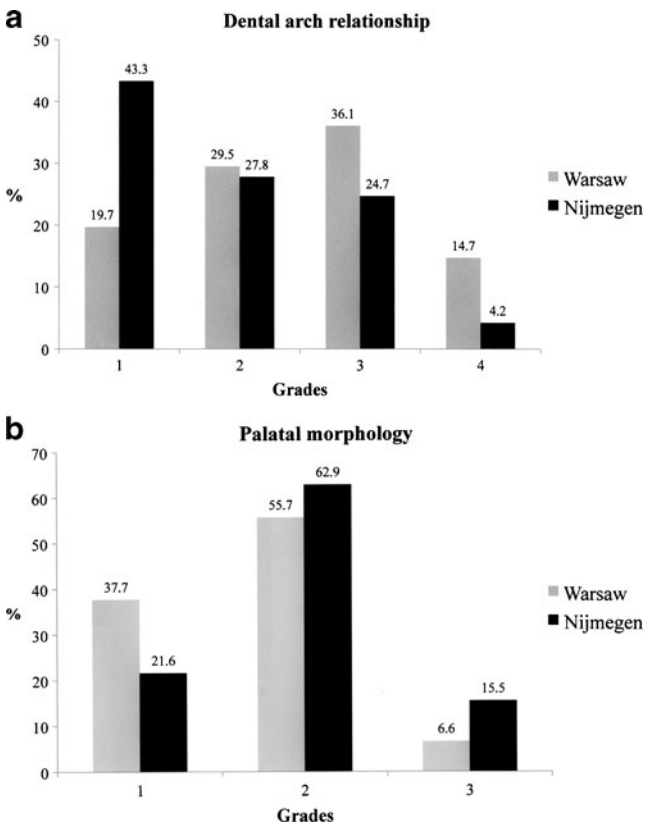


**Fig. 1** Distribution of the EUROCRAN grades in Warsaw and Nijmegen groups (*numbers over the bars* represent percentage of distribution of the grades). **a** Dental arch relationship. **b** Palatal morphology

Mutual spatial position of apical bases and dental arches is the deciding factor during scoring with the EUROCRAN system. Maxillary morphology and position has the greatest influence on the allocation of outcome category since its growth in UCLP is often considerably disturbed. Mandibular morphology and position are usually assumed as less important. This assumption is valid when individuals from the same population are compared. However, when examined samples descend from various populations, ethnic differences in growth patterns may affect the findings. Susami et al. [37] found poorer dental arch relationship in Japanese patients in comparison with Norwegian counterparts. They concluded that a racial difference in craniofacial growth pattern characterized by a high prevalence of mandibular prognathia (class III malocclusion) in northeastern Asian populations might have contributed to worse rating. On the contrary, in populations where mandibular retrognathia (class II malocclusion) is more prevalent, dental arch relationship in subjects with UCLP may be

more favorable. Data from studies of non-cleft [38] and UCLP subjects [39] suggest that craniofacial form in Dutch population demonstrates features conducive to occurrence of skeletal class II malocclusion. Epidemiological evidence confirms a relatively high prevalence of class II malocclusion in The Netherlands [40] and lower in Polish population [41]. Therefore, the genetic make-up of the general population might also have contributed to better dental arch relationship in Nijmegen sample.

The initial cleft size has been suggested to influence the outcome of treatment as in some studies, patients with wider clefts demonstrated poorer craniofacial growth [42,43]. To counterbalance potential inequivalence of the Warsaw and Nijmegen groups regarding initial cleft size, as not all subjects had the dental casts taken pre-surgery and the width of the cleft could not have been measured in all children, consecutively treated patients were included into the samples. This allowed obtaining equivalence of the samples as for size and severity of the cleft [44].

The results of this investigation should be interpreted cautiously since the design of this study—intercenter comparison of treatment outcome—does not allow identification of the elements of treatment protocols responsible for a favorable or unfavorable result. This design is valuable in assessing the outcome of primary surgeries, but it does not permit to establish the key beneficial or harmful features of a specific treatment as a general conclusion [45].

It should also be mentioned that due to problems with speech development, the surgical protocol of treatment of UCLP employed in Nijmegen has been modified. At present, a hard palate closure is performed at the age of 18 months. Therefore, DHPC is no longer practiced.

Based on the results of this study, the following can be concluded:

1. Dental arch relationship following a one-stage surgical protocol was worse than following a three-stage protocol.
2. Palatal morphology in a one-stage protocol was better than following a three-stage protocol; the difference, however, was likely clinically insignificant.

**Conflict of interest** Piotr Fudalej, Christos Katsaros, Catharina Bongaarts, Zofia Dudkiewicz, and Anne Marie Kuijpers-Jagtman do not have any financial interests involved in this study.

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