Effect of Infant Orthopedics on Facial Appearance of Toddlers With Complete Unilateral Cleft Lip and Palate (Dutchcleft)

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Objective: **To evaluate the effect of infant orthopedics (IO) on facial appearance of 54 patients with unilateral cleft lip and palate (UCLP), aged 4 and 6 years.**

Design: **Prospective two-arm randomized controlled clinical trial in three Cleft Palate Centers in the Netherlands (Dutchcleft-trial).**

Interventions: **Patients were divided randomly into two groups. Half of the patients (IO+) had a plate until surgical closure of the soft palate at the age of ± 52 weeks; the other half (IO−) received no intervention.**

Main outcome measures: **Facial appearance at 4 and 6 years of age assessed on full face photographs and photographs showing only nose and mouth. Ratings were performed on a VAS-scale by professionals and laymen.**

Results: **At 4 years of age the full face pictures of IO+ children were scored to be more attractive than those of IO− children. However, this difference had disappeared at 6 years of age. At the age of 6, only professionals saw a significant difference on nasolabial photographs between IO+ and IO−. Regression analysis showed a minor effect of occlusion, lip revision, or type of nose reconstruction on the esthetic results.**

Conclusions: **IO had a positive effect on full facial appearance of UCLP children at the age of 4 years, but at the age of 6, only professionals saw a positive effect of IO on the nasolabial photographs. This is irrelevant for UCLP patients since they deal with laymen in their daily life.**

KEY WORDS: *esthetics, cleft palate, treatment outcome, infant orthopedics, randomized clinical trial, multicenter*

The effect of infant orthopedics (IO) in unilateral cleft lip and palate (UCLP) would seem to be well known by now. The contrary is true, however. The subject has been studied for decades, but the controversy about the effect of IO still exists. Besides other claimed advantages, IO is said to improve facial appearance of children, because lip surgery should be easier, and maxillary growth might be stimulated or adjusted positively (Graf-Pinthus and Bettex, 1974; Hotz and Gnoinski, 1976; Gnoinski 1990; Winters and Hurwitz, 1995). However, this view is not supported by everyone (Ross, 1987; Asher-McDade et al, 1992; Winters and Hurwitz, 1995); probably lip surgery alone will have the same effect. Because of the uncertainty of the effect of IO, a prospective randomized clinical trial was performed in three Cleft Palate Centers in the Netherlands (the Cleft Palate Centers of Nijmegen, Amsterdam, and Rotterdam) to investigate the effect of IO with a passive plate in children with complete unilateral cleft lip and palate

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The research is part of the Dutch intercenter study into the effects of infant orthopedic treatment in complete UCLP (Dutchcleft), carried out in a collaboration between the Cleft Palate Centers of the Radboud University Nijmegen, Academic Center of Dentistry in Amsterdam, and Erasmus MC University Medical Center in Rotterdam (coordinating orthodontists A.M. Kuijpers-Jagtman and B. Prahl-Andersen)

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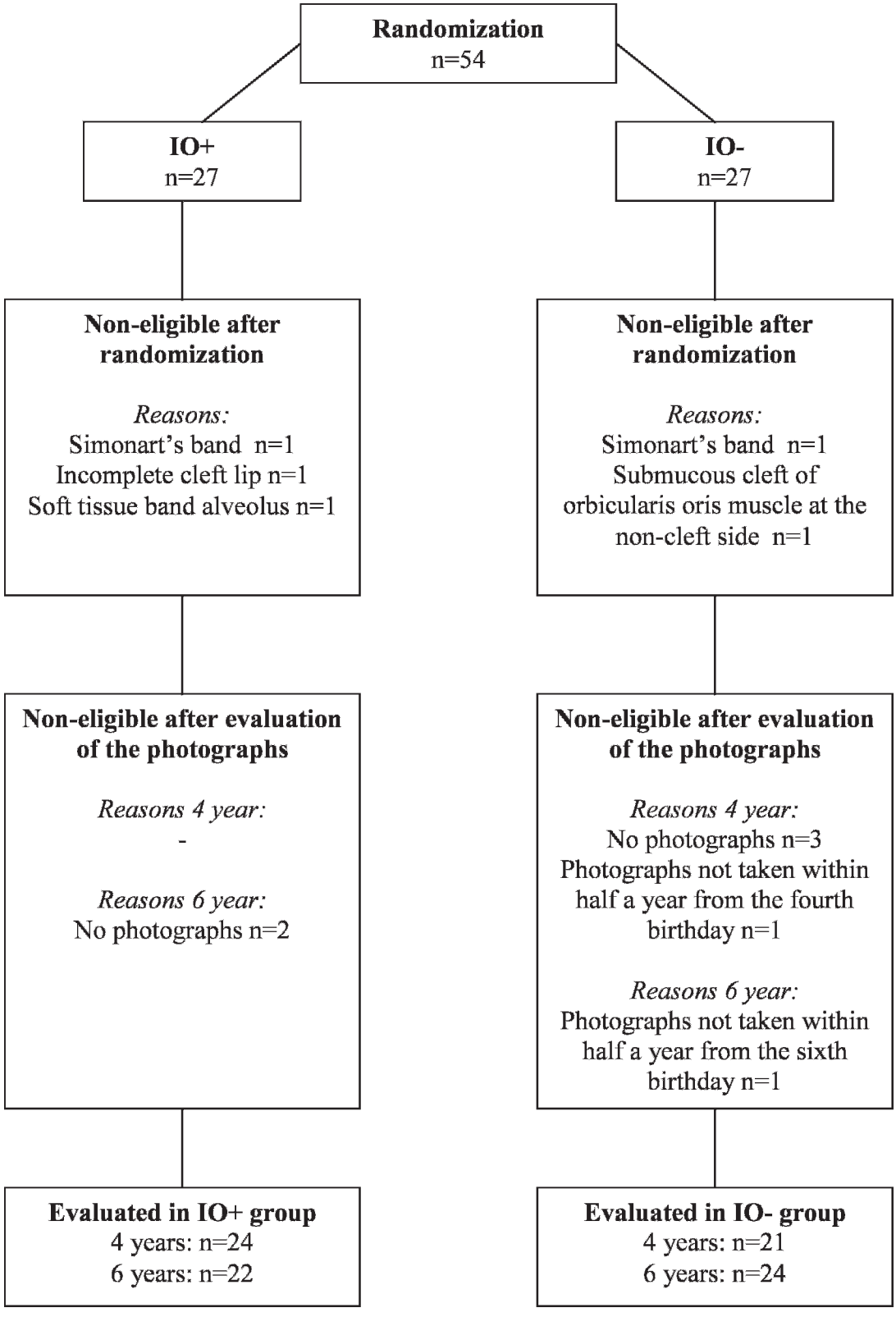

FIGURE 1 Flow diagram of trial children with the reasons for exclusion of evaluation (IO−, no infant orthopedics; IO+, infant orthopedics).

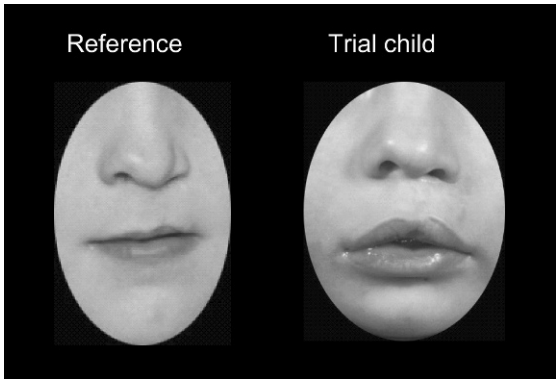

FIGURE 2 Example of presentation slide with the reference picture on the left and a nasolabial area photograph on the right.

(Kuijpers-Jagtman and Prahl-Andersen, 2006). The first results showed that IO had a temporary effect on maxillary arch dimensions, which did not last beyond surgical soft palate closure (Prahl et al., 2001; Bongaarts et al., 2006). Also, IO could not prevent collapse of the maxillary arch (Prahl et al., 2003; Bongaarts et al., 2006). In the occlusion at the age of 4 and 6 years, no differences between patients with infant orthopedics (IO+) and those without (IO−) could be shown (Bongaarts et al., 2004). Feeding and the nutritional status of the infants were not improved by IO (Prahl et al., 2005). Data published in 2004 showed the cost-effectiveness of the speech outcome at the age of 2.5 years: listeners (speech therapists) were asked to rate the speech quality on a 10-point scale of 10 IO+ children and 10 IO− children. The IO+ group had a significant better rating for speech. The resulting cost-effectiveness ratio was 1041 euro for 1.34 points of speech improvement (Konst et al., 2003c, 2004). An evaluation of the speech data at the age of 6 still has yet to be performed. More detailed speech findings have been published elsewhere (Konst et al., 1999, 2000, 2003a, 2003b). Finally, the results of the esthetic scores at age 1.5, showed no effect of IO on facial appearance (Prahl et al., 2006).

The purpose of this paper is to report on the effect of IO on facial appearance in children with UCLP, aged 4 and 6 years. The hypothesis tested was that the facial appearance of the IO+ group would be better than that of the IO− group.

Patients and Methods

This study was designed as a prospective two-arm randomized controlled clinical trial in the Cleft Palate Centers in Nijmegen, Amsterdam, and Rotterdam, in the Netherlands. The local ethical committees approved the study protocol, and informed consent was obtained from all participants. The inclusion criteria were complete UCLP, infants born at term, both parents white and fluent in the Dutch language, and trial entrance within 2 weeks after birth. The exclusion criteria were soft tissue bands and other congenital malformations. Figure 1 shows the sample till the age of 6 with the reasons for exclusion of evaluation. Between 3 and 6 months of age, all included children were assessed by the geneticist of their own cleft lip and palate team as being nonsyndromic.

TABLE 1 Sample characteristics. Some variables are presented in percentiles because of skewness (P10, P50, and P90)*

	IO+ (n = 27)			*IO− (n = 27)*		
Gender: male/female (n)	20/7			21/6		
Side of cleft: left/right (n)	17/10			18/9		
Patients per treatment center† 1/2/3 (n)	7/11/9			7/10/10		
Age 4-year photographs (years)	mean: 4.0 range: 3.8–4.3			mean: 4.0 range: 3.8–4.5		
Age 6-year photographs (years)	mean: 6.0 range: 5.9–6.3			mean: 6.0 range: 5.9–6.4		
	P10	P50	P90	P10	P50	P90
Age at trial entrance (days)	0	3	7	1	6	13
Birth weight (g)	2660	3350	4020	2920	3600	4280
Cleft width at birth (mm)	9.5	12.5	14.4	8.6	12.4	16.4
Age lip repair (days)	117	127	142	117	125	138
Age soft palate closure (days)	355	375	438	301	367	389

* P10, P50, P90 = 10th, 50th, and 90th percentile, respectively.
† Treatment center: 1 = Nijmegen; 2 = Amsterdam; 3 = Rotterdam.

In a previous publication, a detailed description was given with respect to the experimental design, treatment assignment, treatment protocol, and operators (Prahl et al., 2001). A summary of the most important issues is given below.

Treatment

Half of the patients were treated with infant orthopedics by means of passive plates until surgical soft palate closure (n = 27), while half did not receive a plate (n = 27). The plates were made on a plaster cast using compound soft and hard acrylic. The IO+ children had their plates adjusted every 3 weeks to guide the maxillary segments, by grinding at the cleft margins. Maxillary growth and emergence of deciduous teeth indicated the necessity for a new plate. After surgical lip closure, the plate was replaced the same day. Checkups were planned every 4 to 6 weeks following lip surgery. The plate was maintained until soft palate closure. The IO− group visited the clinic at 6 weeks, and before and after lip surgery and soft palate closure. In both groups, lip surgery was performed at the age of 18 weeks by the Millard technique. At lip surgery, the cleft teams of Amsterdam and Nijmegen used the McComb technique for the nose, while the Rotterdam cleft team preferred their own method that combined the McComb and Pigott techniques. Soft palate surgery was performed at the age

TABLE 2 Reliability of professionals and laymen for full faces and nasolabial photographs (Cronbach's alpha)

	Full Face Photographs	*Nasolabial Photographs*	*All Photographs*
All observers	0.94	0.96	0.96
Professionals	0.91	0.94	0.95
Laymen	0.87	0.89	0.91

TABLE 3 Pearson's correlation coefficients between ratings of full face and nasolabial photographs, for professionals and laymen

		Full Face and Nasolabial Photographs			*Professionals and Laymen*
Professionals	4 years	0.739	full face	4 years	0.856
	6 years	0.767		6 years	0.859
Laymen	4 years	0.679	nasolabial	4 years	0.896
	6 years	0.566		6 years	0.921

of about 52 weeks according to a modified Von Langenbeck method including levator muscle repositioning. In the studied age period (until 6 years of age), other interventions were performed if indicated, and included pharyngoplasty (n = 22), lip revision (n = 13; in all cases performed before the age of 4 years), facial mask treatment (n = 1), plate to facilitate speech (n = 15), closure of the anterior palate (n = 6). These interventions were equally distributed over the IO+ and the IO− group.

Data Acquisition

In order to evaluate esthetics, facial photographs were made of all children at the age of 4 and 6. The slides were scanned and saved in two ways: one photograph was saved without changes except for changing all right-sided clefts into left-sided clefts, and one was cropped to a view of the nasolabial area. With these photographs, two PowerPoint (Microsoft, Inc., Redmond, WA) presentations were made of the full face frontal photographs and two of the nasolabial area photographs (Fig. 2). The sequence of the photographs was randomized in every presentation. On every PowerPoint slide in the presentation a photograph of one of the trial children was shown, next to a reference picture. There was one reference picture for the boys and one for the girls.

Twenty-six observers, 16 professionals and 10 laymen, were asked to evaluate the photographs. To be a member of the professional group, the observer had to be a doctor in attendance in a cleft palate team (e.g., otorhinolaryngologist, surgeon, orthodontist); the laymen were the remaining observers. Each slide was shown for 15 seconds. Facial esthetics was scored using a magnitude estimation method (Peerlings et al., 1995; Prahl et al., 2006). The reference picture (average cleft lip and palate appearance) was given a value expressed as a line of defined length ((visual analogue scale) VAS). The observers were asked to compare the experimental picture with the reference picture and to rate the attractiveness of the face in relation to the line length of the reference picture. A shorter line meant less attractive than the reference picture, while a longer line meant more attractive. No limits were given. Secondly, the observers had to express their judgment in a number. The reference photograph was given 100. To calculate reliability, two presentations were scored with the VAS method and two with number scorings. Since most authors of articles concerning esthetics use a VAS-scoring method, these scores were used for further evaluation.

The dental arch relationship was assessed in an earlier study on dental casts using the 5-year-olds' index (Bongaarts et al., 2004).

Statistical Analysis

Reliabilities over the four series of scores were calculated for all observers as Cronbach's alpha. A differentiation was made between professionals and laymen and between full face and nasolabial photographs. By deleting one observer at a time and using the Cronbach's alpha calculation again, the validity of the scores of each observer was checked.

Mean VAS scores and standard deviations were computed for professionals and laymen, for full face photographs and nasolabial photographs. Since all observers had their own scoring range, the scores were normalized. The higher the score the more attractive the photograph was scored. Pearson correlation was calculated between the full face photographs and the nasolabial photographs at the age of 4 and 6 years and between professionals and laymen at 4 and 6 years of age.

Finally, the effect of IO was tested for the full face photographs, and the nasolabial photographs for professionals and laymen, at 4 and 6 years of age with two-tailed *t* tests.

TABLE 4 Number (n), means, and SDs of the esthetic scores for full face photographs, nasolabial photographs for IO+ and IO− at the age 4 and 6 years. Differences between IO+ and IO− were tested with *t* tests†

			4 years				*6 years*			
Variable			*n*	*mean*	*SD*	*p*	*n*	*mean*	*SD*	*p*
Full face	Professional	IO−	21	94.18	12.01	.006**	24	95.21	11.04	.08
		IO+	24	105.27	13.94		22	100.63	9.47	
	Laymen	IO−	21	89.75	11.65	.02*	24	96.19	9.86	.15
		IO+	24	99.10	14.22		22	100.71	11.19	
Nasolabial	Professional	IO−	21	93.06	13.50	.47	24	96.85	11.78	.04*
		IO+	24	95.98	13.09		22	105.41	14.57	
	Laymen	IO−	21	91.20	12.50	.27	24	96.13	13.35	.10
		IO+	24	95.16	10.98		22	103.05	14.25	

† n may vary because of incidental missing values.
* $.05 \geq p > .01$.
** $.01 \geq p > .001$.

Also, regression analysis was done to test the influence of IO, occlusion at 4 or 6 years of age, lip revision, or the type of nose reconstruction done at initial lip closure on the esthetic result.

Results

General

At intake, 54 patients participated in the study. An overview of the sample characteristics is given in Table 1. Two IO+ children hardly used the plate; in one case the plate was mistakenly worn until 78 weeks. These children remained in the IO+ group according to the intention to treat principle. The mean duration of IO was 50 weeks (SD = 16 weeks). The flow diagram in Figure 1 shows the reasons for nonevaluation.

Reliability of Measurements

Table 2 shows the reliability of professionals and laymen for full faces and for nasolabial photographs. When deleting one observer at a time, the reliability values did not change significantly, meaning that all observers were reliable.

Treatment Effect

Table 3 shows the correlation coefficients between full face and nasolabial photographs and between professionals and laymen. A moderate correlation between full face and nasolabial photographs was found. Table 3 also shows that the correlation between professionals and laymen was high.

In Table 4, the effect of IO is shown for full face photographs and nasolabial photographs. A comparison was made between the esthetic scores at different ages (4 and 6 years) for professionals and laymen. Children in the IO+ group were found to have a significantly more attractive appearance than children in the IO− group at the age of 4, looking at full face photographs. For the nasolabial photographs, no significant differences were found. At 6 years of age, the only significant difference was found for the nasolabial photographs scored by professionals. In Figure 3, two examples are shown of esthetic scores (score 96 and 104).

In Table 5, the results of the regression analysis are shown. Besides the effect of IO shown in Table 4, only the 5-year-olds' index influences the esthetic result at 6 years of age in full face photographs, but only to a minimal extent, since the total adjusted R square was 7% or lower.

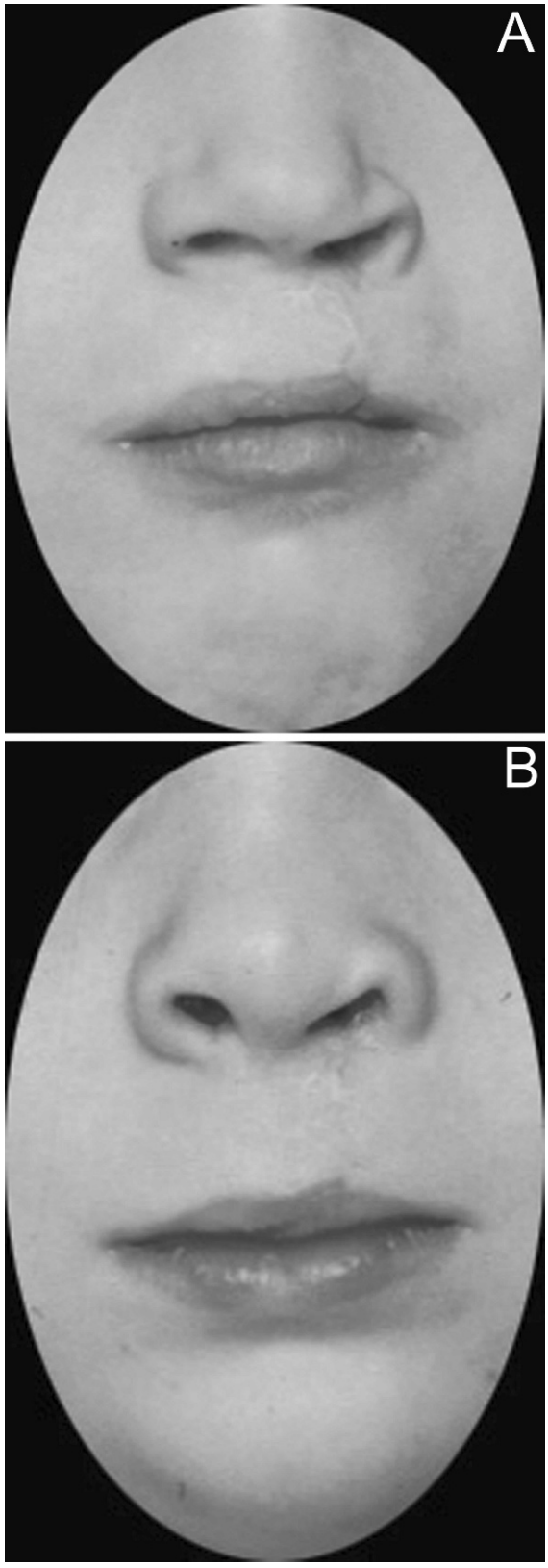

FIGURE 3 Example of a nasolabial picture with esthetic score 96 and 104.

DISCUSSION

The aim of this part of the Dutchcleft study was to evaluate the effect of IO on facial appearance at a young age. The method chosen to test this was comparable to the

TABLE 5 ***p*** **values from regression analysis to test whether IO, occlusion at 4 or 6 years of age, lip revision, or the type of nose reconstruction at initial lip closure influences esthetic result. Adjusted R^2 is given to show how much of the esthetic result can be explained by each of these items**

	Full Face				*Nasolabial*			
	4 years		*6 years*		*4 years*		*6 years*	
	Laymen	*Professional*	*Laymen*	*Professional*	*Laymen*	*Professional*	*Laymen*	*Professional*
IO	.03*	.01*	.24	.15	.39	.53	.11	.04*
5-year-olds' index	.69	.88	.03*	.06	.43	.21	.72	.15
Lip revision	.71	.30	.96	.58	.56	.79	.11	.08
Nose correction	.79	.84	.40	.24	.55	.47	.06	.07
Adjusted R^2	.03	.10	.07	.06	−.06	−.43	.10	.15

* $p < .05$.

methods used by Prahl et al. (2006) and Peerlings et al. (1995). Several methods to score photographs can be found in the literature. Here, VAS scorings were chosen. Peerlings et al. (1995) demonstrated that both line and number scorings show reliable results. Scales like the one made by Tobiasen et al. (1991) or Asher-McDade et al. (1991) were not used because they were employed on children of other ages than in the present study. However, cropped photographs of the nasolabial part of the face were used, as was done by Asher-McDade et al. (1991), to blind for other facial factors. Characteristics of a face, and variation in facial expression were found to blur the judgment of full faces in a positive way (Tobiasen, 1989; Asher-McDade et al., 1991). This effect was also found by Prahl et al. (2006) for the children in the present study at the age of 1.5 years. The same was found in the present study. The nasolabial photographs do not have this problem and can be interpreted with less caution.

Because some studies (Tedesco et al., 1983; Howells and Shaw, 1985; Eliason et al., 1991) found differences between the opinion of laymen and the appreciation of the facial appearance of professional observers, it was decided to ask observers with different backgrounds. Furthermore, Tobiasen (1987) and Okkerse et al. (2001) found a difference between the ratings for boys and girls in appreciation of facial appearance. Therefore, the boys and girls had their own reference pictures.

Although it has been claimed that IO benefits the esthetic outcome of cleft surgery, this has never been tested. Therefore, the results from the present randomized clinical trial cannot be compared to other studies. Reviewing the changes in facial esthetics in Dutchcleft during the first 6 years of life and the differences between IO+ and IO−, it can be noticed that IO had no direct major influence on facial esthetics as measured as early as 18 months of age (Prahl et al., 2006). When growing up, some significant differences between the groups were found, but these showed no consistent pattern over the different age periods. At 4 years of age, full face pictures of children who were treated with infant orthopedics during the first year of life were scored to be more attractive than full face pictures of children without infant orthopedics. However, this difference had disappeared at 6 years of age. The nasolabial photographs showed significance only at 6 years of age for professionals: IO+ was better than IO−. As a child functions in his own social context, mainly consisting of laymen, this result can be considered to be unimportant.

Regression analysis was done to test whether the small difference found between IO+ and IO− could be partly caused by the jaw relationship as expressed by the 5-year-olds' index at 4 or 6 years of age, lip revision, or the type of nose reconstruction at initial lip closure. None of these items could explain the differences between in IO+ and IO−. As is shown in Table 5, only the 5-year-olds' index at the age of 6 had a minor influence on the esthetic scores for full face photographs. A low *p* value was found for lip revision and nose correction at the 6-year evaluation of the nasolabial photographs. This can explain, at most, 15% of the significant differences found between the IO groups. In the literature, no articles were found regarding these relationships.

Conclusion

IO had a positive effect on full facial appearance of children with UCLP at the age of 4 years, but at the age of 6, only professionals saw a positive effect of IO on the nasolabial photographs. This difference is irrelevant for patients with UCLP, since they deal with laymen in their daily life.

Considering all results of Dutchcleft studies to date, there is no indication for the use of IO for patients with UCLP. Those who are promoting different methods of IO, including nasoalveolar molding, should consider the long-term benefits of their interventions using the same rigorous methodology as applied in Dutchcleft.

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