A Randomized Control Trial Investigating the Effect of Presurgical Orthopedics on Feeding in Infants With Cleft Lip and/or Palate

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Objective: **To investigate the controversial assertion that presurgical orthopedics (PSO) facilitate feeding in infants with cleft lip and palate.**

Design: **Randomized control trial of 34 infants with nonsyndromic complete unilateral cleft lip and palate and 16 with cleft of the soft and at least two thirds of the hard palate. Allocation to receive presurgical orthopedics or not used minimization for parity and gender. Other aspects of care were standardized.**

Setting: **The North Thames Regional Cleft Centre.**

Main Outcome Measures: **Measurements were made at 3 months of age (presurgery) and at 12 months of age (postsurgery). Primary outcomes were anthropometry and oral motor skills. Objective measures of sucking also were collected at 3 months using the Great Ormond Street Measure of Infant Feeding. Twenty-one infants also had videofluoroscopic assessment.**

Results: **At 1 year, all infants had normal oral motor skills and no clear pattern of anthropometric differences emerged. For both cleft groups, infants randomized to presurgical orthopedics were, on average, shorter. The presurgical orthopedics infants were, on average, lighter in the unilateral cleft and lip palate group, but heavier in the isolated cleft palate group. Infants with complete unilateral cleft and lip palate randomized to presurgical orthopedics had lower average body mass index (mean difference PSO-No PSO: −0.45 (95% confidence interval [−1.78, 0.88]), this trend was reversed among infants with isolated cleft palates (mean difference PSO-No PSO: 1.98 [−0.95, 4.91]). None of the differences were statistically significant at either age.**

Conclusions: **Presurgical orthopedics did not improve feeding efficiency or general body growth within the first year in either group of infants.**

KEY WORDS: *cleft lip and/or palate, feeding, infants, presurgical orthopedics*

Given the known feeding difficulties in the cleft lip and palate population, management of feeding is a high priority. Numerous techniques are advocated as means of providing symptomatic relief for these infants, but few are evidence-based (Reid, 2004). The use of presurgical orthopedics (PSO) is one such technique. Many claims have been made about the benefits of PSO without data to support them. A number of groups report improved feeding efficiency for both bottle and breast feeding with the use of PSO (Lifton, 1956; Williams et al., 1968; Balluff and Udin, 1986; Goldberg et al., 1988). Claims are made that PSO eliminates low and frustrated feeding (Jones et al., 1982; Balluff and Udin, 1986; Osuji, 1995; Turner et al., 2001), reduces choking episodes (Jones et al., 1982), improves growth (Goldberg et al., 1988), and improves parents' psychosocial well-being (Razek, 1980; Jones et al., 1982). Others dispute this, reporting that the use of PSO does not improve feeding (Berkowitz, 1978; Choi et al., 1991; Prahl et al., 2005) or that there is insufficient evidence to support this (Paradise and McWilliams, 1974).

Several hypotheses have been proposed as to how PSO improves feeding. It has been suggested that PSO provides a rigid opposing surface, allowing compression of the teat or nipple (Osuji, 1995), and reduces potentially painful ulceration of the nasal septum by teats (Huddart and Ziberman, 1977). In ad-

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dition, it has been claimed that PSO corrects abnormal tongue positioning used by infants with cleft lip and/or palate and improves the airway (Huddart and Ziberman, 1977; Osuji, 1995), restores the infant's ability to generate intraoral pressures required for sucking (Schwenzer and Grimm, 1981; Hotz, 1983; Komposch, 1986; Kogo et al., 1997; Trankmann, 2000), minimizes food residue in the cleft (Osuji, 1995), and reduces nasal regurgitation (Huddart and Ziberman, 1977; Jones et al., 1982). It has been hypothesized that it prevents the tongue from exploring and widening the cleft (Razek, 1980; Osuji, 1995). Razek (1980) suggested that parents are reassured because some course of active treatment is being undertaken. The majority of these claims have been made with no scientific basis.

Infant feeding difficulties increase the burden of care for families (Adams et al., 1999). Feeding is a highly emotive area. Mothers of infants with feeding difficulties often experience feelings of inadequacy when unable to feed their infants as they had planned. Constant concern about the amount of feed the infant takes and subsequent growth problems place stress on the family unit. In addition, special feeding equipment and techniques often are needed. Relatives and friends who may be available to offer support to mothers of healthy infants can be reluctant and anxious about helping to feed infants with cleft lip and/or palate. Frequent medical and hospital appointments may be costly and time consuming and may foster a dependency on professionals. PSO can add to an already significant burden of care by increasing the number of hospital appointments and adding maintenance of yet another piece of equipment at a time when parents often are struggling to come to terms with having a baby with a cleft (Solnit and Stark, 1962). This would be unwarranted unless there was evidence that the benefits of the treatment outweigh the increased burden (World Health Organization Expert Committee, 2002). At present, the use of PSO is based on personal preference and varies from team to team. This randomized control trial was undertaken, therefore, to address this issue by objectively assessing the effect of PSO on infant feeding.

The aims of the trial were twofold. The first was to evaluate whether PSO had an effect on feeding in infants with unrepaired nonsyndromic complete unilateral cleft lip and palate (UCLP) or isolated cleft palate (ICP) when assessed at 3 months of age. The research questions posed were whether there were significant differences in the oral motor skills, physiological measures of feeding, and general body growth (weight, length, head circumference, and body mass index [BMI]) of infants with ICP or UCLP managed with or without PSO prior to palate repair. The second aim was to evaluate whether PSO had an effect on feeding in infants with repaired UCLP or ICP assessed at 12 months of age, following palate repair at 6 months of age. At this stage, the investigation aimed to determine whether there were significant differences in the oral motor skills and general body growth (weight, length, head circumference, and BMI) of infants with ICP or UCLP.

METHODOLOGY

Context of the Trial

The trial was carried out by the North Thames Regional Cleft Centre (NTRCC). The twin-site NTRCC consists of St. Andrews Centre for Plastic Surgery, Mid Essex NHS Trust (St. Andrews) and Great Ormond Street Hospital for Children NHS Trust (GOSH). Historically, each center had different practices with regard to the use of PSO; St. Andrews used PSO routinely, whereas GOSH rarely did. All other aspects of care were standardized across the two sites, with one surgeon performing all primary surgery at both sites for several years. Both sites were amenable to changes in protocol to allow randomization of infants to PSO or no PSO groups, rather than to continue following their center's historical standard protocol. There was, therefore, an ideal opportunity for a trial investigating the effects of PSO. The two centers implemented a randomized control trial designed to investigate the effects of PSO on facial growth, dental arch relationships, facial appearance, surgical outcomes, speech development, and feeding. This paper reports the results of the first part of the trial, the effect of PSO on feeding. This study was approved by the Medical Ethics Committee at the Institute of Child Health, University of London.

Patient Selection

Infants referred to the NTRCC who were diagnosed with UCLP or with ICP where the soft palate and at least two thirds of the hard palate was involved were eligible for inclusion in the trial. Infants with these cleft types, but who required cardiac surgery and/or were diagnosed at birth with neurological impairment and/or a syndrome known to adversely affect feeding and/or growth, were excluded.

Allocation to Groups

Once infants were identified as eligible for inclusion, parents or caregivers were provided with verbal and written information about the trial. In cases where the cleft was diagnosed prenatally, parents were informed about the trial at this stage, but were not formally recruited until after the infant was born and the cleft and medical diagnoses confirmed. A written information sheet was provided. Parents or caregivers had 5 days in which to consider participating in the trial. Separate randomization lists were used for the UCLP and ICP groups. Feeding may be affected by parity and sex (Thomas et al., 1970; Thomas et al., 1971). Minimization was therefore used to ensure that the two groups contained similar numbers of first-born, later born, and male and female infants. Data for patient allocation were entered by the researcher using MINIM (Evans et al., 1990; Treasure and MacRae, 1998).

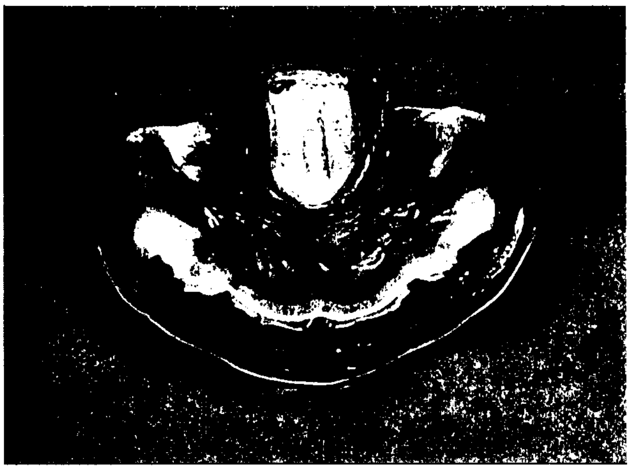

FIGURE 1 **Passive PSO used with infants with ICP.**

Standardized Care

All aspects of care of infants recruited to the trial, including early counseling, feeding management advice, attendance at clinics, and surgery, were carried out according to the NTRCC clinical protocol. Initially, this consisted of counseling in the maternity unit, within 48 hours of the infant's birth, by one of the clinical nurse specialists and/or surgeons. Counseling included discussing the plan of management and surgery involved, as well as showing photographs of other infants pre- and postsurgery and throughout childhood, with supporting literature. The clinical nurse specialist provided general advice about the nature of feeding problems in infants with cleft lip and/or palate. It is standard practice for the NTRCC to recommend the use of adaptive bottles (Mead Johnson and/or Soft Plas; Evansville, IN) in conjunction with vented NUK orthodontic teats (Gerber Products, Fremont, MI). Other strategies to facilitate feeding, such as positioning and frequent burping, were discussed and were demonstrated. When a mother was keen to try breastfeeding, advice was provided with particular reference to ensuring the infant was thriving.

All infants were seen for an initial intraoral impression within 2 weeks of birth, either as an inpatient in the maternity unit or as an outpatient by one of the four named orthodontists involved in the trial. All infants with UCLP had intraoral impressions taken in the week prior to lip repair and again just prior to palate repair. Infants with ICP had impressions taken prior to palate repair at 6 months of age. The impression procedure involved placing a custom-made, light-cured acrylic impression tray filled with Optosil (Heraeus, Hanau, Germany) into the infant's mouth. The loaded impression tray was squeezed gently into place, allowing the impression material to flow into the affected cleft area. This was held in place until the Optosil set, usually within about 45 seconds. The impression then was removed from the infant's mouth, was disinfected, and was sent to the dental laboratory where a dental cast was poured. These casts were used for fabricating the PSO plate (Figs. 1 and 2). If the infant was randomized to the PSO group, the fitting of the plate took place before 2 weeks of age. The plate was adjusted as necessary at the routine appointments. Infants in the UCLP group were fitted with a new plate during their admission for lip repair around 3 months of age. Infants in the ICP group were fitted with a new plate if and when the orthodontist considered it necessary.

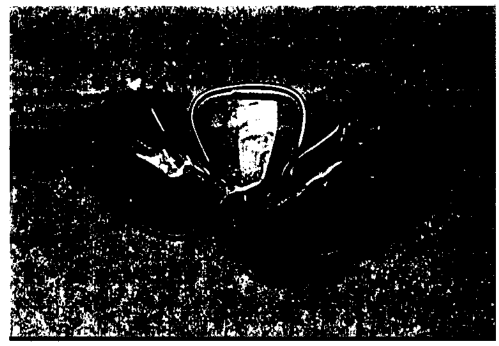

FIGURE 2 **Active PSO used with infants with UCLP.**

For all infants recruited to the trial, the senior consultant plastic surgeon carried out surgery using a standardized technique. For UCLP patients, lip repair and repair of the anterior palate using vomerine flaps was performed as closely as possible to 12 weeks of age. For both the UCLP and ICP groups, palate repair was performed as close as possible to 6 months and was standardized with a no-flap repair where possible. If necessary, von Langenbeck flaps were used. Radical velar muscle dissection (intravelar veloplasty) was undertaken in the repair of the soft palate (Sommerlad, 2000).

All infants attended the cleft lip and palate clinic for a standardized number of appointments in the first year of life. These appointments were modified slightly according to the nature of the cleft (i.e., whether ICP or UCLP).

Regardless of the group to which they were randomized, UCLP infants were seen by one of the named orthodontists five or six times within the first 3 months and a further three times before palate repair. All infants with ICP were seen four times within the first 6 months. The review appointments involved systematic documentation as to how the parents were managing the appliance, whether parents were concerned about any aspect of the appliance, and how feeding was progressing. In addition, the infant's mouth was examined for any signs of rubbing, ulceration, infection, or neonatal teeth eruption, which might alter fitting of the appliance.

Outcome Measures

Because the trial was primarily concerned with any differences in oral motor skills and anthropometry at 3 months of age (prior to any surgical intervention) and 12 months of age (approximately 6 months postcompletion of palate repair), the outcome measures were as follows:

Prepalate Repair Assessed at 3 Months of Age

- Oral motor skills during feeding (measured with the Neonatal Oral Motor Assessment Scale [NOMAS]) (Meyer Palmer et al., 1993)

- Physiological measures of bottle feeding/sucking (using the Great Ormond Street Measurement of Infant Feeding [GOSMIF]) (Masarei et al., 2001; Masarei, 2003)
- Assessment of the pharyngeal stage of swallowing (using videofluoroscopic assessment of feeding in 21 consecutive cases) (Logemann, 1993; Arvedson and Brodsky, 2002)
- Anthropometry (weight, length, head circumference, and BMI) (World Health Organization, 1986; Gibson, 1990; World Health Organization Expert Committee, 1995; Wright et al., 2002)

Postpalate Repair Assessed at 12 Months of Age

- Oral motor skills during feeding (measured with the Schedule of Oral Motor Assessment [SOMA]) (Reilly, 2002)
- Anthropometry (weight, length, head circumference, and BMI) (World Health Organization, 1986; Gibson, 1990; World Health Organization Expert Committee, 1995; Wright et al., 2002)

Assessment Tools

Anthropometry

Anthropometric data (weight, length, and head circumference) are widely used to monitor growth and to provide information about nutritional status in infants and children (World Health Organization, 1986; Gibson, 1990). The data were collected by the researcher, using standardized techniques and following training by a pediatrician. Seca Baby Scales (Seca Precision for Health, Hamburg, Germany) were used to collect weight measurements, with the infants unclothed, lying, or sitting.

Recumbent length measurements were taken using the technique described by Gibson (1990). The infant was placed on a mat, face upward, with his/her head toward a fixed headboard. The infant's head was held gently by a parent so that contact was made with the headboard. The researcher, while holding the infant's feet (with toes pointing upward), keeping the knees straight and ensuring the infant's shoulder blades were in contact with the mat, brought a movable footboard to rest against the infant's heels. The distance between the head- and footboards was measured to the nearest millimeter. Head circumference was measured using a tape measure as described by Gibson and Lohman (1990). The infant was held in a sitting position by a parent or caregiver, with the infant looking straight ahead and the head in a horizontal position. The researcher placed the tape measure just above the supraorbital ridges, covering the most prominent part of the frontal bulge and over the part of the occiput, which gave the maximum circumference. Measurements were made to the nearest millimeter.

Physiological Measures of Feeding

The physiological measures of bottle-feeding were obtained using GOSMIF (Masarei et al., 2001; Masarei, 2003). This specially designed piece of equipment allowed the measurement of the length of sucking bursts, the rate of sucking, the length of individual sucks or peak-to-peak intervals, suck swallow ratios (the number of sucks generated prior to triggering of a swallow), and the percentage of positive pressure generation. In order to ensure that sucking patterns were not affected by the composition of milk (Crook and Lipsitt, 1976; Burke, 1977; Woolridge et al., 1980) all infants were given 5% glucose solution, rather than their familiar expressed breast milk or formula. Infants were fed by their mothers for 5 minutes and this was video-recorded simultaneously.

Oral Motor Assessment

Oral motor skills at 3 months of age were measured using the NOMAS developed by Braun and Meyer Palmer (Braun and Meyer Palmer, 1990; Meyer Palmer et al., 1993). The researcher video-recorded the infant being fed by his/her mother during the GOSMIF assessment.

Oral motor skills at 12 months of age were assessed using the SOMA developed by Reilly et al. (1995) and Skuse et al. (1995). Infants were given a variety of developmentally appropriate food textures by a parent or caregiver, in the manner described in the manual. Up to six textures were assessed, including liquid from a bottle and/or training beaker, puree, semisolid, cracker, and biscuit. Any textures the infants had not been offered previously were omitted. This feeding session was video-recorded and later rated by a dysphagia-trained speech and language therapist not involved in the trial and experienced in the use of the SOMA.

Videofluoroscopic Assessment of Feeding

Videofluoroscopic assessment of feeding was carried out on 21 consecutive infants of either cleft type whether with PSO or No PSO, from both the control and intervention groups. The infants were positioned in a Tumbleform seat (Sammons Preston Rolyan, Cedarburg, WI), in an upright position as similar to their usual feeding position as possible. They were fed liquid barium by a parent or caregiver, from their routine feeding bottle and teat. Ten consecutive swallows were recorded and were analyzed using a specifically designed rating scale adapted from Arvedson and Brodsky (2002).

These studies were rated independently by the researcher and a second speech and language therapist experienced in the videofluoroscopic assessment of pediatric dysphagia.

Assessment Schedule

All infants underwent feeding assessments at 3 months of age and 12 months of age.

Blinding

The oral motor assessments (NOMAS and SOMA) were administered according to the prescribed protocols. In order to ensure there was no bias in the rating of these assessments, they were video-recorded and subsequently were rated by specialist dysphagia-trained speech and language therapists who were not involved in the trial. They were therefore blind as to whether infants had been randomized to the No PSO or PSO group. Anthropometric data were collected by the researcher.

Statistical Analysis

All growth measurements were converted to *z* scores using the SDSGAIN macro (Freeman et al., 1995; Cole et al., 1995, 1998; Child Growth Foundation, 1999; Wright et al., 2002). Comparisons were made between PSO and No PSO groups for UCLP and ICP separately. The *t* test was used for comparison of continuous numeric outcomes where normality could be assumed. Categorical outcomes were compared using exact tests with StatXact version 4.0.1 (Cytel, Inc., Cambridge, MA). All results are presented with 95% confidence intervals (CI) for the differences. Where multiple sucking bursts were measured (i.e., GOSMIF), the median of all available measures for that child on that outcome was used in the analysis.

Sample Size

A shift of 0.8 SD in any of the anthropometry *z* scores was felt to be clinically important and this could be detected with 80% power (5% significance) using two groups of 25 infants. It was therefore planned to allocate 50 infants with ICP and 50 infants with UCLP to either No PSO or PSO.

Results

In total, 60 infants met the inclusion criteria. The majority of these infants were recruited. There were eight infants whose parents did not consent to participate. In addition, there were two infants whom the consultant plastic surgeon considered inappropriate for recruitment due to social problems. In total, 50 infants with cleft lip and/or palate were recruited, 34 with complete UCLP and 16 with ICP. One infant with UCLP was withdrawn from the trial as a result of the development of complex medical problems before intervention had begun. It was initially planned to complete recruitment 12 months prior to the end of the trial, allowing follow-up of infants at 12 months of age. However, recruitment difficulties led to an extension of the recruitment period, resulting in some infants not being followed to 12 months at the time of analysis. As a result, 49 infants had reached 3 months of age during the data collection period. One of these infants was not assessed, because the mother failed to attend the assessment appointment. Thirty-four infants reached 12 months of age during the data collection period. All of these infants underwent the 12-month assessment.

Baseline Data

Approximately two thirds of the recruited infants were boys (UCLP, 21 [63%] and ICP, 9 [62%]). Minimization was used to allocate infants to the No PSO and PSO groups and as a result, the groups were balanced for sex and birth order. Sixteen infants with UCLP were allocated to the No PSO group and 17 to the PSO group. The ICP groups were equal, with eight allocated to the PSO group and eight to the No PSO group. Mean gestational ages for the groups were similar (UCLP: $p = .70$ with CI for the difference in means −0.29 to 0.38 weeks; ICP: $p = .07$ with CI −2.31 to 0.88 weeks). Birth weights were on average slightly higher among the groups allocated to PSO (average 50 g higher for UCLP and 10 g higher for ICP) (UCLP: $p = .77$ with CI −290 to 380 g; ICP: $p = .98$ with CI −570 to 560 g). Representation from ethnic groups was balanced in the ICP groups, but there was a slightly higher proportion of infants of Asian descent (including Indian, Bangladeshi, and "other" Asian) in the UCLP PSO group ($p = .20$). Father's occupational classification (as an indication of social class) was similar in UCLP No PSO and PSO groups. There was, however, a slightly higher but not significant ($p = .36$) proportion of professional occupations in the ICP PSO group as compared with the ICP No PSO group (Table 1).

Orthodontic Input

There was a tendency for infants randomized to the PSO groups to have more orthodontic appointments than those managed without (UCLP PSO mean = 8.88, UCLP No PSO mean = 6.2; $p = .008$, CI 0.73 to 4.63; ICP PSO mean = 7.17, ICP No PSO mean = 5; $p = .1$, CI −0.39 to 4.73). According to the protocol, the PSO and No PSO groups would be expected to have had the same number of orthodontic visits. However, parents of infants managed without PSO did not attend orthodontic review appointments as regularly.

There were few reported problems related to the PSO. In nine infants, orthodontists reported loose fitting plates, which were corrected with slight modifications. In two infants, new plates were made. Orthodontic problems reported included oral thrush (managed in all cases with Daktarin gel, Beerse, Belgium), minor ulceration requiring no intervention, and neonatal teeth interfering with the fitting of the plate and which therefore were removed.

Compliance With PSO

Initially, 23 of the 25 infants allocated to PSO were wearing their PSO all day except for cleaning. In one case, the parents did not want to sleep the infant on his side or front, and expressed anxiety about the plate "dropping" when the infant was sleeping on his back. By 3 months, this family had abandoned using the PSO completely. The parents of the other infant reported that the presence of a neonatal tooth meant that their infant's plate did not fit well and caused him discomfort. By 3 months of age and following removal of the tooth, this infant tolerated his PSO well. One other family had abandoned use of the PSO by 3 months, reporting that there were problems with it fitting securely and the infant not tolerating it.

TABLE 1 Summary of Infants Recruited, Distribution Across Groups: Sex, Referral Site, Gestational Ages, Birth Weights, Birth Order, Ethnicity, and Occupational Classification

		Cleft Type			
		UCLP (n = 33)		ICP (n = 16)	
		No PSO n = 16	PSO n = 17	No PSO n = 8	PSO n = 8
Sex	Male	10	11	4	5
	Female	6	6	4	3
Referral site	GOSH	7	6	4	4
	St. Andrews	9	11	4	4
Gestational age (wk)	Mean	39.61	39.75	40.29	39.21
	SD	1.31	1.38	1.16	1.1
	Minimum	37.2	36	38	38
	Maximum	42	42	42	40.71
Birth weight (kg)	Mean	3.36	3.41	3.47	3.46
	SD	0.39	0.5	0.66	0.37
	Minimum	2.84	2.33	2.43	2.96
	Maximum	4.1	4.03	4.2	3.85
Birth order	Mean	2	1	2	2
	Mode	1	1	1	1
	SD	1	1	1	1
	Minimum	1	1	1	1
	Maximum	5	4	3	3
Ethnic origin	Indian	0	1	2	2
	Bangladeshi	0	2	0	0
	Other Asian	1	1	0	0
	White/U.K.	11	12	6	6
	White/European	3	0	0	0
	Turkish	1	0	0	0
	Black African	0	1	0	0
Fathers' occupational classification	1 (Managers and senior officials)	0	0	0	3
	2 (Professional occupations)	5	3	1	2
	3 (Associate professional and technical occupations)	2	4	1	0
	5 (Skilled trade occupations)	2	3	4	1
	8 (Process, plant and machine operatives	2	0	1	1
	9 (Elementary occupations)	1	2	1	1
	unemployed or student	3	3	0	0

Compliance within the cohort reduced further over time, and only 14 of the 25 infants allocated to PSO wore them for the full 6-month period. Another infant wore the plate for 12 hours a day. The remaining eight infants were not wearing the PSO at all.

Intention to Treat Analysis

The analysis was based on "intention to treat" with PSO at the onset of the trial.

Results Prior to Surgical Intervention (at 3 Months of Age)

Anthropometry

At 3 months of age, infants in the UCLP No PSO group had higher average z scores for weight and height, and lower average z scores for head circumference, than those in the UCLP PSO group. Similarly, infants in the ICP No PSO group had lower average z scores for weight and height, but not head circumference. There were, however, no statistically significant differences in weight, height, or head circumference between the No PSO and PSO groups for UCLP or ICP (Table 2). Although differences were not statistically significant, CIs were wide and the trend suggested that PSO did not lead to an improvement in these measures; it is possible that clinically important differences may not have been detected.

Physiological Methods of Feeding (GOSMIF Measurements)

Three sucking bursts from each infant's GOSMIF assessment were selected for measurement using a predefined set of rules. The raw scores for each of these measures are shown in scatterplots (Figs. 3 through 7). Each sucking burst is represented by a dot. There should be three dots aligned vertically for each infant; occasionally, however, it was not possible to measure the three sucking bursts. Results for nine infants are not included, either because the child was not cooperative for the assessment or due to technical difficulties with recording the data.

TABLE 2 Means, p Values, and Confidence Intervals for Differences Between UCLP (No PSO and PSO) and ICP (No PSO and PSO) for Weight, Height, Head Circumference, and Body Mass Index z Scores at 3-Month Assessment Point

	UCLP					ICP				
	No PSO n = 16 (mean)	PSO n = 16 (mean)	p Values	Average Difference	CI*	No PSO n = 8 (mean)	PSO n = 8 (mean)	p Values	Average Difference	CI
Weight	−0.85	−0.86	.98	−0.01	−0.74 to 0.72	−1.03	−0.98	.92	0.05	−1.13 to 1.24
Height	−0.07	−0.34	.56	−0.27	−1.19 to 0.66	0.13	2.77	.35	2.64	−3.26 to 8.54
Head circumference	−0.26	2.57	.38	2.83	−3.65 to 9.32	−0.40	−0.58	.83	−0.18	−1.91 to 1.55

* All confidence intervals (CI) are for differences in the percentages (PSO - No PSO).

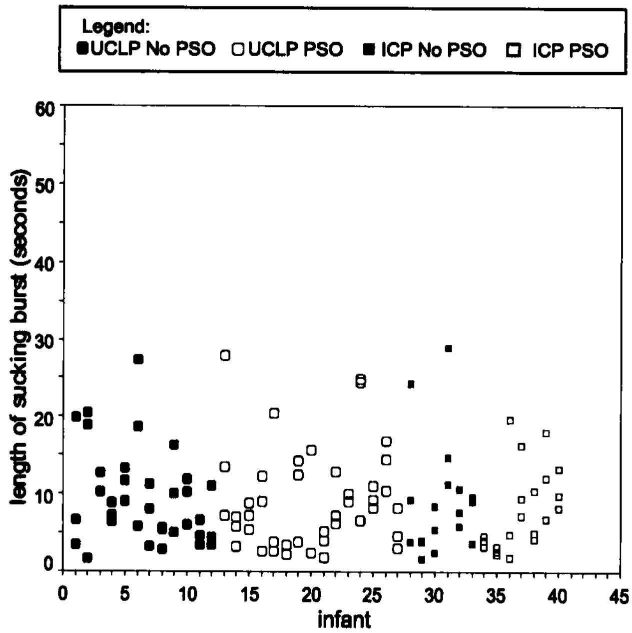

FIGURE 3 Length of first 3 rateable sucking bursts at 3-month assessment.

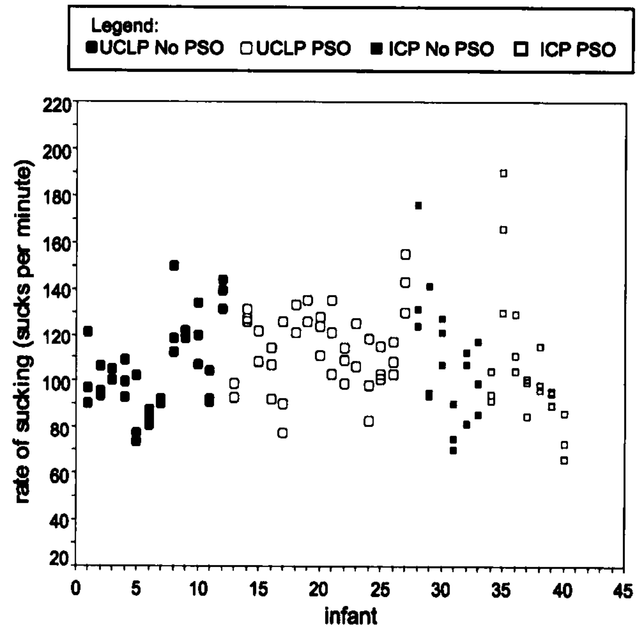

FIGURE 5 Rate of sucking at 3-month assessment.

Length of Sucking Bursts

The majority of sucking bursts were between 2 and 20 seconds in length, however there were several sucking bursts lasting between 20 and 30 seconds. The infants in the ICP groups used slightly longer sucking bursts than did those in the UCLP groups. There is, however, no statistically significant difference between the median length/child for the No PSO and PSO groups, for either UCLP or ICP (UCLP: p = .50, CI −2.67 to 5.26; ICP: p = .32, CI −26.72 to 9.72) (Fig. 3).

Peak-to-Peak Intervals

There was no statistically significant difference in the median peak-to-peak interval (length of individual suck) between the No PSO and PSO groups for either UCLP or ICP (UCLP: p = .501, CI −0.08 to 0.15; ICP: p = .96, CI −0.18 to 0.19) (Fig. 4).

Rate of Sucking

There was a wide range in the rate of sucking. However, again there was no statistically significant difference between

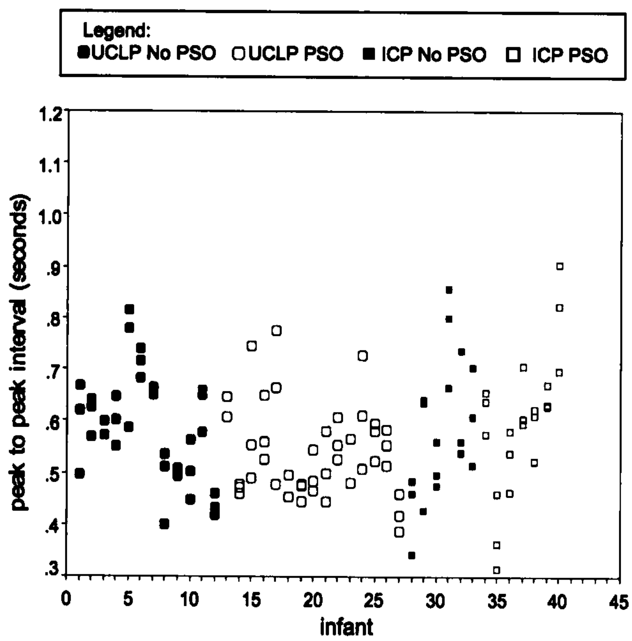

FIGURE 4 Peak-to-peak intervals at 3-month assessment.

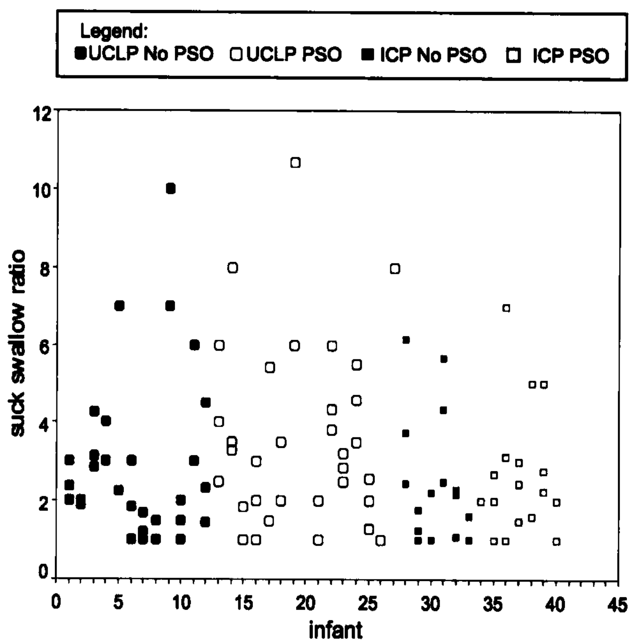

FIGURE 6 Suck-swallow ratios at 3-month assessment.

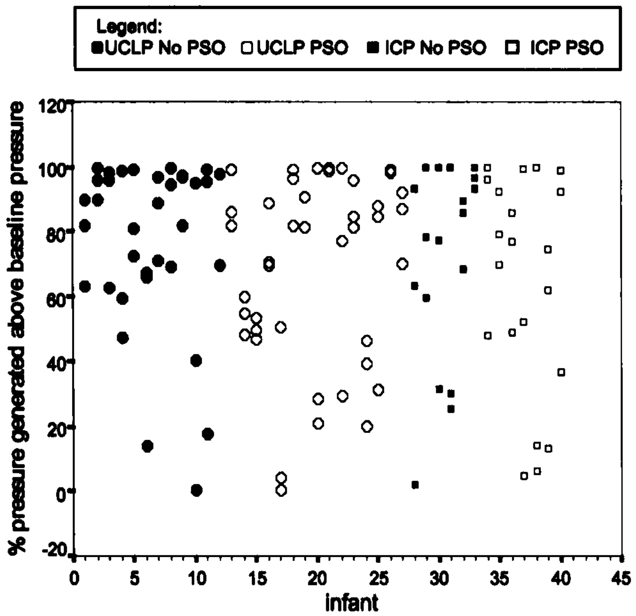

FIGURE 7 Percentage pressures generated above baseline pressure in bottle at 3-month assessment.

the medians for the group dependent on PSO status for either cleft type (UCLP: $p = .54$, CI −24.10 to 13.02; ICP: $p = .84$, CI −26.28 to 31.58) (Fig. 5).

Suck-Swallow Ratios

There was a wide range of suck-swallow ratios. There was, however, no statistically significant difference between the medians for the No PSO and PSO groups for either cleft type (UCLP: $p = .63$, CI −0.83 to 1.35; ICP: $p = .77$, CI −4.19 to 3.18) (Fig. 6).

Percentage Pressure Generation Above Baseline Pressure in the Feeding Bottle

All infants generated a high proportion of positive pressure during bottle feeding, although there was variability. There was no statistically significant difference or consistent patterns in median measures between the No PSO and PSO groups in either the UCLP or ICP group (UCLP: $p = .04$, CI 0.54 to 40.75; ICP: $p = .69$, CI −30.25 to 43.87) (Fig. 7).

Oral Motor Skills

No infants from any group were rated as having normal feeding patterns with the NOMAS at 3 months of age. Twelve infants, however, refused to complete the trial feed. These came from all groups (Table 3). Within the UCLP No PSO group, five infants were rated as having disorganized feeding patterns and seven as having dysfunctional feeding patterns. Similarly, within the UCLP PSO group, six infants were rated as disorganized feeders and seven as dysfunctional. There was no statistically significant difference between the severity of

TABLE 3 NOMAS Ratings at 3-Month Assessment Point

	UCLP		*ICP*	
NOMAS Rating	*No PSO* $n = 16$	*PSO* $n = 17$	*No PSO* $n = 8$	*PSO* $n = 8$
Normal	0	0	0	0
Disorganized	5	6	4	5
Dysfunctional	7	7	1	2
Refused or unrateable	4	4	3	1

ratings between these groups ($p = 1.00$). Infants in the ICP No PSO and PSO groups displayed more disorganized (ICP No PSO n = 4, ICP PSO n = 5) than dysfunctional feeding patterns (ICP No PSO n = 1, ICP PSO n = 2). There was no statistically significant difference in the ratings between the groups ($p = .65$) (Table 3).

Videofluoroscopy Findings

At the oral stage, all infants, regardless of PSO status, demonstrated abnormal tongue configuration during sucking, with uncoordinated stripping of the tongue and reduced compression of the teat. Bolus formation was abnormal in all infants but one, with milk pooling in the lateral sulci and in the floor of the mouth. Milk entered the nasopharynx in 16 of the 21 infants; no infants, however, demonstrated frank nasal regurgitation with milk leaking from the nose.

At the pharyngeal stage, 19 infants triggered the swallow after the bolus had left the valleculae or when the bolus was in the piriform sinuses. Fifteen of the 21 infants demonstrated adequate airway protection with no material entering the larynx. Three infants displayed silent aspiration or material entering the airway, passing below the vocal folds with no reflexive cough or attempt to eject the material (rated as 7 on the Rosenbek scale [Rosenbek et al., 1996]). The aspiration occurred prior to triggering of the swallow. An additional 3 infants displayed reduced airway protection with material entering the airway, contacting the vocal folds and being ejected from the airway (rated as 3 on the Rosenbek scale [Rosenbek et al., 1996]). Pharyngeal residue was evident in about half of the infants (11). All infants cleared this spontaneously with subsequent swallows. There was no significant difference between the No PSO and PSO groups for either cleft type for number of abnormal behaviors rated (Table 4).

Results Following Repair of the Palate (at 12 Months of Age)

Anthropometry

At 12 months of age, infants in the UCLP PSO group had lower average z scores for all the anthropometric measures than those in the UCLP No PSO group had. The reverse was found for weight, head circumference, and BMI (but not height) in infants with ICP. Differences were not statistically significant, however, confidence intervals were wide due to the

TABLE 4 Oral and Pharyngeal Behaviors Rated as Abnormal on Videofluoroscopy

Oral and Pharyngeal Swallow Behaviors/ Events	Number Rated Abnormal					
	UCLP (n = 13)			ICP (n = 8)		
	No PSO (n = 5)	PSO (n = 8)	p value CI*	No PSO (n = 4)	PSO (n = 4)	p value CI
Lip closure	0	0	1 −66 to 49	0	0	1 −69 to 69
Tongue configuration during sucking	5	8	1 −49 to 66	4	4	1 −69 to 69
Compression of teat	5	8	1 −49 to 66	4	4	1 −69 to 69
Bolus formation	5	7	.69 −72 to 41	4	4	1 −69 to 69
Nasal regurgitation	4	6	.99 −66 to 50	3	3	1 −69 to 69
Appropriate triggering of the swallow	5	7	.69 −72 to 41	4	4	1 −69 to 69
Airway protection	2	2	.67 −75 to 41	2	0	.29 −94 to 31
Pharyngeal clearance	3	4	.82 −71 to 46	2	2	1 −69 to 69
Cricopharyngeal function	0	0	1 −66 to 49	0	0	1 −69 to 69

* All confidence intervals (CI) are for differences in the percentages (PSO - No PSO).

small number of infants assessed at this time point. It might have been expected that PSO would lead to an improvement in anthropometric measures. The results did not indicate this (Table 5).

Oral Motor Skills

All infants were rated as having normal oral motor skills using the SOMA at 12 months of age.

Discussion

The first question addressed in this trial was whether PSO had any impact on the physiological aspects of feeding and oral motor skills of infants with unrepaired UCLP or ICP. Few infants in this trial demonstrated normal patterns at 3 months of age. The predominant abnormal features were inconsistent range of tongue and jaw movements, arrhythmic tongue and jaw movements, altered rate of sucking, and incoordination of the suck, swallow, and breathe triad. There was also evidence of abnormal tongue movements on the videofluoroscopic assessments of a subgroup of the trial cohort. It has been suggested that infants may find the liquid barium unpalatable and therefore may have altered their feeding pattern during the videofluoroscopic assessment. However, there is no evidence that this is the case, and videofluoroscopic assessment of feeding is widely regarded as the gold standard for assessment of swallowing in infants. All infants in this subgroup failed to groove or cup the tongue around the teat and the range of tongue movements was reduced. It may be that this was due to being fed with a soft bottle. Eishima (1991) has reported a lack of grooving or cupping around the teat in noncleft infants who were fed with a fast-flow teat. The explanation for the patterns seen in cleft infants may be that less effort was required to transfer milk from a soft bottle and stabilization of the teat by grooving of the tongue was therefore less necessary. This might therefore be considered a normal pattern, because it has been seen in normal infants using a feeding system that required less effort on the part of the infant. Some of the earliest descriptions of feeding problems in infants with cleft lip and/or palate discuss a failure of infants to compress the teat or nipple with their tongue, as confirmed in the videofluoroscopy studies in this trial. Zickefoose (1957) described infants "chewing the nipple/teat" in an attempt to obtain milk from a bottle, and Tisza and Gumpertz (1962) described infants as "milking and squeezing the teat." Clarren et al. (1987) reported a similar pattern for infants with Pierre Robin Sequence, but not with ICP and UCLP. Osuji (1995) hypothesized that if an opposing surface in the form of PSO was provided, infants with cleft lip and/or palate would produce more normal tongue movements, including compression of the teat. The findings of this trial do not support this hypothesis, because all infants failed to compress the teat with the tongue, inferring that PSO did not offer any advantage.

Tongue movements also contribute to the formation and posterior transfer of boli in the oral cavity. Although Brogan et al. (1987) suggested that tongue movements for this purpose are normal in infants with cleft lip and/or palate, the findings of this trial suggest otherwise. All infants, regardless of cleft type or PSO status, showed poor bolus formation and transfer posteriorly. As seen from the videofluoroscopic evidence, residue frequently was present under the tongue, an indication of reduced tongue movements. The reduced range of tongue movements is difficult to explain, given that anatomically the

TABLE 5 Means, *p* Values, and Confidence Intervals for Differences Between UCLP (No PSO and PSO) and ICP (No PSO and PSO) for Weight, Height, Head Circumference, and Body Mass Index *z* Scores at 12-Month Assessment Point

	UCLP					ICP				
	No PSO n = 7 (mean)	PSO n = 13 (mean)	p Values	Average Difference	CI*	No PSO n = 4 (mean)	PSO n = 7 (mean)	p Values	Average Difference	CI
Weight	0.50	0.08	.51	−0.43	−1.76 to 0.91	−0.70	−0.23	.63	0.47	−1.64 to 2.58
Height	0.81	0.53	.63	−0.28	−1.46 to 0.90	0.67	−0.32	.28	−0.98	−2.94 to 0.97
Head circumference	−0.38	−0.68	.61	−0.31	−1.54 to 0.92	−1.64	−0.57	.28	1.08	−1.03 to 3.17
Body mass index	0.06	−0.39	.49	−0.45	−1.78 to 0.88	−2.06	−0.77	.16	1.98	−0.95 to 4.91

* All confidence intervals (CI) are for differences in the percentages (PSO - No PSO).

tongue is unaltered. Noncleft infants have been found to produce sucking movements *in utero* (Bosma, 1986). It might be hypothesized that the tongue movements of infants with cleft lip and/or palate are reduced even *in utero*, with the tongue sitting in the cleft rather than actively moving for sucking and swallowing. Alternatively, infants with cleft lip and/or palate might recognize early that there is no opposing surface for the tongue to contact during sucking, and therefore do not establish this movement pattern.

No significant differences were found in the physiological measures of bottle feeding, including length of sucking bursts, rate of sucking, peak-to-peak intervals, percentage of positive pressure generation and the suck-swallow ratio between the groups of infants managed with or without PSO, for either cleft type before palate repair at 3 months.

It is widely believed that infants with cleft lip and/or palate swallow normally (Shelton et al., 1966; Clarren et al., 1987). There are no objective reports to suggest otherwise. Initially it was planned to use videofluoroscopy assessment only in cases where there were clinical symptoms suggestive of a possible pharyngeal component to the infant's feeding difficulties. However, early in the trial it became apparent that the majority of infants showed coughing/choking or gurgling breath sounds (clinical suggestions of a pharyngeal component to swallowing) during assessment feeds. One such infant demonstrated these clinical signs on a regular basis and therefore underwent videofluoroscopy. The extent of pharyngeal involvement in this infant contradicted reports that infants with cleft lip and/or palate show only oral stage difficulties (Brogan et al., 1987; Clarren et al., 1987; Redford-Badwell et al., 2003). In order to ensure that this was not specific to this infant, a decision was made to assess a consecutive series of infants. Because videofluoroscopy is an invasive procedure and exposes children to radiation, it was decided to assess a limited number of infants. The aims of carrying out this procedure were first, to confirm the presence or absence of pharyngeal stage difficulties, and second, to evaluate the pharyngeal stage of the swallow. This would identify any major differences in components of the swallow, specifically the locations at which the swallow was triggered and the amounts of pharyngeal residue, in infants fitted with PSO and those without. The Ethics Committee of GOSH and the Institute of Child Health gave permission to carry out videofluoroscopy on 21 consecutive infants at GOSH (whether PSO or No PSO). The results of these assessments confirmed that the pharyngeal stage of swallowing differed from that previously reported as normal in infants (Ardran et al., 1958; Dodds et al., 1990; Newman et al., 1991; Logemann et al., 1998; Arvedson and Brodsky, 2002). One view is that noncleft infants trigger swallows at the level of the valleculae (Newman et al., 1991; Arvedson and Brodsky, 2002). In contrast, the majority of infants in this trial did not trigger the swallow until the bolus had reached the piriform sinuses. The reasons for this delay are unclear. Miller (1986) suggested that initiation of the swallow is dependent on sensory feedback from a number of areas, including the faucial arches, uvula, soft palate, and posterior tongue and pharynx. Given the abnormal anatomy and reports of altered oral stereognosis in cleft palate (Hockberg and Kabcenell, 1967) the delay in triggering might be attributable to reduced sensory input. Swallowing is a highly coordinated and complex process and relies on the accurate timing and coordination of more than 20 different muscles. It seems reasonable to hypothesize that the delay observed is a result of abnormal patterns of tongue movements and incoordination of the oral phase that subsequently has an impact on pharyngeal stage muscle movements. If PSO did facilitate more efficient or normal feeding patterns at the oral stage, there would be a subsequent improvement at the pharyngeal stage. This was found not to be the case for either cleft type.

If PSO were beneficial before palate repair, the growth patterns for infants managed with PSO would be expected to be better than those managed without PSO, more closely resembling normal infants. The majority of infants had decreased z scores for weight in the first month of life while their feeding routine was being established (data not shown). However, all infants showed improved growth by 3 months of age (data not shown), whether they were assigned to the No PSO or the PSO group. There were no significant differences in any of the mean z scores (weight, length, head circumference, BMI) for the PSO and No PSO groups within each cleft type at the 3 and 12 month assessment points (Tables 2 and 5). Hence these results provided no evidence that PSO were effective in improving feeding to any extent that was clinically relevant.

In order to address the question of whether PSO had any effect on feeding following palate repair, similar questions were asked. All infants were rated as having normal oral motor skills at 12 months of age, irrespective of PSO grouping. Most of the studies of feeding in infants with cleft lip and/or palate focus on feeding prior to surgical intervention (Pashayan and McNab, 1979; Razek, 1980; Styer and Freeh, 1981; Jones et al., 1982; Clarren et al., 1987; Richard, 1991; Kogo et al., 1997; Glass and Wolf, 1999; Shaw et al., 1999). Feeding difficulties are common and are due to the infant's inability to generate the sucking pressures required to transfer milk from the bottle or teat. Although there are no prior reports of feeding after palate repair, it is generally accepted that the feeding problems resolve spontaneously. The finding of this trial, that all infants had normal oral motor skills at 12 months of age, 6 months following palate repair, supports this.

The next question addressed was whether there were differences in the anthropometric measures of weight, height, head circumference, and BMI between the groups of infants managed with and without PSO at 12 months of age. If PSO had an effect on feeding efficiency, then differences in growth measurements would have been expected. There were, however, no significant differences in growth, height, head circumference, or the overall measure of BMI. Although some of the CIs were wide, indicating imprecision of the trial results due to limited numbers of infants, there were no consistent trends.

It is widely accepted that infants with cleft lip and/or palate may be slow to gain weight while their feeding regime is being established, but that they return or catch up to approximately their birth centile by the age of 2 years (Ranalli and Mazaheri, 1975; Avedian and Rubery, 1980; Lee et al., 1997). In this trial, the majority of infants in all groups showed catch-up growth for weight by 12 months of age, returning to or surpassing their birth-weight z score. There were some differences between the z scores for weight, height, head circumference, or BMI for individual infants; however, these differences were less than 1 SD and were not considered to be clinically important.

The World Health Organization recommends that weight and height data are collected allowing weight-for-height measures or BMI to be calculated (1995). It is suggested that if an infant shows a drop in z scores for both weight and length, long-term malnutrition or poor health is indicated, whereas a drop in weight but not height suggests recent or continuing weight loss. The World Health Organization (1995) suggests that changes of two z scores for weight-for-height or BMI are significant and require intervention. There were no differences greater than one z score for BMI, which would not be considered clinically relevant.

Compliance was monitored closely in this trial. Parents were questioned by the researcher at each assessment point about the length and frequency of PSO wear. It was felt that parents might not acknowledge inconsistent use of the PSO to the orthodontist, because he was directly involved in its provision and adjustment. To avoid this potential bias, use of the PSO was determined by the researcher.

Compliance was reasonably good immediately postfitting and at 3 months of age. However, by 6 months of age, compliance was poor, with only 14 of the 23 infants wearing their plates consistently throughout the day. The parents of many of these infants reported that there had been occasions when after cleaning, they had forgotten to replace the appliance for feeding. They did not notice any deterioration in feeding and therefore had made an active decision to abandon its use.

Conclusion

The tentative findings of this trial were that PSO did not improve feeding efficiency before palate repair at 3 months of age or following palate repair at 12 months of age. Similarly, the many hypotheses as to how PSO facilitate more efficient feeding by acting as an obturator and providing an opposing surface prior to repair of the palate were not supported. Although the small numbers allow us only to exclude differences of fairly large magnitude as illustrated by the CIs, estimates were remarkably similar. If feeding efficiency had been improved, a significant difference in the growth of infants randomized to the PSO groups would have been expected. This was found not to be so.

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