A Review of Feeding Interventions for Infants With Cleft Palate

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Objective: **A literature review was conducted to identify feeding interventions recommended for infants with cleft conditions. Selected articles were critically appraised using an evidence-based practice framework to determine the strength of the evidence underpinning each intervention.**

Design: **Electronic databases were searched for reports of cleft palate feeding interventions. The selected articles were coded as being data driven or not; those containing data were then critically appraised using a recognized evidence hierarchy. Finally, each report was ascribed a level of evidence (from I to IV), depending on the quality of data presented.**

Results: **Fifty-five articles published between 1955 and 2002 were reviewed. There are currently no completed systematic reviews relevant to this body of literature (level I evidence). Two well-designed randomized controlled trials (level II evidence) were found. These were considered to provide the strongest evidence for feeding intervention techniques. These articles described a combination of interventions, including early feeding and nutrition education, as well as assisted feeding methods for infants with isolated cleft conditions. Three examples of level III.3 evidence were also found. Fifty (91%) of 55 articles reviewed were non–data-driven reports of expert opinion (level IV).**

Conclusions: **A paucity of evidence rated as either moderate or strong prevailed, underscoring the need for ongoing scientific evaluation of feeding interventions used with infants who have cleft palate. A number of factors, including the heterogeneity of samples studied, lack of replication of trials, and small sample sizes, affected the type and strength of evidence underpinning specific feeding interventions.**

KEY WORDS: *cleft palate, evidence-based practice, feeding, infancy, outcomes*

Feeding difficulties associated with cleft palate have been documented for many years. In nonsyndromic cases, the underlying problem is thought to be failure to generate sufficient negative intraoral pressure (suction) during feeding (Clarren et al., 1987; Choi et al., 1991; Wolf and Glass, 1992; Arvedson, 1993; Trenouth and Campbell, 1996; Oliver and Jones, 1997). This in turn affects attachment to the breast or artificial nipple and extraction of milk, as well as bolus organization, retention of the bolus in the mouth before swallow initiation, and swallow initiation itself (Wolf and Glass, 1992). Sequelae to oral-nasal coupling are reported to include excessive air intake, nasal regurgitation, fatigue, coughing, choking and gagging on fluids, prolonged feeds, and discomfort (Styer and Freeh, 1981; Jones et al., 1982; Clarren et al., 1987; Carlisle, 1998). Parents may also fear the task of feeding their infant (Zickefoose, 1957).

Literature regarding the feeding of infants with cleft palate is replete with the potential consequences of feeding difficulties. An example of this is the association of feeding difficulties with death in developing countries (Wilcox, 1994). Furthermore, morbidity, such as failure to thrive (Pandya and Boorman, 2001) and breast-feeding malnutrition (Livingstone et al., 2000), has been described even in developed countries. A number of studies have reported slow weight gain in infants with cleft palate, especially in the first few months of life (Avedian and Ruberg, 1980; Jones, 1988; Richard, 1991, 1994; Lee et al., 1997). Moreover, feeding difficulty, surgical admission, clinic visits, and other factors have been reported to reduce maternal responsiveness to the infant with a craniofacial anomaly and disrupt attachment (McWilliams et al., 1984; Speltz et al., 1990).

There are reports of health benefits associated with appropriate and improved management of feeding problems in infants with cleft conditions. Pandya and Boorman (2001) reported a significant decrease in failure-to-thrive rates for all infants with cleft palate, including syndromic cases after implementation of an early feeding program that involved domiciliary visits, breast-feeding support, feeding education, and monitoring of growth. However, although there is increasing emphasis on neonatal intervention, including seamless care from hospital to the community setting (Clinical Standards Ad-

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visory Group, 1998), debate exists about the most efficacious interventions for infants with feeding problems. Preferred management strategies vary from team to team and among clinicians. Intervention may include modified nipples and bottles, direct breast-feeding, particular feeding techniques, feeding plates, and advice on specific nutrition or lactation issues.

Contemporary practice demands that intervention be evidence based, that is, an ''integration of individual clinical expertise with the best available external clinical evidence from systematic research'' (Sackett et al., 1997). This allows the clinician to deliver the most appropriate intervention to a particular patient. The impetus to provide evidence-based intervention is threefold: patients expect this level of intervention, professionals have a responsibility to ensure delivery of the most efficacious intervention, and health care administrators demand the most effective outcomes for minimal cost (Law and Baum, 1998). With this in mind, the aim of this report was to determine what feeding interventions are reported and recommended for infants with isolated cleft conditions and to determine the evidence underpinning each of these.

METHODS

A systematic literature search was conducted using the electronic databases MEDLINE, CINAHL Cochrane Database, ACP Journal Club, DARE, CCTR, and Healthstar with an unrestricted time period. Key search terms were *cleft palate, infant feeding, feeding efficiency, bottle-feeding, breast-feeding,* and *feeding obturators.*

Exclusion Criteria

Foreign language material was excluded, because there was no available translation service at the time of writing. Reports specifically addressing conditions such as Pierre Robin syndrome and/or other syndromes known to encompass specific and severe feeding problems related to respiratory effort or factors other than cleft palate were excluded from analyses because interventions were likely to differ from those applied to cleft palate alone. For example, the use of nasopharyngeal tubes and other techniques to relieve airway obstruction and nasogastric tubes to meet nutrition and hydration needs are commonly used for infants with Pierre Robin sequence (Glass and Wolf, 1999) but not for those with isolated cleft palate. Lastly, reports examining postsurgical feeding protocols were also disregarded, because these were concerned with reinitiating oral feeding and avoiding wound dehiscence postsurgically rather than addressing feeding problems experienced by subjects.

Procedure

Five broad intervention themes were identified. These included feeding equipment, feeding techniques, breast-feeding, prostheses and nutrition/lactation advice, and combinations of all the aforementioned. Reports were first grouped according to the type of intervention. Then, if the report was data driven, it was critically appraised according to the criteria devised by Greenhalgh (2001) to determine the methodological quality and the appropriateness of the analyses. If necessary, articles were reclassified to reflect their true methods. Lastly, reports were ascribed a level of evidence (e.g., level I, systematic review) after The Joanna Briggs Institute for Evidence Based Nursing and Midwifery Levels of Evidence (http://www.joannabriggs.edu.au) (Table 1) so that the strength of the evidence underpinning interventions could be identified. For example, the strongest level of evidence (level I) is considered a systematic review of controlled trials and the weakest a report of expert opinion (level IV).

TABLE 1 Levels of Evidence*

I	Strongest†	Evidence obtained from a systematic review of all relevant randomized controlled trials
II	Strong	Evidence obtained from at least one properly designed randomized controlled trial
III.1	Moderate	Evidence obtained from well-designed controlled studies without randomization
III.2	Moderate	Evidence obtained from well-designed cohort or case-control analytic studies preferably from more than one center or research group
III.3	Limited	Evidence obtained from multiple time series with or without the intervention; dramatic results in uncontrolled experiments
IV	Weak	Opinion of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees
Other‡	Weakest	Papers such as published reports from parents and health professionals not expert in cleft care

* Levels of evidence adapted from work in the series *Best Practice*, published by The Joanna Briggs Institute for Evidence Based Nursing and Midwifery, ISSN: 1329-1874, http://www.joannabriggs.edu.au (accessed 6-4-03).

† Qualitative labels assigned by the author.

‡ Additional level of evidence created to manage reports from parents and others not considered expert in cleft care.

To test for reliability of results, the author recoded all reviewed documents 6 months after the original work. Intrajudge reliability for coding was 93%. Another examiner coded 10 articles. Interjudge reliability was 90%. When there was disagreement, discussion using Greenhalgh's (2001) checklists was undertaken until the raters concurred, and the article was reclassified.

RESULTS

The search strategy yielded 48 articles concerned with feeding interventions for infants with cleft palate. After applying exclusion criteria, 43 were selected for review. Hand searching of the gathered articles yielded another 13 references, 12 of which were consistent with inclusion criteria and selected for review. A total of 55 journal articles were included in this review. The reports were published between 1955 and 2002 (Table 2) in a range of English-language journals (Table 3). The results from this literature search are as follows.

What Feeding Interventions Are Reported for Infants With Cleft Conditions?

Five broad intervention themes were identified. These included feeding equipment (bottles, teats, cups, spoons), feed-

TABLE 2 Distribution of Reviewed Journal Reports by Year of Publication

Year	*No. of Reports*
1955–1959	2
1960–1964	0
1965–1969	1
1970–1974	5
1975–1979	1
1980–1984	8
1985–1989	13
1990–1994	8
1995–1999	11
2000–2002	3
Total	55

TABLE 3 Distribution of Reviewed Reports by Journal

Journal	*No. of Reports*
Cleft Palate-Craniofacial Journal	9
Medical Journal of Australia	1
Clinical Paediatrics	1
Nursing Journal of India	1
Journal Human Lactation	1
International Journal of Paediatric Dentistry	1
AWHONN-Lifelines	1
British Journal of Plastic Surgery	1
RCSLT Bulletin	2
Nursing Times	4
Western Journal of Medicine	1
NAACOGS Clinical Issues in Perinatology and Women's Health Nursing	1
Current Problems in Paediatrics	1
Journal of Paediatric Nursing	2
Archives of Disease in Childhood	2
Plastic Surgery Nursing	2
Journal of the American Dietetic Association	1
Pediatrics	2
Journal of Craniofacial Surgery	2
Journal of Oral and Maxillofacial Surgery	1
Ear Nose and Throat Journal	1
Special Care in Dentistry	2
Journal of Paediatric Dentistry	1
British Dental Journal	1
Infants and Young Children	1
Canadian Medical Association Journal	1
Journal of Prosthetic Dentistry	1
Journal of the American Dental Association	2
Plastic and Reconstructive Surgery	2
ASDC Journal of Dentistry for Children	1
Quintessence	1
International Journal of Paediatric Otorhinolaryngology	1
Professional Nurse	1
Obstetric Gynaecology and Neonatal Nursing	1
Children	1
Total	55

ing techniques (e.g., Richard's 1991 Enlargement, Stimulate, Swallow, Rest [ESSR] method), breast-feeding, prostheses, and nutrition/lactation advice. Combinations of interventions were also recommended.

What Evidence Underpins the Feeding Interventions Reported?

The evidence underpinning the five intervention themes for infants with cleft conditions varies. Each intervention theme will be discussed in turn and the evidence examined. Table 4 contains details of each data-driven study, including the sample characteristics, a summary of the intervention, the outcomes measured, and the results. Table 5 contains details of intervention techniques currently supported by weak evidence, usually clinical opinion. Further investigation is indicated to determine the usefulness of each technique.

Feeding Equipment Supported by Moderate-to-Strong Levels of Evidence

Two randomized controlled trials (level II) comparing feeding equipment have been published. These reports provide moderate-to-strong evidence that (1) modified equipment (a compressible bottle and NUK orthodontic nipple [MAPA GmbH, Zeven, Germany]) combined with parental counseling can lead to significantly greater weight gain and head circumference in nonsyndromic infants who have cleft lip, cleft palate, or combined cleft lip and palate compared with a control group at 12 months of age (Shaw et al., 1999), and (2) modified equipment (Mead Johnson cleft palate feeder or a rigid bottle and crosscut teat) and a nutrition intervention protocol can support normal growth during the first 18 months of life in infants who have cleft palate or combined cleft lip and palate (Brine et al., 1994).

Compressible Bottles and Parental Counseling

Shaw et al. (1999) described a randomized trial concerned with feeding equipment, specifically bottles. Infants with nonsyndromic cleft lip, cleft palate, or combined cleft lip and palate (n = 101) were randomized at birth to one of two groups that compared compressible to standard rigid bottles. Both groups used a NUK orthodontic nipple. Randomization in this parallel study was based on the cleft condition (cleft lip, cleft palate, or combined cleft lip and palate) but did not control for other variables, such as birth weight, sex, or parental ethnic origin, which may have influenced outcomes. Follow-up was at 12 months. Nutritional gain based on anthropometry (weight, crown-heel length, and occipitofrontal circumference) was measured from baseline. The main outcomes (weight, crown-heel length, and occipitofrontal circumference) were analyzed using a general linear model containing covariates for sex, cleft type, ethnicity, estimated weight for expected date of delivery, and bottle type. *A priori* power calculations suggested that the study had sufficient power to detect a large effect size.

Although better growth was detected in the compressible bottle group at 12 months of age, early feeding success in both groups might have been partially attributable to early feeding support and parental counseling provided by a specialist health visitor. This intervention was not specifically measured; thus, its effect cannot be substantiated without further investigation. Also, the authors acknowledge the possibility of unintentional

subtle systemic bias due to a lack of blinding for anthropometric measures.

Modified Nipples and a Nutrition Intervention Protocol

Brine et al. (1994) reported the results of a small, single-center, unblinded randomized trial concerned with feeding equipment and a nutrition intervention protocol. Thirty-one infants (median age, 15 days; age range, 0 to 64 days) with either cleft palate or combined cleft lip and palate were randomized to one of two groups that compared a squeezable cleft palate nurser (Mead Johnson) to a conventional rigid bottle used with a standard crosscut nipple. Randomization procedures in this parallel study were not described, but the authors note that they accounted for both cleft type and sex. Both groups received nutritional intervention, which included feeding technique instruction, nutrition counseling at each clinic visit, use of the same standard formula for 12 months, and introduction of solids at 6 months. Follow-up was at 18 months, and the primary outcome measures were mean energy and protein intakes at 3 and 6 months of age and anthropometry (weight, length, head circumference, scapular skinfold thickness, triceps skinfold thickness, and midarm circumference) during the first 18 months. Data were analyzed using a repeated-measures analysis of variance (ANOVA), with the results suggesting that both feeding methods were effective in supporting normal growth. The authors reported, however, that their data support the need for feeding and nutrition education and an organized nutrition intervention. This intervention was not specifically measured during the trial.

Other Feeding Equipment

A variety of feeding equipment is presented in the cleft palate literature supported by weak evidence, most of which is considered expert opinion. A brief discussion of each type of equipment and evidence follows.

Artificial Nipples

As stated above, crosscut nipples used with either rigid or compressible bottles are said to be useful for infants with cleft conditions when combined with nutrition intervention protocols (Brine et al., 1994). Clarren et al. (1987) claim that infants with isolated cleft palate may benefit most from being fed using crosscut nipples; however, no experimental evidence is offered to support this claim (level IV). Artificial nipples with an enlarged orifice and fast flow rate have also been recommended (Jacobs, 1983; Martin, 1983; Porterfield, 1988) and these too without rigorous evaluation (level IV). Some authors caution against the use of these nipples, because the rapid flow may imperil the infant's ability to synchronize sucking, swallowing, and breathing if milk is delivered directly to the pharynx (Glass and Wolf, 1999; Miller and Kummer, 2001).

Numerous other nipples have been described throughout the years, such as those containing a one-way valve for controlling fluid flow and vacuum build-up (Shirley and Cocke, 1971; Haberman, 1988). One of these, the Haberman Feeder (Medela, 1994), incorporates a long soft nipple with a slit opening and a one-way valve between the bottle and nipple. The nipple can be positioned to allow three different flow rates and, when compressed by the feeder, delivers milk to the infant. It has been claimed that the soft pliable nipple enables the infant to express fluid independently (Barone and Tallman, 1998). To date, however, only one small series of cases ($n = 6$), described by Campbell and Trenouth (1987) (level III.3), have examined its use. In uncontrolled experiments, Campbell and Trenouth (1987) reported faster feeding times, less vomiting, satisfactory weight gain, and parental acceptance for infants with various cleft conditions.

The use of conventional rigid bottle and standard pierced nipple combinations instead of modified equipment (e.g., compressible bottles, crosscut nipples) was recommended only once (Fisher, 1991). These are the bottle and nipple combinations typically used by noncleft infants and used as the control in experimental studies.

Compressible Bottles

Compressible bottles allow the feeder to deliver milk to the infant who is unable to generate suction and extract fluid independently. Compensation for infants with cleft conditions who also have oral stage feeding problems in this manner has been termed *assisted feeding* (Bannister, 2001). Many experts have described compressible bottles or bottle liners used with a variety of nipples (Kelly, 1971; Paradise and McWilliams, 1974; Clarren et al., 1987; Barone and Tallman, 1998; Scheurele, 1998; Glass and Wolf, 1999; Miller and Kummer, 2001). None of these reports contain data supporting the use of the equipment; thus, the evidence for prescribing it is weak (level IV). Some authors suggest that particular subgroups of infants with cleft conditions may benefit more than others from assisted feeding. For example, Clarren et al. (1987) claim that infants with combined cleft lip and palate and wide clefts of the hard palate may particularly benefit from assisted feeding. This would be powerful information for the clinician if it were supported by evidence. To date, however, there have been no data-driven studies comparing the outcomes for infants with different cleft conditions using the same feeding equipment and receiving no other intervention(s). Therefore, it is unclear whether the infants who benefit most from the use of compressible bottles can be identified solely by the size and location of their cleft. Conversely, it is unclear whether one intervention alone, such as compressible bottles, provides maximal benefit for improving an infant's feeding ability. A combination of interventions, such as those evaluated by Shaw et al. (1999), Brine et al. (1994), and Richard (1994), may well be preferable.

Cups

Cup feeding is an artificial feeding method generally used to complement breast-feeding. It is more commonly used for

TABLE 4 Data-Driven Feeding Interventions Studies for Infants with Cleft Palate or Cleft Lip that Provide the Strongest Levels of Evidence for Practice*

Intervention	*Citation*	*Level of Evidence*	*Method*	*Subjects*	*Summary of Intervention*	*Measured Outcomes*	*Results*	*Comments*
Feeding equipment	Shaw et al. (1999)	II	Randomized controlled trial	N = 101 consecutively born infants with CL, CP, CLP (nonsyndromic, medically well)	Randomly assigned to squeezable or rigid bottle (with NUK orthodontic nipples) and followed up for 12 months	Anthropometric measures, reliability of the feeding method, mothers' report of ease and pleasure of feeding and estimate of infant contentment	Statistically significant differences in weight between groups at 12 months of age and in head circumference. Increased growth in the group using the compressible bottle. The health visitor outreach program was a significant advance in total care, offering unique opportunities for counseling and support.	Both feeding methods achieved acceptable weight gain. The presence of a health visitor conducting the trial and thus providing early feeding education may have helped maximize both methods. Anthropometric measures were not carried out blind.
Feeding equipment	Brine et al. (1994)	II	Randomized controlled trial	N = 31 (median age, 15 days) nonsyndromic CLP or CP	Two feeding methods: Mead Johnson feeder (squeezable bottle and long narrow crosscut nipple) *or* rigid bottle with a standard (crosscut) nipple. All infants also had nutritional counseling, instruction on feeding technique, and the same caloric formula. All had same time for intro of solids; 22 CLP infants also had maxillary obturators after 2 weeks of age.	Mean energy and protein intakes at 3 and 6 months and growth measures during the first 18 months.	Both nipples found to be adequate. A clearly defined nutrition intervention protocol as well as equipment was recommended.	Small sample size, unblinded trial
Feeding techniques	Richard (1994)	III.3	Case controlled experimental study	N = 69 bilateral and unilateral CLP	Two groups (ESSR vs control). ESSR included enlarging the nipple hole, stimulating sucking, waiting for a swallow, monitoring infant cues during feeding and resting. Controls were fed using a nipple with an enlarged hole (i.e., "traditional" cleft feeding). All infants had a palatal obturator fitted.	Retrospective chart review of birth weight and weight at surgery and age at surgery collected.	Infants fed using the ESSR method had a significant increase in weight gain.	Two groups not drawn from the same cohort, not randomized. Low representation of females especially in the control group. No data for previous maternal experience with feeding, dietary history, which may have influenced findings. All had presurgical orthopedic plates. Findings not broadly generalizable.
Prosthesis and lactation advice	Turner et al. (2001)	III.3	Prospective experimental study with multiple baselines and multiple interventions.	N = 8 CL, CLP, and CP newborns (all fed with expressed breast milk EBM to some extent).	Prospective study, A B1 C1 B2 C2 design; A = baseline for 3 direct breastfeedings, B1 = baseline for 3 Haberman feeding/instruction on bottle use, C1 = minutes to feed with the palatal obturator and breastfeed, B2 = obturator removed and 3 feedings on Haberman timed, C2 = obturator reintroduced and Haberman feedings reviewed	Time to feed, intake, growth	The combined use of a palatal obturator and lactation education reduced feeding time and increased the volume of intake and was associated with good growth.	Feeding efficiency was not clearly defined. Time to feed, flow rate, and volume consumed are the implied factors that contribute to efficient feeding. Mothers elected to enter the study; therefore, the cases were highly motivated and possibly not representative of the overall group.
Nutrition and lactation advice	Pandya and Boorman (2001)	III.3	Prospective audit following an intervention	N = 68 cohort of consecutive cleft cases (± syndrome) awaiting primary surgery	Prospective audit of growth (weight) after introduction of a feeding specialist to team. Care provided from birth for first 3 weeks and then transferred to a community service.	Weight gain, fail to thrive (FTT) (defined as weight below the fifth percentile or "a drop in weight across percentile bands correlating with SD scores indicating a downward shift of 2 SDs".	FTT rates reported prospectively CL = 8% (2/25) UCLP = 9% (1/11) BCLP = 20% (1/5) CP = 26% (9/43) 11/68 had syndromes	Mainly descriptive data

* CL = cleft lip; CP = cleft palate; CLP = combined cleft lip and palate; ESSR = Enlargement, Stimulate, Swallow, Rest; EBM = expressed breast milk; UCLP = unilateral cleft lip and palate; BCLP = bilateral cleft lip and palate.

TABLE 5 Feeding Interventions for Infants with Cleft Palate or Cleft Lip and Palate that are Currently Supported by Weak Evidence

Intervention	*Citation*	*Level of Evidence*	*Method*	*Subjects*	*Summary of Recommendation*	*Comments*
Standard rigid bottles and pierced nipples	Fisher (1991)	IV	Report of experience	Infants with cleft palate ± lip	Fisher (1991) asserts that modified nipples and bottles are not required for infants with cleft conditions.	Shaw et al. (1999) conducted a randomized controlled trial that demonstrated that infants who were fed using a compressible bottle and who also followed a nutrition intervention protocol had better weight gain at 12 months compared with counterparts using a standard bottle and NUK orthodontic teat. This study supports modified equipment NOT standard bottles and nipples.
Fast flow nipples	Jacobs (1983) Martin (1983) Porterfield (1988)	IV	Report of experience	Infants with cleft palate ± lip	Artificial nipples with large holes are recommended so that infants may passively receive a bolus of milk where a cleft palate prevents them from extracting it independently from the bottle.	Fast flow nipples may imperil the infant's ability to synchronise sucking, swallowing, and breathing if milk is delivered directly into the pharynx. Fast flow nipples may release a bolus that is unusually large and difficult for the infant to manage (Glass & Wolf, 1999; Miller & Kummer, 2001).
Cup feeding	Danner (1992) Lang et al. (1994)	IV	Report of experience	Infants with cleft palate ± lip	Cup feeding is recommended for infants who are trying to establish breast-feeding under the premise that it will circumvent the need for bottle feeding and resultant ''nipple confusion.''	Cup feeding is both recommended and cautioned in the broader literature on infant feeding. Dowling et al. (2002) question the efficacy and efficiency of cup feeding, particularly because the duration of feeding measured in their study was lengthy and intake low (due to spillage). The safety of the technique is also questioned in a report by Thorley (1997), who describes a case of infant aspiration after cup feeding. Other researchers such as Howard et al. (1999) provide preliminary evidence that cup feeding may be a useful technique for infants who are having difficulty establishing breast-feeding.
Direct breast-feeding	Danner (1992) Willis (2000)	IV	Report of experience	Infants with cleft palate ± lip	Various breast-feeding positions and techniques are described by both authors.	Danner (1992) asserts that infants should breast-feed for 45 minutes at least and then have complimentary feeds. Elster et al. (1994) caution that lengthy feeds may result in caloric loss and excessive expenditure of energy in a group of infants recognized as having poor weight gain. Early caloric intake may effect brain growth.

preterm and low-birth-weight infants who are attempting to establish breast-feeding, but it has also been recommended for infants with cleft palate undergoing the same process (Danner, 1992; Lang et al., 1994). Lang et al. (1994) reported their experience using a cup with a number of cases, including one infant who had a unilateral cleft lip and palate (UCLP). Unfortunately, there is no indication whether or not the goal of feeding intervention, breast-feeding, was achieved or data reported about cup feeding duration and outcomes. To date, cup feeding for infants with cleft conditions has not been scientifically evaluated; thus, the evidence for use of this method remains weak (level IV).

Feeding Techniques

Feeding techniques have been described by a number of researchers. The evidence underpinning such techniques is variable. The most notable studies were undertaken by Richard (1991, 1994), who devised the ESSR technique. The 1994 trial compared traditional bottle feeding techniques to ESSR for a total of 69 infants with complete UCLP or bilateral cleft lip and palate (BCLP). The results provide limited but promising evidence (level III.3) that a holistic approach to feeding that incorporates parental education can lead to improved growth at the time of lip surgery (approximately 60 days) for infants with UCLP or BCLP compared with traditional feeding methods (Richard, 1994).

The ESSR Technique

In Richard's (1994) trial, 29 infants underwent a ''traditional method'' of intervention, and later the ESSR method was introduced to an additional 40 infants; thus, the comparison groups were not cohorts. All infants wore palatal obturators. In the ESSR group, anatomical differences between infants with and without cleft palate, a specific feeding method and formula, and time goals for feeding were taught. Outcomes measured were mean birth weight, mean weights at time of surgery, and mean age at time of surgical repair of the cleft lip. Paired *t* tests ($\alpha = .05$) revealed that infants in the ESSR group had better mean weight than the comparison group at time of lip surgery (approximately 60 days).

Other Feeding Techniques

Miller and Kummer (2001) and Glass and Wolf (1999) recommended upright positioning, feeding with an assisted milk delivery system, controlling milk flow rate, and responding to infant cues during feeding as useful strategies for infants with cleft palate (level IV—expert opinion and clinical experience). In addition, they stated that feed times should be limited, because regular lengthy periods of feeding may cause excessive caloric expenditure and also failure to establish well-defined periods of satiety and hunger. Consequently, growth may be negatively affected (level IV—expert opinion). Sidoti and Shprintzen (1995) suggested a 20-minute feed duration for infants with cleft palate, with no more than 30 minutes as the upper limit (level IV expert opinion). To date, there has been no scientific evaluation of positioning, responding to infant cues, or manipulating feed velocity for infants with cleft conditions.

Breast-feeding

Breast-feeding is defined in this report as direct placement of the infant at the breast for feeding.

Breast-feeding and Palatal Obturators

Feeding obturators have been used to facilitate direct breast-feeding for infants with cleft conditions. One report, a small case series, yielded descriptive data (level IV—experience) that suggested that palatal obturators may improve the volume ingested in some breast-fed infants with combined cleft lip and palate (Kogo et al., 1997). Kogo et al. (1997) reported that 4 of 10 infants could suck approximately 22 g per breast-feed under conditions where each was prescribed a Hotz-type palatal plate and the mothers' hand expressed with the infant at the breast. Although the obturator did not ameliorate the need for supplemental feeding, the researchers considered the volume ingested indicative of improved sucking performance and a promising step toward independent breast-feeding.

In a single case report with no data (level IV—experience), Hemingway (1972) described an infant with combined cleft lip and palate who was eventually fully breast-fed at 6 months of age subsequent to a feeding regimen that included a dental palatal plate, dropper feeding, and breast-feeding trials. It is unclear what surgery if any this infant had undergone by 6 months of age and whether this contributed to breast-feeding independence. To date, there has been limited scientific evaluation of the use of prostheses and altered posture to assist the direct breast-feeding of infants with cleft conditions. The use of a palatal prosthesis for feeding in general will be discussed later in this article.

Breast-feeding Techniques and Complementary Feeding

Nine reports provided weak evidence (level IV or ''other'') for various breast-feeding techniques. Two were single case reports containing no data (Grady, 1977; Crossman, 1998), and the remaining articles were reports of personal experience (Brookman, 2000) or expert opinion (Helsing and King, 1985; Dunning, 1986; Fisher, 1991; Danner, 1992; Wilton, 1998; Willis, 2000). There was general agreement that infants with cleft lip rarely experience breast-feeding problems (Shah and Wong, 1980; Kelts and Jones, 1983), whereas those with a large cleft palate or combined cleft lip and palate are likely to have significantly increased difficulty (Clarren et al., 1987). A number of articles acknowledged that supplemental feeding was necessary for infants with cleft palate who are breast-feeding (Kelts and Jones, 1983; Helsing and King, 1985; Danner, 1992; Willis, 2000). Bottles (Grady, 1977), cups, spoons

(Helsing and King, 1985; Danner, 1992; Willis, 2000), droppers, and supplemental nursing systems (Kelts and Jones, 1983; Danner, 1992) were all described as being useful. With the exception of Turner et al. (2001), there has been no scientific evaluation of the many complementary techniques used to assist infants with cleft palate in breast-feeding.

Various feeding positions were also promoted as being useful in facilitating direct breast-feeding (Dunning, 1986; Clarren et al., 1987; Danner, 1992; Brookman, 2000; Willis, 2000) and hand expressing during the breast-feed (Helsing and King, 1985; Danner, 1992; Willis, 2000). Again, information was not supported by evidence.

Prostheses

Feeding obturators are passive devices designed to provide a normal contour to the cleft alveolus and hard palate (Schaaf et al., 1995). They separate the oral and nasal cavities and in doing so provide a surface to appose the nipple during suckling (Glass and Wolf, 1999; Miller and Kummer, 2001). One multiple baseline trial that examined a number of interventions provided limited evidence (level III.3) that the combined use of a palatal obturator and lactation advice can improve the time taken to (breast/bottle) feed, volume of intake, and growth at 4 weeks of age when commenced with newborn infants who have cleft palate or combined cleft lip and palate (Turner et al., 2001).

Palatal Obturators, Lactation Advice, and Breast- or Bottle Feeding

Turner et al. (2001) described a five-phase (A, B1, C1, B2, and C2) withdrawal design that examined supplemented feeds (breast-feeding plus supplemental feeding using formula or expressed breast milk). Infants were supplemented using a Haberman feeder with and without a palatal obturator. Exclusion criteria were applied to 50 consecutive newborns to generate a sample of infants with cleft palate or combined cleft lip and palate (n = 8). Each infant served as its own control. Interventions compared were lactation instruction and palatal obturation. Lactation instruction included correct positioning of the infant, the effects of cleft on feeding, Haberman bottle use, advice on feed duration and breast-feeding techniques, observation of infant feeding cues, and infant-lead feedings. Follow-up for growth parameters was reported at 2 years of age, although the authors note that they continue to collect growth data. Outcomes measured were baseline minutes to feed at the breast (A phase), with a Haberman bottle (B1 phase), or with a palatal obturator used during breast-feeding (with or without supplemental bottle-feeding—C1). In the B2 and C2 phases, the obturator was removed and then reintroduced, respectively, and feed velocity was measured. Anthropometry (height and weight) at birth, 2 weeks, 3 weeks, 4 months, and 1 and 2 years was conducted. A parental satisfaction survey was completed at the end of the five phases. A one-factor ANOVA compared the ''time to feed'' variable across each phase, and a one-sample *t* test was used to compare anthropometric data. The authors report that all infants evidenced a reduction in feeding time and an increase in volume consumed.

Other Prostheses

Feeding appliances have been reported by a number of experts (Lifton, 1956; Williams et al., 1968; Razek, 1980; Jones et al., 1982; Fleming et al., 1985; Balluf and Udin, 1986; Goldberg et al., 1988; Saunders et al., 1989; Kogo et al., 1997). The effects of these appliances have not been tested with scientific rigor; hence, the evidence for use in improving feeding ability remains weak (level IV). One descriptive study suggested that when the obturator extends 2 to 3 mm beyond the hard palate, some suction will be restored (Kogo et al., 1997) albeit not to the levels required for independent feeding (Choi et al., 1991; McKinstry, 1998). Despite this, favorable outcomes have been reported for infants with seemingly intractable feeding problems. For example, Balluf and Udin (1986) reported improved weight gain and shorter time to surgery in a case series (n = 7) of bottle-fed infants with cleft lip and palate after early parental education and prescription of a feeding obturator. Using a similar protocol, Goldberg et al. (1988) reported improved weight gain with one infant who had a cleft of the soft palate. Jones et al. (1982) reported reduced choking, nasal discharge, and bottle feed duration and improved parental confidence in their sample of infants with cleft lip and palate (n = 11) who were prescribed feeding obturators. In the main literature, there has been almost no scientific evaluation of the use of prostheses to promote feeding in infants with cleft conditions.

Nutrition and/or Lactation Advice

Nutrition and/or lactation advice has been included in the suite of intervention options investigated by researchers such as Shaw et al. (1999), Brine et al. (1994), and Turner et al. (2001). However, only one article reported specific outcomes for nutrition and lactation support. A prospective audit of cases provided limited evidence (level III.3) that failure-to-thrive rates significantly decrease under conditions where an early feeding program is used (Pandya and Boorman, 2001).

Neonatal Feeding Support

After discovering high failure-to-thrive rates within an entire cohort of cleft cases, Pandya and Boorman (2001) prospectively evaluated the introduction of a feeding-support nurse who monitored all at-risk infants. Domiciliary visits, breast-feeding support, feeding education, and monitoring of growth were used to support infants and their families from birth. Failure-to-thrive rates dropped significantly from 49% to 26% for infants with cleft palate, 32% to 9% for infants with UCLP, and 38% to 20% for BCLP after the feeding-support nurse initiative.

Discussion

The purpose of this article is to review feeding interventions recommended for infants with isolated cleft conditions and to determine the strength of evidence underpinning each one. Neither postsurgical feeding strategies nor interventions specifically designed for infants with comorbidity such as Pierre Robin sequence, which require specific feeding management not common to infants with isolated cleft conditions, were included in the review. Ideally, only experimental trials would have been included in this article, because these are considered the best form of evidence for evaluating an intervention (Magarey, 2001). However, this review was not restricted in this way for two reasons. First, only a relatively small body of feeding intervention literature with few well-executed controlled trials exists. Second, in a field where commonly used interventions are underpinned by such a paucity of scientific evaluation, it is important to illustrate which interventions are supported solely by clinical experience or expert opinion.

The critical appraisal revealed a general lack of rigorous investigation. Only five published data-driven studies yielded limited-to-strong evidence (levels III.3 to II) to guide clinicians when choosing feeding options for young infants with unrepaired cleft palate or cleft lip and palate (Brine et al., 1994; Richard, 1994; Shaw et al., 1999; Pandya and Boorman, 2001; Turner et al., 2001). Interestingly, these studies investigated combinations of interventions (e.g., nutrition intervention and compressible bottles) rather than single interventions (e.g., crosscut nipples). Data from these studies suggested that feeding education (Brine et al., 1994; Richard, 1994; Shaw et al., 1999; Pandya and Boorman, 2001; Turner et al., 2001) delivered with a nutrition intervention protocol (Brine et al., 1994) can improve outcomes such as weight gain, feed velocity, and fluid intake for cleft infants. Additionally, a number of feeding equipment combinations were shown to positively influence growth, particularly weight gain. These were compressible bottles used with a NUK orthodontic nipple (Shaw et al., 1999), cleft palate feeders, or crosscut nipples used with a standard rigid bottle (Brine et al., 1994; Richard, 1994). At present, there is limited but promising evidence to support the use of palatal obturators and lactation education (such as advice on positioning, bottle use, feed duration, infant feeding cues, and breast-feeding techniques) to improve both breast- and bottle feeding outcomes for infants with cleft palate or combined cleft lip and palate (Turner et al., 2001). A protocol to examine feeding interventions for growth and development in infants with cleft lip, cleft palate, or cleft lip and palate has been published (Glenny et al., 2002), and the systematic review is in progress. This will confirm the strongest evidence available for feeding interventions in cleft palate. To summarize, it seems that no single intervention can be prescribed with confidence to improve feeding outcomes for infants with cleft conditions. Instead, combinations of interventions have yielded the first positive results for directing feeding intervention.

The evidence underpinning many (91%) of the feeding interventions described for cleft palate infants and reviewed in this article was considered weak (level IV). Although the outcomes reported were essentially positive, they were drawn from a relatively small body of literature where the heterogeneity of samples, inclusion of multiple interventions in a single protocol, lack of controls, lack of replication, and failure to use rigorous methods confounded interpretation of results. Not surprisingly, reports of clinical experience and expert opinion predominated. Consequently, an array of modified bottles and nipples, as well as cup feeding and breast-feeding techniques, were recommended, with little evidence of scientific evaluation. Although it is appropriate that experts are consulted on what constitutes best practice when a paucity of scientific evidence prevails (Egan et al., 1998), our patients impel us to move forward with research efforts so that evidence-based interventions can be offered.

A number of theoretical issues seem to confound the investigation of feeding interventions for infants with cleft palate. First, there is no consensus as to what constitutes feeding difficulty, which infants are most at risk, and what the predictors of poor feeding might be. In short, descriptive epidemiological studies that could provide this information have not been undertaken. Instead, feeding interventions have arisen from a structural view of feeding difficulty with little investigation of any other components of feeding, such as oral motor function, swallow function, or mother-infant (psychodynamic) feeding relationships, which may be important. This is not surprising given the lack of descriptive epidemiological work.

Second, little attention has been given to understanding how various feeding methods work and what effect they have on the infant's overall feeding ability. For example, the effect of (1) a palatal obturator on oral proprioceptive feedback during feeding, (2) cup feeding on the development of appropriate oral motor patterns for suckling, and (3) long-term feeding problems on long-term eating behavior are unknown.

Finally, in those studies where interventions were evaluated, more than one intervention was frequently included (e.g., bottle and nipple type combined with general feeding and nutritional advice), and it was difficult to determine which aspect of the feeding intervention might have accounted for the improvement. Analytic epidemiological studies are required to address these intervention questions if they remain relevant subsequent to descriptive epidemiological work.

Some methodological weakness exists in this article. Specifically, the exclusion of non-English literature and lack of a targeted attempt to locate unpublished work may have increased the risk of publication bias. However, the results indicate that many feeding interventions exist for infants with cleft conditions, and those interventions described by Richard (1994), Brine et al. (1994), Shaw et al. (1999), Pandya and Boorman (2001), and Turner et al. (2001) should be regarded as best practice at this time. As previously noted, these interventions include assisted feeding using a compressible bottle, feeding instruction and support, and nutrition monitoring.

It is important that clinicians underpin management practices with proven theory. This is necessary not only to facilitate the best patient outcomes possible but also to appropriately

allocate resources rather than wasting them on less effective interventions (Bannigan, 1997). To this end, it is imperative that descriptive epidemiological research be undertaken to elucidate the feeding problems experienced by infants with cleft palate. Only then should analytical epidemiological studies proceed, that is, the necessary population-based research to inform clinicians and patients about the integrity of intervention techniques and modified equipment.

There is precedent for evidence-based intervention in other clinical populations where feeding problems predominate. An example of this is the preterm population where descriptive studies have yielded rich information on the oral motor function (Lau and Schanler, 1996), sucking performance (Medoff-Cooper et al., 1993; Lau et al., 2000; Gewolb et al., 2001), and oropharyngeal characteristics of subjects (Newman et al., 2001). A number of randomized controlled trials and systematic reviews also exist, examining particular intervention techniques. Examples of these include the investigation by Howard et al. (1999) of the effects of cup and bottle feeding on the physiologic stability of newborns and the systematic review by Pinelli et al. (2002) of nonnutritive sucking as an intervention for neonates.

When researchers interested in cleft palate evaluate feeding interventions with appropriate methodological rigor, the findings may confidently be used to inform clinical practice. Ideally, feeding interventions should reduce stress experienced by the family and infant, promote growth and development, and facilitate a normal feeding pattern.

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