Karin Cadwell, PhD, FAAN, RN, IBCLC Cynthia Turner-Maffei, MA, IBCLC Anna Blair, PhD, CLC Kajsa Brimdyr, PhD Zoë Maja McInerney, MA, CLC

KARIN CADWELL, CINDY TURNER-MAFFEI, ANNA BLAIR, and ZOË MAJA McINERNEY are members of the faculty of the Healthy Children Project at The Center for Breastfeeding in East Sandwich, Massachusetts. At the time of the study, KAJSA BRIMDYR was a member of the faculty of Blekinge Institute of Technology, Department of Business Administration and Computer Science in Ronneby, Sweden. She has since joined the Healthy Children Project faculty.

#### Abstract

Health-promotion goals include increasing the duration of breastfeeding because of its irrefutable advantages to the mother and baby, society, and the environment. However, many mothers experience painful, sore nipples during breastfeeding and stop nursing before they intended (Livingstone & Stringer, 1999). The experimental trial described in this paper randomized 94 breastfeeding women with sore nipples into three treatment groups. Midwives practicing in hospitals in Latvia assessed the participants' breastfeeding practices, then gave the mothers individualized education and corrective interventions using a guided documentation form, the Lactation Assessment Tool (LAT<sup>TM</sup>). In addition, two groups were instructed to use commercial products on their breasts and nipples: breast shells and lanolin cream for one group, and glycerin gel therapy for the other. Nipple pain during breastfeeding was rated by the mothers on a 5-point verbal descriptor scale at each visit, and pain at the start of treatment was compared to pain at the last visit. Analysis of variance (using Fisher's Exact Test) determined that no significant differences existed between the groups: F(2, 86) = 1.34, p > .05. Almost all of the mothers experienced nipple healing, as assessed by the midwife. Mothers in the glycerin gel group were more satisfied with their treatment method, but this finding was not statistically significant. The results of this study indicate that effective care and perinatal education for nursing mothers with sore nipples should include assessment of breastfeeding positioning and latch-on, as well as education and corrective interventions using a guidance tool, whether or not commercial preparations are used.

Journal of Perinatal Education, 13(1), 29–35; breastfeeding, sore nipples, treatment.

National and international health-promotion strategies include increasing breastfeeding initiation and duration rates, as well as eliminating disparities in the care of women and infants in relation to breastfeeding (Cadwell, 1999; U.S. Department of Health and Human Services, 2000). Policy makers, researchers, and professional organizations have pointed to the irrefutable benefits of breastfeeding for babies, mothers, society, and the environment (e.g., decreased health care costs, reduced acute and chronic illnesses, and mother-infant bonding). Unfortunately, as many as 96% of mothers (Graffy, 1992; Ziemer, Paone, Schupay, & Cole, 1990) experience sore, painful nipples during breastfeeding and stop nursing before they intended (Livingstone & Stringer, 1999).

Commercially available preparations such as lanolin-based nipple ointments and other creams are commonly used to reduce pain and promote the healing of sore nipples; however, these treatments have conflicting evidence of effectiveness. Some studies show no benefit to the application of lanolin (Centuori et al., 1999; Nicholson, 1986). Other studies report that modified lanolin or modified lanolin used with breast shells may be efficacious (Brent, Rudy, S., Redd, Rudy, T., & Roth, 1998; Spangler & Hildebrandt, 1993).

Gel dressings have been used successfully to treat non-nipple wounds, including wounds with diagnosed infections (Anderson & Wilkening, 1996, 1997; Demoor, Deffendahl, Whitaker, & Motta, 1994; Halvorson & Mertz, 1996; Morse, 1996). Gel dressings have also been suggested for use on the nipples of breastfeeding mothers presenting with nipple trauma (Cable, Stewart, & Davis, 1997).

One study of sore-nipple treatments examined the safety and efficacy of a gel dressing in combination with massaging expressed breast milk onto the nipple and compared this treatment to the use of modified lanolin and breast shells (Brent et al., 1998). The researchers found that the use of lanolin and breast shells resulted in greater improvement than the use of the dressings plus massaged breast milk, although both groups showed improvement. In the study by Brent and colleagues (1998), mothers were given breastfeeding assessments and management instruction, but no comparison group received assessment and instruction alone.

A strong correlation has been observed between the onset of sore nipples and the positioning and latch-on

of the nursing baby at the breast (Clark, 1985; Gunther, 1945; Hewat & Ellis, 1987; Righard, 1998; Woolridge, 1986). Optimizing the position and latch-on has been recommended in the professional literature for many years, most notably by Gunther in 1945. However, until the study described in this paper, a comprehensive guidance and documentation tool with corrective interventions has not been examined alone and in combination with these common commercial treatments for sore nipples.

A strong correlation has been observed between the onset of sore nipples and the positioning and latch-on of the nursing baby at the breast.

The purpose of this study was to use three different treatment protocols to compare healing, change in nipple pain, and mothers' satisfaction with treatment for sore nipples. In order to examine the effect of changing the breastfeeding position and latch-on using assessment and education and corrective interventions via a guidance document (the Lactation Assessment Tool, or LAT™, of the Healthy Children Project in East Sandwich, Massachusetts), this intervention was offered alone to one group and in combination with two other treatment protocols: lanolin plus shells for one group, and a gel dressing for another group. Earlier studies had reported that both of these treatments using commercial products were effective in reducing sore nipples.

## Method

## **Participants**

Ninety-four participating breastfeeding mothers who could speak and read the Latvian language were sequentially recruited from hospital-based midwifery practices in Latvia from May through October 2000. All institutional review boards approved the study protocol following international human studies procedures. The mothers were randomly assigned to one of three groups. Only healthy, breastfeeding women who had experienced uncomplicated deliveries of healthy term babies in the previous 10 days and who presented

to the midwife with the complaint of sore nipples (defined as persistently painful, cracked, bleeding, or crusted nipples) were eligible. Mothers who had symptoms of a breast infection or inflammation (mastitis), breast abscess or fungal infection, or other persistent pain-related conditions were excluded. Mastitis, breast abscess, and fungal infections were defined according to R. A. Lawrence and R. M. Lawrence (1999).

Of 95 sequentially presenting mothers, one refused to participate in the study, none dropped out, and none were excluded from the study because of confounding breast problems or because of the prior diagnosis of a painful chronic disease. All the mothers were exclusively breastfeeding throughout the study. All mothers were white and fluent in the Latvian language. All materials used in the study were back-translated into Latvian.

Group 1 consisted of 31 mothers randomized into the lanolin/shells, assessment, and education and corrective interventions group. Group 2 consisted of 33 mothers randomized into the glycerin gel, assessment, and education and corrective interventions group. Group 3 consisted of 30 mothers randomized into the assessment and education and corrective interventions group. Sample size, as determined by power analysis, was deemed to be 90 total participants. Each group consisted of 30 participants in order for researchers to be able to detect a medium- to large-effect size with 80% power and .05, using either a one-way analysis or a Fisher's Exact Test to compare proportions. Other characteristics of the sample are described in Table 1. No significant differences existed between the groups in the mean pain rating prior to the intervention: F(2, 89) = 2.24, p > .05.

#### Procedures

Twelve hospital-based midwives who were members of the Association of Midwives of Latvia cared for the mothers who participated in the study. The midwives received training related to the research protocol, skilled assessment of a breastfeeding session, use of research tools, education for breastfeeding management, and appropriate corrective interventions for latch-on and positioning problems. The assessment techniques and corrective interventions used in this study are described in detail elsewhere (Cadwell, Turner-Maffei,

Table 1 Characteristics of Sample Groups\*

| Characteristic          | Group 1 % (n) | Group 2 % (n) | Group 3 % (n) |
|-------------------------|---------------|---------------|---------------|
| Cesarean Birth          | 16 (5)        | 24 (8)        | 13 (4)        |
| Primip                  | 59 (18)       | 55 (18)       | 58 (17)       |
| Previously Breastfed    | 40 (12)       | 33 (11)       | 29 (9)        |
| Nipple Redness          | 52 (16)       | 55 (18)       | 40 (12)       |
| Visible Nipple Fissures | 94 (29)       | 97 (32)       | 100 (30)      |

<sup>\*</sup> *Note:* Group 1, n = 31; Group 2, n = 33; Group 3, n = 30.

O'Connor, & Blair, 2002) and summarized in Table 2. Post-tests—using video, live models, and photographs —assured that the midwives correctly, consistently, and accurately used the assessment and documentation tools. Although other tools have been developed to "score" early breastfeeding sessions with the goal of identifying mother-baby couples who need close follow-up (Riordan, 1998), no comprehensive documentation guidance tool is available comparable to the one that was developed for this study. The LAT<sup>TM</sup> incorporates assessment parameters mentioned in the breastfeeding literature as well as suggested corrective interventions designed to optimize latch-on and positioning. Inter-user consistency was established with the midwives prior to the study through intensive training on how to recognize and evaluate a baby's latch. The training and testing of the midwives was repeated until 100% agreement was reached on a section of the LAT<sup>TM</sup>. Other evidence for validity and reliability has not been established for this documentation and guidance tool.

After determining eligibility, informed written consent was obtained from the participants. Each mother was then randomized into one of the three groups, according to whichever prepackaged instruction and care kit was next in the queue. The midwife then assessed the condition of the breast and nipple using the LAT<sup>TM</sup>, photographed the nipple area before and after a breastfeeding, observed and documented the breastfeeding, and offered corrective intervention regarding positioning, latch-on, and suckling. The mother was asked to evaluate the discomfort of suckling by scoring her own nipple pain. She did this at each visit, using a 5-point verbal descriptor scale modified from Hill and Humenick (1993). Earlier studies of nipple pain have

**Table 2** Latch-on and Positioning Parameters (LAT™) with Corrective Interventions

#### LAT<sup>TM</sup> Assessment Parameters Corrective Intervention

- Latching process (root, gape, seal, suck)
- Angle of mouth opening at breast
- Lip flange
- Baby's head position
- Baby's cheek line
- Baby's height at breast
- Baby's body rotation
- Baby's body relationship
- Nursing dynamic

- Assure baby begins with rooting, then gapes, seals, and sucks • 160° minimum mouth angle
- Top and bottom lip not turned in
- Nose and chin close to breast
- Smooth cheek line
- Nose opposite nipple to start
- Baby's chest to mother's breast
- Baby horizontal across mother's chest
- Bursts of suck (swallow 2:1 or 1:1) and breast moves rhythmically with suck

used scales of this type because verbal descriptor scales are easy to use and thought to produce reliable data (McGuire, 1984). Test-retest reliability on a similar scale was established by Ziemer and colleagues (1990) and found to be r = .88. The scale used in this study ranged from 1 to 5 with the following anchor-point descriptors:

- 1) no pain, just the tugging feeling of the baby moving my breast;
- 2) minor discomfort;
- 3) moderate pain;
- 4) severe pain; and
- 5) the worst pain I can imagine.

The mothers who were randomized into Group 1 and Group 2 also received commercial sore-nipple treatment products and were instructed to use them on their breasts and nipples between visits. Mothers in Group 1 were given instruction to allow the nipples to air dry after each nursing, wash their hands, and then apply Lansinoh® lanolin cream (Lansinoh Laboratories, Inc., Oak Ridge, TN, USA) and wear breast shells (Hollister, Inc., Libertyville, IL, USA) until the next nursing. Mothers in Group 2 received instructions to wash their hands and apply Soothies<sup>TM</sup> (Puronyx, Inc., Vista, CA, USA) glycerin gel therapy, according to the manufacturer's instructions. Because concern has been raised about infant exposure to propylene glycol (Cable, 2001), this glycerin gel dressing (without propylene glycol) was selected.

At each of the follow-up visits, the midwife ranked the symptoms and signs of wound healing: 1) better/ resolved, if the pain was absent and skin surface was intact; 2) the same or no obvious change, if the pain persisted or the skin surface was still broken and no signs of wound healing were evident; and 3) worse, if the pain persisted and the skin surface was broken with purulent exudates and signs of extension of lesions. These criteria were modified from Livingstone and Stringer (1999). Inter-user consistency was established prior to the study with the participating midwives.

All participants could be seen for a maximum of three additional visits within 10 days of the initial visit or until resolution of symptoms occurred, whichever came first. Mothers were instructed to contact the midwife immediately if their sore-nipple condition worsened.

Responses to a 4-point questionnaire designed to measure the mother's satisfaction with the prescribed treatment were collected at the last visit. Mothers were asked to rate themselves as very satisfied or somewhat satisfied with the treatment, or as somewhat dissatisfied or very dissatisfied with the treatment.

## Results and Discussion

Analysis of the change in pain was tested using a t-test for differences in the mean pain ratings between the first and last visits. Change in the amount of pain as rated by the participants was tested using an analysis of variance (ANOVA) to test for differences in average pain ratings at the final visit to the midwife.

We found that almost all participants had ratings that indicated less nipple pain after the intervention. The average pain rating at the first visit was 3.42. At the last visit, the average pain rating was 1.69 (t(174) = 12.79, p < .001). Nipple condition as rated by the midwives also improved. At the final visit, 80 (90%) of the participants' nipple conditions were rated by midwives as *better/resolved*, and 3 (3%) were rated as *worse* ( $\chi^2 = 199.94$  (df = 3, p < .001). The remainder were rated as *no change*.

Almost all study participants had ratings that indicated less nipple pain after the intervention.

In addition, the pain rating of all three groups was reduced. The average pain rating at the final visit to the midwife was  $1.48 \ (SD=.72)$  in the lanolin/shells group (Group 1),  $1.90 \ (SD=1.29)$  in the glycerin gel group (Group 2), and  $1.68 \ (SD=.86)$  in Group 3, which received no commercial product. Analysis of variance determined no significant differences existed between these groups: F(2, 86) = 1.34, p > .05.

The nipple condition of all three groups as rated by the midwives was improved. There were 28 (93.3%) participants in the lanolin/shells group, 27 (93.1%) in the glycerin gel group, and 25 (89.3%) in the nocommercial-product group who were rated as having improved nipple condition. A chi-square analysis determined that no significant differences existed in the number of mothers in each of these groups who were rated by the midwives as having improved nipple condition  $\chi^2(2, n=80) = .177, p > .05$ ).

Three mothers (9%) in Group 1 (lanolin, shells, and corrective intervention) and three mothers (9%) in Group 3 (corrective intervention alone) were dissatisfied with their treatment. No mothers (0%) in Group 2 (glycerin gel and corrective intervention) were dissatisfied with their treatment. The finding that a higher proportion of mothers in the glycerin gel treatment group were satisfied with their treatment was not statistically significant.

Each of the three methods examined was found to be effective for the treatment of sore nipples in breast-feeding mothers. Because of ethical concerns, the researchers in this study chose not to include a group of mothers with sore nipples to whom no assessment and corrective interventions were offered. The mothers in Group 3 (who received only comprehensive assessment of breastfeeding with education and corrective interventions to improve positioning and latch-on) were found to have their nipples healed and their pain de-

creased to the same extent as the mothers in the groups that used the commercial preparations.

Assessment and education and corrective interventions were the treatments common to all three groups. Because the groups had similar results, it is tempting to speculate that assessment and education and corrective interventions guided by the LAT<sup>TM</sup> are effective therapies. However, the caretaking that the mothers received from the midwives (also common to all groups) may have been the therapeutic intervention and the basis of the results. What can be concluded is that almost all mothers with sore nipples with fissures respond to treatment interventions with healing and pain reduction, and that mothers should be encouraged to seek help from knowledgeable and skilled resources.

Although not statistically significant, the trend in this study was toward the mother's being more satisfied with the glycerin gel therapy. A larger sample size in a future study may clarify the relationship between mothers' satisfaction and this intervention. Future research might also determine the aspects of the treatment that mothers found to be satisfactory and unsatisfactory. These results should also be examined in another population.

This study examined only mothers who already had sore nipples, and the results cannot be applied to the use of modalities for the prevention of sore nipples in nursing mothers. Future studies must examine the question, "If assessment and education and corrective interventions are provided early in the postpartum period, can the percentage of breastfeeding mothers who stop breastfeeding be reduced?"

More research is also needed to determine which of the multiple treatment strategies in each group contributed to healing and reduction of pain. The study was preceded by training in order to assure inter-user comfort and accuracy with the tools, especially the guidance documentation tool, the LAT<sup>TM</sup>. Whether or not the LAT<sup>TM</sup> can be successfully used without training is unknown, but should be examined.

More research is needed to determine which of the multiple treatment strategies in each group contributed to healing and reduction of pain.

Breastfeeding is an acknowledged strategy for optimizing child health outcomes and should be supported. Sore nipples are a commonly occurring problem in newly delivered, breastfeeding mothers and are linked to untimely weaning. Breastfeeding mothers can be supported through assessment and education and corrective interventions for the treatment of sore nipples, in addition to the use of commercial therapies.

## Authors' Note

The authors gratefully acknowledge the contributions of the participating members of the Association of Midwives of Latvia: Iveta Baumgarte, Aiva Bērzina, Agita Ciemina, Dace Gailuma, Signe Irša, Antra Kupriša (President), Aija Mikova, Renate Putene, Ingrida Savicka (Past President), Dina Velde, and Iveta Žilvinska. We also extend grateful acknowledgement to Nelda Kaleja for her translations.

Funding support for this study was received from The Healthy Children Project, The American Breastfeeding Institute, Health Education Associates, Inc., and Maturna, Inc.

## References

- Anderson, R., & Wilkening, C. (1996, September). Seconddegree flash burn clinical case study demonstrating positive patient outcomes using a hydrogel sheet dressing. Paper presented at the Clinical Symposium on Wound Management, Reno, NV.
- Anderson, R., & Wilkening, C. (1997, April). *Impressive healing and scar revision for massive full thickness trauma to soft tissue using combined treatment modalities.* Paper presented at the Symposium on Advanced Wound Care, New Orleans, LA.
- Brent, N., Rudy, S., Redd, B., Rudy, T., & Roth, L. (1998).
  Sore nipples in breastfeeding women: A clinical trial of wound dressings versus conventional care. Archives of Pediatrics and Adolescent Medicine, 152, 1077–1082.
- Cable, B. (2001). Hydrogel dressings [Letter to the Editor]. *Journal of Human Location*, 17(4), 295.
- Cable, B., Stewart, M., & Davis, J. (1997). Nipple wound care: A new approach to an old problem. *Journal of Human Lactation*, 13, 313–318.
- Cadwell, K. (1999). Reaching the goals of "Healthy People 2000" regarding breastfeeding. *Clinical Perinatology*, 26(2), 527–537.
- Cadwell, K., Turner-Maffei, C., O'Connor, B., & Blair, A. (2002). Maternal and infant assessment for breastfeeding

- and human lactation: A guide for the practitioner. Sudbury, MA: Jones and Bartlett.
- Centuori, S., Burmaz, T., Ronfani, L., Fragiacomo, M., Quintero, S., Pavan, C., Davanzo, R., & Cattaneo, A. (1999). Nipple care, sore nipples and breastfeeding: A randomized control trial. *Journal of Human Lactation*, 15(2), 125–130.
- Clark, N. (1985). The study of four methods of nipple care offered to postpartum mothers. *New Zealand Nursing Journal*, 78(6), 16–18.
- Demoor, M. A., Deffendahl, C., Whitaker, K., & Motta, G. (1994, October). Clinical evaluation of an absorbent hydrogel dressing: Solo and combination wound management approaches. Paper presented at the Clinical Symposium on Pressure Ulcer and Wound Management, Nashville, TN.
- Graffy, J. P. (1992). Mother's attitudes to and experience of breastfeeding: A primary care study. *British Journal of General Practice*, 42, 61–64.
- Gunther, M. (1945). Sore nipples causes and prevention. *Lancet*, 2, 590–593.
- Halvorson, M., & Mertz, J. (1996, June). *The use of hydrogel dressing in multiple settings*. Paper presented at the Wound Ostomy Continence Nurses Conference, Seattle, WA.
- Hewat, R. J., & Ellis, D. J. (1987). A comparison of the effectiveness of two methods of nipple care. *Birth*, 14(1), 41–45.
- Hill, P. D., & Humenick, S. S. (1993). Nipple pain during breastfeeding: The first two weeks and beyond. *Journal of Perinatal Education*, 2(2), 21–34.
- Lawrence, R. A., & Lawrence, R. M. (1999). *Breastfeeding: A guide for the medical profession* (5th ed.). St. Louis, MO: Mosby.
- Livingstone, V., & Stringer, J. S. (1999). The treatment of Staphylococcus aureus infected sore nipples: A randomized comparative study. *Journal of Human Lactation*, 15(3), 241–246.
- McGuire, D. B. (1984). The measurement of clinical pain. *Nursing Research*, 33, 152–156.
- Morse, K. (1996, September). Elasto-Gel: A product with unique properties especially suited for the treatment of infants and children with special needs. Paper presented at the Clinical Symposium on Wound Management, Reno, NV.
- Nicholson, W. L. (1986). Cracked nipples in breastfeeding mothers: A randomized trial of three methods of management. *Breastfeeding Review*, 9, 25–27.
- Righard, L. (1998). Are breastfeeding problems related to incorrect breastfeeding technique and the use of pacifiers and bottles? *Birth*, 25(1), 40–41.
- Riordan, J. (1998). Predicting breastfeeding problems. *AWHONN Lifelines*, 2(6), 31–33.

- Spangler, A., & Hildebrandt, E. (1993). The effect of modified lanolin on nipple pain/damage during the first ten days of breastfeeding. *International Journal of Childbirth Education*, 8, 15–20.
- U.S. Department of Health and Human Services, Office on Women's Health. (2000). HHS blueprint for action on breastfeeding. Washington, DC: Author.
- Woolridge, M. W. (1986). The aetiology of sore nipples. *Midwifery*, 2, 172–176.
- Ziemer, M. M., Paone, J. P., Schupay, J., & Cole, E. (1990). Methods to prevent and manage nipple pain in breastfeeding women. Western Journal of Nursing Research, 12(6), 732–744.