

Nipple Shields: A Review of the Literature

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Abstract

Nipple shields have become commonplace in the United States for a wide range of breastfeeding problems. This article is a summary of the current literature describing the evidence for nipple shield use. The authors reviewed all available articles on nipple shields and selected 13 studies for inclusion. The studies were organized into three categories: physiologic responses, premature infants, and mothers' experiences. This review concludes that current published research does not provide evidence for safety or effectiveness of contemporary nipple shield use.

Introduction

ANIPPLE SHIELD (NS) IS A DEVICE that a mother places over her nipple-areolar surface prior to nursing, most often to help the baby latch onto the breast. NS use has been recorded in history for at least 500 years. Historically, NSs were fashioned from many materials such as silver, wood, lead, pewter, and animal skins. By the second half of the 20th century, NSs were routinely made from rubber, followed by thin latex and silicone in the last 3 decades. Health professionals have understood that NSs can blunt nipple stimulation, thereby decreasing maternal hormonal responses to breastfeeding,¹⁻³ but that concern waned with the development of thin silicone shields. A series of articles in a 1996 *Journal of Human Lactation* issue seemed to spearhead a new cautious-yet-positive attitude towards NSs.⁴ Case reports, chart reviews, and a survey illustrated how NSs may be used to encourage and keep infants at the breast as long as their use is well supervised.^{1,5-9} Despite the paucity of research in this area, NSs have become very popular among breastfeeding women. NSs are often introduced to new mothers in the hospital for flat nipples or failure of the infant to latch within the first 2 days postpartum. They are also used for a variety of problems such as sore nipples, prematurity, oversupply, and transitioning infants from the bottle to the breast. Mothers can easily purchase an NS in a retail store in many communities in the United States, obviating the need to seek professional supervision for safe NS use.¹⁰ In this article, we review the empiric evidence regarding the use of NSs.

Methods

Study selection

Two reviewers independently reviewed all abstracts and titles for inclusion. Studies were included in this review if

authors reported original research investigating the use of an NS for breastfeeding. Case studies ($n=5$) and editorials ($n=7$) were read but not analyzed for this review. Research concerning NSs for uses other than breastfeeding such as for purposes of measurement of milk flow, reconstructive surgery, or cancer treatment was not included.

Search strategy

The authors performed a literature search in PubMed, CINAHL Plus, MEDLINE, and PsychINFO for articles published between 1980 and 2009 and written in English. Search terms included "nipple shield" and "breastfeeding." Secondary references were scanned, and relevant studies were obtained. The initial search yielded 97 articles, which, after elimination of duplicate results, unrelated research, case studies, and editorials, resulted in 13 articles investigating NS use for breastfeeding. Both reviewers independently read these articles and divided the studies into three categories including (a) physiological responses to NS use ($n=3$), (b) NS use in the preterm infant population ($n=2$), and (c) mothers' experiences using an NS ($n=8$).

Results

Physiological responses

Three studies examined the physiologic response during breastfeeding with an NS. Woolridge et al.³ compared two types of NSs ("Mexican hat" [$n=16$] and thin latex [$n=18$]) with mother-infant dyads at 5-8 days postpartum. Results showed that the use of the "Mexican hat" severely impaired milk transfer with a mean volume of 19.5 g compared to a mean volume of 46.4 g without an NS. The thin latex shield also reduced milk transfer to a mean of 29.9 g, but it was not significantly different than milk transfer of 38.4 g in the

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absence of an NS. Compared to breastfeeding with no NS, video-recorded infant suckling patterns were also significantly altered when a "Mexican hat" was in place, whereas little difference (e.g., sucking frequency or pauses) was observed when mothers used the latex NS. The relationship between this author and the manufacturer of a new thin latex NS is unclear as this new product was tested in the hospital where the study was done. This nonrandomized study is limited by its small sample size and possible heterogeneity between the two groups of lactating women and their infants since the author does not describe certain characteristics of the subjects such as abundance of milk supply, age, and parity for the mother or birth weight and gestational age of the infant.

Amatayakul et al.¹¹ described prolactin and cortisol levels in three groups of breastfeeding women as well as the infant suckling time and milk transfer with and without a thin latex NS at 1 week postpartum. Group 1 mothers ($n = 16$) breastfed without an NS, group 2 mothers ($n = 16$) breastfed with the NS, and group 3 mothers ($n = 18$) served as a control by applying an NS and not breastfeeding. Based on 10 blood samples collected before, during, and after the feeding, no significant differences in prolactin and cortisol levels were found between groups 1 and 2. The most important finding was that of significantly reduced milk transfer to infants when breastfeeding with the NS. The median milk transfer to infants in group 1 was 47 g compared to group 2 with a transfer of 27 g. The authors attributed this difference to the likely inhibition of oxytocin release in mothers using the NS in group 2. Infant suckling time was not significantly different between groups 1 and 2 (range, 8–16 minutes for both). The authors concluded that a thin latex NS does not impact hormone release during breastfeeding. Unfortunately, this well-designed study had a small sample size with few details characterizing the similarities or differences among the three groups. Although there were no significant hormone differences between groups 1 and 2, the hormones levels were only measured on day 7 postpartum and cannot be generalized to a breastfeeding mother's hormone responses over time when using an NS.

Auerbach¹² also investigated milk transfer with an NS. Twenty-five mothers tested two NS types ("old"-Cannon Babysafe [Glemsford, UK] with four small holes and "new"-altered design with a single hole) while serving as their own controls during two pumping sessions (pumping the right or left breast per session). The study enrolled mothers 6 weeks to 14 months postpartum who were accustomed to using a breast pump. The subjects expressed significantly more breastmilk during pumping sessions with no NS in place compared to pumping with either type of NS. Mothers pumped four times more milk without the new altered design of NS and six times more milk without the old NS. The author cautioned clinicians against using the NS as a first intervention and described that the NS as a barrier over the mother's nipple interferes with infant suckling patterns and normal nipple stimulation such that it likely poses a risk to establishing and sustaining an adequate milk supply. This interesting study supports the other two studies above that found a decrease in milk transfer with the NS. Lactating women generally do not use a breast pump with a NS in place, so any generalizations of this study's findings would be limited if applied in clinical practice.

Premature infants

Two published studies investigated the use of NSs with premature infants. Clum and Primono¹³ in 1996 performed a chart review to describe how NS use in premature infants affected milk transfer and the effect of the NS on breastfeeding outcome at hospital discharge. In the facility where this study occurred, health professionals typically used NSs for premature infants who demonstrated difficulty latching without the shield for an average of 5 days. They did not use an NS if the baby did not transfer milk well with an NS. Thirty charts were reviewed, and 15 of these charts had complete data with infants ranging from 25 to 36 weeks gestation. The average age of first NS use was 34.87 weeks. Using milk transfer data from the first episode of NS use, only two of 15 infants transferred 100% or more of the prescribed amount of intake. Nine of the 15 took at least 50% of the prescribed amount. At the time of discharge, 14 of the 15 infants were breastfeeding to some degree, and three of the 15 still used the NS to some extent. The authors reported that NS use facilitated the transition from gavage to breastfeeding in this group of infants. This study did not explore maternal responses to NS use but overall indicated that the mothers seemed positive about infant feeding, more confident, and less frustrated with breastfeeding when using the NS. The authors of this retrospective descriptive study were careful to conclude that their findings could not be generalized to all premature infants, and they provided no long-term data on breastfeeding outcome such as infant growth and maternal milk supply.

The second study, by Meier et al.¹⁴ in 2000, was a retrospective analysis of data for 34 premature infants to determine the effect of NSs on milk transfer and duration of breastfeeding. More than 90% of the infants in this study used NSs because of ineffective attachment to the breast or falling asleep within minutes of latching. The volume of milk transferred to the baby while using an NS was compared to the milk transfer volume during the feeding without an NS. All 34 infants consumed more milk with the shield than without, with a mean of 14.4 mL difference. The mean transfer of milk without a shield was 3.9 ± 7.0 mL, indicating poor milk transfer, compared to 18.4 ± 13.2 mL with the shield. Mean duration of breastfeeding for the 34 infants was 169 days, and mean duration of NS use was 33 days. There was no association between duration of NS use and duration of breastfeeding, so the authors concluded that NS use does not impact duration of breastfeeding. The authors suggested that NSs are not indicated for infants who breastfeed effectively, but that they are very effective for use in premature infants who do not transfer milk well without a shield. The authors also indirectly implied that women do not need to pump after feeding like women who supplement their infants with a bottle or cup after feeding. This study was sponsored by a corporation that manufactures NSs.

The authors describe the duration of breastfeeding, but because there is no definition of breastfeeding or data on maternal milk supply, it is hard to determine this population's success in breastfeeding. Comparing duration of NS use with duration of breastfeeding can be misleading when breastfeeding is not defined. Some infants may continue to nurse once a day with an NS, and this could be considered a longer duration of breastfeeding. It would be ideal to compare the

duration of exclusive breastfeeding in premature infants using an NS with a similar population not using an NS.

Mothers' experiences

Eight studies reported mothers' experiences with NS use. Maternal support for lactation was available and utilized by most mothers in all of these studies. Four study designs were prospective, and four were retrospective.

Chertok et al.¹⁵ conducted a prospective two-part pilot study using a telephone survey to evaluate maternal satisfaction with NS use and a within-subject design to examine maternal hormone levels during breastfeeding and infant weights for breastfeeding with and without the NS. Part 1 surveyed 32 healthy mothers who delivered term healthy infants and had used or were still using an NS. Survey data were collected on average at 13 days postpartum. Reasons for NS use included infant latch problems ($n = 16$), nipple pain and anatomical problems ($n = 12$), and a combination of maternal and infant problems ($n = 4$). Although 12 mothers viewed NS use as a complication for breastfeeding, there was no correlation between this perception and discontinuation of NS use. Mothers described value in using an NS and credited its use with preventing early discontinuation of breastfeeding.

Part 2 to this study involved five mothers who had completed the survey. Three blood samples (immediately before and at 10 minutes and 20 minutes after breastfeeding commenced) were collected for analysis of prolactin and cortisol levels during two feeding sessions between 2 and 4 weeks postpartum. Mothers used an ultrathin NS during session 1 and breastfed without the NS during session 2. There were no significant differences in the observed trends of either prolactin or cortisol levels comparing the two sessions. Milk transfer between the two groups did not differ significantly, with an average intake of 65.3 g. The authors viewed an NS as an important intervention that did not impact milk transfer and could prevent early discontinuation of breastfeeding among mothers who experience substantial breastfeeding difficulties.

The author's conclusion from the Part 1 data was that NSs may prevent premature breastfeeding termination. However, mothers began exclusive or near-exclusive feeding, and approximately 44% of mothers went on to use formula supplementation. Nearly a quarter of the mothers indicated their efforts to increase their milk supply. The open-ended questions about maternal satisfaction were not shared in the article; therefore it is unknown how these challenges with supplementation and milk supply impacted maternal attitude of NS use.

Part 2 was too small of a sample size with too few feedings studied, such that these results cannot significantly impact recommendations for the effect of NS use on duration of breastfeeding, maternal milk supply, and infant growth.

Another telephone survey conducted by Chertok¹⁶ and published in 2009 evaluated the effect of NSs on infant weight gain. Fifty-four mothers with term infants who had experience nursing with and without an NS were enrolled. The mothers used an NS for a variety of reasons, including flat or inverted nipples, nipple pain, engorgement, or infant latch difficulties. The mothers were surveyed at birth and 2 weeks, 1 month, and 2 months postpartum. By 2 months postpartum 65% of the mothers had discontinued NS use, and 17% of all mothers had weaned. Infant weight gain at 2 weeks, 1 month,

and 2 months postpartum did not differ between subjects using an NS or not; however, 41% of infants were receiving formula by 2 weeks and 59% by 2 months. The author did not disclose the amount of formula given in relationship to duration of NS use or the amount of breastmilk taken by infants whose mothers were using an NS. Despite this, the author concluded that NS use is not associated with insufficient weight gain and that the practice of breast pumping and vigilant infant weighing when mothers use NSs should be reevaluated.

This study calls into question whether NS use is more likely to be associated with formula use. Although the study concluded that infant weight gain is not affected by NS use, it did not address the effect of NS use on maternal milk supply. By 2 months postpartum 17% of the mothers had weaned, and 59% were using formula, such that only 19% of mothers were still exclusively breastfeeding compared to a national 31% exclusive breastfeeding rate at 3 months in the United States in 2004.¹⁷ This would imply that NS use may be associated with insufficient lactation in the long term.

Another prospective study by Nicholson¹⁸ in 1988–1989 compared three groups of mothers before hospital discharge, <1 week postpartum, and 3 months postpartum. Mothers in groups 1 ($n = 186$) and 2 ($n = 636$) had been seen by the hospital lactation consultant before discharge, with each mother in group 1 given an NS, while mothers in group 2 were not given an NS. Group 3 ($n = 349$) was composed of a convenience sample of mothers not seen by the lactation consultant but surveyed before discharge with data collected on five separate days with corresponding follow-up 3 months later during the time of the study. Although significantly more mothers in group 2 (breastfeeding problems without a NS) discontinued breastfeeding before discharge compared to mothers in group 1 (breastfeeding problems and NS use), this difference disappeared at 3 months. Data collected at 3 months postpartum showed breastfeeding continuation rates of 55% for group 1, 63% for group 2, and 67% for group 3. Significantly fewer group 1 mothers (NS-using) were breastfeeding 3 months postpartum compared to group 3 mothers (those who were not seen by the lactation consultant before discharge). The author suggested that NS use did not interfere with breastfeeding initiation, and because no significant difference in breastfeeding duration at 3 months postpartum was found among mothers in groups 1 and 2, NS use should not be considered to negatively impact lactation.

This nonrandomized study did not provide any comparison of group characteristics, and discrepancies in sample sizes could yield inaccurate statistical results if lacking normal distribution. Provider bias regarding which mothers were given NSs could also have influenced study results. Although exclusivity, two broad diagnoses, and a listing of other possible interventions were discussed, a severity measure for the breastfeeding problems, the interventions concurrently used, and long-term effects from NS use were not described. It is also conceivable that in the context of a problematic breastfeeding experience, perceived need of an NS or diminished milk supply might contribute to a mother's decision to discontinue breastfeeding. The results of this study cannot presume causality, thus preventing the researcher from concluding that NSs have no impact on lactation.

In the final prospective study, Pincombe et al.¹⁹ examined the effect of Baby Friendly Hospital Initiative (BFHI) practices

on duration of breastfeeding, defined as any feeding, in 2003 among 317 first-time mothers. BFHI-Step 9 (giving no artificial teats or pacifiers to breastfeeding babies) was investigated during telephone interviews using three separate questions relating to NS use in addition to other breastfeeding-related questions at 1 week, 6 weeks, 3 months, and 6 months postpartum. Although NS use was not tested as a single variable, a higher rate of weaning was found among mothers who used artificial nipples, including NSs, compared to mothers who offered the breast exclusively. Breastfeeding duration was also shorter for mothers who did not experience all of the basic BFHI practices (e.g., using no artificial nipples including an NS, feeding > 1 hour of birth, receiving feeding assistance, giving only breastmilk to the infant, and rooming-in) compared to those mothers who experienced all of these practices. Despite the significant findings, the authors cautioned against interpreting a causal relationship between the use of artificial nipples and higher rates of weaning as mothers who used artificial nipples may have already encountered feeding issues.

This study has significant limitations in evaluating the effects of NS use. Although the overall findings on hospital practices and artificial nipple use can guide future research, interviewing mothers specifically about past and present breastfeeding and NS use is necessary to assert any useful conclusions on feeding outcomes.

Four retrospective studies included two chart reviews and two studies using telephone surveys with mothers who had used NSs. In a private practice setting, Bodley and Powers⁹ conducted a chart review among 10 women who were given a thin silicone NS 1–18 days postpartum for sore nipples and latch difficulties. Duration of NS use ranged from ≤6 weeks to 3.5 months. Nine of the 10 mothers reported positive experiences after transitioning their infants from NS to breast with no negative impact on weight gain, while the 10th mother switched to bottle feeding as infant weight gain may have been compromised. Some mothers expressed their milk sporadically, and none of the mothers supplemented during NS use.

The sample size of mothers from which these case studies were drawn was not reported, and it is likely that this chart review may be biased towards a very small subset of mothers. Including the characteristics of the larger sample would be useful in determining the significance of these cases. This study indicates that exclusive breastfeeding for most of these mothers, identified at risk for weaning without NS use, was possible for up to 16 weeks. While it is emphasized that the early phase of exclusive breastfeeding with an NS is possible to maintain, the lack of data on duration and experience of breastfeeding beyond this time point limit their claim that mothers can provide adequate breastmilk for their infants in the long term.

Another chart review by Wilson-Clay⁸ identified 32 mothers out of 248 women cared for at a private lactation clinic who had been given a thin silicone NS. The thin silicone NS was used as an intervention to correct infant breast refusal, difficulties with latch, or sore nipples at 2–47 days post-birth. The majority of mothers were primigravidas (81%) and bottle feeding (75%) upon receiving the NS. Despite extensive lactation support, 38% of these mothers weaned at <6 weeks, 51% breastfed beyond 6 weeks, and 6% fed human milk by bottle. For this group of mothers, duration of breastfeeding ranged from 1 week to 17 months with a mean of 4 months.

Fifteen mothers presented with flat/inverted nipples and were significantly more likely to discontinue breastfeeding <6 weeks. Although this finding was statistically significant, the author discussed a number of other factors aside from nipple protractility that may have contributed to discontinuation of breastfeeding. The author noted that even when breastfeeding improved clinically, fatigue, depression, anxiety, and other psychosocial factors appeared to cause mothers to modify feeding plans. Considering the varied and complex maternal physiological and emotional factors, the author suggested that NS use may lead to positive outcomes when the breastfeeding dyad is on a sure path to weaning. This chart review demonstrates that a seasoned lactation consultant can have some success with NS use in cases of infant breast refusal. The author is careful to point out how infant growth needs to be closely monitored and that mothers who use NSs often need psychosocial support.

In another retrospective study, Brigham⁶ carried out informal telephone surveys at 7–19 months post-birth with 51 of 126 mothers who had used an NS either in the hospital or at the outpatient breastfeeding clinic. This study included not only healthy, term infants, but also infants born prematurely or diagnosed with Down syndrome. An NS was introduced on average at 6 days postpartum with a range of <24 hours of birth to 42 days postpartum. Reasons for NS use primarily pertained to infant latch problems. The average length of NS use was 27 days with a range of 2 days to 4.5 months. Eight mothers continued breastfeeding their 8–15-month-olds, while 43 mothers reported breastfeeding duration ranging from 7 days to 13 months. Forty-four of the 51 mothers (86%) viewed the NS as helping them to continue breastfeeding. Of those 44 mothers, 37 weaned from NS use.

This study described a hospital-based lactation department's position on NS use and its clients' self-reported NS use and satisfaction with a 40% survey response rate. An example of survey questions was not provided. Data were collected in an informal manner by multiple lay volunteers, possibly resulting in inconsistent data collection. Sample characteristics were not reported, breastfeeding was undefined, and survey data did not include information about milk supply or amount of pumping. Because of this lactation department's positive view on NSs, interventions using NSs may have been more frequent and used for potentially less severe issues such as early latching. This combined with volunteer interviewer attitudes and a self-selecting sample of mothers may have led to biased results.

Powers and Tapia²⁰ also conducted an informal telephone survey to document mothers' reasons for and perceptions of use of a silicone NS as well as duration of NS use and infant weight gain. Data were collected from 202 of 287 eligible mothers who were 1 month to 3 years postpartum and who had discontinued NS use. The most frequently reported reasons for NS use were flat nipples ($n = 125, 62\%$), disorganized infant suck ($n = 88, 44\%$), and sore nipples ($n = 49, 24\%$), with some mothers reporting more than one reason ($n = 12, 6\%$). Although introduction of the NS ranged from 1 day to 42 days postpartum, 122 (60%) mothers began using the NS on days 1–2 after delivery. The duration of NS use ranged from one feeding to 5 months with a median duration of 2 weeks. Although the study collected both positive ($n = 126, 62\%$) and negative (not reported) statements regarding NS use, 178 (88%) mothers responded yes to the question, "Do you feel the

nipple shield helped you to succeed at breastfeeding?" The authors emphasized the need for clinicians to assess and work with infant capabilities as well as determine the mother's level and tolerance for pain and frustration in order to provide "quick" assistance that could prevent mothers from discontinuing breastfeeding.

This study focused on largely positive retrospective accounts of NS use from a small, homogenous sample of mothers with little attention given to negative accounts. The interviewer or interviewers were undisclosed, and specific sample characteristics were not collected. Mothers' self-reports, collected up to 3 years postpartum, may be subject to faulty recall. Furthermore, asking mothers if the NS helped them succeed at breastfeeding might elicit socially desirable positive responses and therefore diminishes the value of these data. The authors provided the survey questions, but the responses for most of these questions were not disclosed in the article. For example, no data were provided regarding gestational age of the infants and how much formula supplementation was used. This study is mainly valuable for its descriptions of why the subjects thought they used NSs, although these reasons were specific to lactation practices in their communities.

Discussion

Several limitations exist with the current literature. The physiological studies provide preliminary information regarding maternal hormonal patterns and infant suckling response with NS use, but they did not directly examine the relationship between NS use and long-term outcomes such as milk supply, infant weight gain, and duration of lactation. Most studies focused on healthy, term infants and therefore might not represent the range of infants who need an NS. In addition, sample sizes for these studies were very small, but yet all demonstrated a decrease in milk transfer when the NS was in place. Only one study of five lactating women documented the effect of breastfeeding with and without a NS on an individual's prolactin response. Larger studies need to evaluate the effect of NSs on maternal lactation hormone responses.

This review only identified two small studies involving premature infants and NS use despite current widespread use of NSs in the preterm population.¹⁰ It is important to recognize that in one study, NSs were only used if the infants demonstrated difficulty with nursing such as poor latch or poor milk transfer.¹³ In the other study, the authors acknowledged that infants should only use the shield if breastfeeding is problematic, and the infants included in the study were those who did not breastfeed well without a shield.¹⁴ None of the reviewed studies provided evidence that routine NS use in premature infants is necessary to improve intraoral pressures. Based on these studies, NS use in the premature population should not be routine, but should be considered in cases where infants have demonstrated persistent difficulty with sustained breastfeeding and milk transfer. Milk transfer while using an NS should be assessed, and NS use should be discontinued if milk transfer is not good.

The studies of mothers' subjective reports suggest that they had positive experiences using an NS, with most mothers continuing to nurse after discontinuing NS use. Given the

small sample sizes, limited follow-up time, and lack of meaningful statistical measures, these studies should be cautiously interpreted. The authors of these studies carefully but consistently recommended that NSs had a role in preserving breastfeeding in certain situations, but there is little empiric evidence to support that this intervention is safe past 6 months postpartum. None of these studies defined breastfeeding among these mothers who used an NS, and what is of further concern is that these limited studies did not address the impact of NS use on a mother's attitude towards lactation after subsequent births. For the majority of infants in these studies, infant weight gain was not a problem during NS use, although in general the studies did not report the amount of bottle feeding with expressed breastmilk or formula. It appears that NSs are commonly used as an intervention for flat/inverted nipples despite the findings that even with the NS, significantly more mothers with flat/inverted nipples discontinued breastfeeding prematurely compared to mothers using NSs for other reasons.⁸

The current body of evidence does not include well-designed mixed methods studies and large prospective trials investigating the need for and impact of early NS introduction on breastfeeding duration. Therefore, attempts to establish normal breastfeeding should be made first before introducing an NS. The two studies done with premature infants should not be used to support NS use in the near-term or full-term population in the first several days postpartum. Introducing NSs in the first postpartum week may seem like an easy fix for a frustrated family, but such intervention may preclude a thorough evaluation of the mother-infant dyad to determine why breastfeeding has been problematic and may cause more problems such as lack of effective milk transfer, sore nipples, and loss of milk supply. The pervasive use of NSs as an intervention in the very early course of breastfeeding can relay a false message of breastfeeding success and safety to mothers. Widespread retail access to NSs might also signal to mothers that NS use is a norm that warrants little concern. Mothers who use an NS should be followed by a knowledgeable health professional to help them transition away from NS use, monitor infant growth, and screen for milk supply changes or other breastfeeding problems.

Conclusions

The current literature does not support many of the current practices regarding NS use. The available evidence does not demonstrate that NSs are safe in the long term for milk supply, infant weight gain, or duration of breastfeeding. Rather than assuming that NSs are safe until proven otherwise, healthcare providers should consider NSs an unknown risk and limit their duration of use whenever possible, until further evidence demonstrates their long-term safety.

Acknowledgments

We wish to thank Audrey Tluczek, Ph.D., R.N., for her editorial assistance in reviewing this article before submission. Fellowships supporting A.C.M.'s work were funded by the National Institute for Nursing Research Predoctoral Traineeship in Patient-Centered Interventions (5T32NR007102) and the Gwendolyn H. Shapiro-Wisconsin Distinguished Graduate Fellowship.

Disclosure Statement

The authors have no institutional or commercial affiliations that might pose a conflict of interest regarding the publication of a manuscript. The authors have no other types of affiliation, including consultantships, honoraria, stock ownership, equity interests, arrangements regarding patents, or other vested interests regarding nipple shields.

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