

# Could Silicone Be Safer? Randomized, Prospective Analysis of Complications Associated with Usage of Silicone Nursing Pads Versus Cotton Nursing Pads

**Abstract:** Eighty breastfeeding women were studied in their first four months post-partum to assess the frequency of adverse events (mastitis, thrush, duct clogging, nipple injury, and breast milk supply issues) in subjects using traditional cotton absorbent pads and silicone nonabsorbent pads. The subjects were randomized to silicone versus cotton pads and assessed monthly via telephone interview by a blinded reviewer. Cotton pad users were 6.3 times more likely to develop mastitis ( $p < 0.01$ ), 5 times more likely to develop thrush ( $p < 0.05$ ), 11.3 times more likely to develop a clogged duct ( $p < 0.01$ ), and 1.8 times more likely to suffer nipple injury ( $p < 0.05$ ). Inadequate milk flow occurred in both groups and was not statistically significant. Several women using cotton pads complained of excessive milk flow; this problem was not observed in silicone pad subjects. The results imply that silicone pad users may experience a statistically significant reduction in breastfeeding complications, except regarding breast milk supply issues.

**Introduction:** Silicone (non-absorbent) nursing pads (LilyPadz<sup>®</sup>) have been commercially available to breastfeeding mothers since they were introduced to the market in December 2002. They appear to offer some distinct and unique advantages over traditional cotton (absorbent) nursing pads (see discussion). Furthermore, they are designed to *prevent* breast milk leakage, the safety of which has been questioned but not studied. Finally, they offer a window of opportunity to study whether or not the practice of using absorbent cotton pads should be considered innocuous or that cotton pads may actually unknowingly contribute partially or wholly to complications breastfeeding mothers experience. We present the data from the first randomized, prospective single-blinded trial comparing silicone pads to absorbent cotton nursing pads to date. The incidence of nipple injury, mastitis, thrush, duct clogging and breast milk supply issues were reviewed.

**Methods:** After obtaining IRB approval for the study, the Department of Lactation Services began enrolling study subjects. The women were assigned in a random fashion to using LilyPadz<sup>®</sup> exclusively or their choice of absorbent pads. Telephone interviews were conducted monthly with a blinded reviewer for four months following enrollment utilizing a standardized questionnaire. A total of 80 subjects were enrolled. 12 (15%) subjects were excluded for the following reasons; 4 had incorrect contact information, 1 had her phone disconnected, 4 quit breastfeeding before 1 month, 2 never answered and never returned phone calls, and 1 switched pads during the study. 44 out of 80 were followed to four months (55%). The data gathered was evaluated monthly and the incidence of mastitis, thrush, duct clogging, nipple injury or soreness, and breast milk supply issues were quantitatively compared between the two groups and expressed as % per month (see tables below).

**Results:** The number of participants declined every month. We used person-month as unit to estimate incidence of side effects. The observed person-months were 144 for silicone nursing pads users and 115 for traditional nursing pads users. The null hypothesis is the side effects incidence in silicone nursing pads users is not different from in traditional nursing pads users. The Poisson model<sup>1</sup> (Breslow and Day, 1987) is used to test the hypothesis:

$$Pr(d=x) = \exp(-\lambda n)(\lambda n)^x/x!$$

Where  $\lambda$  denotes the mean of incidence rate in traditional nursing pads users,  $n$  is the person-months denominator, and  $x$  is the number of incidence cases in silicone nursing pads users. We summed up the probability of incidence cases occurring in silicone nursing pads users under null hypothesis assumption and

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the probability of more extreme number of incidence cases. The summation of these probabilities is presented below.

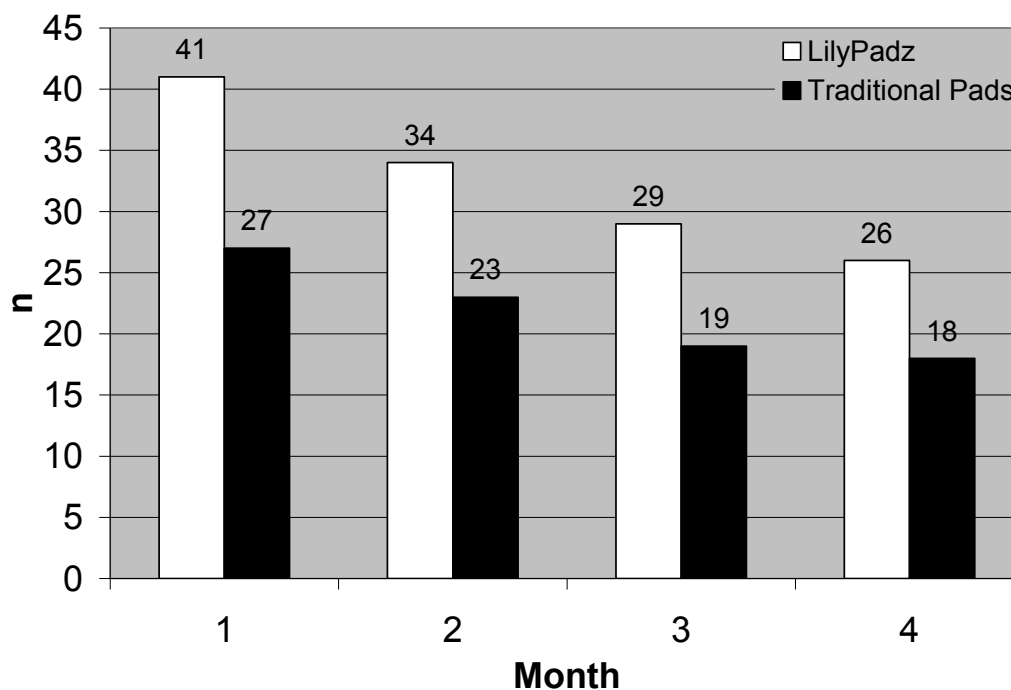
Comparison of incidence of Side Effects for Mothers using Bilaminar Silicone Nursing Pads and Mothers using Traditional Pads (per 100 mother per month).

	Silicone Nursing Pads	Traditional nursing pads	p-value
Mastitis	1.39	8.70	<0.001
Thrush	1.39	6.96	<0.001
Duct clogging	0.69	7.83	<0.005
Nipple injury	9.72	17.39	<0.01
Under supply	6.25	7.83	NS
Over supply	0	3.48	<0.01

<sup>1</sup>Breslow NE and Day NE. Fitting Models to Grouped Data. In: Breslow NE and Day NE. Statistical Methods in Cancer Research. World Health Organization, International Agency for Research on Cancer. Lyon, 1987 page119-176

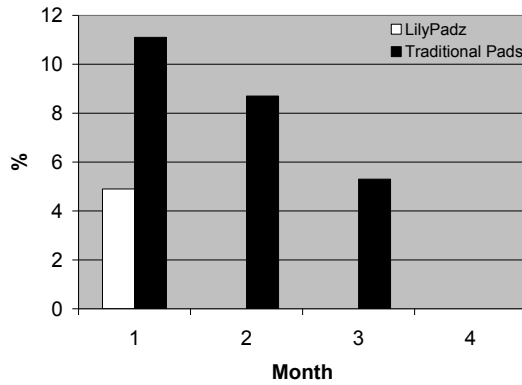
32 subjects were randomized to use traditional nursing pads and 48 subjects were randomized to use silicone pads (LilyPadz®). 12 were excluded as for the reasons mentioned above. The remainder of subjects followed per month is shown in Table 1.

**Table 1. Number of Patients**

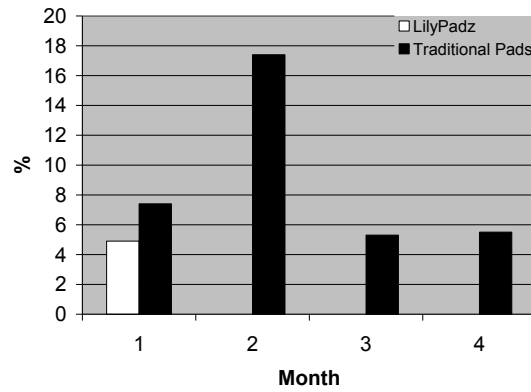


Infectious complications (mastitis and thrush) were significantly increased ( $p < 0.001$ ) traditional pad users. Furthermore, there were no infectious complications with LilyPadz® beyond the first month, whereas mastitis and thrush continued to occur in the traditional pad group in months 2-4 (Tables 2 and 3).

**Table 2. Incidence of Mastitis**

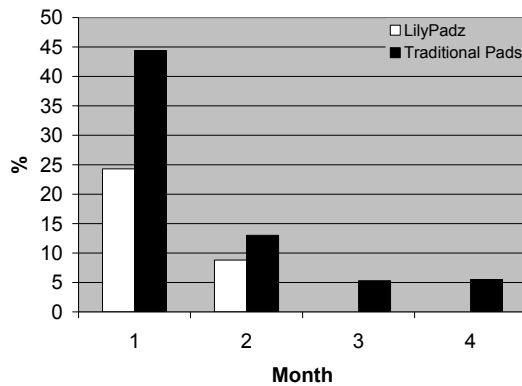


**Table 3. Incidence of Thrush**

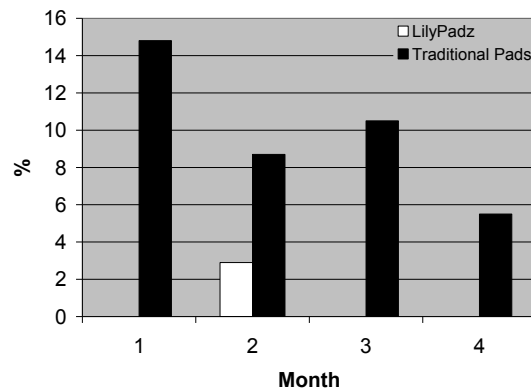


Breast abscess did not occur in either group. Nipple injury (cracking, bleeding, and soreness) occurred with greatest frequency in the first two months in both groups (Table 4), with a statistically significant decreased frequency occurring in the LilyPadz<sup>®</sup> group ( $p < 0.01$ ). Duct clogging (Table 5) was reported almost exclusively in the traditional pad arm, occurring ten times more frequently per person-month in the traditional pad group ( $p < 0.005$ ). Breast milk underexpression occurred with similar frequencies in both groups (Table 6), with a peak in the second month for LilyPadz<sup>®</sup> and the third month for traditional pads. There were four separate reports of breast milk over expression in the traditional group (Table 7). This was not reported in the LilyPadz<sup>®</sup> group.

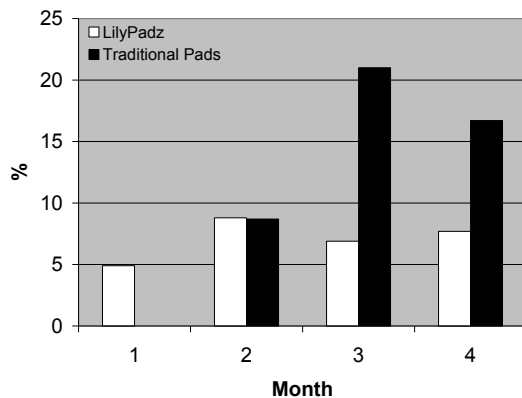
**Table 4. Incidence of Nipple Injury**



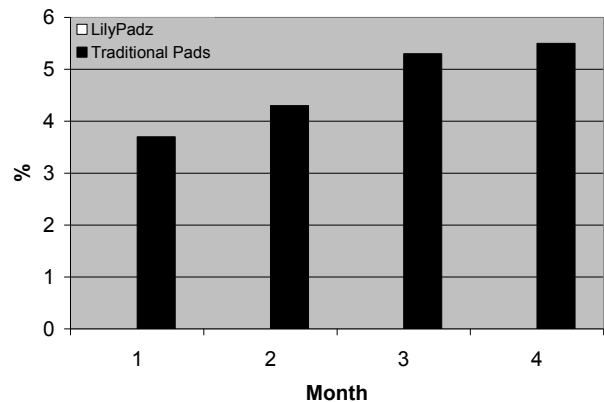
**Table 5. Incidence of Duct Clogging**



**Table 6. Incidence of Milk Undersupply**



**Table 7. Incidence of Milk Oversupply**



## Discussion:

The nipple-areola complex (NAC) is a biologically active composite of erectile dermal tissue and epidermis. Sir Astley Cooper's cadaver studies in 1839 reported 15-20 openings on the nipple<sup>1</sup>. He could only intubate 5-8 of these however, and it is now known that only 5-8 milk ducts truly occur. Dr. Susan Love's theory is that the remainder of the orifices overly sebaceous glands that secrete an oily, lipid substance to lubricate the nipple. Coupled with these sebaceous glands of the areola (Montgomery glands), these glands provide a natural "skin-care system" for the NAC, the importance of which should be emphasized. It is this skin-care system which may provide a protective barrier between the environment and the underlying breast parenchyma and maintains the NAC's suppleness. This barrier is under constant assault by the continuous wet-dry cycle of breastfeeding and the suckling of the infant. An analogy to consider is chapped lips. If one sucked on their lips for 15 minutes every three to four hours and let them air dry they would be at greater risk of chapping. This may be aggravated by cotton pads that retain the moisture of expressed milk, acting as a potential solvent and a macerating agent. Moist wound healing principles maintain that too little or too much moisture can be hazardous to a wound; therefore even though the moisture may be soothing to an injury it further undermines the integrity of this barrier. In contrast, silicone which is used in the wound healing industry, more likely allows the NAC to retain or reproduce its barrier between feedings allowing gas to move freely but retaining a more appropriate degree of moisture. Moreover, injuries that leak serum are at risk by cotton pads which, upon drying, can stick to the wound and reinjure it upon removal (the "wet-to-dry" phenomenon). The silicone gel lining retains the moisture near the wound and prevents desiccation. This allows a true moist wound healing environment and is very gentle on removal. Finally, traditional pads may shift underneath a bra, and the repetitive abrasion may further injure the NAC's barrier. The silicone gel in LilyPadz prevents shifting by being tacky enough to keep the pad in place. Though subjects using silicone pads had a lower overall incidence of nipple soreness and injury, there still were reports of injury and clearly this problem is multifactorial and complex, probably involving more factors of the maternal-infant dyad (such as latch, frequency of feeds, stress, fatigue, etc...). That stated, there clearly is potential for further study and evaluation of silicone and other materials that may better aid the NAC in retaining the proper environment to resist breakdown and injury.

There is increasing evidence suggesting that injury to the integrity of the NAC leads to mastitis. Mastitis places a serious burden on the breastfeeding mother. Several recent prospective studies have reported incidence rates between 9.5%<sup>2</sup> and 20.6%<sup>3</sup> at three months postpartum. Complications of mastitis include breast abscess, recurrence or persistence<sup>4</sup>. Furthermore, weaning due to mastitis has been reported between 8.4% and 10.8%<sup>3,4,5</sup>. In a study by Foxman et al, nipple injury was implicated as the second most significant risk factor for mastitis, second only to a previous history of mastitis<sup>2</sup>. In this study, nipple soreness was more closely associated with mastitis than engorgement. Interestingly, they also studied the relationship between breastfeeding frequency and mastitis and found that women that breastfed more frequently (every 2-3 hours) were 2.5 times more likely to develop mastitis than women who reported a lower frequency (6 or fewer feeds per day). Vogel et al also implicated nipple soreness as a risk factor for mastitis<sup>5</sup>. Wambach noted that in the 24 hours prior to the development of mastitis, sore nipples were second only to feeling tense and overwhelmed, also surpassing engorgement<sup>4</sup>. One of the concerns regarding silicone pads is that by preventing milk leakage stasis and mastitis may occur, but the evidence in this study contradicts that claim and it appears by these studies that nipple injury is a more important factor leading to mastitis.

Candida infections (thrush) are difficult to diagnose and difficult to treat. Like mastitis, the incidence of fungal infection was reduced in silicone pad users. Yeast prefers a warm, dark and excessively moist environment to thrive, such as the groin. A moist, breast-milk laden cotton pad that is not immediately removed provides this environment, with all the substrate bacteria and fungus need to thrive. In contrast, silicone pads prevent milk leakage keeping the NAC's moisture content appropriate and less susceptible to fungal overgrowth. The significant reduction in both fungal and bacterial infections suggests an important advantage for silicone pad users.

To address the reduction in duct plugging observed in the silicone pad arm we should visit the recently revised model of the lactating breast proposed by Ramsay<sup>6</sup>. Via ultrasound investigation Ramsay demonstrated lactating ducts do not have a fixed diameter. On the contrary, the ducts may increase or decrease in girth. One of the mechanisms involved may be the pressure exerted on the duct by the volume of milk it contains and another involves the compliance of the duct itself. In women wearing traditional pads leakage between feedings may allow the ducts to become less distended, which may reduce the ducts' diameter making them more prone to plugging. The lack of leakage associated with the silicone pad theoretically increases the volume of retained milk within the breast, and by virtue of mild backpressure may keep the duct in an open position via mild distention. This is most likely an oversimplification and certainly provides an avenue for further research, perhaps by evaluation of breast ducts in between feedings with ultrasound in both traditional and silicone pad users.

The reduction of breast milk over expression may be a local or neurohormonal phenomenon<sup>7</sup>. Increased pressure in the ductal system may produce afferent neural stimulation, affecting hypothalamic production and/or release of prolactin or oxytocin, the two primary hormones involved in breastfeeding. Down-regulating the production of prolactin may decrease milk production to levels satisfactory for breastfeeding alone. This probably occurs over time and may allow a woman's breast milk to become adapted to the needs of the child eventually, but in the meantime leakage of excess milk between feedings occurs. Local regulation of breast milk flow may be under the control of a "feedback inhibitor"<sup>8</sup>, a protein produced by ductal or alveolar cells within the breast lobule that has autocrine and/or paracrine effects on milk production of the alveolar cells. Unlike prolactin secretion and control, this mechanism probably has a more rapid effect on milk supply by involving a shorter feedback loop. The absence of breast milk over expression in the LilyPadz<sup>®</sup> group may present a potential therapeutic use in women with this problem, particularly if the pads are used by the time they leave the hospital after delivery, as in this study. They may exert their effect by altering the local or neurohormonal factors governing milk production.

Breast milk undersupply was similar in both groups, with an early peak in the LilyPadz group and a later peak in the absorbent pad arm. Breast milk undersupply most commonly occurred after return to work or in periods of increased stress. Again, there appears to be no statistical significance between the two groups when evaluating undersupply of breast milk.

Silicone nursing pads were invented in 2001 by a nursing mother because of her disappointment with the quality and performance of traditional pads, as well as their unsightly appearance. LilyPadz<sup>®</sup> became commercially available in 2002. LilyPadz<sup>®</sup> are composed of two layers of silicone (Fig. 1)



Figure 1

Absorbent pads are designed to collect breast milk leakage whereas LilyPadz® are designed to *prevent* breast milk leakage. This has raised concern about their safety, as traditionally it has been argued that compression of the nipple may lead to complications such as milk stasis, duct clogging, or mastitis. Furthermore, questions about the material used (silicone) and its safety have been discussed despite the fact that silicone is used in such everyday medical devices in wound care, implantable medical devices, and indwelling catheters. Interestingly, absorptive cotton pads have been accepted without undergoing the same scrutiny. Despite these concerns, the incidence of mastitis, thrush, duct clogging, nipple injury and oversupply of breast milk all occurred with greater frequency in the absorbent pad group. These results reached statistical significance.

In summary, it appears that the use of silicone pads does not put the breastfeeding mother at higher risk than traditional pads in terms of complications. In fact, they appear to ***reduce the risk of most complications*** as highlighted in this study, especially infectious complications, duct clogging and over expression of breast milk. The study is small but the results are intriguing and call into question what environmental factors play a role in breastfeeding complications, particularly addressing the nipple-areolar complex as not just a conduit between the breast and the infant but as a biologically active structure that requires a proper moisture balance and protection from microbial overgrowth, and that injury to the NAC and/or maintaining a suboptimal environment may lead to breastfeeding complications. This comparative study between silicone and traditional absorptive nursing pads is the first study of its kind and may represent a step into understanding the factors that lead to the complications that burden the breastfeeding mother.

## ***References***

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