



LilyPadz[®]



Randomized, Prospective Single-Blinded Comparison of Silicone (LilyPadz) versus Traditional Breast Pads



Risks & Hazards of Bilaminar Silicone Breast Pads (LilyPadz). Randomized, Prospective Single-Blinded Comparison of Silicone versus Traditional Breast Pads.

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Background: Silicone Breast Pads (LilyPadz[®]) have been available to breastfeeding mothers for the past two years. They appear to offer some distinct and unique advantages over traditional Breast Pads (see discussion). Furthermore, they are designed to *prevent* breast milk leakage, the safety of which has been questioned but not studied. We present the data from the first randomized, prospective single-blinded trial comparing silicone pads to traditional Breast Pads to date. The incidence of nipple injury, mastitis, thrush, and 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[®] exclusively or their choice of traditional pads. Telephone interviews were conducted monthly with a blinded reviewer for four months following enrollment utilizing a standardized questionnaire. 88 patients have been followed to completion to date (four months). 20 patients have been excluded for quitting breastfeeding in less than 2 weeks, disconnected telephone, or switching pads midstream in the study. The data was then tabulated and compared between the two groups.

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 Breast Pads users and 115 for traditional Breast Pads users. The null hypothesis is the side effects incidence in silicone Breast Pads users is not different from in traditional Breast Pads users. The Poisson model¹ (Breslow and Day, 1987) is used to test the hypothesis:

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

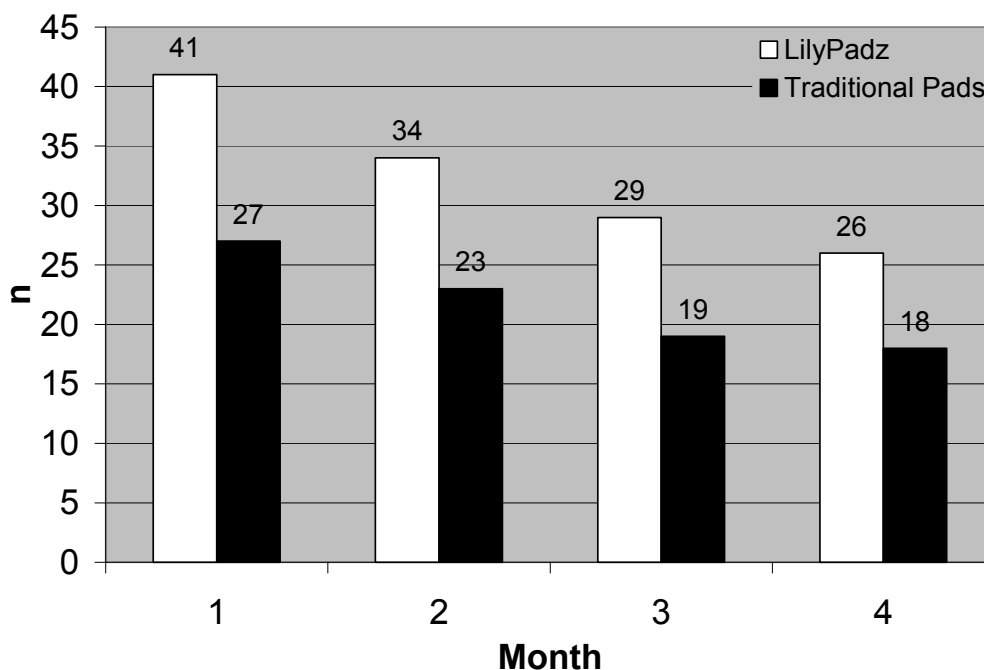
Where λ denotes the mean of incidence rate in traditional Breast Pads users, n is the person-months denominator, and x is the number of incidence cases in silicone Breast Pads users. We summed up the probability of incidence cases occurring in silicone Breast Pads users under null hypothesis assumption and 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 Breast Pads and Mothers using Traditional Pads (per 100 mother per month).

	Silicone Breast Pads	Traditional Breast 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

27 subjects were randomized to use traditional Breast Pads and 41 subjects were randomized to use silicone pads (LilyPadz®). The number of subjects followed per month is shown in Table 1.

Table 1. Number of Patients



Infectious complications (mastitis and thrush) were more than four times ($p < 0.001$) as common in the traditional pad group. Furthermore, there were no infectious complications with LilyPadz® beyond the first month, whereas mastitis and thrush continued to occur in the traditional pad group (Tables 2 and 3).

Table 2. Incidence of Mastitis

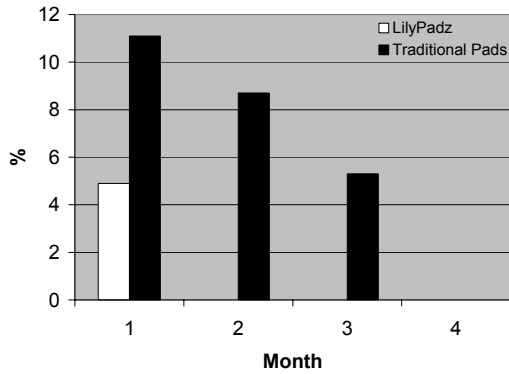
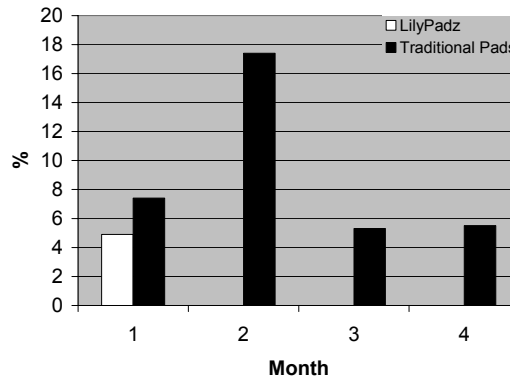


Table 3. Incidence of Thrush



Breast abscess did not occur in either group. Nipple injury (cracking, bleeding, and soreness) occurred with greatest frequency in the first two months as well and is depicted in Table 4, with a statistically significant decreased frequency occurring in the LilyPadz® group ($p < 0.01$). Duct clogging (Table 5) occurred 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 undersupply occurred with similar frequencies in both groups (Table 6), with a peak in the second month for LilyPadz® and the third month for traditional pads. There were four separate reports of breast milk oversupply in the traditional group (Table 7). This was not reported in the LilyPadz® group.

Table 4. Incidence of Nipple Injury

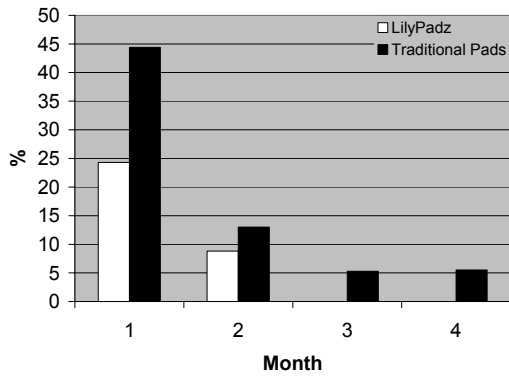


Table 5. Incidence of Duct Clogging

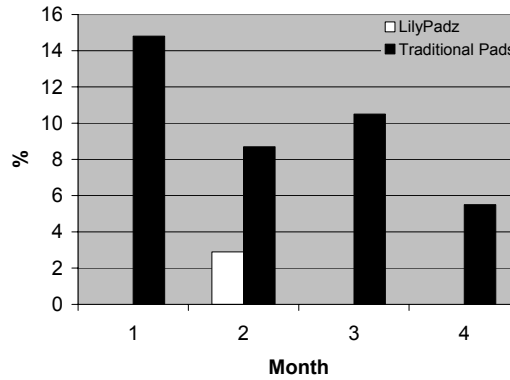


Table 6. Incidence of Milk Undersupply

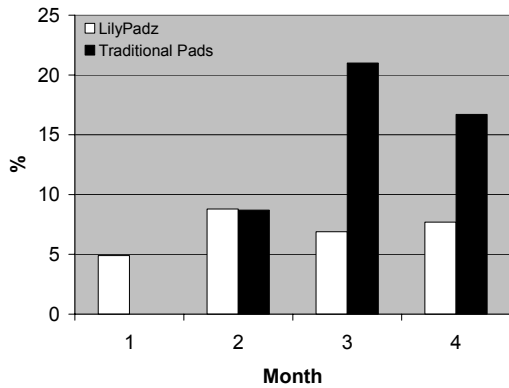
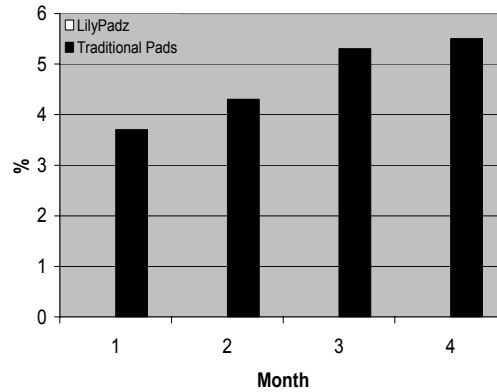


Table 7. Incidence of Milk Oversupply



Discussion: Silicone Breast 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[®] became commercially available in 2002. LilyPadz[®] are composed of two layers of molded silicone (Fig. 1).



Figure 1

Cotton or traditional pads are designed to absorb 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 duct clogging or infection. 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 and indwelling catheters.

The incidence of mastitis, thrush, duct clogging, nipple injury and oversupply of breast milk all occurred with greater frequency in the traditional pad group. These results reached statistical significance. Undersupply issues in both groups appeared similar.

Candida infections (thrush) require a warm moist environment to occur. LilyPadz[®] are designed to keep the breast dry and to minimize leakage, and this may explain why this occurred less frequently in the silicone pad group.

The higher incidence of duct clogging in the traditional pads arm suggests that the etiology of this complication may not arise from compression of the nipple. It may occur in the ducts or sinuses leading to the nipple. Compression of the nipple may indeed increase pressure within the ductal system. This force may be exerted longitudinally and radially. The radial component of this force may oppose the tendency of the ductal walls to oppose each other, forcing the duct to remain patent.

The reduction of breast milk oversupply may be a local or neurohormonal phenomenon. 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. The absence of this complication in the LilyPadz[®] group may present a potential therapeutic use in women with oversupply issues.

Nipple injury was most common in the first two weeks, was usually treated with lanolin, and universally resolved. The incidence of nipple injury was statistically lower in the silicone pad arm. This may be due to prevention of nipple **re-injury** by silicone pads themselves. Cotton fiber pads adhere to nipple injuries and can cause tearing of the fibroserous matrix on removal, similar to the “wet-to-dry” gauze dressing that has fallen into disfavor in wound healing circles. Silicone pads are more alike current wound healing adjuncts in that they promote a moist wound healing environment and do not remove the ingrowth of substances present in the wound.

Breast milk undersupply was similar in both groups. 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.

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 ***have no higher risk of most complications*** as highlighted in this study, especially infectious complications, duct clogging and over-supply. The study is small but the results are intriguing and call into question what environmental factors play a role in breastfeeding complications. This is the first study of its kind and the first breastfeeding product suggesting the possibility of a reduction in the incidence of most breastfeeding complications, potentially providing a major advance in the care of lactating women.



Ultimate non-absorbent Breast Pad.
No leaks. No lines. No worries.

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