Safety of Bilaminar Silicone Nursing Pads (LilyPadz®); Randomized, Prospective Single-Blinded Comparison of Silicone versus Traditional Nursing Pads

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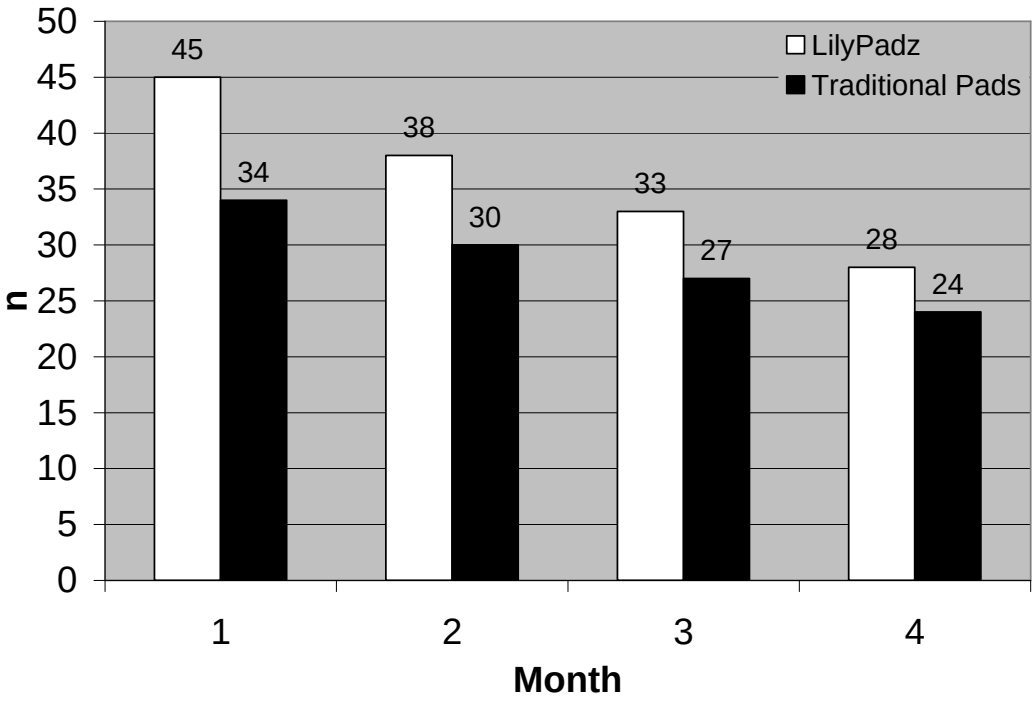
Background: Silicone nursing pads (LilyPadz®) have been available to breastfeeding mothers for the past two years. They appear to offer some distinct and unique advantages over traditional nursing pads (see discussion). Furthermore, they are designed to *prevent* breast milk leakage, the safety of which has been questioned but not studied. We present the data from the first randomized, prospective single-blinded trial comparing silicone pads to traditional nursing pads to date. The incidence of nipple injury, mastitis, thrush, duct clogging and breast milk supply issues were reviewed. The results were quantified and discussed.

Methods: After obtaining IRB approval for the study, the Department of Lactation Services began enrolling 100 subjects. The subjects 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. 21 subjects (16 silicone, 5 traditional) 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. The null hypothesis maintains that there is no difference between the two groups when comparing the incidence of mastitis, Candida infections (thrush), duct clogging, nipple injury, or breast milk supply (too much or too little).

Results: 40 subjects were randomized to use traditional nursing pads and 60 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 were more than twice 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, 3)

Table 2. Incidence of Mastitis

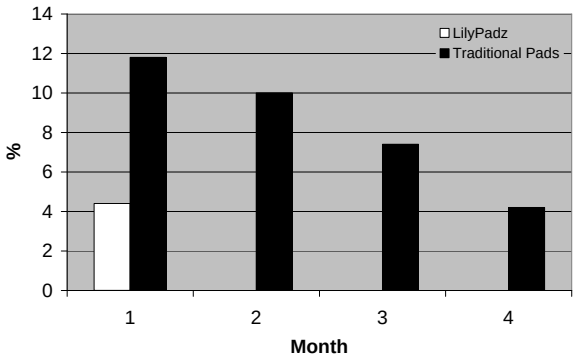
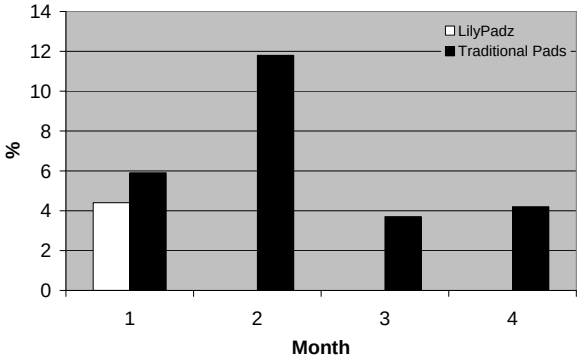


Table 3. Incidence of Thrush



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 decreased frequency occurring in the LilyPadz® group. Duct clogging (Table 5) occurred primarily in the traditional pad arm. 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

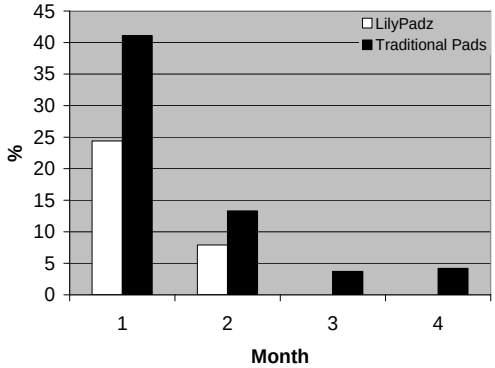


Table 5. Incidence of Duct Clogging

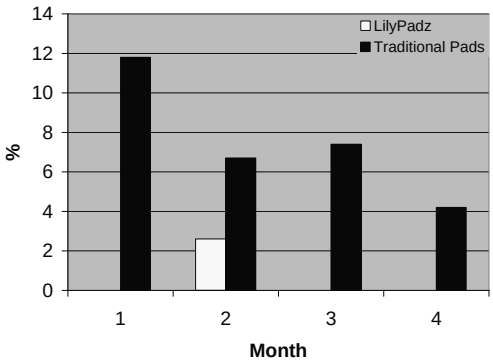


Table 6. Incidence of Milk Undersupply

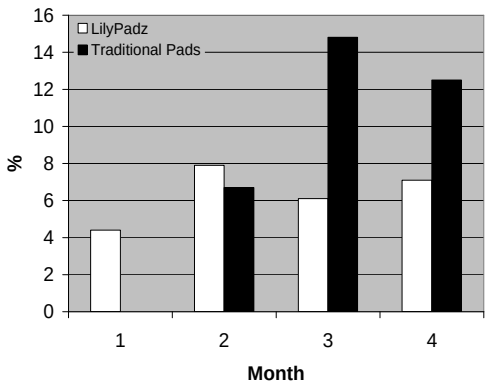
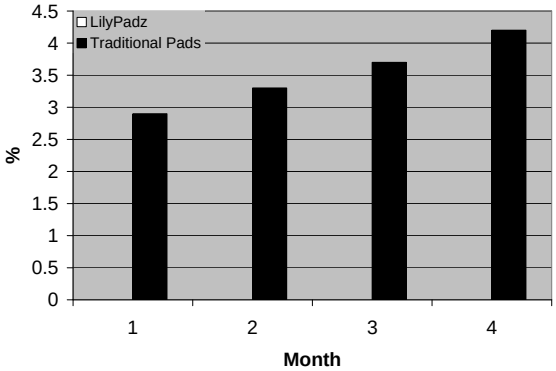


Table 7. Incidence of Milk Oversupply



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

Figure 1

The fundamental difference between traditional pads and silicone pads are that traditional pads are designed to absorb breast milk leakage whereas LilyPadz® are designed to *prevent* it. This has raised concern about the safety of silicone pads, 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. There was a higher rate of nipple injury in the traditional pad group as well. Undersupply issues in both groups appeared similar overall.

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 wall to oppose each other, forcing the duct to remain patent.

The reduction of breast milk oversupply may be a local or neurohormonal phenomenon. Pressure on the nipple itself by the pad may reduce the total volume of milk produced though undersupply issues do not occur with increased frequency. 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.

Breast milk undersupply and nipple injury were similar in both groups. Breast milk undersupply most commonly occurred after return to work or in periods of increased stress. Nipple injury was most common in the first two weeks, was usually treated with lanolin, and universally resolved. Again, LilyPadz® appear to be as safe as traditional pads with respect to these potential problems.

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 may ***reduce the risk of most complications*** as highlighted in this study, especially infectious complications, duct clogging and oversupply. This is the first study of its kind and the first breastfeeding product proven to reduce the incidence of most breastfeeding complications, potentially providing a major advance in the care of lactating women. ■