



STUDY REPORT

MULTI-MAM[®] COMPRESSES

**EVALUATION OF THE RELIEF AND TREATMENT OF NIPPLE PAIN
IN BREASTFEEDING WOMEN**



MULTI-MAM COMPRESSES: EVALUATION OF THE RELIEF AND TREATMENT OF NIPPLE PAIN IN BREASTFEEDING WOMEN

SUMMARY

For an evaluation of the results and comments by the user, Report Forms were provided to Swiss and German midwives and lactation consultants for distribution to breast-feeding mothers using Multi-Mam Compresses for the relief and treatment of nipple pain. A total of 227 forms could be evaluated. Bleeding fissures of the nipple was the most frequent complaint. The seriousness of the complaint was indicated by a number between 0 and 10 and had an average of 7 at the beginning of the treatment. The complaints were suffered for between 3 weeks and 1 day. Complete healing and relief within 2 days of treatment with Multi-Mam Compresses was reported by 101 mothers. In 107 mothers improvement of the seriousness of the complaints was seen, while in 18 cases the application of the Compresses had no beneficial results. These cases all started relatively late after the onset of the nipple problem with the application of the compresses. The appreciation of the Multi-Mam Compresses was great with respect to its quick soothing and cooling effects.

Multi-Mam Compresses were creatively -and successfully- used for a nipple infection of a baby of 3 months and one of 8 days old. A decubitus on the ankle of a 90 year old lady was also treated with Multi-Mam Compresses. The compresses were effectively applied for the treatment of a radiation burn of a breast cancer patient.



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1. INTRODUCTION

Normal neonatal sucking induces visible changes in nipple skin especially swelling and eschar (scab). Blisters, inflamed areas and peeling are also frequently observed (Ziemer 1993). Statistics reveal that 80-95 % of breastfeeding women will experience some degree of soreness with 26 % reporting extreme nipple pain (Newton 1952, Walker 1989).

Feeding becomes an agony, rather than a loving time together with the baby. Painful nipples can also inhibit the let-down (milk ejection) reflex. As the mother becomes more tense a vicious circle has begun that often leads to early weaning (Humble 1994).

Fissuring of the nipple occurs by a combination of external trauma and insufficient moisture in the uppermost layer of the skin. While it is important to address the cause of the trauma (e.g. by correct positioning and latch-on of the baby), adequate moisture must be maintained to facilitate the healing process of the fissure.

In the early 70s it was established that a moist, scab free, environment enhanced the movement of cells across the wound surface and facilitated healing (Rovee 1972). Current wound treatment methods employ the use of moisture to aid healing. A moist environment is critical for epithelisation, the proliferation and migration of epithelial cells across the surface of a wound during healing. (Bolton 2000)

However for the mother with damaged nipples the most pressing issue may not be the time it will take for her nipples to heal but how quickly she can get relief from her pain.

2. MATERIAL AND METHODS

Multi-Mam Compresses are a completely novel approach to the treatment of sore nipples. The bio-active Multi-Mam Gel is impregnated in a soft protective pad of a non-woven material, that is placed over the nipple and can be carried under the bra. The viscosity of the fluid is such that it will not drip from the compress. The outside of this pad is coated with a thin layer of plastic to prevent staining of the cloths. The application by this impregnated compress helps maintain a moist environment and does not stick to skin.

The bio-activity of the gel is based on Aloe Barbadensis extract that contains >0.75 mg/g mannose as acetylated polymannose. This component has proven to be immunomodulatory and effective in cell processes that are involved in inflammation. It therefore has a strong bio-active effect which greatly enhances the healing process and stimulates epithelisation (Davis 1988, Womble 1992). The acetylated polymannose fraction is also responsible for the inhibition of adhesion of certain anaerobic bacteria and the improvement of phagocytosis of macrophages (t'Hart, 1988). Aloe gel appears to provide immediate relief of pain and swelling (Davis 1988). The other components are Glycerin, Xanthan Gum and Capryl Glycol.

Multi-Mam Gel has been tested effectively against the 4 most life threatening infectious micro-organisms for babies; Staphylococcus aureus, beta hemolitical Streptococcus agalactiae, Escherichia coli and Listeria monocytogenes. These microbes are often present on the nipples of breastfeeding mothers.



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Multi-Mam Gel is non toxic and no preservatives have been added. The bio-active gel is totally safe when swallowed by the baby. The compresses are individually packed in a sachet and are to be applied in between feedings. One compress has to be used for each feeding interval.

3. REPORT FORMS

For an evaluation of the results and comments by the user Report Forms were provided to several Swiss and German midwives and lactation consultants for distribution to breastfeeding mothers using Multi-Mam compresses. In the Report Forms the user of Multi-Mam Compresses could fill in a number of questions, the results of the application of Multi-Mam compresses and remarks on the product.

1. Date, Initials, Age
2. Complaint, history of the complaint, seriousness of the complaint expressed by a number between 0 and 10
3. Previous treatment and results thereof
4. Results and seriousness of the complaint after 2 days application of Multi-Mam Compresses expressed by a number between 0 and 10
5. How many days before the complaint had been completely resolved
6. Concomitant treatments
7. Comments

The Report Forms were to be sent to the distributor or handed over to the doctor, midwife or lactation consultant.

4. RESULTS

The 227 Report Forms were collected over a period of six months by the distributors of Multi-Mam Compresses in Switzerland and in Germany. Compresses and the Report Form were given to the breast feeding mother suffering of a nipple pain by the lactation consultant or mid-wife.

The average age was 31 years. The age distribution was 38 mothers of 35-42, 94 mothers of 30-35, 64 mothers of 25-30 and 31 mothers of 20-25. The complaints were noted as; very sensitive, sore nipples, inflamed, damaged nipples and bleeding fissures. One woman noted also yeast, one woman also mastitis and two woman also eczema of the aureolus; all in the age group of 30-35.

The complaints had been present for 1 day to 8 weeks before the use of Multi-Mam compresses. The 8 weeks duration of the complaints was reported two times in the age group of 25-30 and one time in the age group of 30-35. Duration of the complaint of 10 days to 3 weeks was reported 7 times in the age group of 30-42. Otherwise the complaints existed for 1 - 7 days before application of Multi-Mam Compresses.

The seriousness of the complaint was experienced between 3 and 10 with an average of 7 at the start of the use of the compresses. Previous treatments were noted by 72 mothers. Lanolin ointment was the most frequently used product.

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In 107 mothers the complaints had improved considerably after 2 days of application of the Multi-Mam Compresses. In 101 mothers the problem had been completely resolved within 3 days. It were mostly the women who started with the application of the compresses after suffering complaints for over 7 days that reported no dramatic drop in their pain sensation after 2 days. However also here a complete healing was noted after longer application of 10-14 days.

No results were reported by 18 mothers of which 7 said that the product had however a pleasant cooling effect and the problem had not worsened. One said that the symptoms had worsened and one said that the product burned on application. In 2 cases no relevant improvement was noted in the seriousness of the complaint after 2 days, but nevertheless the complaint was reported to be completely resolved after 3 and 5 days.

In the 2 mothers with eczema a very good result was experienced. In the woman who reported yeast no improvement was noted, but the mother was satisfied with the product for the cooling effect. The same was reported by the woman with mastitis.

With the use of Multi-Mam compresses the average of the seriousness of the complaints reported in all 227 Report Forms on day 2 had dropped from 7 to 3. This average includes the 18 mothers who did not benefit of the product and the mothers who started treatment relatively late after the onset of the complaints.

The average pain score of the seriousness of the complaints of the 107 mothers who reported considerable improvement within 2 days with the use of the compresses the score dropped from 7.5 to 2. (Fig. 1).

AVERAGE PAIN SCORE

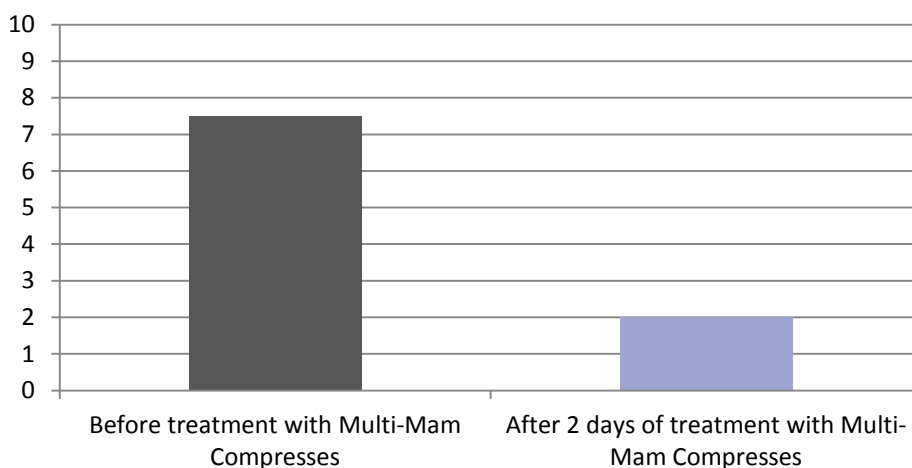


Fig. 1: Reduction of complaint score during treatment

When we look at the group of women who started with the application of Multi-Mam Compresses with a pain score of 7-10, the really serious problem group, we see that the pain score on the second day of application had dropped of the 9 mothers who reported a pain score of 10 to 7.5, of the 16 mothers with a pain score of 9 to 4.75, of the 46 mothers with a



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pain score of 8 to 3.50 and of the 28 mothers with a pain score of 7 to 3. In average the pain score of 8.5 has dropped to half (4.75) within 2 days. Of the mothers who indicated a pain score of 10 we had 2 cases in which no improvement of the bleeding fissures, but however a soothing effect of the compresses, was reported.

Concomitant application of an ointment was reported in 51 cases. Lanolin products were still the most frequently used. As comment the cooling effect as well as the soothing and pain stopping effects were noted. Multi-Mam Compresses were frequently noted to be "very recommendable" and "a super product".

Multi-Mam Compresses were creatively -and successfully- used for a nipple infection of a baby of 3 months and one of 8 days old. A decubitus on the ankle of a 90 year old lady was also treated with Multi-Mam Compresses. The compresses were effectively applied as well for the treatment of a radiation burn of a breast cancer patient.

5. DISCUSSION OF THE RESULTS

All Report Forms have been collected by the distribution partners of BioClin in Germany and Switzerland. We are not aware of any advises by a lactation consultant on better positioning and latching-on of the baby. This was not reported. It is interesting to note that the number of respondents was greatest in the 30-35 years age group.

Only in 2 cases adverse effects were reported; in one case the symptoms had worsened and in one case the product has burned on the sensitive nipple. Most women noted comments. Mostly on the quick cooling and soothing effects of the product, which enabled breastfeeding.

The Result Forms asked for a 2 days result of the application of the compresses, therefore emphasizing the expectation of a fast result. With a drop of the average pain score of 7 to 3 this was indeed shown. It was shown that the quickest results were obtained when the nipple pain was immediately treated with the Multi-Mam Compresses; within 1-2 days after onset.

Initially 72 women reported the use of a product such as a lanolin ointment for the relief of the nipple pain. During the use of the Multi-Mam Compresses this number had dropped to 51 in the concomitant use of a fatty ointment such as a lanolin or Multi-Mam Balm. This can be explained to be the result of the complete resolve of the nipple problem.

The principle of moist wound healing and the efficacy of the formula of Multi-Mam Gel show to be efficacious for the treatment of skin problems in other areas than the nipple and warrant further attention.

6. CONCLUSION

The results of the evaluation of Multi-Mam Compresses for the relief and treatment of nipple pain in 227 mothers are quite impressive with respect to the complete resolve within 2 days.



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A significant number of women were extremely satisfied with the relief of pain, inflammation and nipple damage, which greatly contributed to the continuation of breastfeeding.

7. LITERATURE

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