Clinical trial summary

Correction of inverted nipples

TITLE:
The 'Niplette': an instrument for the non-surgical correction of inverted nipples

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SOURCE:
British Journal of Plastic Surgery (1994) Vol 47, Pages 46–49

Background:

Inverted or non-protractile nipples are a common problem affecting up to 10% of the female population. This can cause psychological distress and interfere with a woman's ability to breastfeed. The anatomical fault lies with a short lactiferous duct which tethers the nipple and prevents it from projecting out. The mainstay of treatment has been breast surgery, where the lactiferous ducts are sectioned out. However this destroys the breast tissue/function and thus prevents breastfeeding.

Product information:

'The Niplette' uses suction to stretch the lactiferous ducts gently in a manner analogous to tissue expansion. It is a simple washable device which incorporates a transparent nipple mould with a sealing flange attached to a valve and a syringe port. (Please refer to Figure 1)

The mould is held over the nipple areola and air is withdrawn using a 5 ml syringe so that the nipple can be sucked into it. The pull is controlled by the patient and they are instructed to pull on the nipple as firmly as comfortable. Initial usage is encouraged as much as possible (day and night). Once the nipple has pulled out to fill the mould, usage is then reduced at a rate dependent upon any tendency to retract.

Study objective:

To assess the efficacy of a new instrument, the 'Niplette', as a non-surgical correction device for inverted nipples.

Method:

22 female patients who were considered for surgical treatment (duct divisions) for their inverted nipples were fitted with the 'Niplette'. Sixteen of these patients were referred from the Roehampton Plastic Surgery Centre and aged between 19-44 yrs (mean 30 years). Two of these patients had failed surgical corrections carried out previously. Another 6 patients were referred from ante-natal clinics because of their nipple inversion and wished to breast feed (they did not want surgical interventions).

Outpatient review occurred monthly until complete sustained nipple correction occurred and then follow-up occurred by telephone to confirm maintenance of the correction.

Figure 1: The 'Niplette' – for the non-surgical correction of inverted nipples

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Results:

- All patients found the 'Niplette' easy to apply and use
- The length of time worn differed between each patient according to their lifestyle; no accurate records were kept
- All patients were able to expose their nipples from the inverted position immediately.
- 18 out of 22 patients were able to pull their nipples to fill the mould in first follow-up appointment. The rate was dependent on the degree of deformity and the amount of usage. At best the nipple filled the mould within 2 days.
- Four patients were able to stop using 'the Niplette' by 2 months and 13 patients by 3 months (Please refer to Figure 2)
- 2 patients had a slight bleeding from their nipples (one patient pulled their nipples too hard as they were deeply inverted and the other patient fitted the device during late pregnancy). For both patients this was no more than just a nuisance.

Conclusion:

This study concluded that 'the Niplette' effectively corrected inverted nipples all cases (even in those patients with deeply inverted nipples) without the need for invasive surgery. As a result underlying breast anatomy was unaffected and mothers could continue to breastfeed without any problems.

Figure 2: A) Patient pre-treatment with deeply inverted nipple.

Figure 2: B) Sustained correction after using the 'Niplette' for 2 weeks (no further use was required)

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