

# Influence of a newly designed breast shield on the dynamics of milk removal: A randomized controlled trial

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## Background:

While many studies have investigated the importance of optimizing pumping patterns for milk removal, the influence of breast shield shape and size on milk removal has not been investigated. This study aimed to investigate the effect of breast shields with either a 105° flange opening angle or a 90° opening angle on milk volume and breast drainage.

## Methods:

This study was a cross-over, randomized-controlled non-inferiority trial (clinicaltrials.gov NCT03091985). Forty-nine mothers exclusively or predominately breastfeeding infants (1-6 months) participated in the study over two study sessions. Participants were randomly assigned to double express for 15 minutes with either the 90° or 105° breast shield on the first session, and the other breast shield on the second session. Primary endpoints were volume of milk expressed (efficiency) and breast drainage (effectiveness) as determined by the metric percent of available milk removed (PAMR). Blinded intention to treat (ITT) and per protocol analyses were performed with non-inferiority margins set at -11 ml for volume of milk expressed and at -10% for PAMR. If non-inferiority was demonstrated, superiority testing was also performed. Comfort was assessed via questionnaire.

## Results:

The 105° breast shield was both non-inferior and superior compared to the standard 90° breast shield for volume of milk expressed (ITT, 9.14ml (1.37 - 16.91),  $p=.021$  and for PAMR (ITT, 3.87% (0.01 - 7.72),  $p=0.05$ ). In addition, the 105° shield was rated as feeling more comfortable ( $p<.001$ ) and as having an improved fit to the breast ( $p<.001$ ) than the 90° shield.

## Conclusion:

Expressing with the 105° opening angle breast shield was more efficient, effective and comfortable compared to the 90° breast shield. This data provides the first evidence that breast shield design can significantly impact pumping outcomes, and that an opening angle of 105° improves both the dynamics and comfort of milk removal.

## Conflict of interest:

This clinical study was conducted and financed by the sponsor Medela AG, Switzerland. Statistical planning and analysis were performed by the independent clinical trial institute (CTU) at the University of Bern, Switzerland.

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