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White paper

Performance study of the Philips Avent Electric Breast Pump

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Benefits of Breastfeeding

A large body of evidence has demonstrated the benefits of breastfeeding[1, 2, 3, 4], particularly validating breast milk as the optimal nutrition for infants and a crucial pillar for both short and long-term health outcomes development. It is also known that breastfeeding reduces several risks of diseases for both mother and child, with a significant impact seen with longer periods of breastfeeding.[5] There are also psychosocial benefits to breastfeeding such as the infant-mother bond.[6]

Breastfeeding benefits are best inferred through direct contact of baby's mouth to mother's breast. However, there are several instances in which an infant may be unable to feed from the breast directly, e.g. when born prematurely or due to illness, but also when the mother and the infant have to be separated for several hours, a common occurrence as women make up approximately half the workforce globally. In such cases, a breast pump may help to support breastfeeding initiation, establishment and/or maintenance of milk supply.[7]

Importance of maintaining milk supply

Basic physiology dictates that appropriate stimulation and frequent emptying of the lactating breast are essential to establish and maintain milk production. This is especially imperative in the first hours and days post-partum. Besides transmitting benefits of colostrum to the infant, frequent stimulation will support development of a healthy milk supply for exclusive breast feeding.

It is known that as a result of the afferent nerve endings in the areola and nipple, the tactile nature of infant suckling causes the release of prolactin and oxytocin, two essential hormones of lactation, into the bloodstream. **Prolactin,** required for milk production and **oxytocin,** primarily responsible for milk ejection are released from the anterior and posterior pituitary, respectively.

Specifically, oxytocin provokes contraction of alveolar cells within the structures of the breast resulting in the flow of milk within the breast.[8, 9, 10, 11] Milk flows from the alveoli through the ductal structures of the mammary gland to the opening of the ducts in the nipple. This process is called the Milk Ejection Reflex (MER) or 'letdown'. As shown in literature, the MER is vital in the lactation process[12, 13], and is strongly associated with a psychosocial trigger.

Although milk production is primarily the focus for mothers and health care professionals, due to the cautions around the availability of appropriate volumes for newborns and growing infants, the MER remains in the background for much of the public's awareness around establishing milk supply. Without MER, no significant amount of milk can be removed from the breast[12, 13], and even when using a strong vacuum pump only a small amount of milk can be expressed. Additionally, there are indications in literature that eliciting a faster MER results in more milk and faster milk removal.[14]

The new era of breast pumping

There is professional consensus that breast pumps are a useful technology in supporting new parents to provide their infant with breast milk. Combined with the added benefits of skin-to-skin contact, demand feeding patterns and allowing for organic hormone stimulation via suckling, it is regarded that an infant suckling directly at breast is the most effective and efficient at expressing the breast milk.

Much of the conventional breast pumps available on the market have primarily focused on utilizing vacuum, with varying profiles of frequency and intensity, as an effective method in removing milk from a lactating breast.

However, studies show that there is a possibility that the MER occurs much faster due to stimulation by baby compared to the different stimulation patterns of a breast pump. This has prompted some investigation into the effect of a compression or tactile component in a breast pump design.[15, 16, 17] Notably, these studies mainly focus on compression implemented as a mechanical component rather than a sensory stimulus of the tactile receptors.

As the effective stimulation of the nipple-areola complex remains essential in the routines of women who wish to feed their infant's breast milk, either directly or through milk expression using a breast pump, Philips Avent has developed an expression kit that provides tactile stimulation directly upon the areola and nipple (collapsing funnel that compresses areola and nipple), known as the "natural motion technology". In addition, the adjoining electric motor unit has optimized vacuum profiles that better mimic the suckling pattern of an infant (particularly the transition time from nonnutritive suckling (NNS) to Nutritive suckling (NS).

To best infer the benefits of such a technology in organic milk expression sessions, Philips Avent conducted a community-based clinical trial in the Netherlands in 2019.

Philips Avent has developed an electric breast pump range attempting to mimic a baby's sucking behavior. Compared to the currently marketed device (our predecessor, the Philips Avent Comfort electric breast pump), the Philips Avent Electric Breast Pump's new features include a new vacuum profile, with a fast vacuum rate application, a smart setting so that the device automatically and smoothly will change from stimulation to expression setting, a high cycle time and high number of vacuum levels. The novel expression kit has a soft silicon shield that collapses during expression in order to stimulate the nipple and areola directly.

Study details

Study population

In total, twenty Dutch mothers completed milk expression sessions in their homes, led by a lactation consultant. Mothers could not participate if they experienced any of the known side effects of breastfeeding / breast pump use (sore nipples, nipple trauma, bruising, engorgement, clogged mammary ducts, lactostasis, mastitis) at the time of the study. The majority of the subjects had an age between 31 and 40 years and were Caucasian. All were breastfeeding their baby since he/she was born and were experienced with using a breast pump.

Figure 1 – Study design

This clinical study was designed as a randomized, crossover trial evaluating the performance of a single and double electric breast pump, and with the novel collapsing expression kit, in healthy lactating mothers.

Each expression session took place at a subject's home and was led by a lactation specialist.

For each subject, a total of four expression sessions took place, which were randomized as per regimen.

Each subject also performed both a single and double expression regimen twice. During each single expression session, the subjects pumped both breasts sequentially (right followed by left).

Each subject was asked to continue expressing until she perceived her breasts as empty. Data was collected in the form of objective measurements of the time to milk ejection reflex and milk volume, and questionnaires completed before and after expression sessions, to collect subjective opinion on the breast pump and overall session.

Ethical consideration

Institutional Review Board (IRB) approval was obtained, prior to consent and enrollment of any subject, and distribution of any test article. The study was planned to be conducted according to the IRB-approved study protocol; International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (GCP) as described in 21 CFR 812.28(a) (1) and ISO 14155 Clinical Investigation of Medical Devices for Human Subjects and applicable national regulations. All subjects provided written Informed Consent before study participation.

Outcomes

Compared with the predecessor device a significant faster time to MER and a significant higher end milk volume is observed. With the use of the novel breast pump technology, it took on average 46.1 seconds for MER to occur with the double pumping regimen and 51.8 seconds with the single pumping regimen.

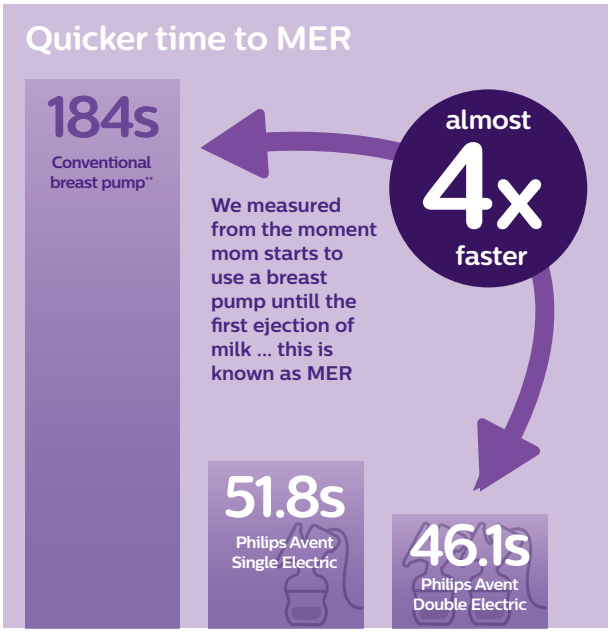

Figure 2– MER results

The majority of the subjects were "Satisfied" or "Very satisfied" with the amount of expressed milk, the time needed to express the total amount of milk, how quickly the MER began, the suction power, the rhythm of the suction pattern, the available suction levels, the comfort and the overall effectiveness of the breast pump. The majority of the subjects scored "Agree" or "Strongly agree" for expression position (comfortable and no need to lean forward), comfort to hold the breast shield on the breast, comfort of the smooth start and automatic change from stimulation to expression phase, gentleness on the breast, soft feel of the breast shield on the skin.

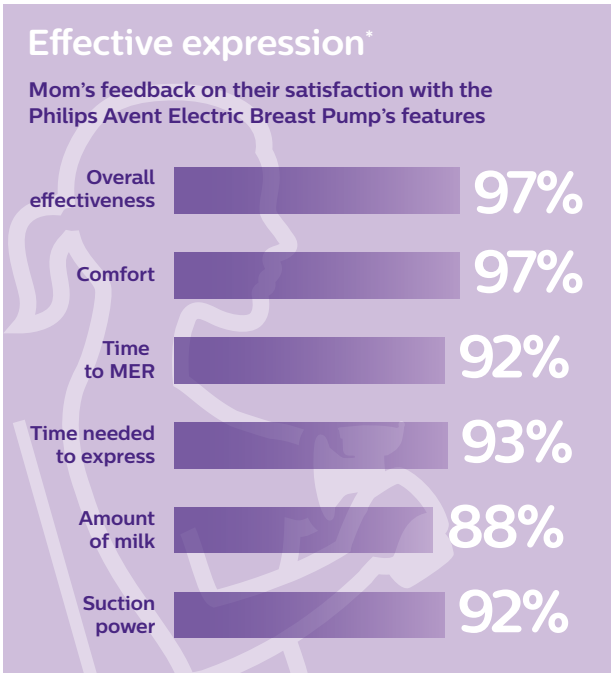

Figure 3 – Mothers feedback on overall effectiveness of the Philips Avent Electric Breast Pump

Conclusion

Breast milk expression remains an important part of balancing the needs of mothers, whether they are away from their infant for a period of time, or simply cannot feed directly at the breast. Supporting mothers to provide their breast milk to infants for as long as possible, remains as a priority for health care entities and industry partners who aim to provide solutions that are underpinned by scientific insights.

By harnessing physiologic insights on tactile stimulation and infant suckling patterns, the new Philips Avent Electric Breast Pump is clinically proven to provide a comfortable and effective experience. With a faster MER, in as little as 46 seconds, mothers were able to elicit a quicker milk flow than the conventional breast pump available on the market. This leaves more time for parents to focus on bonding with their little one, and less time pumping.

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