No. 1 choice of hospitals & mothers

Calma: Feeding solution

Uniquely designed to help maintain a baby's feeding behaviour

"Breastfed infants are able to feed successfully using primarily intraoral vacuum and a tongue movement similar to breastfeeding to remove milk from Calma" Dr Donna Geddes

Calma

Allows babies to use
their natural feeding behaviour
as learnt on the breast

Human milk – the gold standard

Few interventions rival breastfeeding in promoting the health of a mother and her infant. A wealth of scientific evidence demonstrates why, and systematic reviews of the literature have consistently shown that the provision of breastmilk can permanently modify an individual's biological, neural and social growth and development [1]. The Lancet [2] demonstrates this with a profound statement: "If a new vaccine became available that could prevent one million or more child deaths a year and that was moreover cheap, safe, administered orally and required no cold chain, it would become an immediate public health imperative." Breastmilk can do all this and more. From this, breastmilk feeding should be seen as standard, normal nutrition for all newborn infants.

Human milk is species-specific and has been adapted throughout evolution to meet the nutritional requirements of the human infant, supporting growth, development and survival [3]. Breastmilk facilitates safe adaptation to extrauterine life by providing more than just nutrition. The unique, ever-changing constituents of human milk also have developmental and immunological benefits. Breastmilk is an extremely complex biological fluid: it is infused with antibodies to provide protection against infection, something which formula milk cannot do. In addition, breastmilk provides growth-regulatory effects in the form of hormones, growth modulators and growth factors that are not present in artificial substitutes. Certain key components in breastmilk have a unique function. Oligosaccharides, for example, act as decoys for various pathogens, thus preventing their attachment to the gut wall.

Recent research has shown that human milk is a unique source of multipotent stem cells [4]. These living cells have immense differentiation potential, underlining their importance in neonatal development and offering a promising target for stem cell therapy and breast cancer research. This discovery has highlighted the value of human milk for newborn and older infants even more.

The benefits of breastfeeding go beyond the nutritional, developmental and immunological aspects. Bonding and nurturing benefit both mother and baby. However, there are many instances in which an infant is unable to breastfeed directly but can still derive the benefits of breastmilk. The World Health Organisation (WHO) states: "The vast majority of mothers can and should breastfeed, just as the vast majority of infants can and should be breastfed. For those few health situations where infants cannot, or should not, be breastfed, the choice of the best alternative – expressed breastmilk from an infant's own mother, or if not available, breastmilk from a healthy wet-nurse or a human-milk bank, depends on individual circumstances [5]." In whatever way the baby receives breastmilk, it should be considered the norm, and suitable education, knowledge and a warm chain of support all help to make its provision the gold standard for all infants.

Today’s challenges in feeding expressed breastmilk

There are situations in which a mother is unable to breastfeed, whether for medical, social or work-related reasons. Removing milk from the breast is one challenge, and many solutions are now available to support this process. However, feeding the milk to the baby constitutes a new challenge. The principal aim when not feeding at the breast is to create a natural experience, to avoid the baby having to learn a new feeding technique.

Research has shown that the way a baby feeds at the breast is very different from feeding from a standard teat [6–9]. Breastfeeding infants primarily use intraoral vacuum (negative pressure). On the other hand, when feeding from a standard teat milk can flow freely without requiring vacuum, and compression can be used.

Furthermore, it is known that the muscles used for breastfeeding are also different from those used when feeding from a standard teat [10,11]. This requires the infant to learn a different feeding technique.

Some research results show that the use of a standard teat can be linked to malocclusions and the habit of tongue thrusting [12,13], which in turn can lead to an increased risk of otitis media [14].

When comparing breastfeeding and conventional bottle feeding, it has been found that infants feeding at the breast have a greater physiological stability than those feeding from a bottle. In particular, oxygen saturation is higher during breastfeeding than conventional bottle feeding [15–20].

With the development of the WHO / UNICEF “Baby Friendly Hospital Initiative” [5,21], cup feeding became a popular alternative to bottle feeding, as it was suggested that it would help avoid “nipple confusion” caused by the baby drinking from an artificial teat. However, for cup feeding, appropriate training must be in place since there is risk of aspiration if a poor technique is used [22] and milk spillage can also be a significant problem, exposing infants to the risk of under consumption [23]. Studies on the effect of using cup feeding have shown that, compared to bottle feeding, cup feeding confers no significant benefit in maintaining breastfeeding beyond hospital discharge [24,25].

The promotion of breastfeeding is paramount and is always the best option. However, as this is not always possible, safe, research-based alternatives need to be found.

Research and its continuous evolution

Medela continues to be involved in leading-edge basic research. One research initiative has lasted almost 20 years thanks to a special relationship with the Hartmann Human Lactation Research Group of the University of Western Australia (UWA).

Using this research, Medela has been a leading partner in assisting mothers to express milk from the breast by using research-based breastpumps.

Research on Medela’s two-phase breastpumps led Dr Donna Geddes from the UWA to use ultrasound on the lactating human breast. This overturned the knowledge of breast anatomy that had existed for over 160 years [26].

Research and evidence

Figure 1 – Anatomy of the lactating breast [26]

When performing ultrasound scans on the lactating breast, Dr Donna Geddes began to question the anatomical diagrams that appeared in textbooks.

The standard model of the breast was based on anatomical dissections carried out on cadavers by Sir Astley Cooper, who published his results in 1840. Very little research had been carried out since.

The research performed at the Hartmann laboratory made some ground-breaking discoveries that overthrew most of the prior understanding of the anatomy of the lactating breast (Figure 1). The key findings were:

- The number of ductal openings is 4–18 and not 15–20
- The ducts branch closer to the nipple
- The conventionally described lactiferous sinuses do not exist
- Ducts can reside close to the skin surface making them easily compressible
- The majority of the glandular tissue is found within 30 mm of the nipple

This research then led to further questions. If the lactiferous sinuses do not exist, what mechanism does the baby use to remove the milk from the breast? Further research began.

The conventional view of infant sucking comes from a body of excellent research conducted mainly in the 1980s [27–29]. It was based on the earlier understanding of the anatomy of the lactating breast and assumed that the lactiferous sinuses were drawn into the baby's mouth while peristaltic action of the tongue "stripped" the milk from the ducts. The lack of lactiferous sinuses questions this assumption, and further research by Dr Geddes revealed that negative pressure (intraoral vacuum) is the key to milk removal [30].

The key findings of the new research were:

- Vacuum is the key to milk removal
- The tongue moves in an up and down manner without accentuated peristalsis
- The nipple is compressed evenly along its length
- The tip of the nipple does not reach the junction of the hard and soft palates

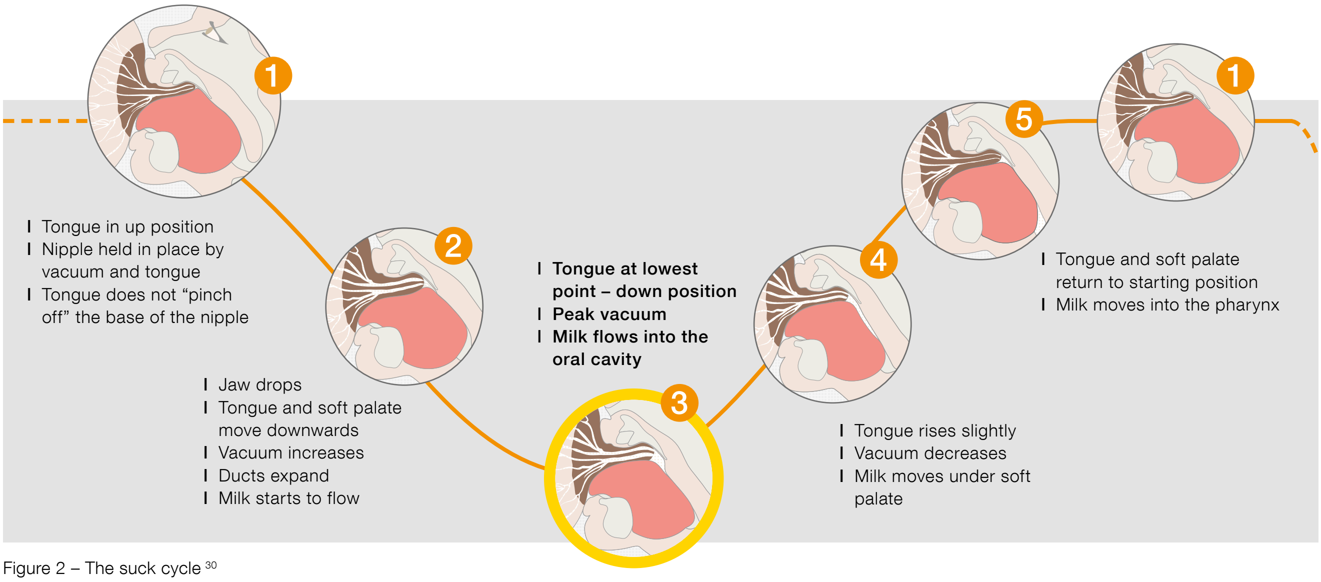

Figure 2 – The suck cycle [30]

During a suck cycle (Figure 2), the vacuum begins at the baseline, increases as the tongue lowers, and reaches a maximum when the tongue is at the lowest point. It is at this point that the milk flows. The tongue then rises and comes to rest again at the baseline – and the milk stops flowing.

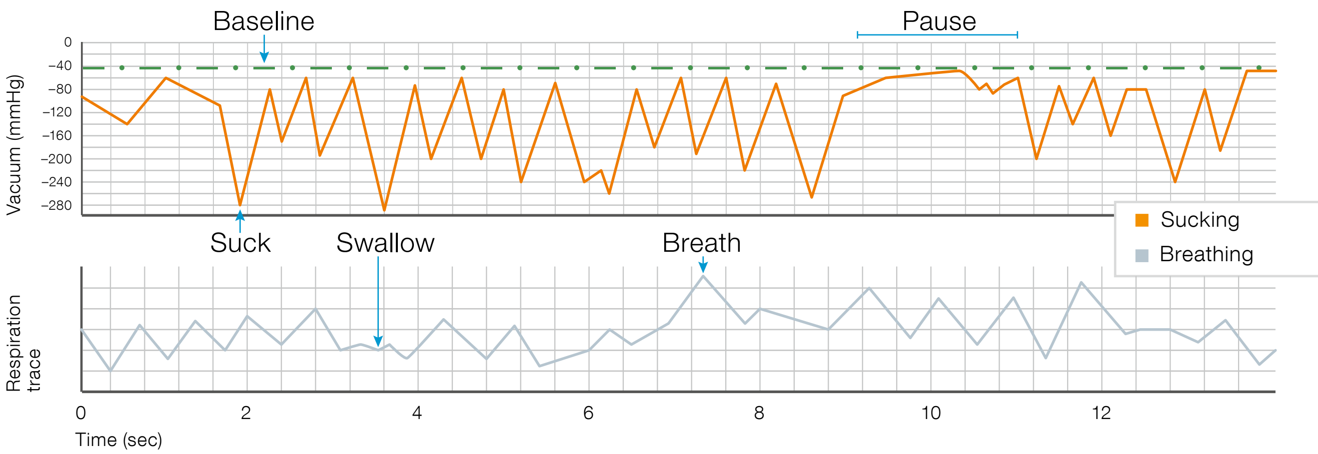

Figure 3 – Example of a synchronised trace of a suck-swallow-breathe pattern [31]

The top graph (Figure 3) shows a baseline vacuum (– · – · – · – ·) of approximately –40 mmHg and a peak vacuum of around –290 mmHg. The breathing (bottom graph) is fairly regular, except when the baby swallows, since babies cannot breathe and swallow at the same time. Note that a swallow can also occur during a suck cycle, and the swallows are not regularly spaced. During a pause, the rate of breathing increases slightly, but a baseline vacuum is maintained. Every baby will have an individual suck-swallow-breathe pattern, which will become more efficient as they age [31].

From vision to reality

Figure 4 – Calma

Research had clearly shown that when breastfeeding, the baby is able to maintain a baseline vacuum, stay attached to the breast, breathe regularly and therefore remain stable and calm.

With that in mind, Medela created their vision to develop Calma (Figure 4), a feeding device based on the baby's natural milk-removing behaviour. Calma's integrated vacuum-controlled valve means, in particular, that the baby is required to create an intraoral vacuum for milk to flow, the baby can maintain a baseline vacuum while sucking, swallowing and breathing and employ an up/down tongue movement to remove milk.

Following the development of Calma, two research initiatives were established, which have produced three peer-reviewed journal articles. One with the Hartmann Human Lactation Research Group from the University of Western Australia [32,33] and the second with Dr Mizuno from Showa University, Tokyo [34].

Hartmann Human Lactation Research Group

The team in Western Australia conducted research aiming to compare feeding at the breast and with the vacuum release teat.

The outcomes they measured were as follows:

1. **Tongue movement and positioning of the nipple in the mouth**
   – Ultrasound imaging was used to measure movement and nipple position.
2. **Intraoral vacuum application during feeding**
   – Intraoral vacuum and 'sucks' were measured with a pressure transducer linked to a small silicone tube placed in the infant's mouth alongside the breast/teat.
3. **Pattern of respiration during feeding**
   – Breathing was recorded using respiratory inductive plethysmography
4. **Heart rate and blood oxygen saturation during feeding**
   – Heart rate and oxygen saturation were measured using a pulse oximeter
5. **Overall patterns of suck, swallow, breathe and pause**

All babies (n = 17) were born after 38 weeks gestation (term) without any oral anomalies such as a cleft palate or ankyloglossia, and all were fully breastmilk fed.

Each baby was monitored for two entire feeds – one feed was at the breast and one using a feed of expressed breastmilk with the vacuum release teat (later called Calma, see Figure 4).

Results

① Tongue movement and positioning of the nipple in the mouth

The Geddes et al. study [33] showed that when the infants were feeding at the breast, or with the vacuum release teat, they used a similar tongue action (Figure 5). As the tongue lowered, the nipple and the teat expanded evenly along their length. There was, however, a larger expansion of the nipple (3.1 mm) than of the teat (1.5 mm), which was expected due to differing flexibilities.

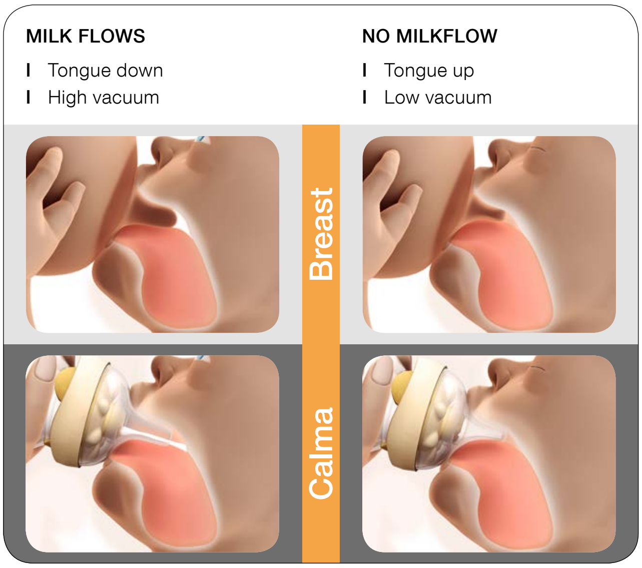

Figure 5 – Up and down tongue movement during milk removal at the breast (upper panel) and with Calma (lower panel).

During breastfeeding, the relationship of the nipple position to the hard-soft palate junction (Figure 6) has been considered important clinically. This study used this landmark to assess whether babies altered the position of the nipple when feeding at the breast or with the teat.

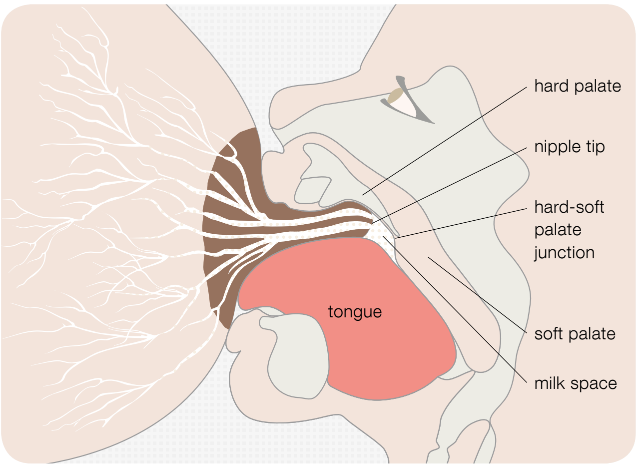

Figure 6 – Internal anatomy of the infant mouth, and nipple position in the tongue down (high vacuum, milk flow) position. The distance can be measured from the nipple tip to the hard-soft palate junction.

The results showed that babies tended to place the teat closer to the hard-soft palate junction in the tongue up position than the nipple (7.8 mm vs 6.9 mm), yet they placed the nipple/teat a similar distance from the hard–soft palate junction when the tongue was lowered (4.7 mm vs 5.3 mm).

It was concluded that the baby was able to place both the nipple and teat in an optimal location in the mouth, and employ an appropriate tongue action to facilitate effective milk removal.

② Intraoral vacuum and milk transfer

Babies were able to successfully maintain a baseline vacuum while feeding both with the vacuum release teat and at the breast.

The baseline varied, reaching approximately –40 mmHg at the breast and up to –30 mmHg with the vacuum release teat. This difference is related to the threshold vacuum required to remove milk from the vacuum release teat, as well as the function of a baseline vacuum. Baseline vacuum is important for positioning the nipple and 'sealing' to the breast. The positioning and sealing of the teat may not require a vacuum as strong as that needed to position and seal to the nipple and breast.

During sucking, babies also had a similar rate of milk transfer per minute when they breastfed or fed with the vacuum release teat, and they also took a similar amount of time feeding at the breast/teat (Table 1). In addition, during nutritive sucking (i.e. milk flow) babies were able to pause and maintain baseline vacuum similarly with both breast and teat. This indicated that the babies were in control of their milk intake and suck-swallow-breathed in their own natural rhythm.

Most importantly, all babies were able to find their own individual feeding pattern with the vacuum release teat, similar to when breastfeeding, and were able to maintain an intraoral baseline vacuum during both nutritive and non-nutritive sucking.

	Breast	Teat
Nutritive milk transfer (g/min)	23.6 ± 14.8	20.3 ± 13.5
Feed duration (s)	623 ± 173	738 ± 336
Nutritive pause duration (s)	3.2 (1.9 – 5.7)	2.8 (1.8 – 4.5)

Table 1 – Milk transfer and pausing during feeding at breast/teat. No significant differences ($p > 0.05$) were observed [33].

③ Suck-swallow-breathe patterns

All babies were able to employ their own individual sucking pattern. When feeding at the breast or with the vacuum release teat, the rate of respiration was similar, as was the rate of sucking. Furthermore, when comparing the number of sucks per swallow and the number of sucks per breath there were also no differences between breastfeeds or teat feeds (Table 2).

This finding means that the coordination of suck-swallow-breathing was not compromised when using the vacuum release teat. The babies were able to safely coordinate their suck-swallow-breathing, and effectively remove milk.

	Respiratory rate (breaths/min)	Suck rate (sucks/min)	Sucks per swallow	Sucks per breath
Breast	59 ± 22	89 ± 19	3.1	1.7
Teat	55 ± 24	88 ± 28	2.7	1.7

Table 2 – Suck-swallow-breathe coordination during feeding at breast/teat. No significant differences ($p > 0.05$) were observed [32].

④ Heart rate and blood oxygen saturation

Blood oxygen saturation levels and heart rates were similar during feeding with the vacuum release teat and during breastfeeding (Figure 7). There was no detectable difference in heart rates, indicating that the vacuum release teat did not cause stress nor compromise the infant. In support of this is the steady rate of breathing the infants had whether feeding at breast or teat (Table 2). This indicates that this teat is conducive to safe and coordinated removal of milk [32].

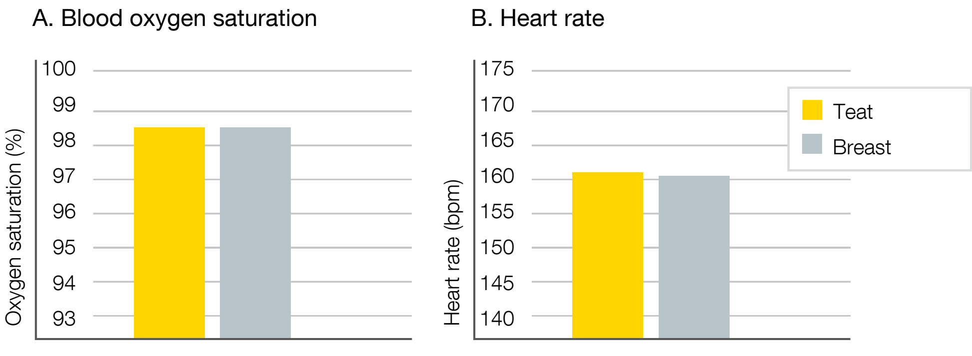

Figure 7 – Graph A represents infant oxygen saturation (%) while feeding at the teat (orange, 98.6 %) and at the breast (grey, 98.6 %). Graph B represents infant heart rate (beats per minute, bpm) while feeding at the teat (orange, 162 bpm) and at the breast (grey, 161 bpm). No significant differences ($p > 0.05$) were observed [32].

Showa University

Dr Mizuno from Showa University, Tokyo, also conducted a research project based on the hypothesis that jaw and throat (perioral) movements and the angle of the mouth would be similar during feeding with a vacuum release teat (later called Calma) and breastfeeding [34].

A total of 20 healthy term infants aged between 1 and 8 months participated in the study. Before the babies fed, markers were placed on the jaw, throat and the side of the eye as shown by the coloured circles in Figure 8. The feeds were video-recorded and the movement between these markers was then analysed with the direct linear transformation technique.

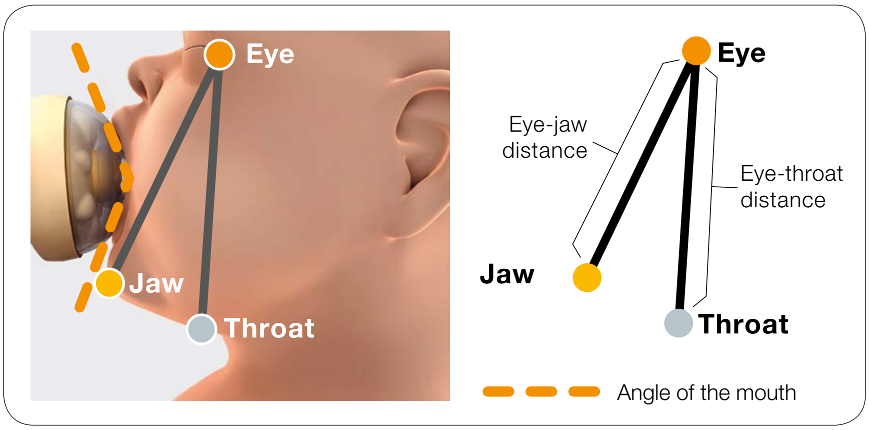

Figure 8 – Measurement of jaw and throat (perioral) movements, and mouth opening angle [34].

Results

The results shown in Table 3 demonstrate that there was no significant difference in either the eye-jaw or the eye-throat measurements when the babies fed with the vacuum release teat or at the breast. In addition, babies opened their mouths to a similar degree when feeding at the breast/teat [34].

	Movement of jaw (cm)	**Movement of throat (cm)**	**Angle of mouth (degrees)**
Breast	2.6 ± 0.5	3.9 ± 0.7	145 ± 10
Teat	2.5 ± 0.5	4.3 ± 1.7	141 ± 10

Table 3 – Perioral movements and angle of the mouth during feeding at the breast/teat. No significant differences ($p > 0.05$) were observed [34].

These results are important since previous studies have reported the angle of the mouth to be 62° [35] when using a standard teat. During breastfeeding, it is known that there is a much wider mouth opening angle than with conventional bottle feeding; in fact, an opening angle of less than 135° is considered an inappropriate latch [36]. This study showed that when infants fed with the vacuum release teat, with its specifically designed wide base, the opening angle of the mouth was much wider, and no different to that measured during breastfeeding (145° breast, 141° teat).

Dr Mizuno states that it has been widely accepted that bottle feeding differs from breastfeeding in many ways. However, the results obtained in this study revealed that this newly developed teat, with its structurally reinforced wide base, reduces the chance of the teat collapsing and provides a more open attachment for the infant. Furthermore, Dr Mizuno suggests that this novel teat may decrease breastfeeding problems related to bottle use [34].

Advantages for the baby

A baby in an established breastfeeding situation creates an individual sucking rhythm, thereby efficiently removing just the right amount of milk at a pace that suits the baby best. This rhythm enables maintenance of good heart rate and oxygen saturation levels due to the ability to suck, swallow, breathe and pause whilst feeding. When feeding with the vacuum release teat, babies were able to remove milk similarly to during breastfeeding, thus ensuring stable, relaxed and calm feeding even when not at the breast.

The key findings of this new research, which scientifically compared breastfeeding and feeding with the vacuum release teat, were that both feeding methods were similar for the following outcomes:

- The tongue movement, nipple positioning and the use of intraoral vacuum to remove milk
- The coordination of sucking, swallowing, breathing and pausing
- The transfer rate of milk and the duration of the feed
- The mouth opening angle (attachment) and the jaw and throat movement
- Physiologic stability as measured by heart rate and oxygen saturation

What about premature infants?

Breastfeeding premature infants

Whilst preterm breastfeeding rates vary worldwide, the incidence and duration of breastfeeding preterm infants continues to be less than that of full-term infants [37]. An inverse relationship between infant gestational age and duration of breastfeeding has been observed [38–40]. The lower incidence is probably related to breastfeeding challenges that preterm infants and their parents face.

Breastfeeding challenges from the infant side are commonly associated with immaturity, medical complications, decreased endurance, weak intraoral vacuum, poor suck-swallow-breathe coordination and/or other difficulties that reduce the infants' ability to apply their natural feeding technique.

Mothers of preterm infants also experience breastfeeding challenges. They may not have a sufficient milk supply due to physiological and emotional challenges partly triggered by premature birth and maternal-infant separation. Depending on the facility and the family circumstances, it might also be difficult for the mothers to be at the infants' bedside the whole time. Moreover, their milk may need to be fortified (especially in the case of infants born weighing less than 1.5 kg [41]) and/or they may not be able to breastfeed due to maternal medication or infection.

Meeting the challenges

The need for a hospital feeding solution to help premature and weak term infants to attain the goal of ever being breastfed for as long as possible is evident. There is a necessity for a feeding device that combines the most successful strategies to support these infants to improve oral feeding skills and get to the breast: self-paced feeding [42] and vacuum build-up training [43].

Improving oral feeding skills will not only accelerate attainment of full suck feeds, thus shortening hospitalisation. It will also reduce the risk of nosocomial infection, lower the financial burden on families and society, allow earlier unification, and facilitate the development of more appropriate mother-infant interaction and bonding.

Calmita is Medela's research-based hospital feeding solution designed to support neonatal oral feeding development. It is a feeding device that allows preterm and term infants to train and apply their natural behaviour to remove milk; particularly the appropriate tongue movement and the application of vacuum including the possibility to maintain a baseline vacuum to suck, swallow and breathe.

A randomised controlled trial with an intention-to-treat strategy that recruited 100 preterm infants was carried out in order to test the effect of the Calmita research device on infant oral feeding development [44]. In addition, ultrasound was used to measure the pattern of tongue movement applied by the preterm infant during feeding at the breast and with the Calmita research device [45].

Outcomes of the randomised controlled trial:

I Earlier discharge home
Using Calmita significantly reduced length of stay by helping the infant to meet hospital discharge criteria earlier. In many NICUs successful full suck feeding is considered as one of the key discharge criteria.

I Natural feeding behaviour
Calmita's vacuum-controlled valve allowed a natural feeding behaviour as the neonate itself controls the milk flow. Therefore, the infant is able to pause and breathe while no milk flows.

I Increased breastfeeding in the hospital
Calmita increases the chance that the neonate can ever be breastfed. By allowing similar mechanical action and tongue movement as at the breast, it supports and protects breastfeeding.

More information about Calmita is available on www.medela-calmita.com

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