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Breast shells for pain and nipple injury prevention: A non-randomized clinical trial

Jessica Oliveira Cecilio [a], Flaviana Vely MendonçaVieira [a,*], Flávia Silva Oliveira [a], Janaína Valadares Guimarães [a], Natalia Del'Angelo Aredes [a], Danielle Rosa Evangelista [b], Suzanne Hetzel Campbell [c]

[a] School of Nursing, Federal University of Goias, Goiânia, Brazil
[b] School of Nursing, Federal University of Tocantins, Palmas, Brazil
[c] School of Nursing, University of British Columbia, Vancouver, Canada

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ABSTRACT

Objective: This study aimed to analyze the effectiveness of breast shells in preventing pain and nipple injury during breastfeeding.
Method: A non-randomized clinical trial was carried out with blinding to the evaluators of the study results. The study included women with ≥35 weeks of singleton pregnancy, no nipple changes, and a desire to breastfeed. Resulting in 62 lactating women. The experimental group used breast shells and health education with clinical demonstration ($n = 29$), whereas the control group used no breast shells ($n = 33$). Pain and nipple injury were assessed three times, twice prenatally and once up to 14 days postpartum.
Results: Nipple injury (50.0%) and nipple pain (67.7%) presented with similar frequency in both groups ($p = 1$). Breast engorgement (35,5%) was associated with nipple pain ($p = 0.019$) and its onset was delayed in the experimental group ($p = 0.001$). Health education contributes to breast and nipple care and increases favorable breastfeeding patterns.
Conclusion: Breast shells do not prevent nipple pain or injury.
Innovation: As far as we know, this is the first clinical research evaluating the use of breast shells since the antenatal care to prevent the occurrence of nipple pain and injury.

1. Introduction

The onset of breast complications during breastfeeding, such as breast engorgement, mastitis, nipple swelling, especially pain and nipple injury, can contribute to early weaning [1], which deprives the lactating mother and newborn of the numerous and extensively described short- and long-term health benefits of breastfeeding [2-4].

Nipple injury can be defined by macroscopic changes in the skin thickness, shape, and continuity and by local color vascular changes associated with pain and discomfort [5-7]. It is often a result of inadequate positioning, latching, and breast engorgement [8-12].

In pathological breast engorgement, the milk accumulated in breast lobules and ducts leaks into the interstitial space, causing lymphatic and vascular congestion and resulting in an inflammatory condition that, if prolonged, can contribute to breast infections, especially if there is a nipple lesion as a "port of entry" to pathogens [11,13]. Edema and hardening of the nipple-areolar complex make it difficult for the newborn to grasp and suckle adequately; therefore, breast engorgement is related to nipple injury as a cause or consequence [14].

Best practices in maternal and child health care include health education activities regarding breastfeeding[7]. Clinical demonstrations on a mannequin and a human anatomical female breast model, focusing on correct breastfeeding technique both in prenatal care [12] and postpartum [15,16] contribute to the prevention of nipple injury in breastfeeding women [12,17-18].

Although pain and nipple injury are frequent complications, there are few clinical studies assessing the use of nipple covers or protective devices during prenatal care to prevent breast complications [12].

Few researchers have been able to clarify the usefulness of devices, such as breast shells, in treating and preventing nipple injury. This gap in knowledge is due to the fact that in these studies, use of the shell started in the postpartum period when a lesion was already present [10,23], or the shell was used with another therapy [10,19,23], contributing to a lack of strong evidence to support usefulness of breast shells.

* Corresponding author at: Setor Leste Universitário, Street 227 Quadra 68, Goiania, Goias 74.605-220, Brazil.
E-mail address: flavianavieira@ufg.br (F.V. MendonçaVieira).

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The breast shell is a plastic device with one part that fits over the nipple and an outer shell with ventilation holes. The shell provides a barrier against friction and pressure on the nipples, allowing the passage of air for aeration of the skin [10,20]. It is made up of two pieces, an inner solid piece with a hole that goes over the nipple and that may collect milk and the other that acts as a protective ventilated shell for the nipple.

Researchers have demonstrated favorable breastfeeding outcomes when the breast shell was used in the treatment of nipple injury and found it to be more effective than anhydrous lanolin with human milk [10] and hydrogel with anhydrous lanolin [20]. Both studies incorporated health education focused on correct breastfeeding techniques [10,20].

This study aimed to analyze the effect of using breast shells since the 35 weeks of pregnancy in preventing pain and nipple injury during breastfeeding. Moreover, it is intended to clarify the best therapy to prevent breast complications and demonstrate whether a comprehensive, individualized, and continuous orientation is sufficient to prevent nipple injury or if adjuvant therapies with covers and devices should be considered. Examining the use of the breast shells to prevent nipple pain and injury during the prenatal period has not been done before.

2. Materials and methods

This non-randomized clinical trial was conducted according to the recommendations of the "Consolidated Standards of Reporting Trials: The CONSORT Statement" and the "Improving the reporting quality of non-randomized evaluations of Behavioral and Public Health Interventions: The TREND Statement" [24].

Sample size calculation was based on a study on health guidance for breastfeeding in the prenatal period with 70 primiparous women from the 36th week of pregnancy [25]. It resulted in a sample of 80 participants randomly distributed between the experimental and control groups, including a 20% loss margin, with a statistical power of 80% and a significance level of 95% ($p = 0.05$).

A total of 81 women undergoing prenatal care in the Unified Health System (SUS) primary care and maternity units were recruited in the city of Goiania, Brazil, between November of 2019 and October of 2021. Participants were divided into an experimental group (EG), with health education on breastfeeding and clinical demonstration and use of breast shells, and a control group (CG) with health education on breastfeeding and clinical demonstration.

The inclusion criteria were age ≥ 18 years; ≥35 weeks of pregnancy calculated by the date of the last menstrual period or obstetric ultrasound; having a landline or mobile phone; and desire to breastfeed.

Exclusion criteria were women with inverted and pseudo-inverted nipples; mothers of twins; or presence of mental illnesses that prevent self-orientation and self-perception.

Inverted or pseudo-inverted nipples can result in difficulties in breastfeeding due to inadequate attachment of the baby, which can favor the emergence of nipple trauma. To eliminate this confounding variable, women with inverted and pseudo-inverted breasts were excluded from the study [8,10].

Participant data was withdrawn if there were obstetric or neonatal complications, if participants discontinued breastfeeding or could not be contacted postpartum after three consecutive phone calls, made on different days and times (Fig. 1).

The study dependent variables were nipple pain and injury. Independent variables were sociodemographic, obstetrical, and neonatal data; information and behavior regarding breastfeeding. To collect the data, it was applied an interviewer-administered questionnaire.

Primary outcomes were nipple pain and injury, and secondary outcomes included breast engorgement, fever, breast care, also time and mode of use and satisfaction with the breast shells for the EG.

After selection collecting informed consent, there were three encounters with the participants: (1) presential and during the antenatal consultants; (2) in one week a second contact was made by telephone; (3) the last encounter occurred after birth.

The first meeting was conducted at the health unit for individual health education. This education session was similar for both CG and EG. It was held in a private environment, lasted 30–40 min, and used a booklet with images created by the researchers. In addition, a clinical demonstration of breastfeeding was provided by the researchers. At the end of the session, EG participants received the breast shell kit.

The protocol of health education on breastfeeding and clinical demonstration was the same for both groups and was applied by the researchers

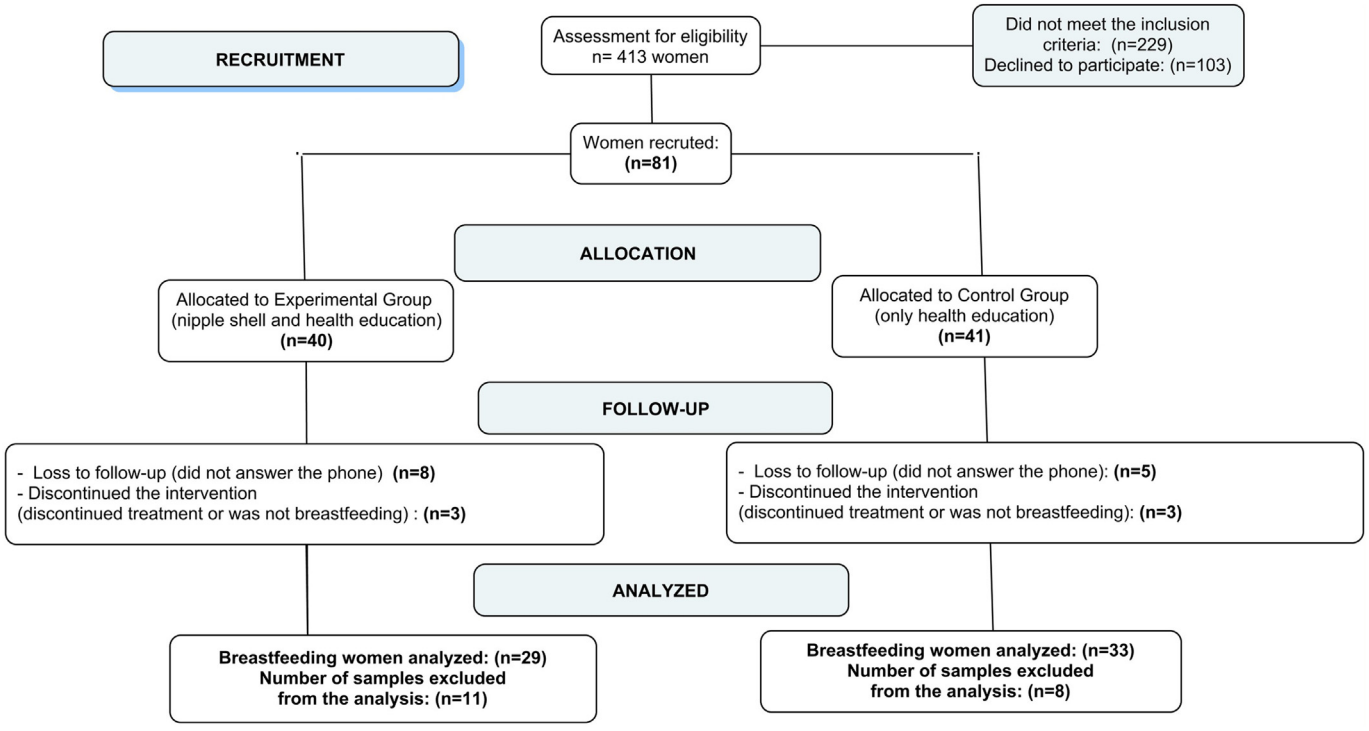

Fig. 1. Flowchart of the procedures used in this study.

with previous training to maintain the same steps during every section of health education. The breast anatomical model and neonatal manikin were used to assist mothers in developing breastfeeding skills through understanding and reproducing the proper positioning and latching of the baby for breastfeeding, assimilation about the mechanisms of milk production, storage and ejection of human milk at the breast, as well as massage and breast milking. An illustrated album, based on the latest breastfeeding orientations of the World Health Organization (WHO), were used to give explanations about breastfeeding.

One week after the first meeting, health education was reinforced by telephone, with a mean duration of 5–10 min for both groups.

The last meeting was held on day 14 of puerperium at the health unit or at the lactating mother's home to assess the variables. At that time, the mode of use and cleaning of the breast shells was evaluated in the EG, as well as the satisfaction of lactating women in using breast shells through a five-point Likert scale ranging from "I loved it" to "I hated it."

Nipple pain intensity was assessed using the numerical verbal pain scale, in which values ≤ 3 correspond to mild pain; 4–6, moderate pain; 7–9, intense pain; and 10, unbearable pain [26]. Nipple injury and breast engorgement were clinically evaluated.

The parameters verified to assess breastfeeding included the general observation of the lactating woman, mother and infant positioning, breast condition, infant latching and sucking, and affective bond. The clinical evaluation of these parameters was classified as favorable, slightly unfavorable and unfavorable according to the researcher's observation and maternal speech using the Breastfeeding Assessment Form [27].

The standard soft base breast shell kit included two pairs of devices for prenatal and postpartum use. Lactating women received an illustrated educational leaflet on the use and care of the nipple, including the specification to perform high-level disinfection in boiling water for 5 min before first use. They were instructed on the use of the breast shell by the researcher who performed the recruitment as follows: start using the breast shells for 2 h during prenatal care, gradually increasing their use from the establishment of breastfeeding, removing the shell at the time of breastfeeding and during sleep; sanitize hands and cup with soap and water every time the device is replaced after breastfeeding; and discard all the milk that had drained into its reservoir.

The research team was composed of nurses with experience in breastfeeding. The team was trained by the main researcher to standardize data collection. The data collection steps were randomly performed by the research team to avoid bias, thus, the researcher who recruited the participants offered health education and guidelines on the use of the shell, however, the clinical observation, data tabulation and analysis of the results of this participant was performed by other researchers on the research team.

To minimize potential bias, the following precautions have been taken, (1) selection bias: participants were recruited initially to the CG and subsequently to the EG, preventing "contamination" of one group with another; (2) confounding bias: the health education protocol and data collection questionnaires were reviewed for experts to reduce the confounders, and data analysis was conducted with statistical stratification; (3) loss of follow up bias: a reinforcement of the orientations were made by telephone contact to avoid forgetfulness and discontinuity; (4) compliance with the intervention components: based on the instructions provided, participants are expected to have performed the necessary procedures. In all contacts with the participants, the intervention was reinforced. In the third and last moment, with the participant, the researcher team questioned her adherence to the research procedures.

The Statistical Package for the Social Sciences (SPSS) was used for data analyses. Descriptive measures are presented for quantitative variables (mean, standard deviation, median, and quartile) and absolute frequencies and percentages are presented for qualitative variables.

The Shapiro–Wilk test was used to verify normality. Student's *t*-test or the Mann–Whitney test were used to compare the two groups according to data distribution.

The Chi-square or Fisher's exact tests were used to compare categorical variables between groups. A 5% significance level was considered in all analyses.

The relative risk (RR) and its 95% confidence interval were calculated to measure the intervention effect on the main outcomes.

Ethical and legal guidelines for human research were followed, as recommended by resolution 466/12 of the National Health Council of the Ministry of Health. The study was approved by the Research Ethics Committee of the Federal University of Goias Clinical Hospital (no. 896,640 and CAAE no. 37382214.2.0000.5078) and was published on the Brazilian Registry of Clinical Trials platform (Registro Brasileiro de Ensaio Clínico–ReBEC, www.ensaiosclinicos.gov.br; registry code RBR-7tvhq8).

3. Results

The groups were homogeneous for sociodemographic characteristics and obstetric and neonatal data, except for paid occupation (EG: 82.8%, CG: 51.5%; $p = 0.020$).

At least 36.4% of lactating women reported having attended high school, and 17.7% had completed higher education. Only 9.7% had less than primary education.

The mean age of the lactating women was 26.5 ± 5.8 years, and most of them self-declared to be *Pardo* and black (71.0%) and having a partner (87.0%). Obstetric and neonatal characteristics are shown in (Table 1).

Of the women who had previously breastfed their child, 51.6% reported experiencing some type of breast complication, such as pathological engorgement (38.7%) or nipple injury (29.0%).

In the third meeting, both groups presented favorable parameters for breastfeeding, and only the breast condition was unfavorable (69.4%) (Table 2). The condition of the breast was evaluated according to the presence of breast complications resulting from breastfeeding, such as signs of engorgement, breast mastitis and nipple changes.

Breast care was frequent in the EG, with 86.2% of EG participants performing massage and milk expression ($p = 0.004$). Furthermore, 86.2% of the EG performed the technique of introducing the little finger in the newborn's mouth to break the latch before stopping breastfeeding, with a significant difference between groups ($p = 0.028$).

In the EG, 48% of the lactating women used the breast shell throughout the day, removing it only to breastfeed and during sleep, and 52% used it at alternate times during the day. However, these data were not significant for the onset of pain ($p = 0.682$), nipple injury ($p = 0.847$), and breast engorgement ($p = 0.562$).

Lactating women who constantly used the breast shell had a later onset of breast engorgement, with a mean of 5.7 ± 3.8 days, while lactating women with non-constant use during the day had breast engorgement with a mean of 3.7 ± 1.1 days.

Four women complained of aesthetic discomfort (13.8%), and two reported areolar edema (6.8%) due to breast shell use. In cases where the breast shell caused discomfort, the woman was instructed to discontinue its use immediately. The perception of increased nipple protrusion with breast shell use was reported by 10 participants (34.5%).

Most rated satisfaction with the use of the breast shell as "loved it" (41.4%) or "liked it" (27.6%), some were "indifferent" (24.1%), and only one (3.4%) rated it as "did not like it." Satisfaction with the use of the breast shell was associated with planned pregnancy ($p = 0.027$).

Half of the lactating women in the sample developed nipple injury (50.0%), with 51.7% of the cases in the EG and 48.3% of the cases in the CG. At the same time, the lactating women experienced nipple pain (68.0%) both in the EG (72.4%) and CG (63.6%), especially bilaterally (43.5%) (Table 3).

The onset of nipple injury occurred on a mean of 2.6 ± 1 days postpartum in the CG and 2.7 ± 1.3 days postpartum in the EG ($p = 0.862$). Nipple pain started concomitantly with nipple injury, on a mean of 2.4 ± 1.2 days postpartum in the CG and 2.1 ± 0.7 days postpartum in the EG.

On average, the CG classified nipple pain as severe (7/10) and the EG as moderate (6/10) (SD ± 2.2) ($p = 0.252$).

Pathological breast engorgement began on the third day (3.1 ± 1.5) in the CG and on the fifth day (4.9 ± 3.1) in the EG, with a significant difference between groups (p 0.01; Mann–Whitney test).

Table 1
Obstetric and neonatal characteristics according to allocation group.

Variables	Allocation group			p[a]
	Control $n = 33$ (%)	Experimental $n = 29$ (%)	Total $n = 62$ (%)	
Parity				
Primiparous	13 (39.4)	16 (55.2)	29 (46.8)	0.323[a]
Multiparous	20 (60.6)	13 (44.8)	33 (53.2)	
Planned pregnancy				
Yes	10 (30.3)	15 (51.7)	25 (40.3)	0.145[aa]
No	23 (69.7)	14 (48.3)	37 (59.7)	
No. prenatal visits				
<6	5 (15.2)	0 (−)	5 (8.1)	0.055[aa]
≥6	28 (84.8)	29 (100)	57 (91.9)	
Type of delivery				
Vaginal	12 (36.4)	13 (44.8)	25 (40.3)	0.676 [a]
Cesarean section	21 (63.6)	16 (55.2)	37 (59.7)	
NB sex[b]				
Female	15 (45.5)	15 (51.7)	30 (48.4)	0.812[a]
Male	18 (54.5)	14 (48.3)	32 (51.6)	
NB weight[b]				
≤2.499 g	3 (9.1)	1 (3.4)	4 (6.5)	0.616[aa]
2, 500–3999 g	29 (87.9)	28 (96.6)	57 (91.9)	
≤4000 g	1 (3.0%)	0 (−)	1 (1.6)	
Skin to skin contact				
Yes	27 (81.8)	21 (72.4)	48 (77.4)	0.562[a]
No	6 (18.2)	8 (27.6)	14 (22.6)	
Breastfed in the delivery room				
Yes	12 (36.4)	14 (48.3)	26 (41.9)	0.49[a]
No	21 (63.6)	15 (51.7)	36 (58.1)	
First breastfeeding				
≤1 h	18 (54.5)	15 (51.7)	33 (53.2)	1[a]
>1 h	15 (45.5)	14 (48.3)	29 (46.8)	
Place of delivery				
Public and ACH[c]	26 (78.8)	22 (75.9)	48 (77.4)	1[aa]
Public and not ACH[c]	2 (6.1)	2 (6.9)	4 (6.5)	
Private	5 (15.2)	5 (17.2)	10 (16.1)	
EBF[d]				
Yes	25 (75.8)	22 (77.9)	47 (75.8)	1[aa]
No	8 (24.2)	7 (24.1)	15 (24.2)	
Breastfeeding on demand				
Yes	30 (90.9)	26 (89.7)	56 (90.3)	1[aa]
No	3 (9.1)	3 (10.3)	6 (9.7)	
Artificial nipple				
Not offered	20 (60.3)	16 (55.2)	36 (58.1)	0.861[a]
Offered	13 (39.4)	13 (44.8)	26 (41.9)	

P-value: [a]Chi-square test, [aa]Fisher's exact test; [b]NB: newborn; [c]ACH: Amigo da Criança Hospital; [d]EBF: Exclusive breastfeeding 15 days postpartum.

Of the variables analyzed, being primiparous was associated with the onset of pain during breastfeeding (82.8%, $p = 0.036$), and the presence of breast engorgement was associated with nipple pain (75.5%, $p = 0.019$). For the assessment of the breastfeeding technique, an "unfavorable" breast condition pattern was significantly associated with pain ($p < 0.001$) and nipple injury ($p = 0.006$).

4. Discussion and conclusion

4.1. Discussion

A systematic review evaluated the most used covers for the prevention of nipple injury, reporting positive results with the use of water or mint gel and guaiazulene (high or moderate recommendation). The authors reinforced the need to explore other cover and protection devices, such as breast shells, which prevent friction in the nipple-areolar complex when used during prenatal care and not only during postpartum [12].

Table 2
Distribution of breastfeeding assessment parameters during postpartum follow-up according to allocation group.

Parameters	Allocation group			p
	Control $n = 33$ (%)	Experimental $n = 29$ (%)	Total $n = 62$ (%)	
General observation				
Favorable	28 (84.8)	28 (96.6)	56 (90.3)	0.363[aa]
Slightly unfavorable	3 (9.1)	1 (3.4)	4 (6.5)	
Unfavorable	2 (6.1)	0 (−-)	2 (3.2)	
Position				
Favorable	20 (60.6)	17 (58.6)	37 (59.7)	1[aa]
Slightly unfavorable	9 (27.3)	8 (27.6)	17 (27.4)	
Unfavorable	4 (12.1)	4 (13.8)	8 (12.9)	
Breast condition				
Favorable	12 (36.4)	7 (24.1)	19 (30.6)	0.501[a]
Slightly unfavorable	15 (45.5)	14 (48.3)	29 (46.8)	
Unfavorable	6 (18.2)	8 (27.6)	14 (22.6)	
Latch				
Favorable	29 (87.9)	22 (75.9)	51 (82.3)	0.173[aa]
Slightly unfavorable	4 (12.1)	4 (13.8)	8 (12.9)	
Unfavorable	0 (−-)	3 (10.3)	3 (4.8)	
Suction				
Favorable	30 (90.9)	25 (86.2)	55 (88.7)	0.696[a]
Slightly unfavorable	3 (9.1)	4 (13.8)	7 (11.3)	
Unfavorable	0 (−-)	0 (−)	0 (−)	
Affective bond				
Favorable	29 (87.9)	28 (96.6)	57 (91.9)	0.360[aa]
Slightly unfavorable	4 (12.1)	1 (3.4)	5 (8.1)	
Unfavorable	0 (−-)	0 (−-)	0 (−)	

P-value: [a]Chi-square test or [aa]Fisher's exact test.

The frequency of nipple injury among lactating women in this study was 50.0%. Another study that used breast shells as a treatment reported the frequency of nipple injury in the first week postpartum to be between 29% and 76% [23]. Nipple injury has a higher incidence in the first week postpartum [6,8,10], emphasizing the importance of interventions to prevent breast complications from the first feeding, thus maintaining breastfeeding.

Breast shells help protect the nipples, avoid friction or attrition, and allow faster healing of nipple injuries [10,23], as evidenced in a randomized clinical trial analyzing breast shells combined with the application of human milk itself, which accelerated nipple injury healing from the third day of use [10].

In the present study, 34.5% of women noticed increased nipple protrusion with the use of the breast shell. Previous studies showed a significant

Table 3
Assessment of pain and nipple injury in lactating women according to allocation group.

Variables	Allocation group			p
	Control $n = 33$ (%)	Experimental $n = 29$ (%)	Total $n = 62$ (%)	
Nipple injury				
Yes	16 (48.5)	15 (51.7)	31 (50.0)	1[a]
No	17 (51.5)	14 (48.3)	31 (50.0)	
Pain				
Yes	21 (63.6)	21 (72.4)	42 (67.7)	1[a]
No	12 (36.4)	8 (26.6)	20 (32.3)	
Breast engorgement				
Yes	19 (57.6)	16 (55.2)	35 (56.5)	1.00[a]
No	14 (42.4)	13 (44.8)	27 (43.5)	
Fever				
Yes	3 (9%)	4 (13.8%)	7 (11.3)	0.671[aa]
No	30 (91%)	25 (86.2%)	55 (88.7)	

P-value: [a]Chi-square test or [aa]Fisher's exact test.

association between nipples classified as inverted, flat, pseudo-inverted, and semi-protruding and the onset of a nipple injury [6-10]. However, nipple preparation during pregnancy does not protect against nipple injury[9] and is not advised for having more risks than benefits [28-29].

A clinical study found no association between breast shells and Hoffman exercises for nipple preparation [22]. However, a case report found nipple hypertrophy after breast shell use for 3 days [30], although with a weak level of evidence for clinical practice and decision making. Notably, variations in nipples, such as inversion, are not an impediment to breastfeeding. Rather, proper breastfeeding technique is essential for successful breastfeeding regardless of the nipple [29].

Nipple pain was present in 67.7% of the lactating women. A Brazilian clinical study on breast shells combined with the application of human milk to the nipples to treat nipple injury reported a frequency of nipple pain in the first postpartum weeks between 36% and 79% [10]. Some authors reported reduced pain scores with the use of breast shells compared to anhydrous lanolin [10], mint gel, and human milk [23] and combined with anhydrous lanolin [20,21].

In the present study, although the pain experienced by lactating women who used the protective device was less intense, the difference between groups was not significant ($p = 0.252$). This finding can be explained by the favorable parameters in the assessment of breastfeeding in both groups which may be due to the exposure to the research team and health education session with demonstration of breastfeeding techniques. A control group of those receiving traditional care may have uncovered greater differences between groups.

The literature associates being primiparous with the onset of nipple injury [6]. In this study, this variable was associated with pain ($p = 0.036$) and concomitant with the onset of injury, which can be explained by the lack of previous breastfeeding experience and the fact that the nipple-areolar complex is being exposed for the first time to stimulus and suction pressure by the newborn and contact with fluids and saliva during breastfeeding [6].

Unfavorable breast condition was significantly associated with the onset of pain ($p < 0.001$) and nipple injury ($p = 0.006$), as this condition suggests difficulties with proper breastfeeding technique. This increased frequency (76.0%) is associated with nipple injury and breast engorgement during breastfeeding assessment and similar results have been documented [31].

The use of the breast shell in this study reduced pathological engorgement in lactating women (34.5%) and delayed its onset until the fifth day postpartum (4.9 SD ± 3.1) ($p = 0.01$). Moreover, the breast shell may have some influence on the drainage of stagnant milk in the breast due to the slight pressure exerted on the breast areola [10] and on reduced discomfort [19], although this hypothesis is not confirmed in the literature [10,23]. The use of the breast shell should be investigated in engorged breasts, since an areola hardened by the presence of stagnant milk in the lactiferous ducts may not accommodate well to the device, facilitating the development of edema at the site, as described by two participants in this study (6.8%).

The resolution of pathological breast engorgement must follow the recommendations for breast massage and manual milk expression, and medications and other therapies may be prescribed according to medical advice [14,18].

Despite not having a significant contribution to the prevention of breast complications, the satisfaction of most lactating women with the use of the breast shell is an important aspect to be addressed since satisfaction leads to improved adherence to the intervention and breast comfort during breastfeeding [10,19].

The main factor associated with lower satisfaction with the use of breast shells ($p = 0.027$) was unplanned pregnancy. Other studies showed that lactating women who had unplanned or unwanted pregnancies are less likely to adhere to favorable breastfeeding behaviors, reinforcing that inadequate family planning can have a negative effect on breastfeeding duration [32].

The use of breast shells was not harmful to pregnant women in the last trimester when respected the right recommendations of use, such as adequate hygiene of the device, and to avoid using the breast shells during sleep, or in the presence of breast engorgement, once in these cases the excess of pressure by the device could cause local edema.

This study reinforces the importance of providing health education on breastfeeding from the prenatal to the postpartum period, especially in demonstrating the proper breastfeeding technique [17,18]. This may have contributed to favorable breastfeeding technique patterns in both groups, particularly in mother and infant positioning (59.7%) and infant latching (82.3%) and suckling (88.7%).

The absence of randomization and double-blinding between groups is a limitation of the study since the conformation and mode of use of the breast shell prevent the creation of matching placebo. Once breast shells are a plastic device with a particular conformation, there was no secure way to blind the experiment. On the other hand, all data was transferred in a code system to the database, avoiding exposure of the participants identity. All data and statistical analyses were conducted and reviewed for blinding assessors. The participants were sequentially allocated between groups due to the period of data collection, in which it was necessary to restructure the strategy for including lactating women to adapt to the new safety protocols implemented in the health units due to the SARS-CoV-2 pandemic.

4.2. Innovation

There are very few studies conducting the use of breast shells for treatment and none evaluating its use for prevention of nipple pain and injury. This lack of recent clinical studies generates insecurity in the prescription of this device for lactating women, once its adequate mode of use to prevent adverse effects is little explored. Often breast shells are confounded with different devices, as the nipple shields, which cooperates to increase misinformation.

We suggest that this study helps to clarify these doubts once breast shells have been applied since the antenatal care to prevent the occurrence of nipple pain and injury. Although there were no significant results on its prevention, breast shells have demonstrated to be associated with more comfort in lactation, once it showed a good satisfaction between the participants and reduced the very common discomfort due to physiological breast engorgement during milk outflow on first days of postpartum.

4.3. Conclusion

The use of breast shells for prenatal care was not effective in preventing the onset of pain or nipple injury. However, there was an association between the use of the shell and a delay of 5 days in breast engorgement, which can infer the need to continue studies with the use of the shell as a device to prevent breast engorgement.

Furthermore, good satisfaction with the use of the breast shell was observed among lactating women in this study.

Providing clinical demonstration of the use of breast shells and health education on breastfeeding during the prenatal period can contribute to the prevention of the main risk behaviors for breast complications in breastfeeding that particularly involve breastfeeding technique and breast and nipple care.

Future research on breast shells should measure the daily use of the device in terms of the number of hours per day it has been used. Although placement of the breast shell is simple, there may be risks of adhesion since it is a plastic or silicone device, with a different mode of use from other gels or ointments. Thus, the dynamics of use can undergo daily adaptations according to the needs and routine of each lactating woman. Moreover, it is important to understand how the number of daily hours of breast shell use can interfere with the prevention or onset of breast complications. In addition, a control group not exposed to the educational session may demonstrate significant differences in nipple pain and injury when provided traditional care.

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CRediT authorship contribution statement

Jessica Oliveira Cecilio: Conceptualization, Methodology, Investigation, Data curation, Writing – original draft, Visualization. **Flaviana Vely MendonçaVieira:** Supervision, Project administration, Funding acquisition, Conceptualization, Visualization, Writing – review & editing, Data curation, Formal analysis, Resources. **Flávia Silva Oliveira:** Data curation, Writing – review & editing, Investigation, Visualization. **Janaína Valadares Guimarães:** Supervision, Methodology, Validation, Formal analysis, Writing – review & editing. **Natalia Del'Angelo Aredes:** Methodology, Validation, Formal analysis, Writing – review & editing. **Danielle Rosa Evangelista:** Methodology, Validation, Formal analysis, Writing – review & editing. **Suzanne Hetzel Campbell:** Validation, Writing – review & editing.

Declaration of Competing Interest

The authors have no conflicts of interest to disclose.

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