

Development of aids to relieve vulvodinia during the postpartum period

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Abstract: Postpartum women live with a low quality of life due to pain caused by episiotomy and perineal laceration. In particular, they endure pain when sitting for long periods of time to breastfeed. The purpose of this study is to develop a sitting aid to alleviate postpartum vulvodinia. This study was conducted in the following four phases from July 2017 to May 2019. They are: material selection and molding, cleaning and disinfection testing, pressure distribution measurement testing, and trial testing by postpartum women. The main material was a 100% polypropylene object with a three-dimensional reticular fiber spring structure and fiber density of 3.8 kg/m². As a result, a sitting aid that withstands washing and disinfection well in the medical field and is breathable. It had moderate resilience and elasticity and reduced pressure on the seating surface for women weighing approximately 45 kg and 55 kg, but we were skeptical about its use for women weighing more than that. The completed sitting aid is noninvasively effective in improving the quality of life of many postpartum women, but the density and thickness of the main material should be reexamined to meet the needs of women in a wider weight range. In addition, a self-administered questionnaire survey of trial users revealed that some women did not experience relief from vulvodinia even after using the sitting aid. Such women also had physical problems such as discomfort in the lower back, difficulty breastfeeding, and difficulty standing up. For women with multiple physical problems, individual causes should be addressed.

Keywords: postpartum women, episiotomy, perineal laceration, vulvodinia

Introduction

Lacerations of the birth canal often occur during the parturition period (1). Lacerations may occur spontaneously at the perineum, cervix, vagina, or vulva, or by extension of a perineotomy wound (1,2). To prevent severe perineal lacerations, perineal massage during pregnancy and parturition (3,4), and Pilates exercises during pregnancy (5,6), However, none of these reports have yet been confirmed to be effective, nor have superior interventions been identified (7). In many countries, perineotomy may be used to prevent severe perineal lacerations (8). The use of elective perineotomy remains useful and should be performed based on clinical judgment and maternal or fetal indications. Even today, perineotomy is routinely performed in some countries (9). There have been reports of the application of herbal creams or herbal oils to perineal incision wounds (10-12), Far-infrared irradiation of perineotomy wounds for pain relief (13), low-frequency therapy (14), and low-level laser therapy (15) have been used, however, their efficacy has not been proven (1,8). There is also a report that auricular acupuncture was effective in relieving vulvodinia in postpartum women, but the number

of patients involved was 29 and the mechanism of action was not reported (16). Thus, perineal lacerations and perineal injuries caused by perineotomy are not only painful but also have significant physical and psychological effects on the lives of many postpartum women (17,18).

Circular seats made of rubber or urethane or postpartum chairs made of urethane covered with synthetic leather have traditionally been used for vulvodinia pain during the sitting position in the postpartum period. However, these have the problem that prolonged use causes vulvar congestion and traction of the skin around the wound, which adversely affects wound healing and wound pain (19). Therefore, it is important to develop an aid that does not increase wound pain and does not interfere with wound healing even after prolonged use in the sitting position during repeated postpartum breastfeeding (20). It is also important that the assistive device be breathable, washable, and disinfectable to maintain hygiene. Effective aids to relieve postpartum vulvodinia have not yet been developed.

The purpose of this study was to develop an assistive device to prevent vulvar pain augmentation that occurs in

the sitting position.

Materials and Methods

This study was conducted in the following four phases. The four phases were conducted from July 2017 to May 2019.

Phase 1. Material selection, molding (July 2017 to December 2017): In this phase, we selected the appropriate materials and developed the initial molds for the sitting aid.

Phase 2. Washing and disinfection tests (January 2018 to November 2018): During this phase, the washability and disinfectability of the materials used in the sitting aid were thoroughly tested to ensure hygiene and safety.

Phase 3. Body pressure distribution measurement test (December 2018 to February 2019): This phase involved testing the pressure distribution characteristics of the sitting aid, using body pressure measurement techniques to assess its effectiveness in reducing vulvar pain.

Phase 4. Trial test by postpartum women (March 2019 to May 2019): In the final phase, the developed sitting aid was trialed by postpartum women to evaluate its practical effectiveness and gather user feedback.

Material

In this study, two materials were selected to develop the sitting aid, focusing on their suitability for the postpartum period. This period is characterized by lochia discharge, making it essential to use materials that are easy to clean and disinfect. Additionally, postpartum women often use sanitary pads, increasing the need for materials that offer breathability to prevent discomfort and skin issues. The selected materials also needed to provide an appropriate level of firmness for comfort and support.

CALFIBER®: *i)* Material: 100% polypropylene, *ii)* Structure: Three-dimensional reticular fiber spring structure, *iii)* Fiber density: 3.8 kg/m², *iv)* Characteristics: High elasticity and resilience, breathability, heat retention, light weight, heat resistance, easy to keep clean.

V-lap®: *i)* Material: 100% polyester, *ii)* Structure: Vertical non-woven fabric structure, *iii)* Characteristics: Breathable, lightweight, heat resistant, disposable.

Both materials satisfy the specific requirements of postpartum care, offering comfort, hygiene, and practicality, essential for products intended for use during the postpartum period.

Molding

Circular seats can cause the vulva to become congested when sitting on them because of the indentation in the middle. Therefore, we devised a shape that does not press on the vulva when sitting and does not cause congestion.

The sitting aid is made by punching the above material into a U-shape in order to support weight on the entire thigh. The shape and size of the sitting aids produced are shown in Figure 1.

Washing and disinfection tests

The washing and disinfection tests were conducted under the general medical instrument washing methods outlined (21). The following three types of washing and disinfection tests were performed using CALFIBER® punched into a U-shape (hereinafter referred to as "U-shaped CALFIBER®"). For each washing or disinfection of the U-shaped CALFIBER®, the size of the nine points shown in Figure 2 was measured with a ruler. In addition, the presence of deformation was visually determined. V-lap® was excluded from the washing and disinfection tests because it is a disposable product.

Test 1: Washing five times in a fully automatic household washing machine on the "standard course" using a laundry net for clothes.

Test 2: Repeat 5 times with a 15-minute soak in a 0.5% sodium hypochlorite solution.

Test 3: Washing with Washer Disinfector (Stihlco DS1000G manufactured by MS Corporation): Washing with tap water for 1 minute (room temperature) ⇒ Drain ⇒ Alkaline detergent 0.5% washing (warm water 90°C for 1 minute) ⇒ Drain ⇒ Neutralize with acid detergent (warm water 50°C for 1 minute) ⇒ Drain ⇒ Rinse (warm water 50°C for 1 minute) Drain ⇒ Final rinse (hot water 80°C for 1 minute) ⇒ Drain ⇒ Dry (50°C to 60°C for 2 minutes) 5 times. The time for each process starts when the water in the tank reaches the set temperature.

Body pressure distribution measurement test

For the body pressure distribution measurement test, we utilized FSA sensors (Vista Medical Ltd; Winnipeg, Manitoba, Canada) to compare the body pressure distribution during seating of three types of seating assistive devices: a rubber circular seat ("rubber seat"), a urethane foam circular seat ("urethane seat"), and a U-shaped seat with a fabric cover over the V-lap® on CALFIBER® (hereinafter referred to as "U-shaped seat"). The body pressure distribution of subjects sitting on the seat was compared. The body pressure distribution of the subject sitting on the seat was approximately 45% of body weight. To evaluate the suitability and effectiveness of the sitting aids specifically for postpartum women, the participants in this study were postpartum women, one for each specified weight category, approximately weighing 45 kg, 55 kg, and 65 kg, respectively. The research procedure consisted of measuring the subjects' weight, setting up the sitting aids, setting up the body pressure distribution measurement test device, having the subjects sit on the seats, and measuring the body pressure distribution.

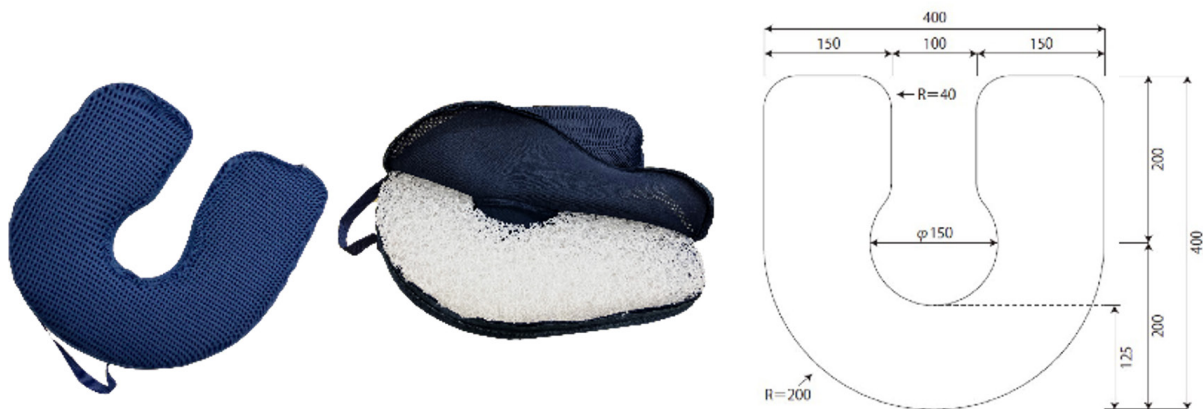


Figure 1. The shape and size of the sitting aids produced.

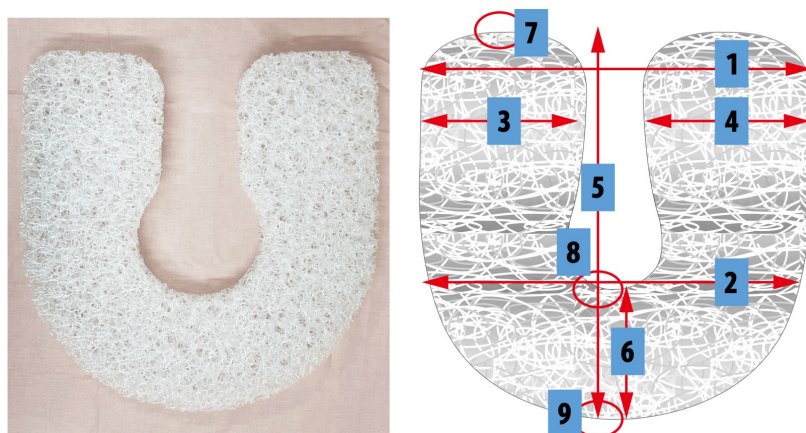


Figure 2. U-shaped CALFIBER®, the size of the nine points.

The test procedure was as follows: *i*) The height of the seat and the floor was adjusted to match the length of the lower leg of the subjects. Subjects were seated without shoes or slippers, ensuring that the soles of both feet were fully in contact with the floor. *ii*) Subjects were instructed to sit deeply, leaning slightly forward with their hands on their knees. After about one minute of position adjustment to find a comfortable posture, data on body pressure distribution were collected. The data collected included images showing the complete shape of the buttocks to ensure comprehensive pressure mapping.

Trial test by postpartum women

Two hundred postpartum women (number and rate of collection: 189, 94.5%) hospitalized at a maternity hospital in Tokyo after vaginal delivery were asked to try the U-shaped seat, compare it with a urethane seat, and answer a self-administered questionnaire. The self-administered questionnaire included age, postpartum weight, newborn weight, number of previous deliveries, method of delivery, presence of episiotomy and perineal laceration, and comfort with the U-shaped seat compared to a urethane seat.

Basic statistics were calculated for the response

results. Spearman rank correlation analysis was performed on the relationship between vulvar pain during seating and other factors. SPSS Statistics Ver. 24 (IBM, USA) was used for the analysis.

Ethical consideration

This study was conducted after obtaining approval from the research ethics review of the National Center for Global Health and Medicine (Approval No. NCGM-G-002376-00).

Participants in the sitting aid trial and the self-administered questionnaire survey were informed of the purpose of the study in writing and orally, and asked to participate in the study on a voluntary basis. Consent was confirmed by submission of a self-administered, unsigned questionnaire.

Results

Evaluation after washing or disinfection

After cleaning and disinfection, no gross deformation was observed in any of the methods and times. The measurements are shown in Table 1. There was virtually no change in size at any point in any cleaning or

Table 1. Measurements after cleaning or disinfection of U-shaped CALFIBERR

Washing or disinfection method	Measuring point	Before (cm)	1 st (cm)	2 nd (cm)	3 rd (cm)	4 th (cm)	5 th (cm)
Household Washer	1	40	40	40	40	40	40
	2	39	39	39	39	39	39
	3	15	15	15	15	15	15
	4	15	15	15	15	15	15
	5	40	40	40	40	40	40
	6	12.5	12.5	12.5	12.5	12.5	12.5
	7	5.8	5.8	5.8	5.8	5.8	5.8
	8	5.9	5.9	5.8	5.8	5.8	5.8
	9	5.7	5.7	5.7	5.7	5.7	5.7
Washer Disinfectant	1	40.0	40.0	40.0	40.0	40.0	40.0
	2	37.0	37.0	37.0	37.0	37.0	37.0
	3	15.0	15.0	15.0	15.0	15.0	15.0
	4	15.0	15.0	15.0	15.0	15.0	15.0
	5	40.0	40.0	40.0	40.0	40.0	40.0
	6	12.5	12.5	12.5	12.5	12.5	12.5
	7	5.8	6.0	6.0	6.0	6.0	6.0
	8	5.9	5.9	6.0	6.0	6.0	5.9
	9	5.7	6.0	6.0	6.0	6.0	6.0
Immersion in 0.5% sodium hypochlorite solution	1	39	39	39	39	39	39
	2	37	37	37	37	37	37
	3	15	15	15	15	15	15
	4	15	15	15	15	15	15
	5	37	37	37	37	37	37
	6	12.5	12.5	12.5	12.5	12.5	12.5
	7	6	6	6	6	6	6
	8	6	6	6	6	6	6
	9	6	6	6	6	6	6

Table 2. Results of body pressure distribution measurement test

Female Weight	Material	Minimum pressure (kPa)	Maximum pressure (kPa)	Average pressure (kPa)	Standard deviation (kPa)
45kg	U-Shaped seat	0.00	15.40	3.50	4.11
	Urethane seat	0.00	26.52	4.17	5.77
	Rubber seat	0.00	21.33	4.25	5.89
55kg	U- Shaped seat	0.00	16.57	4.26	4.52
	Urethane seat	0.00	20.88	4.45	5.38
	Rubber seat	0.00	25.38	4.59	5.94
65kg	U- Shaped seat	0.00	26.66	5.49	5.69
	Urethane seat	0.00	23.64	5.37	6.13
	Rubber seat	0.00	26.66	6.92	5.69

disinfection method or frequency. Additionally, there was no change in tactile feel or color.

Evaluation of Body Pressure Distribution Measurement

The body pressure distribution measurement test was conducted to compare the pressure distribution of U-shaped seats, rubber, and urethane seats, and the results are shown in Table 2.

The test results indicated distinct differences in pressure distribution among the different seat types. Notably, for participants weighing 45 kg and 55 kg, the U-shaped seat demonstrated the lowest body pressure, in terms of both maximum and average pressure. This suggests that the U-shaped seat provided better pressure relief for individuals in these weight categories. Conversely, for participants weighing 65 kg, the urethane

seat showed the lowest body pressure for both maximum and average measurements. This indicates that the urethane seat may be more effective in distributing body pressure for individuals in this higher weight range.

Responses to self-administered questionnaire by trial users

The mean age of the subjects was 32.5 ± 4.1 years, the mean postpartum weight was 59.1 ± 7.6 kg, and the mean birth neonatal weight was $3,059 \pm 354.5$ g. Ninety-six (50.8%) were primiparas and 93 (49.2%) were multiparas. The method of delivery was spontaneous vaginal delivery in 161 (85.6%), suction in 25 (13.3%), and forceps in 2 (1.1%). 93 (54.4%) had episiotomy and 78 (45.6%) did not. 122 (74.4%) had perineal laceration and 42 (25.6%) did not.

Table 3 shows the results of U-shaped seat compared to urethane seat. When asked to compare the urethane seat with the U-shaped seat, about 88% of the respondents reported no or less vulvar pain when seated in the U-shaped seat, and about 76% reported no or less Discomfort due to steaminess. Table 4 shows the association between the presence of vulvodynia and other factors when seated. Sense of back strain, difficulty getting up, difficulty breastfeeding, and discomfort due to steam were significantly associated with the presence of vulvodynia.

Discussion

Production of a sitting aid to relieve postpartum vulvodynia

This study has been instrumental in developing a new sitting aid designed to alleviate vulvodynia in postpartum women, particularly addressing issues arising from prolonged sitting during breastfeeding. For many years, prolonged pressure on the vulva when postpartum women assume the sitting position for breastfeeding has increased the pain of the episiotomy wound (19). In this study, a new sitting aid was developed to solve this problem (2). Although no detailed studies have been conducted, many conventional sitting aids pull on the skin around the episiotomy wound, causing the wound to become congested (19). In addition, many of them were difficult to wash or caused steaminess after prolonged sitting. This research has allowed us to develop a sit-to-stand device using selected materials and designs that can solve many of these problems. In the field of obstetrics and midwifery, there have been many years of research on delivery assistance methods that prevent the occurrence of serious perineal laceration (22) and episiotomy methods that prevent subsequent

perineal laceration (23-25). However, these methods cannot completely eliminate the occurrence of perineal laceration or episiotomy-related discomfort (7,8). Therefore, during the episiotomy procedure and when perineal laceration occurs, it is necessary to be aware of the postpartum woman's quality of life and methods to alleviate vulvar pain. There have been reports on suture methods that reduce postpartum vulvar pain (26). The limitation in the use of drugs during the postpartum period, particularly due to breastfeeding, necessitates non-pharmacological approaches for pain management (27). The development of this new sitting aid is a significant advancement in this regard. It represents a noninvasive, drug-free approach for alleviating vulvar pain in postpartum women, aligning with the need for safe and effective pain relief methods during lactation.

Ease of cleaning and disinfection

A critical aspect of postpartum care involves maintaining hygiene, particularly with tools and aids. The "U-shaped CALFIBER[®]", developed in this study, underwent rigorous cleaning and disinfection tests, proving its resilience and suitability for clinical settings. These tests have demonstrated that the "U-shaped CALFIBER[®]" can be easily sterilized and used as an aid for postpartum bleeding. Because of the excretion of lochia after childbirth, sitting aids often become soiled. It is important that they can be easily washed and sterilized to maintain a hygienic environment, and also reduce the workload for clinical staff, making the "U-shaped CALFIBER[®]" a beneficial addition to postpartum care practices.

Influence of less pressure on the seat surface on pain relief of the episiotomy wound

The results of the pressure distribution measurement test showed that pressure on the seat surface was reduced for women weighing 45 kg and 55 kg. Based on these results, we believe that the product will be less effective for women weighing more than this. Overall, the results highlights that the effectiveness of the seat types in terms of pressure distribution varies depending on the body weight of the user, with the U-shaped seat being more beneficial for lighter individuals and the urethane seat performing better for heavier individuals. Therefore, it is necessary to reconsider the density of the material

Table 3. Results of U-shaped seat compared to urethane seat

respondent	Vulvar pain when seated n (%)	Discomfort due to steaminess n (%)
None	119 (63.0)	63 (33.3)
Mild	48 (25.4)	82 (43.4)
Moderate	19 (10.1)	43 (22.8)
Severe	3 (1.6)	1 (0.5)

Table 4. Association between vulvodynia and other factors during seating

Variable	Sense of strain felt in the lower back	Difficulty breastfeeding	Difficulty stand up	Discomfort due to steaminess
Vulvodynia when seated				
<i>Rs</i>	0.308**	0.364**	0.426**	0.266**
<i>p</i>	< 0.001	< 0.001	< 0.001	< 0.001

Spearman rank correlation analysis. **Correlation is significant at the 0.01 level (2-tailed).

(CALFIBER®) and the thickness of the SEAT in order to meet the needs of postpartum women of various weights in the future.

Postpartum women's needs for sitting aids as indicated by the opinions of trial users

The subjects who used the seating aids developed in this study and participated in the self-administered questionnaire survey can be considered to be an average population of the present day in Japan, based on their backgrounds and an overview of their deliveries. Compared to conventional rubber or urethane seats, the U-shaped seat caused less vulvar pain and discomfort due to steam when seated, and many respondents found it easier to change positions from a sitting to standing position. These results suggest that the moderate elasticity, resilience, and air permeability of CALFIBER® had a positive effect on the sitting posture of postpartum women.

Many of the women who reported having vulvodynia even after using the U-shaped seat also had other problems (back strain, difficulty breastfeeding, difficulty standing up) at the same time. For women with many physical problems, sitting aids alone may not be sufficient to provide vulvodynia relief. For such women, the use of medications that have less impact on lactation and postpartum care of the pelvic floor muscles may be helpful (28-30). In addition to midwives and obstetricians, it may be more effective to involve multiple professions with such individuals.

Limitations and future study

There are two limitations to this study: first, we were unable to confirm the durability of the product with continuous use, and second, we cannot completely rule out reporting bias using the self-administered questionnaire method. Now, the authors would like to make some recommendations for future research. To address these two limitations, the researchers should conduct observations of the productions over time (and also conduct a seated repetitive tapping test) and interview the users.

Conclusion

Through the four phases of this study, a sitting aid that relieves vulvodynia in postpartum women was created using 3D reticulated polypropylene fiber as the primary material. Sitting aids made of materials with moderate elasticity, stretchability, and breathability are effective in relieving postpartum vulvodynia. However, there is room for future improvement in the density and thickness of the material. In addition, women with multiple physical problems, including vulvodynia, need to be treated individually.

Acknowledgements

This study was conducted with the cooperation of Hakuzo Medical, Inc. in providing materials.

We would like to thank the postpartum women who participated in this study. We would also like to thank the staff of Artemis Women's Hospital (Tokyo) for their assistance in data collection. We also thank Dr. Kohei Ogawa of the National Center for Child Health and Development and Mr. Masahiro Nishimura of Hakuzo Medical, Inc. for their advice in conducting the various studies.

Funding: None.

Conflict of Interest: This study was conducted with materials provided by Hakuzo Medical Corporation (Osaka, Japan) for use in making the assistive devices.

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- Received April 3, 2023; Revised December 8, 2023; Accepted December 24, 2023.
- Released online in J-STAGE as advance publication January 20, 2024.
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