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Development of Perineal Electric Massager Experience (Pem-X) to Improve Perineal Elasticity

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Abstract

Perineal injury remains a common concern in vaginal childbirth, with a prevalence of 30.6%. Low maternal perineal massage practice is a contributing factor to decreased perineal elasticity and an increased risk of perineal trauma. This pilot study aimed to develop the Perineal Electric Massager Experience (PEM-X) to support mothers in self-guided perineal massage. The research employed a level 4 Research and Development (R&D) method with a one-group pretest-posttest design. The study sample consisted of two parts: the PEM-X prototype and postpartum mothers who had vaginal deliveries. A purposive sampling technique was used to recruit 10 postpartum mothers who had vaginal deliveries for preliminary testing of the device. The device was developed at the Mechatronics Laboratory, with functional testing conducted at the Electromedical Laboratory of Health Polytechnic of the Ministry of Health Jakarta II and the Maternity Laboratory of Health Polytechnic of the Ministry of Health Jakarta I. During the intervention phase, participants used the PEM-X to massage the perineum independently according to the developed protocol. Field testing was conducted at Lebak Bulus Public Health Center. Data were analyzed using descriptive statistics and paired t-tests. The results showed that the PEM-X device operated stably and functioned well. Preliminary findings demonstrated increased perineal elasticity after device use, along with high user satisfaction in terms of comfort and ease of use. In conclusion, the innovative PEM-X device enhances perineal elasticity and has the potential to reduce perineal injury during childbirth. Further studies with a larger sample size are recommended.

Keywords: perineal elasticity, perineal massage, vaginal delivery

Abstrak

***Pengembangan Alat Perineal Electric Massager Experience (PEM-X) untuk Meningkatkan Elastisitas Perineum**. Cedera perineum tetap menjadi perhatian umum pada persalinan pervaginam, dengan prevalensi 30,6%. Rendahnya praktik pijat perineum oleh ibu merupakan salah satu faktor yang berkontribusi terhadap menurunnya elastisitas perineum dan meningkatnya risiko trauma perineum. Studi percontohan ini bertujuan untuk mengembangkan Pengalaman Pijat Perineum Elektrik (PEM-X) untuk mendukung pijat perineum mandiri di kalangan ibu. Studi ini menggunakan pendekatan Penelitian dan Pengembangan (R&D) Level 4 dengan desain pra-uji dan pasca-uji satu kelompok. Teknik* purposive sampling *digunakan untuk merekrut 10 ibu pascapersalinan yang melahirkan secara pervaginam untuk pengujian awal perangkat. Prototipe PEM-X dikembangkan di Laboratorium Mekatronika dan menjalani pengujian fungsional dan keamanan di Laboratorium Elektromedis Politeknik Kesehatan Kementerian Kesehatan Jakarta II dan Laboratorium Kebidanan Politeknik Kesehatan Kementerian Kesehatan Jakarta I. Pada tahap intervensi, peserta menggunakan alat PEM-X untuk pijat perineum mandiri sesuai protokol yang telah dikembangkan. Pengujian lapangan dilakukan di Puskesmas Lebak Bulus. Data dianalisis menggunakan statistik deskriptif dan uji t berpasangan. Hasil penelitian menunjukkan bahwa perangkat PEM-X beroperasi secara stabil dan berfungsi dengan baik. Temuan awal menunjukkan peningkatan elastisitas perineum setelah penggunaan perangkat, bersamaan dengan kepuasan pengguna yang tinggi dalam hal kenyamanan dan kemudahan penggunaan. PEM-X berpotensi sebagai perangkat pendukung inovatif untuk pijatan perineum mandiri dan pencegahan cedera perineum. Studi lebih lanjut direkomendasikan dengan ukuran sampel yang lebih besar.*

***Kata Kunci:** elastisitas perineum, persalinan pervaginam, pijat perineum.*

Introduction

Perineal trauma is a significant concern in vaginal childbirth, contributing to maternal morbidity and discomfort. Globally, approximately 30.6% of women experience spontaneous perineal tears during delivery, with a higher prevalence among primiparous mothers due to reduced tissue elasticity and lack of perineal preparation (Moura et al., 2024). In Indonesia, the implementation of perineal massage as a preventive effort has been encouraged. Its practice, however, remains limited, often due to lack of knowledge, discomfort, cultural factors, and the perceived difficulty of performing the massage independently (Darmayanti et al., 2024).

Perineal trauma can lead to various short- and long-term complications. These complications include postpartum pain, bleeding, infection, dyspareunia, urinary and fecal incontinence, and reduced quality of life in postpartum women. These complications can interfere with maternal recovery and mother-infant bonding. This study highlights the importance of preventive strategies to increase perineal tissue flexibility during pregnancy (Pergialiotis et al., 2020).

Perineal massage has been tested as a non-pharmacological, low-cost intervention in previous studies. Results showed it improved perineal elasticity and reduced the incidence and severity of perineal trauma and episiotomies during childbirth (Akhlaghi et al., 2019; Venugopal et al., 2022). Despite its proven benefits, many pregnant women fail to apply this technique regularly, leading to underutilization. Previous studies have highlighted the potential of innovative tools to assist in health education and practice. However, few have explored technological solutions that support the independent implementation of perineal massage, particularly among primigravida women (Bai et al., 2024).

Recent advances in maternal health technology have introduced various innovations to support pregnancy and childbirth preparation, including mobile health applications, pelvic floor muscle training (PFMT) devices, biofeedback systems, and digital educational platforms. Several studies reported that technology-assisted interventions may improve maternal engagement, exercise adherence, self-efficacy, and pelvic floor muscle outcomes among pregnant and postpartum women (Hou et al., 2022; Jaffar et al., 2022). Additionally, mobile health technology and biofeedback-assisted pelvic floor muscle training devices have demonstrated effectiveness in maintaining pelvic floor elasticity during pregnancy and the postpartum period (Dufour et al., 2019). Most existing technologies primarily focus on exercise, education, or pelvic floor muscle training rather than directly facilitating self-guided perineal massage practice. Devices specifically designed to improve perineal elasticity through guided massage interventions are still limited, particularly in resource-constrained maternal healthcare settings.

This study introduces a perineal device called the perineal electric massager experience (PEM-X). This tool was developed specifically to help mothers perform perineal massage in a comfortable and controlled manner. It features an ergonomic design, voice guidance, and a light-based timer to promote the correct duration and rhythm of massage, reducing dependency on healthcare personnel. PEM-X was developed not only as an educational aid but also as a practical, supportive device that facilitates consistent and independent perineal massage practice among pregnant women.

Unlike previous research that focused solely on manual techniques or educational interventions, this study proposes a tangible, technology-assisted solution for improving perineal preparation before childbirth. In this study, perineal elasticity was assessed using standardized observational and clinical indicators of perineal tissue flexibility and stretching response before and after the intervention. Measurements were conducted consistently according to the developed study protocol.

The research question addressed in this study is as follows: Can the use of the PEM-X device effectively improve perineal elasticity among women having vaginal childbirth? To answer this, the study used a Research and Development (R&D) approach, combined with a pretest-posttest design to evaluate the tool's effectiveness. The primary objective was to determine whether using the PEM-X enhances perineal elasticity, thereby potentially reducing perineal injury during childbirth.

Methods

Research Design and Development. This study employed a level 4 R&D method adapted from the Borg and Gall model, which includes the stages of identifying problems and potentials, data collection, product design, design validation, design revision, and field testing (Sugiyono, 2019). The study stages are summarized in Figure 1.

The research used a one-group pre-test and post-test approach aimed at evaluating the effectiveness of the PEM-X in improving perineal elasticity. This non-randomized design was selected because the study focused on pilot feasibility testing of a newly developed device. However, the absence of a control group may limit the ability to attribute observed changes solely to the intervention. Therefore, the findings should be interpreted as preliminary evidence and require further confirmation through larger controlled studies.

Setting and Device Development. The device development was conducted in person at the Electromedical and Mechatronics Laboratory of the Health Polytechnic. The materials used to develop the PEM-X device are acrylonitrile butadiene styrene (ABS) and silicone. The study was conducted at Lebak Bulus Public Health Center in South Jakarta during June 2025.

Participants. A total of 10 mothers who had vaginal deliveries were selected through purposive sampling, a technique commonly used in nursing research to recruit participants based on specific criteria. The sample size of 10 participants was considered appropriate for this pilot feasibility study because the primary objective was to evaluate the initial usability, safety, functionality, and preliminary effectiveness of the PEM-X prototype before conducting larger-scale experimental studies. The inclusion criteria were mothers aged 18-40 years, with an intact perineum, no signs of perineal infection or discomfort, and a willingness to participate throughout the study period. Mothers who had delivered via cesarean section or had perineal rupture of second-degree or higher were excluded.

Instruments and Outcome Measurement. The research instruments included a perineal elasticity observation sheet (using a sterile measuring tape in centimeters), a PEM-X functionality checklist, an expert validation form, and a user satisfaction questionnaire. Perineal elasticity was measured using a sterile measuring tape in centimeters to assess tissue stretching response and flexibility before and after the intervention according to a standardized assessment protocol. The expert validation was conducted by professionals in maternal nursing and biomedical engineering and was declared valid and feasible for use.

Intervention Procedure. The intervention procedure involved using the PEM-X device twice daily for seven days, with each session lasting five minutes. The device operated at a vibration frequency of 25 Hz. It was equipped with an automatic timer using LED indicators and audio guidance to assist participants in performing perineal massage consistently and independently.

Data Analysis. Data were analyzed using descriptive statistics and paired t-tests to compare perineal elasticity values before and after the intervention. The significance level was set at $p < 0.05$ (Sugiyono, 2019).

Ethical Considerations. This study received ethical approval from the Health Research Ethics Committee of the Ministry of Health Polytechnic of Health Tanjung Karang, with approval number 037/Perst.E/KEPK-TJK/IV/2025. All participants provided written informed consent prior to participation.

Results

The PEM-X device prototype underwent a comprehensive validation process to ensure safety, usability, and mechanical reliability. Expert reviewers, consisting of obstetric nurses and biomedical engineers, evaluated the design, material safety, and ergonomic features. The validation yielded a total feasibility score of 24 out of 25, indicating excellent acceptability for clinical application (Table 1). Component testing confirmed the durability of the device's core components, with no observed mechanical or electrical failures during repeated usage cycles (Table 2). Stability testing demonstrated that the device consistently maintained a vibration speed of 1200 RPM, fulfilling the operational specification required for therapeutic benefit (Table 3). Functional testing confirmed proper integration of all components and alignment with user safety standards (Table 4).

Problem Identification
↓
PEM-X Development
↓
Expert Validation
↓
Pilot Testing (n=10)
↓
Pre-Post Intervention
↓
Data Analysis

Figure 1. Research Flowchart of PEM-X Development and Testing

Table 1. Feasibility of the PEM-X Device

Dimension	Max Score	Score Obtained
User Safety	5	5
Operational Mechanism Safety	5	5
Tool Performance	5	5
User Comfort	5	4
Maintenance and Cleaning	5	5
Total	25	24

Table 2. Stability of PEM-X Device Operation

Time (minutes)	RPM	Total Rotations
5	1200	6000
10	1200	12000
15	1200	18000
20	1200	24000
25	1200	30000
30	1200	36000
35	1200	42000

Time (minutes)	RPM	Total Rotations
40	1200	48000
45	1200	54000
50	1200	60000
55	1200	66000
60	1200	72000

This research was conducted as a pilot feasibility study in the early stages of device development. Therefore, field testing was conducted with a limited sample of 10 postpartum women who met the inclusion criteria. The purpose of this preliminary test was to evaluate ease of use, safety, user comfort, and initial response to the intervention before conducting a large-scale controlled study. Therefore, the findings of this study cannot be generalized to a wider population.

Component testing results demonstrated that every technical aspect of the device performed within the expected operational range. All tested parameters met the required specifications, confirming that the PEM-X device functioned well during preliminary testing. Following the validation process, field testing was conducted involving 10 postpartum women aged 18-40 who had delivered vaginally. Most participants reported positive experiences and satisfaction regarding the device's comfort and ease of use.

To ensure the device was safe and reliable before field testing, a feasibility evaluation was conducted. This assessment covered five important dimensions, including user safety, operational mechanism, performance, comfort, and maintenance. The detailed results of this evaluation are shown in Table 1. The feasibility of the PEM-X device was assessed based on five dimensions: user safety, operational safety, tool performance, comfort, and maintenance. Expert evaluation yielded a total score of 24 out of 25, indicating a very good level of feasibility.

To assess the consistency of device performance during continuous use, stability testing was carried out. This procedure measured vibration speed (RPM) and total rotations over time to ensure that the PEM-X device could maintain steady operation throughout the recommended usage period. The results are shown in Table 2. The device consistently maintained 1200 RPM across 60 minutes of continuous use. This stability indicates the tool's mechanical reliability and thermal resistance, confirming it is suitable for repeated short-session applications without performance degradation

Table 3 shows that component testing demonstrated that each technical aspect of the device performed within the expected range. All tested parameters met the required specifications, confirming that the PEM-X device is functionally safe and effective to use. Following the validation process, field testing was conducted involving 10 women aged 18–40 years who had given vaginal childbirth. The majority expressed high satisfaction.

In Table 4, the respondent characteristics show that most mothers were in early adulthood (18–35 years), comprising 8 participants (80%). Only 2 participants (20%) were older than 35 years. All participants reported satisfaction with the PEM-X device. Normality was assessed using the Shapiro–Wilk test. The pre-intervention scores were normally distributed (p value 0.885), and the post-intervention scores were also normally distributed (p value 0.151). Since both p values were greater than 0.05, the assumption of normality was met, supporting the use of a paired t-test for statistical analysis.

Perineal elasticity was measured before and after the seven-day intervention period using the PEM-X (Table 5). The mean perineal elasticity score increased from 2.94 cm before the intervention to 3.64 cm after, indicating increased tissue flexibility following device use.

A paired t-test revealed a mean difference of 0.70 cm (95% CI: - 0.81 to - 0.58; $p < 0.001$) between the pre- and post-intervention measurements (Table 6). These findings suggest a potential positive effect of PEM-X on perineal elasticity during initial testing. The small sample size and lack of a control group are limitations of the study. Therefore, the results should be interpreted with caution and cannot establish generalizability to clinical effectiveness. Further research with a larger sample size and a controlled experimental design is needed to confirm these findings.

Table 3. Component Functionality PEM-X Device

Parameter	Test Result	Standard	Description	Conclusion	
				Suitable	Not Suitable
Motor Voltage (V)	3.7 V	3–5 V	Within the standard for small DC motors	✓	
Operating Power (W)	3 W	≤ 5 W	Energy-efficient	✓	
Operating Current (mA)	810.81 mA	≤ 1000 mA	Safe for portable use	✓	
Battery Capacity (mAh)	1500 mAh	≥1000 mAh	Sufficient for device operation	✓	
Battery Operating Duration	±110.9 menit	≥ 60 menit	Long-lasting, equivalent to ~23 sessions	✓	
Target Motor Speed (RPM)	1200 RPM	1000–1500 RPM	Ideal for massage application	✓	
Score				6	

Table 4. Characteristics of the Respondents (N = 10)

Characteristic	n	%
Maternal Age		
Early adulthood (18–35)	8	80
Late adulthood (> 35)	2	20
User Satisfaction		
Not satisfied	0	0
Satisfied	10	100

Table 5. Perineal Elasticity Outcomes

Variable		Mean	S.D.
Perineal Elasticity	Pre	2.94	0.20
	Post	3.64	0.22

Table 6. The Results of The Statistical Test Comparing Elasticity Before and After Using PEM-X

Variable		Mean Difference	CI (95%)		p-value
			Lower	Upper	
Perineal Elasticity	Pre Post	0.70	-0.81	-0.58	0.000

Discussion

Development of PEM-X Device. This study successfully developed the PEM-X using a level four R&D approach, which involved a systematic process comprising needs assessment, prototype design, expert validation, and functional testing. The development was grounded in the urgent need to address persistent rates of perineal trauma during vaginal deliveries, which remain as high as 30.6% in Indonesia (Moura et al., 2024). Traditional interventions, such as manual perineal massage, although clinically recognized for improving tissue elasticity, have shown low adherence due to embarrassment, discomfort, and lack of standardized techniques (Darmayanti et al., 2024; Okeahialam et al., 2024). These barriers underscore the need for an assistive device that can facilitate independent perineal preparation among expectant mothers.

The needs assessment phase involved in-depth interviews with pregnant women in their third trimester and consultations with maternal health professionals. Participants expressed interest in a device that was safe, user-friendly, and easy to use independently. These findings informed the subsequent design process and supported the inclusion of ergonomic features and guided feedback.

The prototype incorporated several innovative features: controlled vibratory stimulation at a consistent 1200 RPM, ergonomic grips, and LED indicators to guide the duration of use according to the recommended perineal massage interval. This design approach is consistent with Pushpakumar et al. (2023), who reported that reminder cues and supportive features may improve self-care interventions. Expert validation demonstrated a feasibility score of 24 out of 25, suggesting good acceptability regarding safety, usability, and operational performance. The validation process involved midwives, obstetric nurses, and biomedical engineers, ensuring a multidisciplinary perspective in evaluating mechanical performance and maternal safety. Expert feedback emphasized the device's potential for integration into antenatal education programs and home-based perineal care.

Further functional testing confirmed the reliability of the PEM-X; repeated trials demonstrated consistent vibration output and structural stability, with no mechanical failures over prolonged use. These findings are consistent with medical device development frameworks that emphasize operational consistency, ease of use, risk management, and user safety as essential requirements before clinical implementation (Marešová et al., 2020).

User Acceptability and Preliminary Outcomes. Subsequent user trials provided additional evidence of acceptability and perceived benefit. All participants (n = 10) reported satisfaction regarding comfort and ease of use. Participants also reported that the PEM-X device reduced discomfort and embarrassment commonly associated with manual perineal massage. Similar findings have been reported in previous studies, such as that by Bidonde et al. (2022), which reported that user-friendly assistive technologies may improve adherence to maternal self-care practices. Lumy et al. (2022) demonstrated that consistent perineal massage effectively improves tissue elasticity and lowers the risk of perineal trauma, underscoring the clinical relevance of devices such as PEM-X.

The development process also highlights the critical role nurses have in facilitating technology adoption in maternal care. Altmiller and Pepe (2022) emphasize that nurses are pivotal in promoting digital health literacy and supporting mothers in integrating innovative tools into their daily care routines. By endorsing and educating patients about PEM-X, nurses can help bridge the gap between technological innovation and practical application, particularly in low-resource or culturally sensitive settings where manual massage may be underutilized.

The paired t-test showed a statistically significant increase in perineal elasticity scores after the intervention period. The mean increase of 0.70

($p < 0.01$) suggests a possible improvement in tissue flexibility following use of the PEM-X device. In line with this, vibration therapy has been shown to improve circulation, muscle relaxation, and connective tissue pliability (Lupowitz, 2022). However, these findings cannot be generalized because the study used a small sample size and lacked a control group. Therefore, the observed changes cannot be attributed solely to the intervention, and the results should be considered preliminary.

These findings are theoretically consistent with studies showing that vibration stimulation can support microcirculation, muscle relaxation, and connective tissue flexibility (Azuma & Akazawa, 2021; Lupowitz, 2022; Pilch et al, 2019). Increased local blood flow and soft-tissue stimulation may contribute to increased tissue extensibility. This synergistic interaction between hormonal changes in late pregnancy, particularly elevated estrogen levels, and mechanical stimulation may amplify elasticity outcomes, making PEM-X an ideal adjunctive intervention during the third trimester (Cabral et al., 2022). However, further controlled studies are needed to confirm the physiological and clinical effects of PEM-X on perineal elasticity.

Age-Related Findings to Control Perineal Elasticity. The increase in perineal elasticity was more noticeable among participants aged 18–35 years compared with participants over 35. These findings are likely influenced by differences in connective tissue characteristics, collagen remodeling, and hormonal responses during pregnancy. As women age, tissue elasticity becomes stiffer than in younger women (Papalia & Martorell, 2021).

In contrast, older participants showed more limited changes in elasticity. Previous studies have shown that aging can affect collagen density, elastin composition, and tissue vascularity, which can impact tissue flexibility (Nolan et al., 2021; Santrock, 2019). However, due to the limited sample size in this study, these findings should not be interpreted as definitive evidence of age-related differences. All participants reported positive experiences with the device's comfort and ease of use. The ability to use the device independently at home may help overcome barriers to manual perineal massage, including embarrassment and discomfort.

The findings of this study also highlight the potential relevance of PEM-X in care provided to support mothers during pregnancy preparation. Perineal trauma remains associated with postpartum pain, impaired mobility, emotional distress, and reduced maternal quality of life. Therefore, interventions that support perineal flexibility may improve maternal comfort and childbirth readiness. The PEM-X device offers several advantages, including standardized vibration output, an ergonomic design, user guidance features, and the ability to support independent self-care practices at home. These characteristics may help overcome common barriers associated with manual perineal massage, such as inconsistent technique, discomfort, and limited compliance.

In the context of maternal care, technology-assisted interventions may provide additional support for nurses and midwives in promoting maternal self-management and antenatal preparation. Although the current findings are preliminary, the integration of supportive devices such as PEM-X reflects the growing role of innovation and patient-centered approaches in maternal healthcare. However, further evidence from a study with a larger sample size and a control group is needed to determine the device's broader clinical applicability and long-term effectiveness.

This study has several limitations. The small sample size and lack of a control group limit the generalizability of the findings and restrict causal interpretation of the intervention's effects. Furthermore, the short intervention period may not fully capture long-term outcomes related to perineal elasticity and the prevention of birth traumas.

Future studies should use randomized controlled designs with larger, more diverse populations to evaluate the long-term clinical effectiveness of

PEM-X, including its effects on perineal tearing, postpartum pain, and pelvic floor outcomes.

Conclusion

In conclusion, the PEM-X device is a feasible and potentially useful technological innovation for supporting self-administered perineal massage. This study demonstrated significant improvements in perineal elasticity after the intervention was administered over seven days, suggesting that PEM-X may contribute to improved tissue flexibility during labor preparation. Improved perineal elasticity could potentially help reduce the risk of perineal trauma during vaginal delivery, although this outcome was not directly measured in this study.

The device also demonstrated operational stability, maternal satisfaction, functional safety, and positive user acceptance during initial testing. By addressing barriers associated with manual perineal massage, the PEM-X can support maternal self-care practices and antenatal care in a more convenient and standardized manner. Furthermore, the short intervention duration of this pilot study may not fully reflect the long-term clinical outcomes associated with preventing perineal trauma. Because this study involved a small sample size and did not include a control group, the findings should not be generalized and cannot yet establish definitive clinical effectiveness. Future research should improve the study design by including randomized controlled trials (RCTs), larger and more diverse samples, and control groups. All of this is needed to evaluate the long-term clinical effects of PEM-X on perineal trauma prevention, postpartum outcomes, and maternal quality of life.

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Data Availability Statement

The resulting datasets are related to data obtained during the tool testing and limited pilot phases. These data are available from the authors upon reasonable request.

Author Contributions

Suryani Manurung: Conceptualization, Methodology, Tool Development, Formal Analysis, Investigation, Writing - Original Draft, Writing - Review & Editing, Supervision, Project Administration. **Yetty Mariani Tambun:** Tool Development, Validation, Formal Analysis, Investigation, Resources, Data Curation, Writing - Review & Editing, Supervision. **Amalia Mely:** Formal Analysis, Investigation, Writing – Original Draft, Supervision, Project Administration.

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