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Original Research

Delivery Mode and the Pelvic Floor Function of Primiparous Women at Early Postpartum: An Observational Retrospective Cohort Study

Xiaolei Chi[1,2,†], Lin Wen[3,†], Lan Chen[1,2], Hongxia Zhu[1,2,*]

[1]Department of Gynaecology, The International Peace Maternal and Child Health Hospital, School of Medicine, Shanghai Jiao Tong University, 200030 Shanghai, China
[2]Shanghai Key Laboratory of Embryo Original Diseases, 200030 Shanghai, China
[3]Department of Gynaecoloy, Jiading Branch of Shanghai General Hospital, School of Medicine, Shanghai Jiao Tong University, 201803 Shanghai, China
*Correspondence: zhuhongxia123@163.com (Hongxia Zhu)
[†]These authors contributed equally.

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Abstract

Background: Different modes of delivery are strongly associated with postpartum pelvic floor muscle (PFM) injury and postpartum pelvic floor dysfunction. This study used Glazer PFM surface electromyography (sEMG) to objectively assess postpartum PFM function to determine the effects of different modes of delivery on pelvic floor function in the early postpartum period in primiparous women. **Methods**: There were 1286 cases of cesarean delivery (CD) and 2099 cases of vaginal delivery (VD). The vaginal delivery group was further divided into four subgroups (A: intact perineum without laceration and first-degree laceration; B: second-degree laceration; C: mediolateral episiotomy; D: forceps delivery). Pelvic floor sEMG indices of the subjects were analyzed at 6–8 weeks postpartum. **Results**: The results showed that the mean peak amplitude of phasic (flick) contractions and the mean amplitude of tonic contractions were both significantly higher in CD than in VD ($p < 0.01$). In contrast, the mean amplitude variability of tonic contractions was lower in CD than in VD ($p < 0.01$). The mean peak amplitude of phasic (flick) contractions and the mean amplitude of tonic contractions were statistically lower in the forceps group than in the other vaginal delivery groups ($p < 0.05$). The mean amplitude variability of tonic contractions was greater in the forceps group than in groups A, B and C ($p < 0.01$). **Conclusions**: Vaginal delivery, especially forceps delivery, may result in impaired pelvic floor muscle function in the early postpartum period compared to cesarean delivery.

Keywords: pelvic floor dysfunction; pelvic floor muscle surface electromyography; postpartum; delivery mode; Glazer protocol

1. Introduction

Female pelvic floor dysfunction (PFD) is a complex syndrome involving impairment of the pelvic floor muscles (PFM) and tissues. Currently, PFD is one of the five most common chronic diseases that seriously affect women's quality of life. Reports show that the prevalence of PFD ranges from 23.7% to 46.5% [1–3]. Pregnancy and childbirth are recognized as the major risk factors for PFD. Prolonged elevated hormone levels during pregnancy can lead to altered metabolism of PFM collagen fibers, resulting in abnormal pelvic floor support structures [4]. In addition, excessive stretching during childbirth causes damage to the PFM, connective tissue, and nerves. Pregnant and postpartum women are more likely to have PFD, up to approximately 49% [5].

PFD seriously affects the physical and mental health of women. Therefore, early diagnosis and timely treatment are extremely important. The early stages of PFD are changes in the biochemistry and electrophysiology of the pelvic floor, which may progress to symptomatic PFD under further damage. Electromyography (EMG) records the electrical potentials generated by the depolarization of muscle fibers. When the electrodes are placed on the skin of the perineum or inside the urethra, vagina, or rectum, it is called surface EMG (sEMG) [6]. Pelvic floor sEMG could be used for early diagnosis of PFD, which is an objective and non-invasive method by recording the change in voltage across the PFM fiber membrane. Several reports have confirmed that sEMG is reliable for measuring PFM in different populations [7,8]. sEMG assessment based on the Glazer protocol is widely used for the evaluation of PFD in postpartum women [9,10]. The Glazer protocol consists of a series of muscle relaxations and contractions, including pre-baseline rest, phasic contractions, tonic contractions, endurance contractions, and post-baseline rest.

As well known, the delivery mode is a crucial risk factor for PFD [11]. It is necessary to predict and/or diagnose the early stage of PFD in postpartum women, since they could be offered timely interventions to prohibit progression. However, the effect of delivery mode on early pelvic floor function remains controversial [12,13]. Most previous studies applied qualitative assessments of the different delivery modes on PFD. This study aimed to quantify the impact of different delivery modes on PFM function at 6–8 weeks postpartum by sEMG based on the Glazer protocol. This study also tried to distinguish the detail types and grade

of PFM impairment, in order to provide the individual therapeutic strategy to patients at the early stage of postpartum.

2. Materials and Methods

2.1 Study Subjects

This is an observational retrospective study conducted by the International Peace Maternity & Child Healthcare Hospital (IPMCH), Shanghai Jiaotong University. A total of 3638 primiparous women with singleton pregnancy who underwent vaginal delivery/cesarean section and pelvic function screening at 42–60 days postpartum between January 2019 and December 2020 at the International Peace Maternity and Child Healthcare Hospital, affiliated to Shanghai Jiao Tong University School of Medicine, China, were selected as study participants. All participants gave official verbal and written consent to participate in the study, and this study was approved by the Medical Science Ethics Committee of the International Peace Maternal and Child Health Hospital.

2.2 Inclusion and Exclusion Criteria

Inclusion criteria were: (1) singleton pregnancy; (2) primipara; (3) vaginal delivery or cesarean section with or without limited grade II perineal laceration; (4) neonatal birth weight less than 4000 g; (5) aged 18–50 years old; (6) underwent pelvic floor examination at 42–60 days postpartum; (7) delivery at 28 or more weeks gestation; and (8) normal mental status with good cooperation during the examination.

Exclusion criteria were: (1) history of chronic constipation, urinary leakage, pelvic floor disorders and pelvic surgery; (2) severe hearing impairment and intellectual disability.

2.3 Research Methods

In general, this study established two study groups, cesarean delivery (CD) group (n = 1286) and vaginal delivery (VD) group (n = 2099), to analyze the effect of these two main delivery methods on PFD. The vaginal delivery group was further divided into four subgroups, including group A with intact perineum or first-degree perineal laceration, group B with second-degree perineal laceration, group C with mediolateral episiotomy, and group D with forceps delivery. Clinical data on pregnancy and delivery were obtained from the electronic medical record system. All subjects were assessed for pelvic floor function at 42–60 days postpartum by measuring pelvic floor muscle sEMG signals using vaginal surface electrodes (Glazer protocol).

2.4 Evaluation Methods

The PFM function was evaluated with vaginal palpation and sEMG. All patients were routinely offered instructions and information about sEMG before the examination by a trained urogynecologist at the Pelvic Floor Diagnosis and Treatment Center. Participants were in a supine position and were requested to be relaxed throughout the entire process of the sEMG examination. During the process, the automated protocol software provided the participants real-time instructions by voice messages and figures on the monitor, with which the participants could relax or contract the PFMs accordingly. The vaginal probe mainly measures the surface EMG values of the puborectal muscle and external urethral sphincter, while the anal probe mainly measures the surface EMG values of the puborectal muscle, external anal sphincter, and levator ani muscles, both of which are effective in measuring pelvic floor muscle surface electromyograms [14]. The vaginal probe was used in this study because participants would have a better experience with the vaginal probe. The sEMG facility used in this study was a Biofeedback electrical stimulator mode MLD A2 (Nanjing Mai Lan De Medical Technology, Ltd., Nanjing, Jiangsu, China). It has 2 channels, composed of Channel 1 to acquire the electromyographic signal by inserting an intravaginal sensor probe into the vaginal cavity; and Channel 2, to acquire the EMG signals from abdominal muscles by electrode patches attaching to the abdomen.

With the collected amplified EMG signal, muscle fiber recruitment and relaxation time, muscle fiber type and fatigue were processed and presented visible interpreted curves on the computer interface by 88 MyoTrac Infiniti system V6.8.11.2. (Thought Technology Ltd., Montreal, Quebec, Canada). The combination of channel 1 and 2 was processed, and the percentage of abdominal muscle engagement was analyzed.

As per the Glazer Protocol [9,10], this study divided the test into four phases.

(1) The rest (pre-baseline) phase: the subjects were instructed to feel the pelvic floor muscle at rest remaining for 10 seconds. During this phase, we assessed the resting state of the PFM and measured the Average Mean Amplitude in μV.

(2) The phasic (flick) contraction phase: the subjects were instructed to quickly contract the PFM, and then fully relax the PFM immediately after contraction (five 2-second contraction with a 2-second rest in-between). To test muscle strength and reaction velocity of the fast muscle fibers (Class II fibers).

Average Peak Amplitude (μV): the mean value of 5 contractions.

Time Before Peak (s): the mean value of 5 contractions.

Time After Peak (s): the mean value of 5 contractions.

(3) The tonic contraction phase: the subjects were instructed to contract the PFM as strongly as possible and hold the contraction for 10 seconds, then fully relax the PFM after contraction for 10 seconds. To test muscle strength and contractile stability of the slow muscle fibers (Class I fibers).

Average Mean Amplitude (μV): the mean value of 5 contractions.

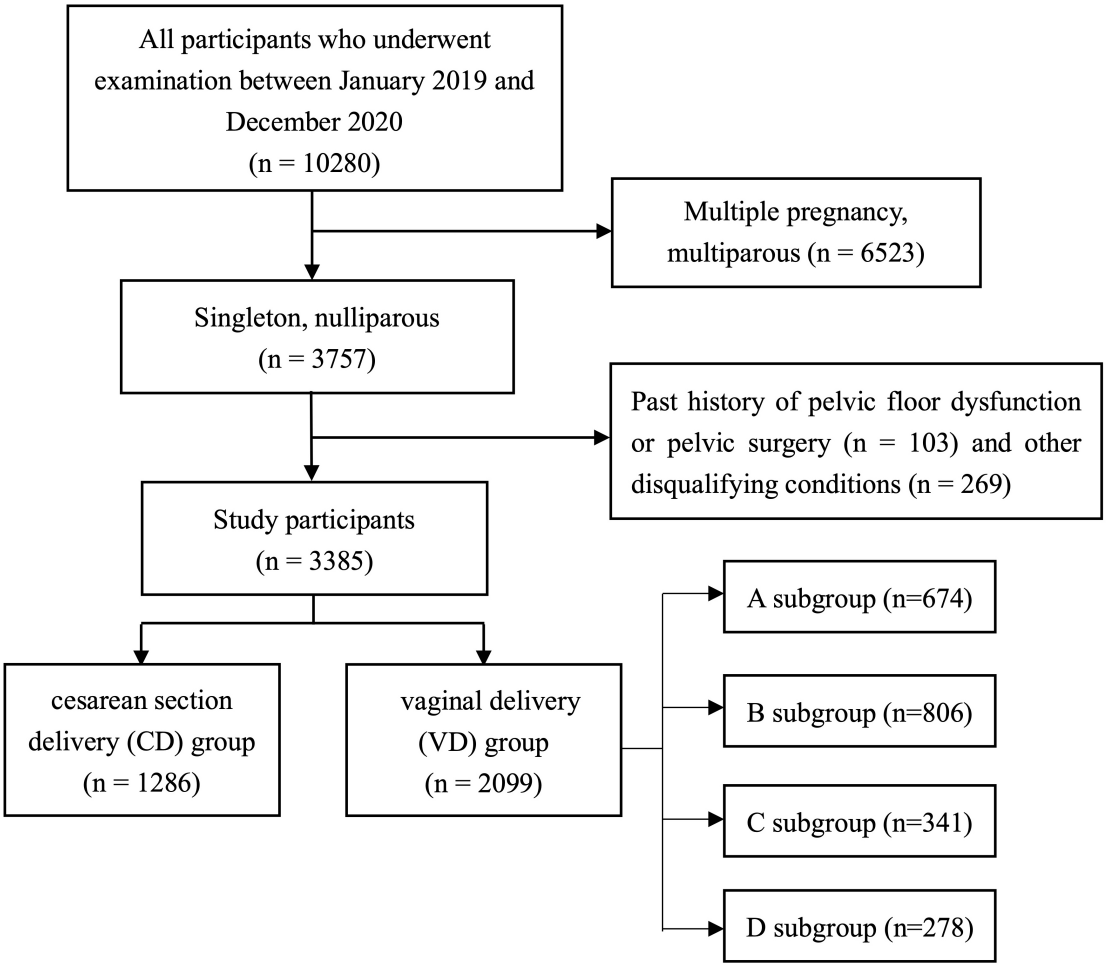

Fig. 1. Flowchart of the protocol used to select the study population.

Mean Amplitude Variability (%).

(4) The rest (post-baseline) phase: the subjects were instructed to feel the PFM at rest for 10 seconds. During this phase, we assessed the resting state of the PFM and measured the Average Mean Amplitude in μV.

2.5 Statistical Methods

All relevant data was entered into Excel to create a database. Statistical analysis was performed with SPSS 26.0 (IBM Corp., Armonk, NY, USA). When data showed normal distribution and equal variance, measurements were presented as $\bar{x} \pm s$ and analyzed by *t*-test for comparisons between two groups and one-way analysis of variance (ANOVA) for comparisons between multiple groups. Those data that did not meet normal distribution or equal variance were presented as median [M (P25, P75)]. The Mann-Whitney U-test was used for comparisons between two groups, and the Kruskal-Wallis rank sum test was used for comparisons between multiple independent samples. Controlling for multivariate confounding effects using multiple linear regression models. $p < 0.05$ was considered statistically significant.

3. Results

This study successfully screened a total of 3385 subjects (Fig. 1), including 1286 cases in the CD group and 2099 cases in the VD group. There were no significant differences in age, body mass index (BMI), gestational age at delivery, and neonatal weight between CD and VD ($p > 0.05$, Table 1). Our analysis showed that the mean peak amplitude of phasic (flick) contractions and the mean amplitude of tonic contractions were both significantly higher in CD than in VD ($p < 0.01$, Tables 2, 3). In contrast, the mean amplitude variability of tonic contractions was lower in CD than in VD ($p < 0.05$, Tables 2, 3). The results showed that the strength of fast muscle (class II fibers) and slow muscle (class I fibers) was higher in CD than in VD, and the variation of slow muscle (class I fibers) was significantly higher in VD. When comparing the value at rest before and after baseline, VD had a lower mean amplitude compared to CD ($p < 0.01$, Tables 2, 3). This study showed that abdominal muscle involvement was significantly higher in VD than in CD ($p < 0.01$, Table 2).

Table 1. Comparison of basic characteristics between the cesarean section delivery group and the vaginal delivery group.

Groups	Sample size	Age (years old)	Gestational age at delivery (weeks)	BMI (kg/m^2)	Neonatal weight (g)
VD	2099 (62.01)	29.93 ± 3.03	38.96 ± 1.16	20.79 ± 2.56	3272.3 ± 337.5
CD	1286 (37.99)	29.99 ± 3.53	38.84 ± 1.36	20.92 ± 2.11	3279.6 ± 423.0
t/Z		–0.466	–0.832	–1.649	–0.530
p-value		0.641	0.405	0.099	0.596

The values are given in the form of a number (percentage) or mean ± standard deviation (SD).

The independent sample *t*-tests or Mann-Whitney U-tests were used for continuous variables.

BMI, body mass index; VD, vaginal delivery group; CD, cesarean section delivery group.

Table 2. Comparison analysis of pelvic floor muscle in surface electromyography (sEMG) data between cesarean section delivery group and vaginal delivery group.

Parameter	Groups		t/Z	*p*-value
	VD (n = 2099)	CD (n = 1286)		
Rest pre-baseline				
Average Mean Amplitude (μV)	4.77 ± 3.98	7.64 ± 5.57	–16.129	0.000*
Phasic (flick) contractions				
Average Peak Amplitude (μV)	33.4 (22.37, 44.67)	42.85 (31.34, 54.70)	–14.883	0.000*
Time Before Peak (s)	0.34 (0.27, 0.44)	0.35 (0.27, 0.45)	–0.646	0.519
Time After Peak (s)	0.41 (0.32, 0.55)	0.42 (0.32, 0.56)	–0.101	0.919
Tonic contractions				
Average Mean Amplitude (μV)	21.90 (14.14, 30.79)	29.64 (20.75, 37.53)	–15.230	0.000*
Mean Amplitude Variability (%)	0.22 (0.18, 0.28)	0.20 (0.16, 0.26)	–8.790	0.000*
Rest post-baseline				
Average Mean Amplitude (μV)	4.83 ± 3.25	7.33 ± 4.72	–16.752	0.000*
Abdominal muscle engagement (%)	16.24 (7.18, 32.24)	10.18 (4.41, 21.35)	–10.840	0.000*

The values are given in the form of mean ± SD or median and interquartile range.

The independent sample *t*-tests or Mann-Whitney U-tests were used for continuous variables.

*: $p < 0.05$.

This study further differentiated into 4 subgroups of vaginal delivery (A: intact perineum without laceration and first-degree laceration; B: second-degree laceration; C: mediolateral episiotomy; D: forceps delivery). There was no statistical difference in maternal age, BMI, gestational age at delivery and neonatal weight among the four subgroups of vaginal delivery ($p > 0.05$, Table 4). Significant differences were identified among the four subgroups of vaginal delivery groups (Table 5). The average mean amplitude of resting before baseline was significantly higher in group C compared to group D. The mean peak amplitude of phasic (flick) contractions and the mean amplitude of tonic contractions were statistically lower in group D than in the other vaginal delivery groups ($p < 0.01$). The mean amplitude variability of tonic contractions was greater in group D than in groups A, B and C ($p < 0.05$). The mean resting amplitude after baseline was shorter in group D than in groups A, B and C ($p < 0.01$) (Table 3). There was no significant difference in the engagement of the abdominal muscles between the 4 subgroups of vaginal delivery ($p > 0.05$, Table 5).

4. Discussion

In this study, analysis of pelvic floor sEMG data at 6–8 weeks postpartum in primiparous women showed that fast muscle strength was slightly but significantly weaker in VD compared to CD, and for the slow muscle, muscle strength and stability of contractile control were both significantly weaker in VD compared to CD. The function of the pelvic floor muscles decreases significantly after pregnancy, and the supporting force becomes weaker. The high pressure exerted on the pelvic floor by pregnancy and childbirth causes damage to the PFM, connective tissue and nerves, ultimately leading to PFD [15]. Multiple previous studies have shown that the incidence of PFD, such as pelvic organ prolapse (POP), stress urinary incontinence (SUI), etc., is significantly higher in women with vaginal delivery compared with cesarean section [16,17]. Blomquist *et al.* [18] found that the cumulative incidence of POP, SUI and overactive bladder (OB) after vaginal delivery was associated with reduced PFM strength. A meta-analysis [19] of a total of nine studies also showed that PFM strength was significantly lower in the VD group than in the CD group. This study suggests that vaginal delivery, as a major risk factor for impaired postpartum PFM strength, may affect postpar-

Table 3. Multiple linear regression models of delivery mode and 4 groups of vaginal delivery.

Rest pre-baseline			Phasic (flick) contractions		Tonic contractions		Tonic contractions		Rest post-baseline	
Average Mean Amplitude			Average Peak Amplitude		Average Mean Amplitude		Mean Amplitude Variability		Average Mean Amplitude	
	β (95% CI)	p	β (95% CI)	p	β (95% CI)	p	β (95% CI)	p	β (95% CI)	p
Delivery mode										
VD	0 (Ref.)		0 (Ref.)		0 (Ref.)		0 (Ref.)		0 (Ref.)	
CD	2.88 (2.55, 3.20)	<0.001*	9.14 (7.86, 10.42)	<0.001*	7.02 (6.06, 7.97)	<0.001*	–0.03 (–0.03, –0.02)	<0.001*	2.49 (2.22, 2.76)	<0.001*
Vaginal delivery subgroups										
D	0 (Ref.)		0 (Ref.)		0 (Ref.)		0 (Ref.)		0 (Ref.)	
A	0.07 (–0.48, 0.63)	0.793	5.75 (3.28, 8.21)	<0.001*	4.03 (2.23, 5.83)	<0.001*	–0.03 (–0.05, –0.01)	<0.001*	0.81 (0.36, 1.26)	<0.001*
B	0.34 (–0.2, 0.88)	0.222	4.05 (1.64, 6.45)	<0.001*	3.33 (1.57, 5.09)	<0.001*	–0.02 (–0.04, –0.01)	0.003*	0.97 (0.53, 1.41)	<0.001*
C	0.66 (0.04, 1.29)	0.038*	4.12 (1.34, 6.91)	0.004*	3.57 (1.53, 5.6)	<0.001*	–0.02 (–0.04, –0.01)	0.012*	0.84 (0.33, 1.35)	0.001*

Model adjusted for age, BMI, parity, number of miscarriages, number of induced abortions, birth weight of newborns, gestational age.

*: $p < 0.05$; 95% CI, 95% confidence interval.

Table 4. Comparison of characteristics of vaginal delivery subgroups.

Subgroup	Sample size	Age (years old)	BMI (kg/m^2)	Gestational age (weeks)	Neonatal weight (g)
A	674	29.75 ± 3.08	20.65 ± 2.49	38.94 ± 1.04	3251.6 ± 318.2
B	806	29.92 ± 2.90	20.91 ± 2.58	39.06 ± 1.06	3291.1 ± 320.9
C	341	29.99 ± 3.10	20.74 ± 2.78	38.87 ± 1.61	3256.2 ± 398.1
D	278	30.35 ± 3.13	20.81 ± 2.36	38.83 ± 1.01	3287.5 ± 346.7
Z		6.380	6.066	5.065	7.727
p-value		0.095	0.108	0.167	0.052

The values are given in the form of mean ± SD.

The Kruskal-Wallis test was applied to multiple independent samples.

A, without perineal laceration + first-degree laceration; B, second-degree perineum laceration; C, mediolateral episiotomy; D, forceps delivery. Z, the z-value in the Kruskal-Wallis test.

Table 5. Analysis of pelvic floor EMG data in 4 groups of vaginal delivery.

Parameter	Groups of vaginal delivery				*p*-value
	A (n = 674)	B (n = 806)	C (n = 341)	D (n = 278)	
Rest pre-baseline					
Average Mean Amplitude (μV)	3.87 (2.07, 5.99)	4.01 (2.22, 6.36)	3.86 (2.35, 6.64)	3.49 (1.84, 5.73)	0.037*
Phasic (flick) contractions					
Average Peak Amplitude (μV)	34.18 (24.46, 45.42)	33.39 (22.46, 44.66)	33.95 (23.36, 44.59)	29.19 (18.38, 40.08)	0.000*
Time Before Peak (s)	0.33 (0.26, 0.43)	0.34 (0.26, 0.44)	0.35 (0.27, 0.46)	0.35 (0.28, 0.46)	0.184
Time After Peak (s)	0.41 (0.32, 0.54)	0.42 (0.32, 0.55)	0.41 (0.32, 0.55)	0.43 (0.33, 0.60)	0.325
Tonic contractions					
Average Mean Amplitude (μV)	22.85 (15.10, 31.89)	22.39 (14.19, 31.04)	22.32 (14.31, 30.82)	17.51 (12.18, 27.02)	0.000*
Mean Amplitude Variability	0.22 (0.18, 0.28)	0.22 (0.18, 0.28)	0.23 (0.19, 0.28)	0.24 (0.19, 0.32)	0.002*
Rest post-baseline					
Average Mean Amplitude (μV)	4.23 (2.62, 6.46)	4.48 (2.60, 6.67)	4.35 (2.33, 6.55)	3.31 (1.91, 5.72)	0.000*
Abdominal muscle engagement	15.71 (7.17, 31.76)	16.45 (7.48, 32.09)	15.07 (6.86, 31.81)	19.72 (7.54, 36.61)	0.300

The values are given in the form of a number (percentage) or median and interquartile range.

Nonparametric test (Kruskal-Wallis H test) were used for multiple independent samples of continuous variables.

A, without perineal laceration + first-degree laceration; B, second-degree laceration; C, mediolateral episiotomy; D, forceps delivery.

*: $p < 0.05$.

tum PFM function by decreasing the strength of the fast and slow muscles and the stability of the slow muscles.

Several studies [19,20] have suggested that elective cesarean section may protect the pelvic floor muscles. This study found that the mean values of pre- and post-baseline sEMG were higher in the CD group than in the VD group in early postpartum. Guo *et al*. [21] found that the pre-baseline resting pressure was higher in the CD group in early postpartum compared with the VD group, which is consistent with our findings. The resting baseline amplitude reflects the resting activity of the PFM, which is essential to maintain the pelvic organs in optimal position [22,23]. The lower resting baseline amplitude in the VD group indicated the greater resting underactive status of the PFM [9].

Numerous studies have shown that assisted vaginal delivery, especially forceps delivery, significantly increases the risk of PFD. The study reported that the risk of fecal incontinence and POP was significantly higher in those who had an assisted vaginal delivery compared to a spontaneous vaginal delivery [24]. Meyer *et al*. [25] reported a higher incidence of PFM weakness (20% *vs.* 6%) in women with forceps compared to spontaneous delivery at 10 months postpartum. Of all types of vaginal delivery, forceps delivery is associated with the highest risk of pelvic floor damage, mainly due to the potential destruction of pelvic floor muscles, nerves and connective tissue. Weakened PFM strength can be caused by levator avulsion injuries and extensive levator hiatus [26]. Our results suggest that forceps delivery has the worst effect on PFM function of all vaginal deliveries in the early postpartum period, mainly by reducing the strength of the fast and slow muscles and the stability of the slow muscles. And for those who require forceps delivery as a high-risk PFD population, pelvic floor function assessment should be performed in the early postpartum period, and a precise and effective strategy for postpartum PFM recovery should be initiated as early as possible.

To date, there are no reports comparing abdominal muscle engagement between different modes of delivery. In our clinical routine, the EMG signal representing the engagement of the abdominal muscles was captured by an additional channel through the patch attached to the abdomen. Our results showed that abdominal muscle engagement was significantly higher in VD compared to CD. The possible reason for this could be the compensatory use of the abdominal muscles in the vaginal delivery group, as they had weakened pelvic floor muscles. The discordance between the pelvic and abdominal muscles was more pronounced in women who delivered vaginally, so their pelvic floor muscles need more attention and follow-up.

This study recruited a large sample size in the final analysis, which can reduce the bias and provide reasonable comparisons in different study groups. And this study applied the modified Glazer protocol to evaluate the signal data of pelvic floor sEMG, which demonstrated the precise extent and detailed type of PFM in dysfunction based on a quantitative approach. It is powerful to support the comprehensive and accurate analysis of the effect of different deliveries on PFM function in the early postpartum period.

This study also has several limitations. First, this study only focused on the detection of EMG signals on the vaginal surface, and lacked further diagnosis of PFD. Second, due to the small sample size of third-degree perineal lacerations, this study did not have sufficient power to analyze third-degree perineal lacerations in vaginal delivery. Third, we educate all women delivering at our hospital about pelvic floor muscle screening 6–8 weeks postpartum, but about 20% of women still do not get screened as promised. Although we were not biased in our counseling and most of these women were out of town and returned home after delivery, it is possible that this may have had an impact on the results of the study. Finally, this study only assessed pelvic floor sEMG at 6–8 weeks postpartum, which may not be sufficient to access final pelvic muscle function. Therefore, a long-term epidemiologic follow-up study is suggested.

Routine mediolateral episiotomy in low-risk pregnant women is controversial. Some believe that routine mediolateral episiotomy not only protects the anal sphincter [27], but also protects against the defects of central support from the anterior vaginal wall [28]. In contrast, others believe that routine mediolateral episiotomy increases the incidence of episiotomy infection and pain, postpartum hemorrhage, and urinary tract dysfunction [29]. A systematic review [30] showed that mediolateral episiotomy was not beneficial in preventing urinary and fecal incontinence and pelvic floor relaxation and, ironically, increased the incidence of dyspareunia. In this study, there was no statistical difference in sEMG testing between the mediolateral episiotomy group, the vaginal delivery with hard protected perineal integrity group, and the 1st and 2nd degree lacertation groups. This study found that episiotomy did not significantly protect pelvic floor muscle function compared with the perineal integrity group and the 1st and 2nd degree perineal laceration groups. Therefore, episiotomy should be performed after careful evaluation.

5. Conclusions

In this study, the analysis showed that the strength of the fast and slow muscles, the baseline resting amplitude and the stability of the slow muscles were weaker in the vaginal delivery group, especially in the forceps delivery subgroup, than in the cesarean delivery group at 6–8 weeks postpartum.

Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Author Contributions

XC, LW and HZ designed the research study. LC, LW and HZ performed the research. LC analyzed the data. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

All subjects gave their informed consent for inclusion before they participated in the study. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethics Committee of the International Peace Maternity and Child Health Hospital, School of Medicine, Shanghai Jiao Tong University (No. GKLW 2023-024-01).

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Conflict of Interest

The authors declare no conflict of interest.

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