# **Original Research**

# Study on the effect of electric current intensity stimulation combined with biofeedback pelvic floor muscle training on postpartum pelvic floor dysfunction

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### Summary

Aim: To explore the effect of different electrical stimulation intensities combined with pelvic floor muscle training on postpartum pelvic floor dysfunction. *Methods:* 720 patients with pelvic floor dysfunction diagnosed following vaginal delivery were randomly divided into intervention and control groups. The control group was treated with conventional electrical stimulation combined with pelvic floor muscle training. Patients in the intervention group were treated with electrical stimulation of increasing intensity. The electrophysiological indices of pelvic floor function, SUI incidence, ICI-Q-SF, POP-Q, PFIQ-7 and PISQ-12 scores were compared between the two groups. *Results:* Following treatment, patients in the intervention group had significantly higher pelvic floor muscle type I, type II muscle strengths, slow muscle average myoelectric values, fast muscle maximum myoelectric values, front resting average myoelectric values, rear resting average myoelectric values, and vaginal resting pressure, compared to the control group. There was no difference in the Bp, D, GH, PB and TVL measurements between the two groups. SUI, ICI-Q-SF and PISQ-12 scores were significantly lower in the intervention group, but there was no difference in the PFIQ-7 score. *Conclusion:* Use of higher intensity electric stimulation combined with pelvic floor muscle training appears to improve the electrophysiological indices of pelvic floor function and POP-Q parameters, as well as reducing the severity and incidence of urinary incontinence and improving sexual function.

Key words: Different intensity electrical stimulation; Pelvic floor muscle training; Postpartum pelvic floor functional disease.

### Introduction

Female pelvic floor dysfunction (PFD) constitutes pelvic organ prolapse (POP), stress urinary incontinence (SUI) and fecal incontinence. It is a common women's health issue that significantly affects the quality of life. There are many causes of PFD. Recent epidemiological studies showed that pregnancy and childbirth are independent risk factors for postpartum PFD. Pregnancy and vaginal births often result in damage to the nerve, ligaments and fascia of the pelvic floor, thus increasing the risks of postpartum stress urinary incontinence and PFD [1]. The incidence of PFD in childbearing women in China has been reported to be as high as 35% [2], causing significant short- and longterm psychological and physical impacts [3]. Vaginal natural tissue repair is an effective method for the treatment of rectocele [4], however surgical intervention is not without risks. Therefore, patients mightay prefer conservative treatments such as pelvic floor muscle training [5]. Indeed, clinicians have reached a consensus that women should be provided with advice on the prevention of UI during the antenatal and postnatal period [6]. A wide range of interventions has been used for the treatment of urinary and fecal incontinence, including conservative methods such as pelvic floor muscle training (PFMT), lifestyle interventions, behavioral

training, continence devices, as well as pharmaceutical interventions and surgery [7]. UK guidelines recommend 150 min of moderate to vigorous intensity physical activity per week, [8] with postnatal women recommended to gradually work towards this by 4 to 6 weeks post birth [9]. In the early postpartum period, rehabilitation exercises can improve the electrophysiological indexes of the pelvic floor and promote tissue repair. Beyond the 6-month postpartum period, rehabilitation may effectively reduce the risk of PFD in later age. Moen et al. [10] reported that more than 70% of patients with PFD were unable to correctly contract the pelvic floor muscle. Therefore, PFMT was often combined with biofeedback (BF) and electrical stimulation (ES) in clinical practice. PFD is related to the decrease in pelvic floor contractility, POP is associated with a reduction in class I muscle strength, and SUI is related to the decline in class II muscle strength [11, 12]. Pelvic floor muscle training can enhance the contractility of the patients' pelvic floor muscles through muscle training, strengthen the coordination of pelvic floor muscles, and promote better patient outcomes. Its curative effect has been widely recognized in clinical practice [13]. Recent developments in electrical stimulation therapy have seen increasing use in patients with PFD, with good effect. However, we propose that, due to the deep position of class I pelvic floor muscles, traditional electric

Group	Age (year)		BMI (kg/m <sup>2</sup> )		Gestational	age (week)	Newborn weight (kg)	
	Range	Mean $\pm$ SD	Range	Mean $\pm$ SD	Range	Mean $\pm$ SD	Range	Mean $\pm$ SD
Intervention group $(n = 362)$	21~39	$26.63 \pm 4.20$	22~31	$26.78 \pm 3.26$	$38^{1/7} \sim 40^{5/7}$	$39.17 \pm 1.36$	$3.00\pm3.90$	$3.45\pm0.40$
Control group $(n = 358)$	20~37	$26.59 \pm 4.18$	23~31	$27.01 \pm 3.46$	$37^{5/7} \sim 40^{3/7}$	$39.26 \pm 1.38$	2.95~3.96	$3.47 \pm 0.51$
t	-	0.1281	-	0.9178	-	0.8813	-	0.5851
p	-	0.8981	-	0.3590	-	0.3785	-	0.5587

Table 1. — *Demographic data of participants*.

stimulation therapy may provide inadequate stimulation of these muscle groups, leading to ineffective treatment. This raises the question of whether increasing the intensity of electrical stimulation would help in the treatment of PFD. To our knowledge, there is a paucity of information in the literature and hence we aim to address this hypothesis in the current study.

### **Data and Methods**

### General information

We carried out a randomized controlled trial of 720 patients who were admitted to the Jinshan Branch of Shanghai Sixth People's Hospital from January 2017 to April 2019 with a diagnosis of PFD. The trial was approved by the ethics committee of Jinshan Branch of Shanghai Sixth People's Hospital and all participants provided informed consent (approval number: jszxyy201703). The study was undertaken in accordance with CONSORT guidelines to ensure the rationality and accuracy of the clinical research results.

Inclusion criteria were: 1, patients received no prior rehabilitation treatment during the antenatal period. They were diagnosed as stage I pelvic floor dysfunction disease by symptoms, signs and POP-Q staging, with or without stress urinary incontinence; 2, full term parturient, spontaneous vaginal delivery; 3, age > 18 years.

Exclusion criteria were: 1, antenatal patients with pelvic floor dysfunction; 2, patients with liver and kidney dysfunction; 3, patients with malignant tumor; 4, patients with poor treatment compliance, unable to cooperate with the study.

Patients were divided into the intervention group (362 cases) and the control group (358 cases). The baseline demographics, BMI and delivery details of the participants are shown in Table 1. There were no significant differences between the two groups (p > 0.05) in terms of age, BMI, gestational age or newborn weight.

# Methods

Two trained clinicians provided the patients in both groups with treatment and training guidance within the period of 42-60 days after delivery. Biofeedback pelvic floor muscle training using the Phenix neuromuscular stimulation therapy was employed for this study. The vaginal electrode was inserted with the patient in a flat position. The

parameter selection frequency was 50 Hz, the stimulation cycle was 2 s, and the wave width was 200 IZS. The current intensity was increased gradually from 0 to a level where the patient experiences muscle contraction without discomfort. The current intensity range was 10-20 Ma and the electrical stimulation treatment lasted for 15 minutes. After completion of the electrical stimulation treatment, the instrument was switched to the biofeedback mode and the patient was guided to actively carry out pelvic floor muscle contraction and relaxation training for 15 minutes. Patients were also instructed to perform voluntary anal lifting and pubococcygeal muscle contraction and relaxation training at home, 20 minutes per session, twice daily. The electrical stimulation and biofeedback training were undertaken twice weekly.

The intervention group underwent the same treatment as above, but after 10 minutes of electrical stimulation the current intensity was increased to a level that did not cause noticeable discomfort in patients. The current strength for the intervention group was 6-8 Ma higher than that in the control group. All patients were evaluated after two months of continuous treatment.

### Observation index

Patients were assessed for electrophysiological index of pelvic floor function, POP-Q score, SUI incidence and ICI-Q-SF score, PFIQ-7 score and PISQ-12 pre- and post-treatment.

### Decision criteria

Electrophysiological indexes of pelvic floor function: the electrophysiology, muscle strength, fatigue degree, vaginal resting pressure and dynamic pressure of class I and II muscle fibers were measured by Phenix USB4 screen (France Shanshan company). 1. Muscle strength measurement: pelvic floor muscle type I muscle fiber, contraction lasted for  $0{\sim}5$  s, and muscle strength was  $0{\sim}V$  grade, below 3 Grade was abnormal. The second type of pelvic floor muscle fibers contracted  $0{\sim}5$  times, and the muscle strength was  $0{\sim}v$  grade, and below 3 Grade was abnormal. 2. Muscle fatigue: the percentage of decrease from the highest point of the starting point to the highest point of the endpoint of 6 s is fatigue, average is 0, and negative is abnormal.

Table 2. — Comparison of electrophysiological indexes of pelvic floor function between control and intervention groups before and after treatment (mean  $\pm$  SD).

Group	Class I muscle fiber strength (grade)		Class I muscle fiber fatigue (%)		Class II muscle fiber strength (grade)		Class II muscle fiber fatigue (%)		Vaginal resting pressure $(cmH_2O)$	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control group (n = 358)	$1.57 \pm 0.34$	$3.37 \pm 0.49$	-4.52 ± 0.47	-3.29 ± 0.37	$1.15 \pm 0.23$	$3.72\pm0.54$	-4.17 ± 0.58	-3.18 ± 0.32	31.25 ± 3.69	$35.17 \pm 3.66$
Intervention group (n = 362)	$1.61 \pm 0.36$	$3.55 \pm 0.54$	-4.53 ± 0.51	-2.51 ± 0.22	$1.17 \pm 0.24$	$3.88 \pm 0.65$	-4.24 ± 0.67	-2.89 ± 0.27	31.57 ± 3.59	39.82 ± 4.18
t	1.533	4.685	0.274	34.334	1.142	3.594	1.499	13.136	1.179	15.886
p	0.126	0	0.784	0	0.254	0	0.134	0	0.239	0
Group	Mean myoelectric value before rest (uV)		Mean myoelectric value of slow muscle (uV)		Mean myoelectric value after rest (uV)		Maximum myoelectric value of fast muscle (uV)		Vaginal dynamic pressure (cmH <sub>2</sub> O)	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control group (n = 358)	$1.31 \pm 0.25$	$3.29 \pm 0.28$	23.52 ± 0.47	29.89 ± 0.37	$0.78 \pm 0.21$	$2.91 \pm 0.49$	32.17 ± 0.58	39.68 ± 0.40	60.25 ± 30.69	69.10 ± 30.66
Intervention group (n = 362)	$1.30 \pm 0.26$	$3.41 \pm 0.39$	$23.53 \pm 0.51$	$30.12 \pm 0.42$	$0.77 \pm 0.22$	$3.14 \pm 0.58$	$32.24 \pm 0.67$	$39.89 \pm 0.37$	$59.57 \pm 30.59$	$76.92 \pm 28.18$
t	0.526	4.747	0.270	7.799	0.624	5.750	1.489	7.311	0.298	3.562
p	0.599	0	0.787	0	0.533	0	0.137	0	0.766	0.000

Table 3. — Comparison of POP-Q scores between control and intervention groups before and after treatment [ $\bar{x} \pm SD$ , cm].

Group _	Aa spot		Ba spot		Ap spot		Bp spot		C spot	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control group (n = 358)	-1.73 ± 0.12	-2.38 ± 0.13	-1.42 ± 0.69	-2.21 ± 0.33	-2.71 ± 0.36	-2.85 ± 0.24	-2.63 ± 0.44	-2.81 ± 0.14	-4.90 ± 0.18	-5.20 ± 056
Intervention group (n = 362)	-1.72 ± 0.23	-2.69 ± 0.21	-1.39 ± 0.67	-2.30 ± 0.52	-2.72 ± 0.28	-2.91 ± 0.35	-2.64 ± 0.45	-2.82 ± 0.32	-5.00 ± 0.12	-5.33 ± 065
t	0.705	2.365	0.592	2.469	0.833	2.691	0.302	0.549	0.877	2.889
p	0.481	0.018	0.554	0.014	0.405	0.007	0.763	0.583	0.381	0.003
Group	D spot		GH		РВ		TVL spot			
	Before treatment	After treatment								
Control group (n = 358)	-5.72 ± 0.33	-6.40 ± 0.19	$3.03 \pm 0.14$	$3.09 \pm 0.15$	$3.32 \pm 0.16$	$3.30 \pm 0.16$	$8.70 \pm 0.15$	$8.73 \pm 0.17$		
Intervention group (n = 362)	-5.71 ± 0.29	-6.42 ± 0.15	$2.96 \pm 0.16$	$3.19 \pm 0.38$	$3.31 \pm 0.12$	$3.39 \pm 0.25$	$8.58 \pm 0.14$	$8.80 \pm 0.19$		
t	0.443	1.575	6.250	9.901	0.943	5.769	11.111	8.154		
p	0.665	0.116	7.1412	1.027	0.346	1.199	1.599	2.314		

POP-Q score: the furthest end of prolapse does not exceed the introitus at maximum Valsalva in the supine position. The POP-Q considers six defined points: two anterior points (Aa and Ba), two posterior points (Ap and Bp), and two apical points (C and D). The Aa point is located at the midline of the anterior wall of the vagina and is approximately 3 cm from the outer urethral orifice. Point Ba represents the farthest part of the anterior wall of the vagina from the vaginal cuff or anterior vaginal fornix to point Aa. Point C is the most distant part of the anterior lip of the cervix. Point D represents the position of the posterior fornix and is omitted during a total hysterectomy. The Ap point is located at the midline of the posterior wall of the vagina and is approximately 3 cm from the hymen. The Bp point represents the farthest position of the upper part of the posterior wall of the vagina from the vaginal cuff or posterior fornix to the Ap point. POP-Q also considered three other measurement methods: total vaginal length (TVL), genital hiatus (GH) and perineal body (PB).

Diagnostic criteria for stress urinary incontinence: involuntary leaking of urine with increased abdominal pressure. The severity of stress urinary incontinence [14]: according to the brief form ICI-Q-SF of urinary incontinence questionnaire filled by the international urinary incontinence Advisory Committee. A higher score corresponded to a more severe degree of urinary incontinence.

Pelvic floor disease life impact Questionnaire-7 (PFIQ-7). Scoring standard: 0 for no effect; 1 for mild impact; 2 for moderate impact; 3 for severe impact. A higher score corresponded to a greater impact on the quality of life.

A short form of the pelvic organ prolapse / urinary incontinence sexual questionnaire (PISQ-12) score [15]: the score includes 12 items, a total of 48 points, with a higher score corresponding to a worse quality of sex life.

To minimise the research error, the evaluation and examination of pelvic floor electrophysiological indexes and biofeedback electric stimulation treatment were all performed by the same person (the same machine operation). Secondly, the POP-Q stage examiner was blinded to the results of the previous examination and measured each point to the nearest 0.5 cm. Finally, data collection and statistical analyses were completed by the same person.

### Statistical methods

Spss22.0 software was used to analyze the data. Measurement data was expressed as the mean  $\pm$  standard deviation ( $\tilde{\mathbf{x}} \pm \mathrm{SD}$ ), with comparison between groups conducted using the *t*-test. Numerical data were expressed as a percentage (%), and comparison of the rate used the  $\chi^2$  test, with p < 0.05, indicating the difference was statistically significant. The incidence of urinary incontinence = the number of cases of urinary incontinence / the total number of cases  $\times$  100%.

### **Results**

Comparison of electrophysiological indexes of pelvic floor function between the two groups before and after treatment

No significant differences were observed between the two groups (p>0.05) before treatment (Table 2). After surgery, the muscle strength of pelvic floor muscle type I, type II, slow muscle type I, fast muscle type II, pre rest, post rest, static vaginal pressure and vaginal dynamic pressure in the intervention group were significantly higher than in the control group (p<0.05). Furthermore, the fatigue degree of class I and class II muscle fibers in the intervention group were significantly improved compared with the control group (p<0.05).

Comparison of POP-Q scores between control and intervention groups before and after treatment

There were no significant differences in POP-Q between the two groups (p>0.05) prior to treatment (Table 3). Following surgery, the points Aa, Ba, Ap and C in the intervention group showed significantly improved POP-Q scores compared with the control group (p<0.05), while the points Bp, D, GH, PB and TVL showed no significant difference (p>0.05).

Incidence of stress urinary incontinence and ICI-Q-SF scores before and after treatment in the control and intervention groups

Prior to the procedure, there was no significant difference in the incidence and severity scores (ICI-Q-SF) between the two groups (p > 0.05; Table 4). After the procedure, the incidence and severity score (ICI-Q-SF) in the intervention group were both significantly lower than those of the control group (p < 0.05).

Comparison of PFIQ-7 score and PISQ-12 score between the control and intervention groups before and after treatment

Before treatment, there was no statistical difference (p > 0.05) in the PFIQ-7 and PISQ-12 scores between the two groups (Table 5). After treatment, the PFIQ-7 score in the intervention group was lower than in the control group, but the difference was not significant (p > 0.05). The PISQ-12 score was significantly lower than in the control group (p < 0.05).

### **Discussion**

The pelvic floor muscles and fascia are critical support structures for pelvic organs such as the bladder, uterus and rectum. However, these supportive tissues are susceptible to damage during pregnancy, especially at the time of vaginal delivery [16]. When pregnant women deliver through the vagina, the fetal delivery causes the pregnant women's pelvic floor structure to be squeezed, resulting in mechanical damage Harm [17, 18]. Due to the secretion of estrogen, relaxin and other hormones during pregnancy, the morphology and structure of the muscle fiber collagen is

Group	Incidence of urina	ary incontinence	ICI-Q-SF score			
	Before treatment	After treatment	Before treatment	After treatment		
Control group (n = 358)	177 (49.44)	97 (27.09)	$2.96 \pm 0.48$	$2.37 \pm 0.41$		
Intervention group ( $n = 362$ )	183 (51.12)	52 (14.36)	$2.93 \pm 0.47$	$1.64 \pm 0.35$		
$\chi^2$	0.089	17.774	0.847	25.704		
p	0.766	0.000	0.397	0.000		

Table 4. — Incidence of SUI and severity score (ICI-Q-SF) before and after treatment  $[n(\%), \bar{x} \pm SD]$ .

Table 5. — Comparison of PFIQ-7 and PISQ-12 scores between the control and intervention groups before and after treatment  $[\bar{x} \pm SD]$ .

Group	PFIQ-7	score	PISQ-12 score		
	Before treatment	After treatment	Before treatment	After treatment	
Control group (n = 358)	$19.02 \pm 9.36$	$8.37 \pm 8.29$	$40.57 \pm 4.24$	$37.62 \pm 3.83$	
Intervention group $(n = 362)$	$18.86 \pm 8.70$	$7.29 \pm 8.38$	$40.73 \pm 4.28$	$28.49 \pm 3.61$	
t	0.237	1.738	0.504	32.908	
p	0.813	0.083	0.615	0.000	

altered. This affects soft tissue function in the pelvic floor and can weaken the pelvic floor muscle groups, thus increasing the risk of postpartum stress urinary incontinence [19, 20]. Pregnancy and delivery are independent risk factors for pelvic floor dysfunction [21]. De C A et al. [22] also pointed out that the pelvic floor injury of the pregnant women in vaginal delivery was more severe than that of the women in cesarean section, and the incidence of pressure urinary incontinence and other pelvic floor dysfunction was higher. Physical therapies such as PFMT and ES with or without BF are the standard first-line therapies for conservative treatment and prevention of SUI in women [23]. PFMT combined with biofeedback and ES is a non-invasive and effective treatment for female SUI, with surface electromyography being a useful test to assess the curative effect [24]. Therefore, the critical points of treatment are to restore the muscle strength of the pelvic floor and to reverse the damage sustained by the soft tissue of the pelvic floor during pregnancy and delivery. Pelvic floor muscle exercise, electrical stimulation and biofeedback can improve the contractility of pelvic floor muscle, improve the blood circulation to the pelvic floor, enhance the contractility of pelvic floor muscle, and help to strengthen postnatal PFD such as SUI and pop.

Pelvic floor muscle training improves muscle strength through active exercise [25, 26]. It can increase blood circulation to the pelvic floor and improve the patients' control and coordination ability through muscle group movement, exercise of the urethra sphincter, enhancement of contraction ability and of the micturition reflex [27]. Yoo *et al.* [28] reported that 57% of patients were cured using biofeedback combined with pelvic floor exercise.

In this study, we sought to improve the therapeutic effect of biofeedback training by transforming the electrical signal of pelvic floor muscle activity into a visual cue.

This helps patients to establish a correct autonomous muscle training program, undergo continuous treatment, assist them in forming conditioned reflex, and enhance precise muscle regulation ability and bladder control [29]. This study showed that the incidence and severity score (ICI-Q-SF) observed in the intervention group was significantly lower than the control group (p < 0.05). At the same time, electrical stimulation therapy can promote autonomic contraction of pelvic floor muscles, stimulate the repair of damaged nerve fibres and enhance the sensitivity of pelvic floor muscles [30]. Early changes that hint at pelvic floor dysfunction are various biochemical and electrophysiological events. However, should further damage occur, symptomatic pelvic floor dysfunction may manifest. Here, we showed that after two months of treatment between 42-60 days postpartum, the strength of pelvic floor muscle type I, type II, slow muscle, fast muscle, anterior resting, posterior resting, vaginal resting pressure and dynamic vaginal pressure in the intervention group were all significantly higher than in the control group (p < 0.05). The fatigue level of type I and type II muscle fibers was also significantly improved compared with the control group (p < 0.05). From these results, we conclude that effective electrical stimulation can promote the recovery of nerve cell function and improve the electrophysiological indexes of the pelvic floor.

Further, in the intervention group, points Aa, Ba, Ap and C in the POP-Q staging system were significantly improved compared to the control group (p < 0.05), while the PFIQ-7 and PISQ-12 scores were reduced. During the middle and later period of treatment, we observed that increasing the electric stimulation current intensity improved the patient's pelvic floor electrophysiology and enhanced the therapeutic effect on SUI and the quality of life. Our study demonstrates for the first time that increased current intensity during electrical stimulation therapy results in improved treat-

ment outcomes. This could be due to adequate stimulation of type I muscle fibres located deep in the pelvis.

However, we acknowledge several limitations to our study. Firstly, differences in patient tolerance can result in different initial current thresholds and mid-term current enhancement values. This can lead to inconsistent current intensities within the group. Secondly, there is no set standard for the initial threshold and level of current intensity. Thirdly, in the middle period of therapy, patients may have slight electrophysiological paralysis symptoms, which could reduce their sensitivity to current. If excessive current is used, pelvic floor muscle fatigue, inadequate relaxation or even aggravated urinary incontinence symptoms may occur. Therefore, clinician discretion was used in these situations.

Our study demonstrates that patients with postpartum PFD respond favorably to intense electrical stimulation therapy when combined with pelvic floor muscle training. In this study, patients with POP-Q stage I had minor pelvic floor dysfunction. Therefore, it is important to perform pelvic floor muscle training following childbirth, especially after vaginal delivery. However, we caution that our study involved a relatively small number of samples and that further investigations should be carried out in large, multicenter clinical research settings. For the prevention and treatment of pelvic floor dysfunction, we conclude that an individualized approach with initial non-surgical treatment options should be considered. The use of electrical stimulation therapy for the treatment of PFD would appear to play an increasingly important role.

### Acknowledgments

It was supported by Shanghai Jinshan Health Committee (grant No: JSKJ - kTMS -2017 - 11) and research fund for medical consortium construction of Shanghai Sixth People's Hospital Medical Group (grant No: 02.2Y02.07.023).

# **Conflict of Interest**

The authors declare no conflict of interest.

Submitted: April 10, 2020 Accepted: June 22, 2020 Published: December 15, 2020

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