Impact of pelvic floor muscle training on sphincter function and quality-of-life in patients who underwent low anterior resection: A comparative evaluation

 Cem Batuhan Ofluoglu,[1] Isa Caner Aydin,[2,*] Yunus Emre Altuntas,[3] Kenan Cetin,[4]
 Rahsan Inan,[5] Noyan Ilhan,[3] Firat Mulkut,[1] Hasan Fehmi Kucuk[3]

[1]Department of General Surgery, University of Health Sciences, Sancaktepe Sehit Prof. Dr. Ilhan Varank Training and Research Hospital, Istanbul, Turkiye

[2]Department of Gastroenterology Surgery, University of Health Sciences, Kartal Kosuyolu Higher Specialty Training and Research Hospital, Istanbul, Turkiye

[3]Department of General Surgery, University of Health Sciences, Kartal Dr. Lutfi Kirdar City Hospital, Istanbul, Turkiye

[4]Department of General Surgery, Canakkale Onsekiz Mart University Faculty of Medicine, Canakkale, Turkiye

[5]Department of Neurology, University of Health Sciences, Kartal Dr. Lutfi Kirdar City Hospital, Istanbul, Turkiye

ABSTRACT

OBJECTIVE: Our study aimed to determine the impact of pelvic floor muscle training (PFMT) on sphincter function and overall well-being in patients who underwent low anterior resection (LAR) and diverting ileostomy due to rectal cancer. For this purpose, anal electromyography (aEMG), low anterior resection syndrome (LARS) score, and the European Organization for Research and Treatment of Cancer quality-of-life questionnaires (EORTC-QLQ)-C30 (generic for cancer) and CR29 (specific to colorectal cancer) were used. The primary endpoint of our study is to determine the effect of PFMT on sphincter function by aEMG, the secondary endpoint is to evaluate the effect on quality-of-life using the LARS score, EORTC-QLQ-C30 and CR-29 questionnaires.

METHODS: Conducted between January 2017 and April 2018 at a tertiary hospital's general surgery clinic, the study included 32 patients between the ages of 18 and 75 who underwent low anterior resection and diverting ileostomy surgery. The patients were divided into two: the Study Group (SG), which started PFMT after surgery, and the Control Group (CG), which was not subjected to additional exercises. Six months after closure of the diverting ileostomy, both groups were evaluated with aEMG, LARS scores, and EORTC-QLQ-C30 and CR-29.

RESULTS: aEMG duration values were significantly lower in the SG (17.6 m/sec vs. 19.9 m/sec; p=0.001). Additionally, a significant decrease in SG, major LARS rates (12.5% vs. 62.5%; p=0.004) and LARS scores (23.1 vs. 30.0; p=0.003) was observed. While there was no significant difference between the groups in EORTC-QLQ C30, increased sexual interest and decreased fecal incontinence were observed in SG in EORTC-QLQ-CR29.

CONCLUSION: PFMT significantly improves LARS scores, quality-of-life questionnaires and aEMG parameters, positioning PFMT as an accessible, non-invasive, easy-to-use first-line treatment option in the treatment of LARS.

Keywords: EMG; EORTC-QLQ; Kegel exercise; LARS; rectal cancer.

*The current affiliation of the author: Department of Gastroenterology Surgery, Ministry of Health Zonguldak Ataturk State Hospital, Zonguldak, Turkiye

Correspondence: Cem Batuhan OFLUOGLU, MD. Saglik Bilimleri Universitesi, Sancaktepe Sehit Prof. Dr. Ilhan Varank Egitim ve Arastirma Hastanesi, Genel Cerrahi Klinigi, Istanbul, Turkiye.
Tel: +90 216 606 33 00   e-mail: dr.cemofluoglu@gmail.com

The widespread use of neoadjuvant therapy in treatment protocols for rectal cancer, combined with improvements in surgical oncological principles, currently yields better results in terms of survival and quality-of-life [1]. With the introduction of total mesorectal excision in rectal cancer surgery, sphincter-sparing surgery has emerged as the gold standard treatment method. Even though the hypogastric nerve is usually visible and preserved, and the sphincter remains undamaged in most cases, patients might still experience fecal and urinary incontinence, as well as temporary or permanent impotence. All these post-treatment dysfunctions are collectively referred to as low anterior resection syndrome (LARS) [2]. It is estimated that 90% of patients suffer from this syndrome [3].

Currently, there is a multimodal approach to treating LARS. One of the treatment options is pelvic floor muscle training (PFMT), also known as Kegel exercise. This exercise has no side effects and can easily be incorporated into daily routines without any specialized equipment or preparation. Kegel exercises were first introduced by Arnold Kegel for pelvic floor muscle strengthening in 1948 [4]. It has been suggested by Martellucci [5] that every patient discharged after a low anterior resection (LAR) procedure should commence Kegel exercises. In existing literature, the impact of Kegel exercises on LARS has mainly been assessed through quality-of-life questionnaires and incontinence scores [6]. However, no study has yet incorporated anal electromyography (aEMG) findings among post-surgery patients.

The aim of this study is to assess the influence of PFMT on sphincter function and quality-of-life. We evaluated the benefits of PFMT using aEMG, LARS score, and the European Organization for Research and Treatment of Cancer quality-of-life questionnaires (EORTC-QLQ)-C30 (cancer-specific generic) and CR29 (specific to colorectal cancer) among patients who underwent LAR due to rectal cancer.

MATERIALS AND METHODS

Design
This was a prospective randomized clinical trial conducted from January 2017 through April 2018 in a tertiary-level hospital. The study was approved by the Kartal Dr. Lutfi Kirdar City Hospital Ethics Committee (date: 27.09.2018, number: 2018/514/138/3). It was con-

Highlight key points
- PFMT significantly enhances sphincter function.
- PFMT reduces LARS score.
- PFMT has positive effects on quality-of-life.
- PFMT should be an easy-to-apply, non-invasive, cost-effective, first-line treatment option for LARS.

ducted in accordance with the Declaration of Helsinki. All participants gave informed consent after the study had been explained, including their right to withdraw from the trial at any time without prejudice to their further medical care.

Inclusion and Exclusion Criteria
Rectum cancer patients, aged 18–75 and volunteering with informed consents, were included in the study. All the patients were sexually active. They all received neoadjuvant chemotherapy and radiotherapy. All patients had sphincter-preserving total mesorectal excision and diverting loop ileostomy as a standard surgical procedure.

Patients, who were operated on under emergency conditions, who could not answer the questions appropriately due to their mental status, who were operated on previously due to a colorectal or proctological disease, or who had recurrence or metastatic disease were not included in the study.

Randomization and Study Groups
Thirty-two patients who provided the mentioned conditions were included in the study. Patients were randomized into two groups, a study group (SG) and a control group (CG), via computer. Patients were evaluated for incontinence before the first operation using the Wexner fecal incontinence score (WIS) [7].

The Kegel exercises were presented to 16 patients in the SG via a video after the first operation. Exercise routine portrayed as three times a day in four sets. A set contributes ten consecutive contraction movements. Exercise programs were given to the patients in written form afterwards. Patients in the CG (n=16) did not exercise. Both groups were followed for 15-day periods in the polyclinic controls. The exercise status of the patients in the SG was checked from exercise diaries. Exercise was continued for another six months after the ileostomy was closed.

Outcomes

The primary outcome of the trial was evaluation of the impact of PFMT on LARS with aEMG. The secondary end point was the evaluation of bowel function and quality-of-life with the LARS score and the EROTC QLQ-C30 and CR29 questionnaires.

Data

The patients were evaluated in terms of parameters such as age, gender, BMI, smoking, diabetes mellitus (DM), abdominal operation history, disease stage, American Society of Anesthesiologists (ASA) value, time taken for ileostomy closure, distance of the anastomosis to the anal canal that is thought to affect their urogenital functions, continence status, and quality-of-life.

Assessment of Response to PFMT

The quality-of-life questionnaire, LARS score and aEMG were used to evaluate the effect of PFMT on LARS.

The EMG examinations were performed by a single physician in the hospital's neurology clinic. The procedure was performed with patients lying on their left sides in a flexed position at the hips and knees. EMG examinations were conducted using a two-channel EMG device (Neuropack sigma MEB-9400K, Nihon Kohden, Tokyo, Japan) with standard concentric needle EMG electrodes measuring 25 mm in length, 0.30 mm in diameter, and a recording area of 0.0021 mm². The filter settings were adjusted to low and high frequencies of 5Hz–10 kHz; a sweep speed of 10 ms/div; and sensitivity of 100 microvolts/div.

Needle insertions were made at least from 3 separate points on the line connecting the anal orifice and the mucocutaneous junction, at an angle of 30° to the skin surface in all four quadrants of the anal sphincter. During the resting position, tonic activity motor unit potential (MUP) recordings were obtained from each quadrant for approximately 1 minute, and then patients were asked to voluntarily contract and hold a strong muscle contraction for 10 seconds. After recording 30–40 MUPs at rest, the 20 with the shortest rise time were selected for analysis. Quantitative EMG analysis involved decomposition of MUPs to calculate rise time, amplitude, duration, area, phase, and turns [8].

Interference patterns of the MUPs obtained during voluntary maximal contraction were semi-quantitatively assessed with visual and auditory feedback. They were categorized as decreasing or complete interference pat-

terns. When the second MUP continued to fire above 10 Hz after the onset of the first MUP, it was defined as a decreasing interference pattern. Findings were categorized as normal, neurogenic, and myogenic based on these parameters. Prolonged (>15 ms), polyphasic (phase number >4), and decreased interference pattern MUPs, along with fibrillation and positive sharp waves at rest, indicated neurogenic damage. Short-duration (<4 ms), polyphasic, and early interference pattern MUPs were considered myogenic (muscle damage) [8].

Questionnaires

The EROTC QLQ-C30 and QLQ-CR29 questionnaires were used to measure quality-of-life [9, 10]. The QLQ-C30 consists of 30 questions about functional outcome scales (physical, life roles, emotional, cognitive and social) and symptom outcome scales (fatigue, nausea and vomiting, diarrhea, insomnia, dyspnea, loss of appetite, pain, constipation, financial difficulties). The module QLQ-CR29 is an extension of the QLQ C30 questionnaire related to specific colorectal cancer functional scales (self-image, life changes, weight, sexual functioning) and symptoms of the disease. The scores were generated according to the EORTC scoring guidelines. All the scales range in score from 0 to 100 and a high scale score represents a higher response level. A high score for a functional scale corresponds to a high or healthy level of functioning, while a high score for a symptom scale represents a high level of symptomatology. The LARS score is an internationally validated self-administered questionnaire developed as a simple tool to assess bowel function after a low anterior rectal resection [11]. It consists of five elements: incontinence of flatus, incontinence of liquid stool, frequency, clustering, and urgency. Each element is individually weighted, and a summative score is derived (range, 0–42). Bowel dysfunction severity is categorized as no LARS (range, 0–20), minor LARS (range, 21–29), and major LARS (range, 30–42). These tests were applied by surgical nurses working in the general surgery service who did not know the patient groups.

Statistical Analysis

All statistical analyses were performed using SPSS (Statistical Package for Social Sciences) software, version 22 (SPSS Inc., Chicago, IL, USA). While evaluating the study data, the suitability of the parameters to the normal distribution was evaluated using the Shapiro–Wilk test. While evaluating the study data, besides descriptive

statistical methods (mean, standard deviation, and frequency), a Student t-test was used for comparing normally distributed parameters between two groups, and the Mann–Whitney U test was employed for comparisons of non-normally distributed parameters between two groups. The Fisher–Freeman–Halton test was used to compare qualitative data. Results with a p-value less than 0.05 were considered "statistically significant."

At this level of significance, the alpha error was 0.05 and the beta error was 95%. A sample size of 15 in each group would be required to detect such a difference in aEMG. Assuming a 10% dropout rate, 16 patients were required in each group.

RESULTS

Twenty of the 32 patients included in the study were male, and the average age of the patients was 56.7±11.5 (range: 20–72). Sixteen (50%) of the patients were active smokers, and four (12.5%) of them had known diabetes mellitus diagnosis. Histologic results in both groups showed that 6 were patients recorded in stage 1, 20 patients were recorded in stage 2 and 11 patients were recorded in stage 3. The demographic and clinical characteristics of the patients who were randomized into two groups (age, gender, BMI, length of ileostomy closure, distance of the anastomosis to the anal canal, smoking, education level, DM, ASA score, tumor stages, WIS) did not show any difference (p>0.05) (Table 1).

When EMG results are evaluated; EMG amplitude (0.56 vs. 0.57; p=0.888), EMG phase (9.84 vs. 10.83; p=0.266), EMG turns (9.81 vs. 9.97; p=0.884), EMG rise time (289.18 vs. 271.53; p=0.214), EMG area (0.73 vs. 0.77; p=0.747), values did not show any difference. The EMG time values in the SG were found lower than the CG (17.6 m/sec. vs. 19.9 m/sec; p<0.001) (Table 2).

In SG, 9 patients developed minor LARS, 2 patients developed major LARS while in 5 patients LARS didn't happen; in CG 6 patients developed minor LARS and 10 patients developed major LARS. The LARS score in the SG was found lower than the CG (23.1 vs. 30.0; p=0.003). The major LARS rates were found lower in the SG (12.5% vs. 62.5%; p=0.004) (Table 3).

Global health status (68.23 vs. 67.19; p=0.883), physical functioning (85.42 vs. 74.58; p=0.132), role functioning (86.46 vs. 75; p=0.546), emotional func-

TABLE 1. The comparison of patient's characteristics between two groups

	Group S n=16	Group C n=16	p
Age, Mean±SD	53.7±13	59.6±9.2	0.15
Gender, (%)			1
Male	62.5	62.5	
Female	37.5	37.5	
Smoker, (%)	56.3	43.7	0.72
DAAV, Mean±SD	5.9±2.3	5±1.9	0.25
Ileostomy duration*, month, Mean±SD	6.1±1.6	6.4±2.2	0.72
DM, (%)	12	12	1
ASA, (%)			0.6
I	6.3	0	
II	62.5	62.5	
III	31.3	37.5	
The history of abdominal operation, (%)	56	56	1
Tumor stage, (%)			0.08
I	31.3	6.3	
II	37.4	75	
III	31.3	18.7	
Educational background, (%)			0.61
Illiterate	0	6.3	
Primary school	25	43.7	
Secondary school	37.4	25	
High school	31.3	18.7	
Collegian	6.3	6.3	
Wexner faecal incontinence score	3.6	3.9	0.8

SD: Standard deviation; DAAV: Distance of anastomosis to anal verge; DM: Diabetes mellitus; ASA: American Society of Anaesthesiologists; *: The interval from surgery to ileostomy closure.

TABLE 2. The comparison of patient's EMG results between two groups

	Group S Mean±SD	Group C Mean±SD	p
EMG time	17.62±1.95	19.96±1.29	**0.000***
EMG amp	0.56±0.26	0.57±0.14	**0.888**
EMG phase number	9.84±2.39	10.83±2.53	**0.266**
EMG number of turns	9.81±3.02	9.97±2.88	**0.884**
EMG area	0.73±0.36	0.77±0.22	**0.747**
EMG rise time	289.18±46.66	271.53±30.33	**0.214**

SD: Standard deviation; EMG: Electromyography; Student t test; *: P<0.05.

Table 3. The comparison of patient's LARS score results between two groups

	Group S	Group C	p
Lars score, Mean±SD	23.19±6.27	30.06±5.56	[1]**0.003***
Lars score final (%)			[2]**0.004***
No lars	31.3	0	
Minor lars	56.3	37.5	
Major lars	12.5	62.5	

SD: Standard deviation; LARS: Low anterior resection syndrome; 1: Student t test; 2: Fisher-Freeman-Halton test; *: P<0.05.

Table 4. The comparison of patient's EORTC QLQ-C30 results between two groups

	Group S Mean±SD	Group C Mean±SD	p
Global health status	68.23±23.61	67.19±15.05	[1]**0.883**
Physical functioning	85.42±16.37	74.58±23.12	[2]**0.132**
Role functioning	86.46±19.45	75±33.33	[2]**0.546**
Emotional functioning	73.96±19.45	71.88±33.32	[2]**0.505**
Cognitive functioning	88.54±14.55	73.96±33.87	[2]**0.340**
Social functioning	90.63±14.87	79.17±31.91	[2]**0.481**
Fatigue	24.31±20.37	34.03±29.11	[2]**0.456**
Nausea and vomiting	3.13±6.72	16.67±25.09	[2]**0.134**
Pain	18.75±23.47	29.17±27.55	[2]**0.224**
Dyspnea	4.17±11.39	8.33±25.82	[2]**0.948**
Insomnia	22.92±23.47	22.92±33.82	[2]**0.648**
Appetite loss	16.67±24.34	14.58±29.74	[2]**0.549**
Constipation	18.75±34.36	20.83±26.87	[2]**0.424**
Diarrhea	35.42±37.45	35.42±33.26	[2]**0.906**
Financial difficulties	8.33±14.91	20.83±31.91	[2]**0.309**

EORTC QLQ: European Organization for Research and Treatment of Cancer quality-of-life; SD: Standard deviation; 1: Student t-test; 2: Mann-Whitney U test.

Table 5. The comparison of patient's EORTC QLQ-CR 29 results between two groups

	Group S Mean±SD	Group C Mean±SD	p
Body image	86.11±17.45	77.08±27.66	**0.501**
Anxiety	70.83±36.26	68.75±35.42	**0.809**
Weight	81.25±27.13	81.25±29.74	**0.948**
Sexual interest	68.75±35.42	35.42±28.46	**0.010***
Urinary frequency	12.5±26.87	12.5±20.64	**0.737**
Blood and mucus in stool	9.38±8.54	15.63±11.33	**0.110**
Stool frequency	29.17±21.52	43.75±27.13	**0.150**
Urinary incontinenece	12.5±26.87	12.5±20.64	**0.737**
Dysuria	12.5±23.96	14.58±24.25	**0.738**
Abdominal pain	27.08±34.89	33.33±38.49	**0.597**
Buttock pain	27.08±34.89	33.33±38.49	**0.597**
Bloating	27.08±27.81	33.33±34.43	**0.689**
Dry mouth	16.67±24.34	35.42±30.96	**0.068**
Hair loss	10.42±20.07	8.33±19.25	**0.695**
Taste	2.08±8.33	12.5±29.5	**0.265**
Flatulence	20.83±23.96	18.75±27.13	**0.673**
Faecal incontinence	14.58±24.25	35.42±30.96	**0.039***
Sore skin	10.42±23.47	27.08±34.89	**0.085**
Embarrassment	27.08±27.81	25±35.49	**0.634**
⬜mpotence	20.83±23.96	18.75±27.13	**0.673**
Dyspareunia	20.83±23.96	18.75±27.13	**0.673**

EORTC QLQ: European Organization for Research and Treatment of Cancer quality-of-life; SD: Standard deviation; Mann-Whitney U test; *: P<0.05.

In the EORTC QLQ-CR29 test, the parameter of interest in sexuality was founded higher in the SG (p<0.01). Fecal incontinence rates in the same survey were found lower in the SG (p<0.039). Other parameters such as body image (86.11 vs. 77.08; p=0.501), anxiety (70.83 vs. 68.75; p=0.809), weight (81.25 vs. 81.25; p=0.948), urinary frequency (12.5 vs. 12.5; p=0.737), blood and mucus in stool (9.38 vs. 15.63, p=0.11), stool frequency (29.17 vs. 43.75; p=0.15), urinary incontinence (12.5 vs. 12.5; p=0.737), dysuria (12.5 vs. 14.58; p=0.738), abdominal pain (27.08 vs. 33.33; p=0.597), buttock pain (27.08 vs. 33.33; p=0.597), bloating (27.08 vs. 33.33; p=0.689), dry mouth (16.67 vs. 35.42; p=0.068), hair loss (10.42 vs. 8.33; p=0.695), taste (2.08 vs. 12.5; p=0.265), flatulence (20.83 vs. 18.75; p=0.673), sour skin (10.42 vs. 27.08; p=0.085), embarrassment (27.08 vs. 25; p=0.634), impotence (20.83 vs. 18.75; p=0.673), dyspareunia (20.83 vs. 18.75; p=0.673) were similar (Table 5).

tioning (73.96 vs. 71.88; p=0.505), cognitive functioning (88.54 vs. 73.96; p=0.34), social functioning (90.63 vs. 79.17; p=0.481), fatigue (24.31 vs. 34.03; p=0.456), nausea and vomiting (3.13 vs. 16.67; p=0.134), pain (18.75 vs. 29.17; p=0.224), dyspnea (4.17 vs. 8.33; p=0.948), insomnia (22.92 vs. 22.92; p=0.648), appetite loss (16.67 vs. 14.58; p=0.549), constipation (18.75 vs. 20.83; p=0.424), diarrhea (35.42 vs. 35.42; p=0.906) and financial difficulties (8.33 vs. 20.83; p=0.309) parameters didn't show any differences regarding EROTC QLQ-C30 parameters (Table 4).

DISCUSSION

In our study, the group receiving PFMT demonstrated shorter aEMG durations, lower LARS scores, and fewer instances of major LARS compared to the group that did not receive PFMT. Additionally, in the group undergoing PFMT, the EORTC QLQ-CR29 quality-of-life questionnaire showed increased interest in sexuality and reduced instances of fecal incontinence. These results indicate that PFMT positively impacts sphincter function.

Our study evaluated the effect of PFMT on sphincter function using subjective parameters, such as quality-of-life questionnaires, and objective parameters like the LARS score and aEMG. The elevated aEMG results and LARS scores in both groups could be attributed to the reduced colon length post-surgery or potential sphincter-nerve damage [2]. The literature reports increased incontinence, stool frequency, and antidiarrheal drug usage in patients who underwent neoadjuvant radiotherapy [12–14]. Ileostomy formation and an extended ileostomy duration (more than six months) are additional risk factors for LARS [15, 16]. Our study showed no significant differences between the two groups regarding neoadjuvant treatment, ileostomy status, duration, or surgical procedures.

Currently, there isn't a universally accepted gold standard treatment for LARS. Treatment options under pelvic floor rehabilitation include PFMT, biofeedback (BF) training, and rectal balloon training (RBT). Other alternatives for treatment-resistant cases are sacral nerve stimulation, percutaneous tibial nerve stimulation, transanal irrigation, and 5-HT3 receptor antagonists. PFMT seeks to enhance muscle strength, coordination, and contraction timing. In BF, patients receive visual and auditory feedback regarding pelvic floor muscle activity, allowing them to voluntarily contract the external anal sphincter in response to rectal distention. RBT aims to augment rectal sensitivity by progressively decreasing rectal balloon distention [17].

Existing literature on PFR is limited. Allgayer et al. [18] conducted a prospective study involving 95 pull-through patients, assessing the post-radiotherapy impact on continence. Of these, 41 patients underwent postoperative radiotherapy while the rest did not. All participants received PFR. Both groups showed improved incontinence scores following PFR. Similarly, Kim et al. [19] assessed patients with fecal incontinence post-anterior resection. These patients received BF, and improvements were observed in anorectal pressure, rectal capac-

ity, and incontinence scores. In our study, we exclusively relied on aEMG for sphincter evaluations, smilar to the approach by Kim et al. [19]. However, they didn't include a separate control group.

Laforest et al. [20] examined patients with fecal incontinence post-total mesorectal excision. Rehabilitation recipients exhibited reduced dyschezia, though fecal incontinence scores remained similar across groups. Our study compared the aEMG results, LARS scores, and quality-of-life questionnaire outcomes of PFMT users and non-users. General quality-of-life assessments revealed no significant group differences. However, the colorectal cancer quality-of-life questionnaire indicated heightened interest in sexuality in the SG, along with reduced fecal incontinence scores.

Studies show that major LARS rates range between 45% and 56% for patients in their first postoperative year [14, 21–23]. Bondeven et al. [24], using the LARS score, found a 40% major LARS rate for patients past their first postoperative year. Our data indicates a reduced LARS rate within the first postoperative year for the PFMT group. Major LARS rates were 12.5% in the SG, compared to 62.5% in the CG, aligning with other studies.

A notable limitation across studies is the inconsistency in protocols related to techniques and application durations. While some studies adopted PFR durations of a year or longer [6, 19], others ranged between 10 and 17 weeks. Additionally, treatment methodologies varied, such as differences in neoadjuvant therapy rates and surgical techniques. Our study consistently employed total mesorectal excision with loop ileostomy post-neoadjuvant therapy for rectal cancers. Both groups were observed for 24 weeks post-loop ileostomy closure. Presently, a definitive gold standard for LARS treatment remains elusive.

Our study is pioneering in its simultaneous evaluation of PFMT's impact on LARS treatment using anal EMG, quality-of-life questionnaires, and the LARS score. This research's strengths lie in its larger patient cohort compared to other studies, patient monitoring via exercise diaries, and comprehensive functional outcome assessment using both quality-of-life questionnaires and the LARS score.

Unfortunately, due to our center's practice of referring patients after they've undergone neoadjuvant treatment, we were unable to conduct preoperative aEMG. Although it was initially planned, the absence of this data forced us to modify the protocol to incorporate WIS.

Conclusion

In conclusion, PFMT emerges as a non-invasive, affordable approach that integrates seamlessly into daily routines without requiring specialized equipment and presents no side effects. It doesn't interfere with other treatments, allowing patients to incorporate exercises effortlessly. Given these benefits, this study posits PFMT as a primary treatment option for LARS. Future randomized controlled trials with broader participation and extensive preoperative and postoperative data assessment are anticipated to provide further clarity.

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