

Original Research Article

Simple Anal Reinforcement with Anal Encirclement Using an Artificial Ligament in Patients with fecal Incontinence: A Single-center Observational Study

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Abstract

Objectives: Surgical repair of anal sphincter defects in patients with fecal incontinence (FI) has been associated with excellent or good short-term results; however, its benefits have been shown to deteriorate over long-term follow-up. When sphincteroplasty fails or is not feasible, the subsequent surgical options are limited. This study aimed to evaluate the efficacy of anal encirclement using the Leeds-Keio ligament in patients with FI.

Methods: The inclusion criteria for the procedure were failure of or unsuitability for sphincteroplasty and the presence of a patulous anus (diameter, ≥ 35 mm). The artificial ligament was routed outside the external anal sphincter at the depth of the middle anal canal under caudal epidural anesthesia.

Results: Fourteen patients (mean age, 79.4 years; 8 females) with FI were included. Of these, seven (50%) showed a $\geq 50\%$ reduction in the Cleveland Clinic Florida Fecal Incontinence Score (CCFIS). The mean CCFIS of 13.6 at baseline significantly improved to 7.9 3 months after surgery. The mean maximal anal resting pressure significantly increased from 16.8 mmHg to 22.6 mmHg. Postoperatively, temporary fecal impaction was observed in one patient (7%). None of the cases required removal of the artificial ligament or additional operative interventions for FI during the mean follow-up period of 31.9 months.

Conclusions: Anal encirclement using the Leeds-Keio ligament was technically simple and safe and achieved good short-term outcomes. Therefore, this technique appears to be a simple solution for sphincter defects and may become an important surgical option for patients with FI and a patulous anus.

Keywords

anal encirclement, anal sphincter, fecal incontinence, Leeds-Keio ligament, Thiersch procedure

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Introduction

Fecal incontinence (FI) is defined as the involuntary or uncontrollable loss of solid or liquid stools[1]. FI adversely affects patients' quality of life, causes serious disability, and leads to increased welfare costs[2]. Conservative treatments, including dietary management, pharmacotherapy, and pelvic floor rehabilitation, are encouraged as first-line treatments[3]. However, surgical intervention may be required if these conservative measures fail. Sacral neuromodulation is

a promising new therapy for FI; however, due to its advanced technology and high cost, its use is restricted to highly specialized hospitals in developed countries[4].

Surgical options are usually indicated when FI occurs secondary to anatomic disruptions, such as a sphincter defect or weakness. The most common surgical procedure performed for sphincter defects is the overlapping sphincter repair[3]. When surgical repair is not feasible or fails, reconstruction of a neosphincter may be required. Stimulated graciloplasty and implantation of an artificial sphincter have proven suc-

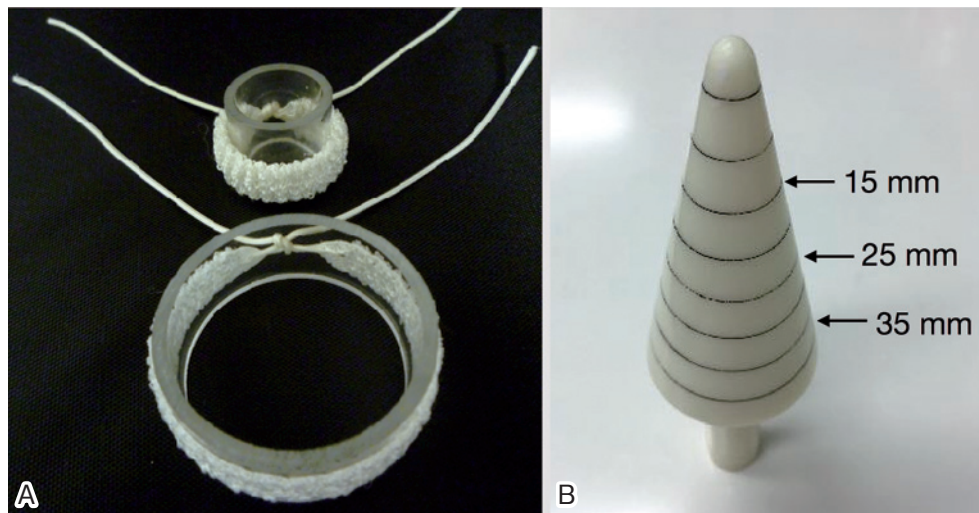


Figure 1. (A) The Leeds-Keio ligament for use in the Thiersch procedure. It is composed of a 1-cm wide stretchable tape and two threads. When the tape is fully contracted, its circumference is 5 cm (back side) and can be stretched up to 10 cm (front side). (B) A caliber ruler for measuring the anal diameter. It has eight lines in 5-mm increments.

successful in a high proportion of selected patients. However, these procedures are technically complicated and are associated with high morbidity and cost; thus, only a few patients could benefit from them[4]. These considerations highlight the importance of identifying a safe, simple, and low-cost procedure that can be practically applicable.

In 1891, Thiersch[5] reported a simple procedure wherein the anus is encircled using a ring of silver wire to treat rectal prolapse. Subsequently, this anal encircling method (Thiersch procedure) was also applied to patients with FI with anal relaxation[6]. This simple and low-cost method was initially considered promising but was gradually abandoned due to the high postoperative recurrence rate. The main cause of recurrence is extraction of the encircling material due to fecal impaction, local infection, or tissue erosion[7]. Teflon tape, silicone bands, silastic sheets, nylon threads, and polyethylene mesh are currently used in the Thiersch procedure, but they are rigid materials, and tissue erosion or fecal impaction can occur due to the non-stretchability of these prostheses[8-12].

Leeds-Keio ligaments, originally invented for the reconstruction of the knee ligament, has been in clinical use since 1982[13]. The artificial ligament is tape-shaped with a mesh texture knitted from polyester filaments and shows adequate tensile intensity for reconstruction of the anterior cruciate ligament. Furthermore, endurance tests have demonstrated that the artificial ligament has satisfactory durability[13]. Iwaware et al.[14] modified the artificial ligament for the Thiersch procedure and used it for patients with rectal prolapse. The modifications made were as follows: 1) stretchability was increased to prevent tissue erosion and fecal impaction; 2) threads were equipped to tie the ligament tape;

3) the ligament tape and threads were covered with vinyl film to avoid contamination during insertion. We also used the artificial ligaments for patients with rectal prolapse and, owing to its good expandability, the patients did not experience tape removal due to difficulty in defecation[15,16].

As the Leeds-Keio ligament used in the Thiersch procedure exhibits expandability as well as contractility, we hypothesized that the artificial ligament would simulate a physiologic sphincter mechanism; therefore, we applied it to patients with FI with a relaxed anus. This study describes the operative technique and outcome of anal encirclement using the Leeds-Keio ligament in patients with FI.

Methods

This study was a retrospective review of medical records, wherein we analyzed the efficacy of anal encirclement using a Leeds-Keio ligament (LK-5T-130, Yufu Itonaga Co., Ltd., Tokyo, Japan) (Figure 1A) in the treatment of FI. All processes of this study were confirmed by our Institutional Ethics Review Board (approval no. K16-002), and we obtained written informed consent from all patients.

Study population

This study involved consecutive patients who underwent the Thiersch procedure for FI from January 2016 to December 2020. All patients failed first-line therapies for FI such as pharmacotherapy, biofeedback, and electrical anal stimulation. The inclusion criteria for the Thiersch procedure for FI at our hospital were failure of or unsuitability for sphincteroplasty and an anus relaxed to a diameter of approximately ≥ 35 mm (Figure 2A) as measured by a caliber ruler

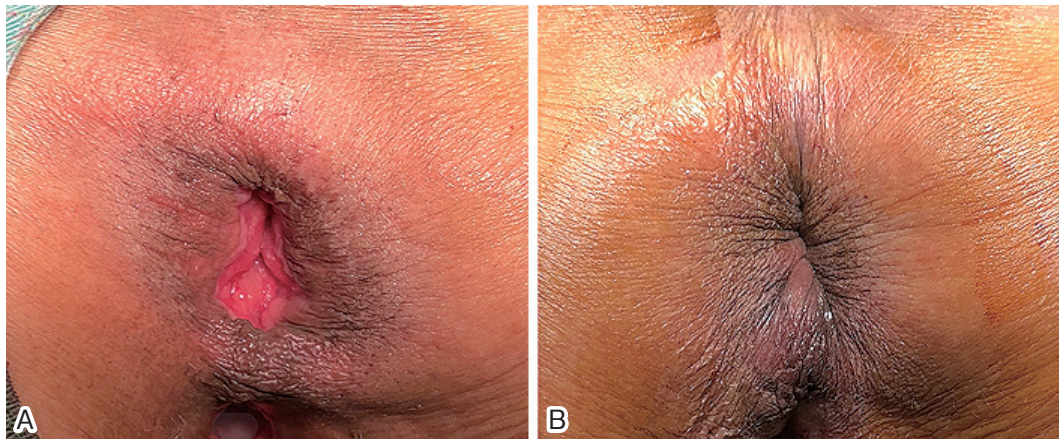


Figure 2. A patulous anus with a diameter of 40 mm before anal encirclement (A). The anus closed to a diameter of 20 mm after the surgery (B).

(Figure 1B). Patients with grade 4 hemorrhoids, large rectocele (>4 cm), or complete rectal prolapse were excluded because these conditions may conceal the FI symptoms.

Clinical assessments

Preoperative assessments consisted of a questionnaire survey based on the Cleveland Clinic Florida Fecal Incontinence Score (CCFIS), digital rectal examination, proctoscopy, anal manometry, and defecography, when necessary. The CCFIS was the sum of five parameters; a total score of 0 indicated complete continence, while a score of 20 signified the most severe FI[17].

Manometric studies were performed with the patient in the left lateral position using a one-channel microtip transducer mounted on a flexible catheter (P-1401; Star Medical Inc., Tokyo, Japan). The maximum resting pressure (MRP) was measured with a rapid pull-through technique. Subsequently, the maximum squeeze pressure (MSP), the highest value recorded in the anal canal of any depth, was recorded.

Surgical technique

Preoperative preparation consisted of the administration of two suppositories (sodium bicarbonate and anhydrous sodium phosphate) immediately before surgery. The Thiersch procedure was performed in the jackknife position under caudal epidural anesthesia.

Two small incisions were made anteriorly and posteriorly, approximately 3 cm away from the anal margin, and the incisions were deepened to 2 cm. For females with a narrow perineum, the anterior incision was taken as far away from the anus as possible. The surgeon passed the forceps through the right ischiorectal space, grasped one thread of the Leeds-Keio ligament at the anterior incision (Figure 3A), and pulled it out of the posterior incision. This maneuver was repeated on the left side, and care was taken to avoid ligament tape twisting (Figure 3B). The surgeon peeled off

the vinyl film protecting the ligament and tied the attached threads (Figure 3C). As a result, the ligament tape was placed outside the external anal sphincter at the depth of the middle anal canal. Initially, the actual anal diameter was measured with a caliber ruler; however, later, it was found that tying the equipped threads at the base would result in a proper caliber (20-25 mm) (Figure 2B).

Patients with coexisting rectal intussusception or mucosal prolapse underwent sclerotherapy using aluminum potassium sulfate and tannic acid (ALTA) prior to anal encirclement. For rectal intussusception, 0.5-1.0 mL of ALTA solution (J-Dolph Pharmaceutical, Osaka, Japan) was evenly injected into the corresponding rectal submucosa at 10-20 locations (multi-point injection)[15,16]. In cases with mucosal prolapse, four-step injection[18] was performed on the three main cushions. After the surgery, the patients were administered prophylactic oral antibiotics for 3 days and then hospitalized for a week in anticipation of postoperative defecation difficulty.

Outcome measures

Follow-up visits for 3 years after surgery were encouraged in all patients. The follow-up assessments consisted of CCFIS measurements, anal manometry, proctoscopy, and digital rectal examination. We analyzed changes in the CCFIS, MRP, and MSP at baseline and 3 months after surgery as well as postoperative complications.

Statistical analysis

The Wilcoxon signed-rank test was used to compare pre- and post-surgery values for the CCFIS, MRP, and MSP. The two-sided significance level was set at 5%. Data were processed using EZR software (version 1.11; Saitama Medical Center, Jichi Medical University, Saitama, Japan).

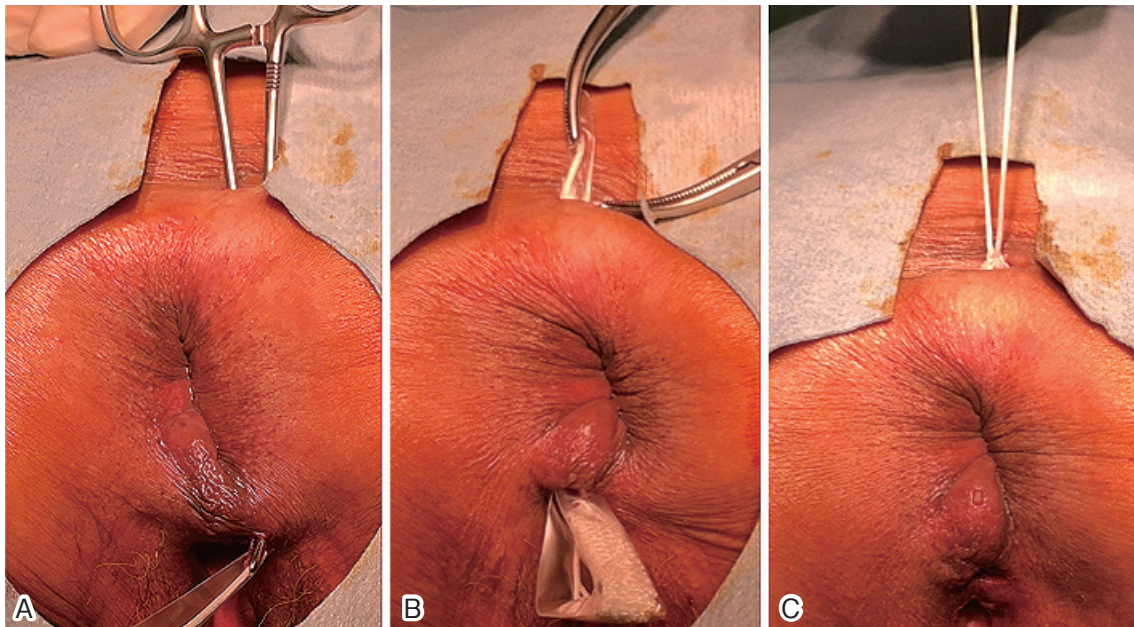


Figure 3. Thiersch procedure. Two incisions were made anteriorly and posteriorly. The surgeon passed forceps through the right ischiorectal space, grasped one thread of the Leeds-Keio ligament at the anterior incision (A), and pulled it out of the posterior incision. This maneuver was repeated on the left side (B). The surgeon peeled off the vinyl film protecting the ligament and tied the attached threads (C).

Table 1. Demographic Characteristics of Each Patient.

No	Sex	Age	BMI	VD	Previous anorectal or pelvic floor surgery	Concomitant anorectal diseases
1	F	73	23.2	1		Mucosal prolapse
2	F	83	34.0	0	Hysterectomy	Intussusception, rectocele
3	F	86	24.3	2	Delorme's operation	
4	F	73	21.5	3	Hysterectomy	Intussusception, rectocele
5	M	74	26.6	–	Mucosal plication for RP	Mucosal prolapse
6	M	79	26.7	–		Mucosal prolapse
7	F	80	24.8	2	Sclerotherapy for RP	
8	F	80	20.3	2	Hemorrhoidectomy	Intussusception
9	M	80	23.7	–	Mucosal plication for RP	
10	F	81	19.4	2	Sclerotherapy for RP	
11	M	88	23.0	–	Sphincteroplasty	
12	M	74	22.7	–	Mucosal plication for RP	
13	M	79	22.8	–	Sclerotherapy for RP	
14	F	82	26.8	2		Intussusception

BMI, body mass index; VD, vaginal delivery history; RP, rectal prolapse.

Results

From January 2016 to December 2020, the Thiersch procedure using the Leeds-Keio ligament was performed in 70 patients with either or both rectal prolapse and FI. Of these, 14 patients with FI (mean age, 79.4 years; range, 73-88 years) who met the inclusion criteria were included in this study. The types of FI symptoms were passive and urge in 10 cases, passive in two cases, and urge in two cases. The

characteristics of the patients are summarized in Table 1.

The planned procedure was successful in all 14 patients. Seven patients (50%) with coexisting anorectal disease received injection sclerotherapy prior to tape insertion. The mean dose of ALTA solution was 23.1 mL (range, 15-31 mL). None of the patients showed intraoperative complications. All except one patient showed a reduction in CCFIS after treatment (Table 2). Of these, seven patients (50%) showed a $\geq 50\%$ reduction in CCFIS. The mean CCFIS of

Table 2. CCFIS and Manometric Data of Each Patient before and after Surgery.

No	CCFIS			MRP (mmHg)			MSP (mmHg)		
	Baseline	3 months	12 months	Baseline	3 months	12 months	Baseline	3 months	12 months
1	12	6	–	16.0	15.0	–	66.0	55.5	–
2	20	8	6	21.0	34.5	–	56.0	73.5	–
3	12	6	7	19.0	27.5	26.5	65.5	54.0	68.5
4	11	5	5	12.0	15.5	21.0	94.0	95.5	86.5
5	14	9	11	20.0	18.5	19.0	46.0	44.5	40.5
6	18	10	10	5.5	23.0	29.0	119.5	118.5	135.5
7	13	6	6	13.0	11.0	–	46.5	80.5	–
8	14	7	4	28.5	31.5	26.0	80.0	81.0	69.5
9	12	7	10	16.0	27.0	–	59.0	68.5	–
10	15	11	12	22.5	22.5	13.0	65.5	59.5	31.0
11	18	12	–	18.5	33.5	20.5	43.5	52.5	97.5
12	14	14	–	8.0	11.0	–	81.5	97.0	–
13	8	1	1	13.0	20.0	26.5	192.0	158.5	215.0
14	10	8	–	21.5	25.5	18.5	60.0	56.5	40.5
Mean	13.6	7.9	7.2	16.8	22.6	22.2	76.8	78.3	87.2

CCFIS, Cleveland Clinic Florida Fecal Incontinence Score; MRP, maximal resting pressure; MSP, maximal squeeze pressure. Data for some patients at 12 months after surgery were not available.

Table 3. Changes in the CCFIS before and after Surgery (n = 14).

	Baseline	3 months	p-value
Total CCFIS	13.6 (3.2)	7.9 (3.1)	<0.001
Solid	2.7 (1.5)	1.3 (1.4)	0.004
Liquid	2.6 (1.5)	0.4 (1.1)	<0.001
Gas	2.3 (1.8)	1.4 (1.4)	0.054
Wears pad	3.5 (1.1)	3.1 (1.4)	0.165
Lifestyle alteration	2.7 (1.7)	1.9 (1.7)	0.018

CCFIS, Cleveland Clinic Florida Fecal Incontinence Score. Data are shown as mean (standard deviation).

13.6 ± 3.2 at baseline significantly improved to 7.9 ± 3.1 at 3 months after surgery (Table 3). The mean MRP had significantly increased 3 months after surgery; however, there was no significant change in MSP (Table 4). Data for some patients were not available at 12 months, but improvements in CCFIS and MRP appeared to be maintained (Table 2).

The mean duration of postoperative follow-up was 31.9 months (range, 12-66 months). Postoperative complications were observed in one male patient (7.1%) who suffered from several episodes of fecal impaction, which were subsequently controlled with the use of suppositories. Removal or breakage of the ligament tape did not occur in any patient during the follow-up period. In addition, none of the patients received or demanded additional operative interventions for FI during the follow-up period.

Table 4. Changes in the Manometric Data before and after Surgery (n = 14).

	Baseline	3 months	p-value
MRP (mmHg)	16.8 (5.9)	22.6 (7.5)	0.005
MSP (mmHg)	76.8 (37.6)	78.3 (30.0)	0.735

MRP, maximal resting pressure; MSP, maximal squeeze pressure. Data are shown as mean (standard deviation).

Discussion

This study demonstrated that anal encirclement using the Leeds-Keio ligament in the management of FI was easy to perform, safe, and achieved good short-term results. This was confirmed by improvements in the validated severity score and objective manometric data.

Surgical repair for sphincter defects by direct apposition or overlap techniques has been associated with excellent or good short-term results in up to 85% of patients; however, the benefits deteriorate with long-term follow-up[19]. In elderly individuals, sphincter degeneration progresses with age[20]; therefore, the success rates tend to decrease over time after surgery. In this regard, the Thiersch procedure, wherein the sphincter muscle is supported with a prosthesis, would be a more durable repair for elderly patients with a patulous anus.

Although the use of the Thiersch procedure in the management of FI has been described in a few reports, most of these studies were small observational series and included patients with rectal prolapse as well as those with FI. Devesa et al.[12] used a flat elastic band made of silicone for

the Thiersch procedure. Their study showed that in 33 patients with FI, the mean CCFIS of 15 ± 5 at baseline significantly improved to 7 ± 4 after surgery. Lim et al.[21] also used a silicone band in 17 patients with FI, and the mean CCFIS significantly improved from 17 ± 2 to 5 ± 2 at 2 months after surgery. Horn et al.[9] used a polyester-impregnated silastic mesh and reported good or excellent results in 6 of their 11 cases. Moreover, Poole et al.[8] reported that FI was cured in six out of nine cases using the same type of mesh. Of all these studies, only one involved anal manometry assessments before and after the Thiersch procedure. Devesa et al.[12] showed that the MSP did not change, but the MRP improved modestly from 43 to 53 mmHg, which was similar to our results.

As described above, the Thiersch procedure for FI provides appropriate symptom improvement. However, it may cause complications that require extraction of the inserted prostheses. Devesa et al.[12] reported that the silicone band was removed in 13 cases (39%) due to infection, skin erosion, or breaking of the sling over the mean follow-up period of 37 months. Horn et al.[9] also reported removal of the silastic sling in four cases (25%) due to local infection over the mean follow-up period of 25 months. Sainio et al.[11] used a polypropylene mesh in 14 patients with rectal prolapse and three with FI, and the mesh tape was removed in three patients (18%) due to postoperative fecal impaction. Conversely, Lim et al.[21] reported that local infection was observed in three patients (18%), but the silicone band did not require removal. None of the cases in this study developed tape infection or required removal; however, in our previous study using the Leeds-Keio ligaments for 106 patients with rectal prolapse, 11 (10%) required tape removal due to local infection[16]. In our experience, local infections or tape exposures are more likely if the ligament tape is not inserted neatly, cleanly, or deeply. Therefore, a surgeon experienced in inserting the ligament tape correctly should have a low risk of such complications. In case of local infection or tape exposure, the ligament tape should be immediately removed, and a new tape can be reinserted using the same technique after approximately 1 month after local inflammation heals[16].

Currently, polypropylene or silicone materials are often used for the Thiersch procedure because they are inert, elastic, and tough[7]. The most important technical aspect of the Thiersch procedure is proper adjustment of the caliber and tension of the sling. Most reports recommended tightening the sling to the extent that an index finger is properly tightened[8,9,12]. Sainio et al.[11] also used the index finger to adjust the caliber but advocated that the Thiersch procedure should not be performed in patients with severe constipation to avoid fecal impaction. On the other hand, Lim et al.[21] showed that using a silastic tube with a 10-cm circumference of the sling could improve FI while avoiding fecal im-

paction.

The advantage of the Leeds-Keio ligament is that it is more stretchable than other types of slings. The ligament expands up to 10 cm in circumference according to stool size and can contract quickly after evacuation; thus, it can function like the anal sphincter. Moreover, its size is exclusively designed for use in the Thiersch procedure, and the surgeon can obtain an appropriate caliber by tying the attached thread tightly. Therefore, it is not necessary to insert a finger or other instruments into the rectum, and the procedure can be completed more cleanly. These properties contribute to smooth rectal evacuation, anal continence, and reproducibility of the proper caliber. However, we found that the ligament tapes that were removed due to infection in patients with rectal prolapse were less elastic and stiffer than those at the time of insertion[16]. We speculate that this is due to the effects of infection and mesh structure of the tape, which makes it adherent to surrounding tissues. Therefore, we expect that stretchable materials having a smooth surface and long-lasting elasticity will be developed as alternatives to mesh materials.

This study was limited by its small sample size and its retrospective design. In addition, all patients were ≥ 70 years of age, and their quality of life was not formally assessed. About half of the patients had concomitant anorectal diseases, which themselves can cause FI. Therefore, our results may have inadvertently included the therapeutic effects of treating these diseases with ALTA injection therapy[22]. Further, our study reports early clinical results; therefore, additional studies with a larger number of patients and longer follow-up periods are necessary to confirm the effectiveness and reliability of the procedure.

In conclusion, anal encirclement with the Leeds-Keio ligament is technically simple and can be performed under local or regional anesthesia; thus, the procedure is widely applicable in elderly patients with FI and a patulous anus. In addition, patients with comorbidities such as rectal intussusception or mucosal prolapse, which are common in the elderly with a relaxed anus, can be concurrently treated with injection sclerotherapy. Our results suggest that the artificial ligament provides a physiologic sphincter mechanism and anal reinforcement. Accordingly, this technique may be an important surgical option for patients with FI and a patulous anus.

Conflicts of Interest

There are no conflicts of interest.

Author Contributions

Tatsuya Abe contributed to the concept and design, data acquisition and analysis, and drafted and revised the manuscript; Masao Kunimoto, Yoshikazu Hachiro, Shigenori Ota, Kei Ohara, and Mitsuhiro Inagaki contributed to data acqui-

sition, revised the manuscript, and approved the final version.

Approval by Institutional Review Board (IRB)

This research was approved by the institutional review board of Kunimoto Hospital (approval code, K16-002).

Disclaimer

Tatsuya Abe is one of the Associate Editors of Journal of the Anus, Rectum and Colon and on the journal's Editorial Board. He was not involved in the editorial evaluation or decision to accept this article for publication at all.

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