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ORIGINAL ARTICLE

Does clinical score accurately support fecoflowmetry as a means to assess anorectal motor activity in pediatric patients after anorectal surgery?

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ABSTRACT

Purpose: We investigated the relationship between Krickenbeck score (KS) and fecoflowmetry (FFM) parameters and assessed the characteristics of this new questionnaire test by comparing Kelly's clinical score (KCS) in pediatric patients with anorectal surgery for anorectal malformation (ARM) and Hirschsprung's disease (HD).

Methods: We enrolled pediatric patients who underwent anorectal surgery for ARM or HD. Bowel function was assessed with KS and KCS thereafter, FFM and anorectal manometry (AM) were conducted. Patients were divided into subgroups according to each parameter of the scoring system and each FFM parameter was compared among the KCS or KS subgroups, respectively. Moreover, correlation analyses were conducted between FFM and AM parameters.

Results: The comparison of FFM parameters among the subgroups of KCS showed that F_{max} in the KCS staining 2 group was significantly higher than that in KCS staining 1 group and the F_{max} in KCS sphincter squeeze 1 group was significantly higher than that in KCS sphincter squeeze 0 group. Moreover, F_{max} in the KCS "good" group was significantly higher than that in the KCS "fair" group. The comparison of FFM parameters among the subgroups of KS parameters showed that TR in the no soiling group was significantly higher than that in the KS grade 2 soiling group. FFM and AM parameters showed a significant positive correlation between F_{max} and voluntary squeezing anal pressure.

Conclusion: FFM clarified the different characteristics of two scoring systems, namely, KCS reflects the anal sphincter performance, whereas the KS soiling score might reflect the tolerance and evacuation ability.

1. Introduction

The goal of treating patients with pediatric anorectal surgery for anorectal malformations (ARMs) and Hirschsprung's disease (HD) is to achieve good continence and proper fecal behavior in daily life. To reach this goal, the accurate and objective evaluation of postoperative bowel function is crucial, To date, several questionnaire tests have been developed and are commonly used as conventional methods for evaluating the postoperative bowel function, including Kelly's clinical score (KCS), Pena's criteria for the assessment of continence and the Rintala bowel function score.[1–3] Recently, the Krickenbeck score (KS) has been reported to be a more useful system for evaluating the postoperative bowel functions of patients with ARMs as it was established to more focus on assessing postoperative constipation than any previous scoring system.[4] However, given the nature of questionnaires, this method like the others is subjective and qualitative and none of these scoring systems are generally accepted internationally. Moreover, defecation is

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generated by the sum of the function of all mechanisms of anorectal evacuation, so the evaluation of these dynamic functions appears to be difficult using a simple questionnaire alone. Anorectal manometry (AM) is widely used as the objective assessment of the anorectal function able to confirm the activity of the external and internal sphincter muscles. Intrinsic tonic activity of the internal sphincter muscle is reported to be responsible for resting anal pressure, and high anal pressure value is important for good continence.[5] The incontinence of liquid is reported to be associated with a reduction in internal sphincter muscle activity.[6] However, bowel function is a configuration of various factors such as rectal motility, compliance of the colorectum, muscle activity related to the evacuation of feces including the anal sphincter muscles, coordination between rectal contraction and anal canal relaxation, and others. Therefore, the accurate measurement of bowel function cannot be obtained only based on anal sphincter activity.

To mitigate the abovementioned drawback of AM, fecoflowmetry (FFM) was originally introduced by Shafik et al to assess defecation disorders in adult patients.[7,8] The advantages of FFM are its noninvasive nature and ability to simulate the act of defecation as well be conducted under natural conditions. We previously reported the availability of FFM in pediatric patients with anorectal surgery.[9,10] It would be ideal to be able to assess the bowel function of patients who receive pediatric anorectal surgery by the combination of the scoring system, anorectal manometry, and FFM. However, the simultaneous examination of these assessments is often difficult due to limitations relating to cost, time, and equipment availability in daily practice. For this reason, bowel function is often assessed only by a scoring system approach because of its simplicity and noninvasiveness. Therefore, it would be meaningful to understand the relationship between a scoring system and the parameters of an objective technique able to assess bowel function such as FFM. There has been previous research published investigating a relationship between KCS and the FFM parameters,[9,10], but no report has yet analyzed the relationship between the most recent scoring system (KS) and the parameters of FFM in pediatric patients with ARM and HD.

Given this fact, the present study sought to investigate the relationship between KS and the FFM parameters and to assess the characteristics of this new questionnaire test by comparing KCS in pediatric patients who underwent anorectal surgery for ARM and HD.

2. Methods

This paper is a study of pediatric patients who underwent postoperative FFM after anorectal surgery for HD or ARM between January 2006 and November 2019 at each hospitals. This study was approved by the ethical committees for human subjects at each hospitals (Approved no. 19074 and no. 155). Written informed consent was obtained from the families of the included patients before their involvement in the study.

At the beginning of the study, each patient's fecal condition was assessed using KCS, which considers three basic parameters: continence, staining, and sphincter squeeze. Patients were scored according to the sum total of these three basic parameters as good (5–6 points), fair (3–4 points), or poor (0–2 points). In addition, KS was applied, similarly consisting of three parameters; voluntary bowel movement (VBM), soiling, and continence.[4]

Prior to FFM, each patient underwent AM (InSIGHT®: Sandhill Scientific Inc., Highlights Ranch, CO, USA) and resting anal pressure, and voluntary squeezing anal pressure were measured to discern the activity of the anal sphincter muscles. These anal pressures were measured with infused water filled through the open-tip method without sedation. The patients were positioned in the left decubitus posture. A lubricated balloon catheter (4 mm in diameter, equipped with six pressure sensors, and the Dent sensor) was inserted into the anus and the patients were asked to relax when the resting anal pressure was measured, then asked to squeeze strongly as possible when voluntary squeezing anal pressure was measured.

Next, FFM was performed using a scale-redesigned uroflowmeter with a maximum flow rate of more than 100 mL/s (Takei Medical and Optical Company, Tokyo, Japan), which consists of a weight transducer, an amplifier, and a chart recorder. Prior to the FFM examination, the patients were prepared with a 50% glycerine enema (2 mL/kg body weight) to clear the bowels. Warmed normal saline (37 °C) was injected into the rectum as imitate stool using a 6-French catheter in the left decubitus position under monitoring of anorectal pressures. The patients were asked to retain the enema fluid for as long as possible and, when the urge to defecate could no longer be suppressed, they were placed on the fecoflowmeter in a sitting position and left alone while defecating to eliminate psychologically inhibitory factors.

FFM evaluates the bowel function by measuring the following parameters: the tolerance rate of intended normal saline solution in the colorectum (TR), the evacuative rate (ER), the evacuative volume (EV), the maximum fecal stream flow rate (F_{max}) and the fecoflow pattern (FFP). The tolerance volume (TV) is the intended tolerance volume (mL) of warmed normal saline as the imitation of stool. The TR is [TV/20 mL/kg × body weight (kg)] × 100 (%). The EV is the volume of imitated stool (mL) evacuated into the fecofloemeter. The ER is (EV/TV) × 100 (%). F_{max} is the maximum fecal flow rate in mL/sec in the fecoflow curve recorded on the fecoflometer. The fecoflowmetric pattern (FFP) was classified into three types according to Yagi's classification-block (Fmax > 45 mL/s), segmental (15 mL/s < Fmax < 45 mL/s), and flat (Fmax < 15 mL/s)-as previously reported.[9]

3. Statistical analyses

All statistical analyses were performed with the JMP® Pro 11 software program (SAS Institute Inc., Cary, NC, USA). Continuous data were presented as means ± standard deviations. At first, all patients were divided into subgroups according to each parameter of the scoring system and each FFM parameter was compared among the subgroups of the KCS or KS parameters, respectively using Wilcoxon's test. In addition, correlation analyses were conducted between FFM and AM parameters using Spearman's rank correlation. Differences and the results of the correlation analysis were considered as significant at $p < 0.05$.

4. Results

The total number of enrolled patients was 20, including 15 male and five female patients. The mean ages at surgery and at the time of FFM were 1.21 ± 0.37 and 7.70 ± 2.45 years old, respectively. Of all patients, six had the low type of ARM (LARM), nine had the intermediate type of ARM (IARM), one had the high type of ARM, and four had HD. The baseline characteristics and KCS and KS grades of the patients with ARM, LARM, IARM, HARM and HD are shown in Table 1. In the evaluation of differences in FFM parameters among the KCS parameter subgroups, F_{max} in the KCS staining score 2 group was significantly higher than that in the KCS staining 1 group ($p = 0.045$), whereas, the other FFM parameters displayed no statistically significant differences between these two KCS staining score groups (Fig. 1a). In addition, F_{max} in the KCS sphincter squeeze 1 group was significantly higher than that in the KCS sphincter 0 group ($p = 0.045$) (Fig. 1b). On the other hand, there were no statistically significant differences observed in FFM parameters

Table 1
The baseline characteristics and the numbers of KCS and KS of the patients with ARM, LARM, IARM, HARM and HD.

Table 1 The baseline characteristics and the numbers of KCS and KS of the patients with ARM, LARM, IARM, HARM and HD

		Total (n=20)	ARM (n=16)	LARM (n=6)	IARM (n=9)	HARM (n=1)	HD (n=4)	LHD (n=1)	SHD (n=3)
	Gender (M/F)	15/5	12/4	4/2	7/2	1/0	3/1	1/0	2/1
	Age (years)	7.70±2.45	7.99±2.45	8.58±3.06	7.24±1.82	11.16	6.54±2.41	5.33	7.19±3.21
KCS	Total score (mean±SD)	4.45±1.14	4.5±1.03	5.16±0.75	4.00±1.00	5	4.25±1.70	5	4±2.00
KCS	Continence score (2/1/0)	12/8/0	9/7/0	3/3/0	5/4/0	1/0/0	3/1/0	1/0/0	2/1/0
KCS	Staining score (2/1/0)	10/10/0	8/8/0	5/1/0	2/7/0	1/0/0	2/2/0	1/0/0	1/2/0
KCS	Sphincter squeeze score (2/1/0)	9/9/2	8/7/1	5/1/0	3/5/1	0/1/0	1/2/1	0/1/0	1/1/1
KCS	KCS evaluation (Good/Fair/Poor)	10/9/1	8/8/0	5/1/0	2/7/0	1/0/0	2/1/1	0/1/0	1/1/1
KS	Voluntary bowel movement (Yes/No)	20/0	16/0	6/0	9/0	1/0	4/0	1/0	3/0
KS	Soiling Grade (No/1/2/3)	8/7/5/0	7/5/4/0	3/1/2/0	4/3/2/0	0/1/0/0	1/2/1/0	0/1/0/0	1/1/1/0
KS	Constipation Grade (No/1/2/3)	13/0/5/2	11/0/4/1	4/0/2/0	6/0/2/1	1/0/0/0	2/1/0/1	1/0/0/0	1/0/1/1

M: Male, F: Female, KCS: Kelly's clinical score, KS: Krickenbeck score
ARM: Anorectal malformations, LARM: Low-type of anorectal malformations, IARM: Intermediate-type of anorectal malformations, HARM: High-type of anorectal malformations
HD: Hirschsprung's disease, LHD: Lont-type of Hirschsprung's disease, SHD: Short-type of Hirschsprung's disease

between the two KCS continence groups. Upon comparing FFM parameters between each KCS evaluation group, F_{max} in "good" patients was significantly higher than that in "fair" patients ($p = 0.030$) (Fig. 1c). However, the other FFM parameters showed no statistically significant differences between the KCS evaluation groups (Table 2).

All patients achieved VBM at the time of FFM. Eight patients achieved no soiling, whereas seven and four patients suffered grades 1 and 2 soiling according to KS, respectively.

Subgroup size for the KS parameters is presented in Table 3. In the evaluation of a difference in FFM parameters among each KS group, TR in the no soiling group was significantly higher than that in the grade 2 group ($p = 0.047$) (Fig. 2). Thirteen patients achieved no constipation, whereas five and two patients suffered grades 2 and 3 constipation, respectively. There were no statistically significant differences noted in the comparison of FFM parameters among the three constipation grading groups (Table 3).

Although AM was successfully performed in 15 patients, five patients failed to complete the procedure adequately because they could not understand the instructions regarding how to squeeze their anal canal. In the correlation analyses between FFM and AM parameters, there was a statistically significant positive correlation between F_{max} and voluntary squeezing anal pressure ($r = 0.632$; $p = 0.012$), although there was no statistically significant correlation between F_{max} and resting anal pressure (Fig. 3). Conversely, there was no statistically significant correlation between the other FFM parameters and AM parameters.

5. Discussion

Today, several scoring systems including KCS, Pena's criteria for the assessment of continence, and the Rintala bowel function score are used as validated questionnaires for the assessment of postoperative bowel function in pediatric patients.[1–3] These scoring systems consist of subjective parameters and focus only on fecal continence, excluding elements required to assess bowel control. Bowel control is defined as the ability to voluntarily pass stool combined with the ability to retain stool. In 2005, KS was established to address this weak point.[4,11]

FFM was first introduced as a modality for the evaluation of defecation disorders in adult healthy subjects and constipated patients. Since its inception, however, there have been several reports published in which FFM was used to assess the bowel function of pediatric patients.[9,10] In one previous report on using FFM to compare the bowel function of healthy children and pediatric patients with idiopathic chronic constipation, the former group

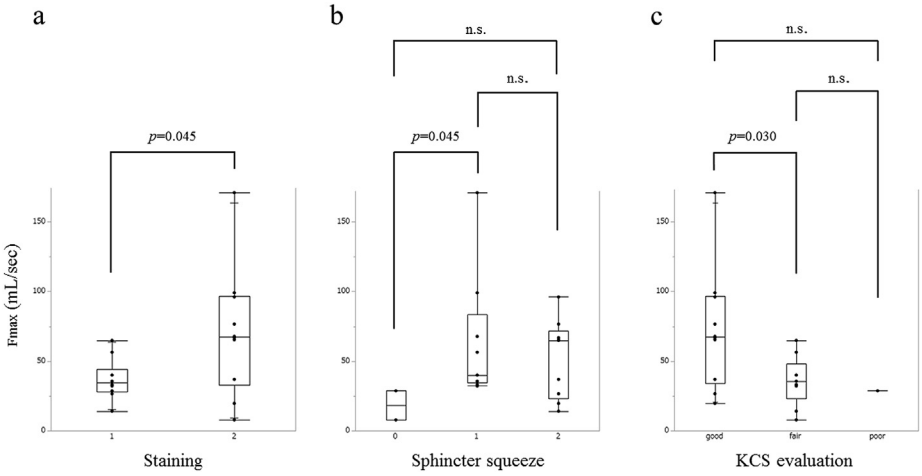

Fig. 1. F_{max} in the staining score 2 group (a), sphincter squeeze 1 group (b) and KCS good group (c) were significantly higher than that in the staining score 1, sphincter squeeze 0 and KCS fair group, respectively ($p = 0.045$, 0.045 and 0.030).

showed a massive fecoflowmetric curve, short evacuative time, and high fecal flow rate in contrast with the latter population.[12] Other previous reports have suggested that FFM as well as FFP are reliable and useful reflections of anorectal motor activity that are valid for evaluating the postoperative bowel function in pediatric patients with ARM and HD.[9,10] Among the parameters of FFM, patients with TRs of greater than 70% and high values of F_{max} were reported to achieve good continence.[9,10] F_{max} is considered to be reflected by anal sphincter performance and greater than 45 mL/s is considered to be a cutoff value indicating good continence in pediatric patients with anorectal surgery.[9] Meanwhile, TR reflects the capacity to retain the imitated stool, and low TR patients are considered to display true fecal incontinence.

In the present study, the F_{max} in KCS "fair" patients was 36.02 ± 17.96 mL/s, which was slightly lower than the finding of a previous report.[9] KCS depends upon subjective observations thoroughly, and the scores are ordinal variables. We speculate that KCS "fair" patients have the potential to return to better bowel function with the proper management of bowel movements by way of prokinetic drugs or diet control. Separately, patients with good staining scores or a grade of "good" according to KCS classification scheme showed a significantly high value of F_{max}, which was consistent with previous reports.[9,10]

Of note, one previous report that compared FFM and KCS in pediatric patients with anorectal surgery for ARM and HD indicated that there were statistically significant correlations between TR in FFM, and continence in KCS, while F_{max} in FFM showed a statistically significant correlation with total KCS score.[9,10]

The present study comparing FFM parameters with KCS parameters reported that the mean F_{max} in no staining patients was 70.72 ± 46.30 mL/s and that in KCS staining 1 (occasional staining) patients was 37.17 ± 14.58 mL/s, for a statistically significant difference between the two groups. However, the TRs of the two groups showed no statistically significant difference. Therefore, staining of the underwear in the included patients was considered to be caused by overflow incontinence resulting from constipation rather than incontinence. In addition, F_{max} in the "good" group per KCS was 72.60 ± 43.78 mL/s and that in the "fair" group per KCS was 36.02 ± 17.96 mL/s, with a statistically significant difference, which was consistent with previous data that indicated that F_{max} of more than 45 mL/s are considered to have achieved clinically favorable bowel function.[9,10]

On the other hand, no previous report has investigated the relationship between FFM and KS. Previous scoring systems have focused on fecal continence, and the involvement of constipation in bowel function has traditionally been underestimated.[11] KS consists of voluntary bowel movement, soiling, and constipation. This scoring system is based on previous findings indicating that the major postoperative problem observed in pediatric patients who underwent anorectal surgery is motility disturbance, which results in chronic constipation, and overflow incontinence. Given the new findings of the present study, TR in no soiling patients was 77.56% ± 74.79% and that in KS grade 2 soiling patients was 41.29% ± 28.00%, for a statistically significant difference. These present results suggest that higher TRs might be an indicator of higher compliance of the colorectum, which results in more favorable continence and the prevention of soiling. In addition, the soiling score of KS might reflect the ability of tolerance and evacuation.

Internal and external anal sphincter muscle activities are associated with fecal continence and the importance of preservation of these muscles during surgery has been proposed.[13,14] Resting anal pressure is reflected by the activity of internal anal sphincter muscle.[15] The rectoanal pressure gradient is reported to be the main barrier against propulsive activity of the bowel and low

Table 2
Comparison of FFM parameters between the subgroups of KCS.

	Continence score		Staining score	Sphincter squeeze score			KCS evaluation		
	1 (occasional accidents)	2 (no soiling)	1 (occasional accident)	2 (always clean)	0 (no contraction)	1 (weak and partial squeeze)	2 (strong and effective squeeze)	Poor (0–2)	Fair (3–4)	Good (5–6)
Number of patients	8	12	10	10	2	9	9	1	9	9
TV (ml)	309.50 ± 178.19	332.91 ± 176.84	285.90 ± 151.83	361.20 ± 192.38	181.00 ± 168.29	343.88 ± 207.75	334.88 ± 136.83	62	303.00 ± 135.94	368.20 ± 191.17
TR (%)	60.49 ± 33.37	72.22 ± 25.06	67.17 ± 30.92	67.88 ± 27.40	30.93 ± 29.37	76.66 ± 26.13	66.52 ± 26.46	10.16	69.91 ± 25.59	71.12 ± 27.19
EV (ml)	213.58 ± 116.02	249.64 ± 87.45	219.91 ± 111.37	250.53 ± 34.37	106.15 ± 8.69	263.60 ± 96.71	235.52 ± 92.95	112.3	208.53 ± 114.65	271.53 ± 70.49
ER (%)	80.94 ± 46.05	82.67 ± 30.28	85.23 ± 39.58	78.72 ± 34.37	107.21 ± 104.53	86.13 ± 29.58	72.21 ± 24.32	181.13	68.97 ± 25.55	83.77 ± 30.44
F_{max} (ml/sec)	47.46 ± 21.91	58.26 ± 45.64	37.17 ± 14.58	70.72 ± 46.30*	18.25 ± 14.77	63.92 ± 45.65**	51.90 ± 28.43	28.7	36.02 ± 17.96	72.60 ± 43.78***

*p = 0.045 vs. Staining 1, **p = 0.045 vs. Sphincter squeeze 0, ***p = 0.030 vs. KCS fair.
TV: Tolerance volume, TR: Tolerance rate, EV: Evacuative volume, ER: Evacuative rate, Fmax: Maximum fecal flow rate.

Table 3
Comparison of FFM parameters between the subgroups of KS.

	voluntary bowel movement	Soiling grade			Constipation grade		
	Yes	No (No soiling)	1 (Occasionally)	2 (Everyday, no social problem)	No (No constipation)	2 (Requires laxatives)	3 (Resistant to laxatives)
Number of patients	20	8	7	5	13	5	2
TV (ml)	323.55 ± 173.04	365.00 ± 157.11	360.71 ± 210.99	205.20 ± 94.28	363.61 ± 185.36	286.40 ± 117.28	156.00 ± 132.93
TR (%)	67.52 ± 28.44	77.56 ± 74.79*	74.79 ± 25.32	41.29 ± 28.00	71.62 ± 23.73	69.36 ± 33.56	36.33 ± 37.01
EV (ml)	235.22 ± 98.56	265.43 ± 98.93	261.77 ± 92.43	149.70 ± 63.25	260.89 ± 88.96	228.10 ± 93.51	86.15 ± 36.98
ER (%)	81.98 ± 36.23	77.08 ± 30.40	81.59 ± 30.28	90.35 ± 55.74	79.93 ± 30.10	79.07 ± 13.99	102.56 ± 111.10
Fmax (ml/sec)	53.94 ± 37.58	48.57 ± 27.77	67.47 ± 52.17	43.60 ± 27.65	53.96 ± 42.81	66.90 ± 21.11	21.40 ± 10.32

*p = 0.047 vs. grade 2.
KS: Krickenbeck score, TV: Tolerance volume, TR: Tolerance rate, EV: Evacuative volume, ER: Evacuative rate, Fmax: Maximum fecal flow rate.

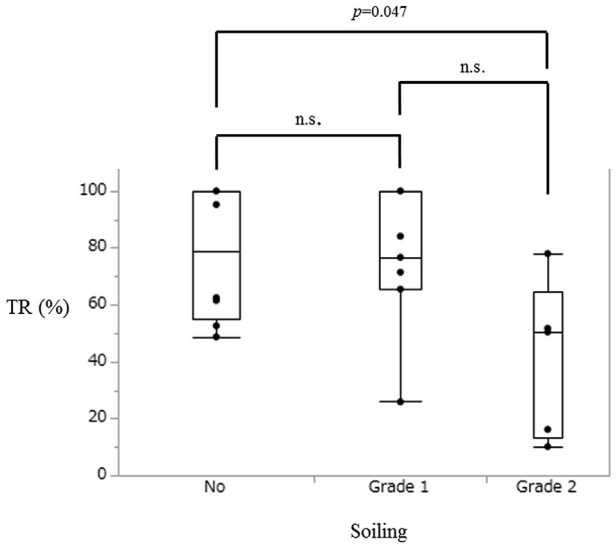

Fig. 2. Comparison between FFM parameters and KS parameters subgroups revealed that TR in no soiling patients was significantly higher than that in Grade2 soiling patients ($p = 0.047$).

resting anal pressure involved in fecal incontinence, and preservation of the internal anal sphincter muscle activity is important for postoperative fecal continence in pediatric patients.[5] In addition, impairment of the internal anal sphincter muscle results in the loss of rectoanal inhibitory reflex.[16,17] Separately, good activity of the external anal sphincter muscle is necessary to maintain urge continence and the activity of the external anal sphincter muscle reflects voluntary squeezing anal pressure.[18]

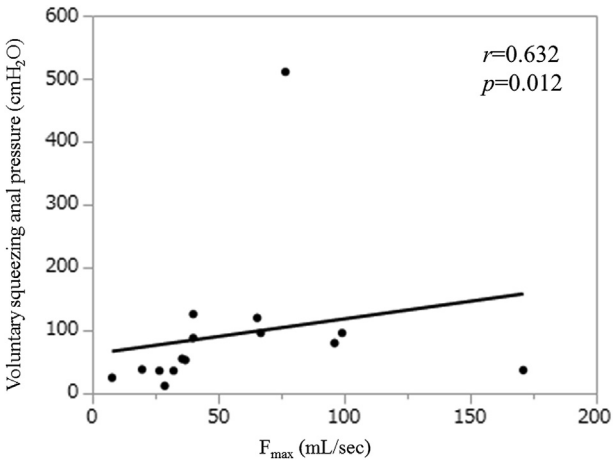

Fig. 3. Relationship between F_{max} and the voluntary squeezing anal pressure, where statistically significant positive correlations were found ($r = 0.632$; $p = 0.012$).

In a previous analysis of the comparison between FFM and AM among postoperative patients with ARM and HD, there were statistically significant positive correlations between resting anal pressure and F_{max} noted,[8,9], which indicated that F_{max} is reflected by anal sphincter muscle activity and compliance of the colorectum. However, in the present study, there was no statistically significant correlation between F_{max} and resting anal pressure recorded. In contrast, there was a statistically significant positive correlation between F_{max} and voluntary squeezing anal pressure. A previous report published concerning the relationship between FFM and AM indicated that rectal contractile activity synchronized with relaxations of the anal canal had no direct correlation to good scores in FFM parameters in patients who underwent surgical repair for ARM.[19] This discrepancy is considered to be caused by the fact that actual bowel function involves not only internal and external anal sphincter muscles but also other undetectable factors such as motor activity of the pelvic floor muscles and puborectalis muscle. Based on the present result, patients who achieved higher F_{max} tended to have adequate activity of the external anal sphincter muscle, and this finding corresponded with the result of the comparison among sphincter squeeze score groups in KCS.

In summary, the investigation of a relationship between FFM and KCS parameters showed a significant difference in F_{max} among the two staining score groups, two sphincter squeeze score groups, and three KCS classification groups, which suggested that, in addition to sphincter squeeze score, KCS classification, and staining score reflect the state of anal sphincter performance. On the other hand, the investigation of a relationship between FFM and KS parameters revealed a significant difference in TR among the two soiling grade groups, supporting that the soiling score of KS might reflect the ability of tolerance.

This study had several limitations, including the small number of participants and the heterogeneity of patient backgrounds. Differences in disease type and reconstruction procedures might have led to the changes in anatomical configurations and physiological functions that influenced the results of the present study. In addition, there were no patients with continence score 0, staining score 0 in KCS, neither with no voluntary bowel movement and soiling Grade 3 in KS in the present study, which also might affect the results of the present study.

An increase in the number of study participants including a large number of the patients with frequent incontinence and with inappropriate voluntary bowel movement and greater regulation in including disease types or surgical procedures are necessary to better reveal the relationships between FFM parameters and clinical outcomes. Despite these limitations, we believe that this study offers some novel information about the relationship between FFM

parameters and the most recent clinical scoring system (KS) in postoperative pediatric patients with ARM and HD.

In conclusion, the present retrospective study investigated the relationship between FFM parameters and KCS or KS parameters. FFM clarified the different characteristics of these two scoring systems, although the study population was small, potentially influencing its results. Overall, KCS and staining score appear to reflect the anal sphincter performance, whereas the soiling score of KS might reflect the tolerance activity. FFM may be suitable to use in the conduct of comprehensive anorectal motor activity assessment including KCS and KS evaluations in postoperative patients with anorectal surgery. Further larger studies are warranted to better elucidate the detailed characteristics of KS.

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Author contribution

Naruki Higashidate and Suguru Fukahori designed the research study, analyzed the data, and wrote the paper; Minoru Yagi and Yoshiaki Tanaka designed the research study and wrote the paper; Sinji Ishii and Naoki Hashizume analyzed the data; Nobuyuki Saikusa, Saki Sakamoto, Tomohiro Kurahachi, and Masahiro Ohtaki performed the research.

Declaration of competing interest

The authors have no competing interests to disclose.

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