Received: 4 February 2020 | Accepted: 14 April 2020
DOI: 10.1002/nau.24374

ORIGINAL CLINICAL ARTICLE

Reliability of manometry for assessing pelvic floor muscle function in healthy men

Mifuka Ouchi RPT, PhD[1,2] | **Takeya Kitta MD, PhD**[1] | **Yui Takahashi RPT**[1] | **Hiroki Chiba MD, PhD**[1] | **Madoka Higuchi MD**[1] | **Mio Togo MT, MS**[1] | **Nobuo Shinohara MD, PhD**[1]

[1]Department of Renal and Genitourinary Surgery, Graduate School of Medical Science, Hokkaido University, Sapporo, Japan

[2]Department of Physical Therapy, School of Rehabilitation Sciences, Health Sciences University of Hokkaido, Tobetsu, Japan

Correspondence
Takeya Kitta, Department of Renal and Genitourinary, Graduate School of Medical Science, Surgery, Hokkaido University, Kita 15 Nishi 7; Kita-ku, Sapporo, Hokkaido 060-8638, Japan.
Email: kitta@fb3.so-net.ne.jp

Funding information
Japan Society for the Promotion of Science, Grant/Award Number: 18K17648

Abstract

Objectives: To the best of our knowledge, no study has examined the reliability of assessment methods for male pelvic floor muscle (PFM) function. Therefore, this study aimed to clarify the reliability of manometry with an anal sensor (Peritron cat 9300A) to assess PFM function in healthy men.

Methods: Healthy male subjects (n = 21) without urinary leakage underwent testing to assess PFM function, and intra- and interrater reliability tests among examiners were performed. The PFM function included maximal anorectal squeeze pressure, endurance, mean anorectal squeeze pressure, gradient, and area under the curve during PFM voluntary contraction.

Results: Participants had a median age of 38 years (range 26-51), and a mean BMI of 23.2 ± 2.0 kg/m^2. Satisfactory intra- and interrater reliability scores were found for resting pressure, anorectal squeeze pressure, and endurance. The intra-rater reliability of resting pressure, anorectal squeeze pressure, and endurance were 0.71, 0.89, and 0.75 for examiner 1 and 0.72, 0.89, and 0.87 for examiner 2. The interrater reliability for resting pressure, anorectal squeeze pressure, and endurance were 0.58, 0.93, and 0.61, respectively.

Conclusions: This is the first prospective study showing the favorable intra- and interrater reliability of manometry for PFM function in healthy men. Our findings demonstrated that manometry can provide both reliable and reproducible data regarding PFM function in continent men, suggesting Peritron cat 9300A can be used to evaluate the PFM function in men.

KEYWORDS
healthy men, intra- and interrater reliability, pelvic floor muscle function

1 | INTRODUCTION

The pelvic floor muscle (PFM) is one of the skeletal muscles in women and men that is innervated by pudendal nerves from S2 to S4 nerve roots of the sacral plexus. Kegel[1] was the first researcher to note PFM injury induced by vaginal delivery and the ability to restore PFM function with exercise using a perineometer. The Oxford grading system is most frequently used by physiotherapists to grade PFM function.[2] Although a digital examination is essential for assessing PFM function,[3] a manometer allows functional evaluation of PFM to detect pressure delivered by PFM contractions and provides numerical values for comparisons. Previous studies using a manometer reported that PFM functions have been measured from the perspectives of maximal voluntary contraction, endurance, resting pressure, and area under curve during PFM contractions.[4-6] Vaginal pressure is used to objectively assess the strength and endurance of PFM contractions in women. Recent studies have confirmed the reliability of a perineometer to evaluate therapeutic effects in patients with pelvic floor dysfunction.[5,6] Studies have measured vaginal pressure to determine the effect of pelvic floor muscle training (PFMT) in female patients with stress urinary incontinence.[7-10] Previous studies showed that PFMT may be effective in men after radical prostatectomy.[11-13] Most studies have used the Pad test to assess the efficacy of PFMT in patients after radical prostatectomy.[14] Theoretically, PFMT can strengthen PFM function via exercise protocols that aim to overload skeletal muscles and improve active urethral pressure against increased intra-abdominal pressure.[15] However, PFM function needs to be measured objectively to determine whether the PFM contributes to urinary leakage in men after radical prostatectomy. To the best of our knowledge, no previous studies have investigated the intrareliability and interreliability of the use of manometry with an anal sensor to assess PFM function. The objective of this study was to clarify the reliability of manometry with an anal sensor for assessing PFM function in healthy men.

2 | METHODS

2.1 | Subjects

This study was conducted at the Department of Urology at our University. Twenty-five healthy male subjects participated in this study. The inclusion criteria were ages 20 to 64 years and the ability to demonstrate PFM contraction as assessed via palpation of the surface of the PFM. Exclusion criteria were any lower urinary tract symptoms, serious psychiatric or neurologic disease, lower urinary tract infection, taking hormonal medicine, or judged unsuitable for the study by a urologist. No subject had previous experience with regular PFMT. Subjects were told not to exercise during the study period to eliminate the chances of impacting the training and detraining effects. All participants provided written informed consent.

2.2 | Assessment tool

Figure 1A,B shows the microprocessor-based manometer with an anal sensor (Peritron cat 9300A; Laborie,

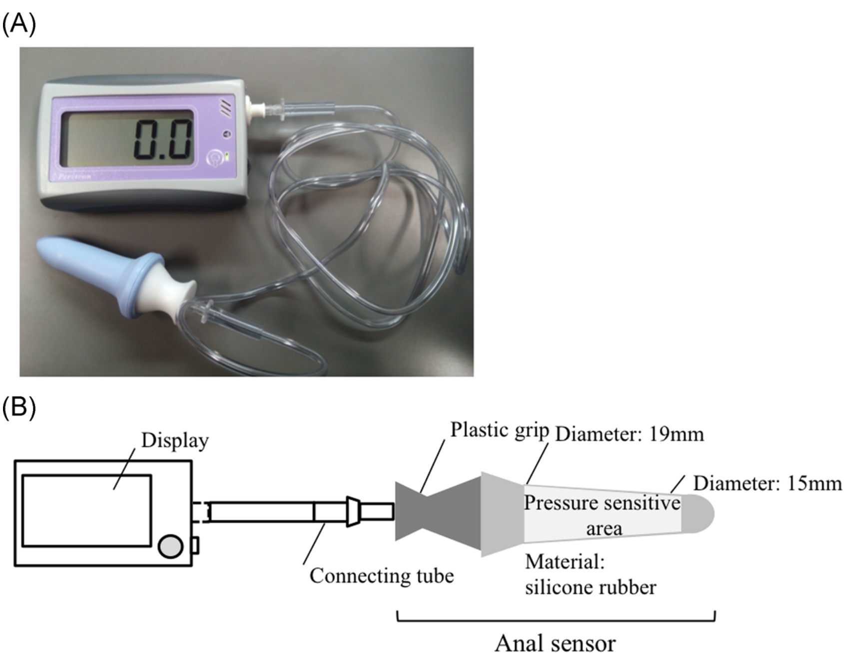
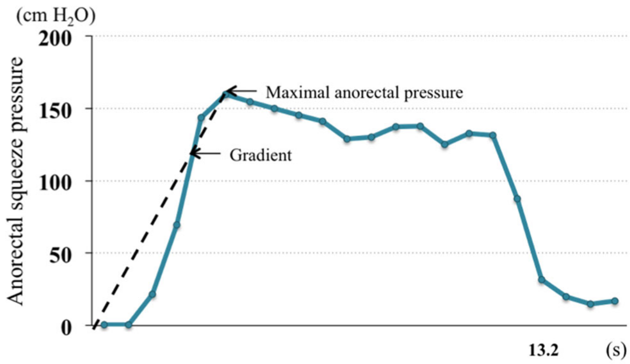


FIGURE 1 A, Peritron cat 9300A (Laborie, Canada). B, Materials for the Peritron 9300A. Anorectal pressure was assessed as pelvic floor muscle function. During voluntary contractions of the pelvic floor muscle, signal pressure measurements from the pressure-sensitive area of the anal sensor were interpreted by a microprocessor, and a numerical value was displayed in cm H_2O

Canada) that was used to measure the PFM function. The sensor consisted of an air-filled silicone rubber sensor connected to a manometer with a pressure transducer. The sensor was connected to the display unit via a 120-cm male Luer anal sensor. The unit of pressure was displayed numerically in cm H_2O. The maximum error for the accuracy of pressure was less than 0.7 cm H_2O within operating temperatures (range, 10-30°C). The anal sensor was used at atmospheric pressure without inflation. A water-based lubricant was applied to the anus to avoid any discomfort and pain.

2.3 | Procedures

Two examiners performed the tests so that for inter- and intrarater reliability could be assessed. For examiners, a standardized measuring protocol that included exact instructions and consistent voice volume were implemented to assure correct and reproducible data. Subjects were assessed as follows: (a) at the completion of the testing protocol at the first visit, (b) at the completion of the repeated testing protocol at the second visit. Two different examiners participated in interrater and intrarater reliability tests at each visit. The order of the two examiners was randomized. Muscle function was assessed using maximum voluntary PFM contraction alone. When we assessed PFM strength, subjects were given standardized instructions to "squeeze and lift or tighten and pull up the PFM as hard as you can" for maximal contraction of the PFM. All subjects were placed in a lateral position with knees drawn up at 45° and a pillow placed under the head. All participants were instructed to breathe normally, and not to strain and tilt the pelvis. They practiced till being able to contract the PFM without hip adductor, gluteal, or rectus abdominis muscles before assessing PFM functions to eliminate common errors seen during voluntary PFM contractions. PFM function, including the maximum voluntary anorectal squeeze pressure, endurance, average anorectal squeeze pressure, gradient, and area under the curve were measured three times each at both sessions, and the mean value of measurements was used (Figure 2). Before the PFM squeeze pressure contraction, the resting pressure was recorded. The anal resting squeeze pressure was reset to zero outside of the body and then the anal sensor was inserted into the anus. During the assessment of PFM function, each subject was instructed to exhale first, and kept breathing in and out during assessing the duration of PFM contraction. A respiratory pattern was standardized during PFM contraction. The respiratory pattern was observed in each trial, and confirmed participants respired in the same pattern throughout the session. Each maximum anorectal squeeze pressure was continuously measured until the subjects hold breath or accessory muscles contracted. With careful examination, we assessed independent PFM contraction was performed. We defined maximum contraction time as until the subjects hold breath, accessory muscles contracted.



Parameterers

Maximal anorectal squeeze pressure (cm H_2O)	159.5
Endurance (s)	13.2
Average (cm H_2O)	94.5
Gradient (cm $H_2O \cdot s^{-1}$)	44.3
Area under the curve (cm $H_2O \cdot s$)	2078.5

FIGURE 2 Evaluation of pelvic floor muscle functions by the peritron cat 9300A. This graph demonstrates an example when a male healthy participant contracted his pelvic floor muscle voluntarily. Peritron can record the following parameters: maximal anorectal squeeze pressure, duration, average, gradient, and area under the curve. Maximal anorectal squeeze pressure is the peak value of anorectal squeeze pressure during contraction of the pelvic floor muscle. Duration is measured when pressure reaches above 5 cm H_2O. Average means area under the curve of anorectal squeeze pressure divided by contraction duration. Gradient is the peak value of anorectal squeeze pressure divided by the time taken to reach the maximum. Area under curve is anorectal squeeze pressure sampled 10 times per second, and divided by 10, multiplied by duration time. Maximal value of area under curve is 9999 cm $H_2O \cdot s$. All parameters are calculated numerically

2.4 | Data analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) 23.0J for Mac (IBM, Armonk, NY). All participants were included in the data analysis. Data distribution was assessed with the Shapiro-Wilk test for continuous data. Intra-rater and interrater reliability of the two examiners were evaluated.

Those analyses were performed by calculating two different measures of agreement: intraclass correlation coefficient (ICC) for relative reliability and Bland-Altman 95% limits of agreement (LOA) for absolute reliability. We defined ICC as less than 0.00 poor, 0.00-0.20 slight, 0.21-0.40 fair, 0.41-0.60 moderate, 0.61-0.80 substantial, and 0.81-1.00 almost perfect.[16] Each association between two examiners and between sessions was examined by calculating Pearson or Spearman correlation coefficients. A paired-*t* test or the Wilcoxon signed-rank test was conducted to compare findings between sessions within each examiner. An independent *t* test or the Mann-Whitney U test was conducted to compare findings between the two examiners. Bland-Altman analysis[17] was used to evaluate absolute errors and calculate minimal detectable changes. The significance level was set at $P < .05$.

3 | RESULTS

Of the 25 healthy participants, 4 men withdrew due to personal reasons (1 moved away, 1 could not contract his PFM properly and 2 did not return for the second session). Data for participants who dropped out were excluded from the analysis. The median age of the 21 participants was 38 years (range, 26-51), and mean BMI was 23.2 ± 2.0 kg/m^2. Table 1 shows male PFM functions, including resting pressure, maximal anorectal squeeze pressure, endurance, average squeeze pressure, gradient, and area under curve using the manometer with the anal sensor. There were no subjects who ceased trials due to adverse events, including discomfort and/or pain. Also, no subjects complained of side effect, such as pain and/or rectal bleeding after sessions. There were no significant differences between session 1 and 2 within examiner 1 for any parameter. There were no significant differences between session 1 and 2 within examiner 2 in resting pressure, maximal anorectal squeeze pressure, endurance, and area under curve; however, mean average squeeze pressure and gradient were significantly higher than in session 2 than in session 1 ($P < .05$). Table 2 and Figure 3A,B show intrarater reliability and results from the Bland-Altman analysis for PFM function between sessions. Although the ICC value for the gradient in examiner 1 was fair, other parameters showed substantial to almost perfect intrarater reliability. The correlation coefficients of most parameters were strong, whereas the gradient had a moderate correlation coefficient in both examiners ($P < .05$). The value for anorectal squeeze pressure had the highest interrater reliability (Table 3). However, interrater reliability for resting pressure and endurance was moderate. The correlation coefficient of anorectal squeeze pressure was strong, but resting pressure, endurance, and gradient were moderately correlated.

4 | DISCUSSION

This is the firsts study investigating intrarater and interrater reliability for PFM functions in healthy men. Our results show that there was moderate to almost perfect reliability in intra-and interrater reliability of resting, anorectal squeeze pressure, and endurance. From those findings, PFM functions can be measured by using the manometer positioned in healthy men.

TABLE 1 Male pelvic floor muscle function using a manometer with an anal sensor (n = 21)

		Session 1	Session 2
Examiner 1	Resting pressure, cm H_2O	46.9 ± 11.7	47.2 ± 15.4
	Anorectal squeeze pressure, cm H_2O	163.9 ± 33.9	164.7 ± 43.0
	Endurance (s)	19.5 ± 9.5	20.3 ± 8.1
	Average squeeze pressure, cm H_2O	74.7 ± 20.8	75.8 ± 21.7
	Gradient, cm $H_2O \cdot s^{-1}$	75.6 ± 53.3	80.7 ± 61.9
	Area under curve, cm $H_2O \cdot s$	8853.2 ± 1706.2	9355.1 ± 1518.9
Examiner 2	Resting pressure, cm H_2O	48.8 ± 11.0	47.3 ± 13.6
	Anorectal squeeze pressure, cm H_2O	160.2 ± 37.8	162.4 ± 44.3
	Endurance (s)	17.2 ± 5.8	18.0 ± 7.4
	Average squeeze pressure, cm H_2O	73.2 ± 24.5	80.5 ± 25.4[a]
	Gradient, cm $H_2O \cdot s^{-1}$	66.7 ± 62.9	89.2 ± 62.3[b]
	Area under curve, cm $H_2O \cdot s$	9055.9 ± 1717.7	9110.7 ± 1788.4

Note: Data are presented as mean ± SD.

[a]$P < .05$. Paired *t* test or Wilcoxon signed-ranks test was conducted to compare sessions 1 and 2 within each examiner.

[b]$P < .05$. Independent *t* test or the Mann-Whitney U test was conducted to compare examiner 1 and 2 within each session.

TABLE 2 Intra-rater reliability, mean difference, and Bland-Altman analysis for male pelvic floor muscle function between sessions

			ICC 95% CI		Bland-Altman analysis: Consistent error 95% CI			Bland-Altman analysis: Proportional error		
		ICC (1.1)	Lower	Upper	Lower	Lower	*P*-value	CC	*P*-value	MDC_{95} (LOA)
Examiner 1	Resting pressure	0.71	0.28	0.88	−6.36	5.77	.92	−0.32	.15	26.11
	Anorectal squeeze pressure	0.89	0.73	0.95	−12.20	10.67	.89	−0.38	.08	49.23
	Endurance	0.75	0.39	0.90	−4.53	2.82	.63	0.20	.39	15.83
	Average squeeze pressure	0.87	0.68	0.95	−7.87	5.63	.73	−0.07	.77	29.06
	Gradient	0.47	−0.29	0.78	−36.56	26.31	.73	−0.15	.50	135.35
	Area under curve	0.85	0.63	0.94	−1000.6	−3.01	.04	0.18	.43	−1785.7 782.03
Examiner 2	Resting pressure	0.72	0.32	0.89	−3.82	6.83	.56	−0.24	.28	22.94
	Anorectal squeeze pressure	0.89	0.73	0.95	−14.26	9.92	.71	−0.26	.25	52.07
	Endurance	0.87	0.68	0.95	−2.92	1.23	.40	−0.38	.09	8.94
	Average squeeze pressure	0.86	0.66	0.94	−14.76	0.20	.05	−0.06	.80	32.21
	Gradient	0.79	0.49	0.91	−44.75	−0.22	.04	0.01	.96	−79.80 34.83
	Area under curve	0.97	0.92	0.98	−351.14	241.61	.70	−0.11	.63	1276.14

Abbreviations: CC, correlation coefficient; CI, confidence interval; ICC, intraclass correlation; LOA, limit of agreement; MDC_{95}, 95% minimal detectable change.

Although previous studies have assessed PFM strength with a manometer or the Oxford scale after prostatectomy,[18,19] to the best of our knowledge, the reliability of PFM function assessments in men has not been addressed. The present study showed that manometry is a reliable tool to evaluate PFM function in healthy men. This finding may help guide function-centered assessment of the efficacy of PFMT for patients after prostatectomy.

There are various manometers for assessing PFM. The Peritron was used in the present study because it is accessible, portable, simple to use, and has a high reliability for women.[5,6,20-22] Reliability of manometers has been well established in nulliparous and parous women.[4-6] Recent studies conducted ICC to analyze the degree of agreement within or among raters. Intra-rater reliability values of Peritron used in women placed in different positions, including bent-knee lying, supine, sitting, and

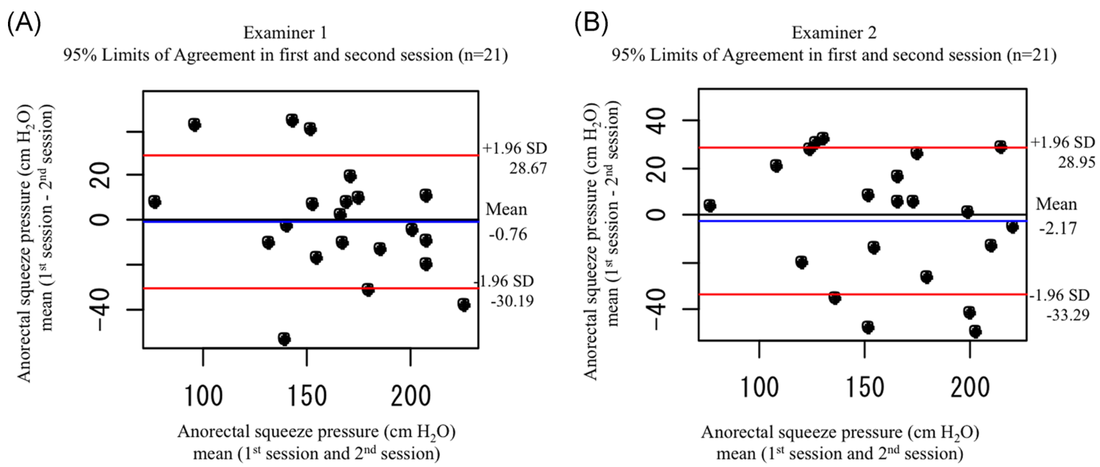


FIGURE 3 A,B, Representative data showing 95% limits of agreement and means between the first and second sessions in anorectal squeeze pressure of each examiner. The blue lines show the mean difference, and red line shows the 95% limits of agreement. These figures show the same tendency for consistent and proportional errors. Of 21 subjects, most plots were located between 95% limits of agreement and converged on the mean line. The Bland-Altman plot showed good agreement between the first and second sessions in anorectal squeeze pressure, but with a reasonably wide limit of agreement

TABLE 3 Interrater reliability, mean difference, and Bland-Altman analysis for male pelvic floor muscle function between examiners

					Bland-Altman analysis						
			ICC		Consistent error						
			95% CI		95%CI			Proportional error			
		ICC (1.1)	Lower	Upper	Lower	Upper	*P*-value	CC	*P*-value	MDC_{95} (LOA)	
Examiners	Resting pressure	0.58	−0.36	0.83	−7.51	3.77	.49	0.06	.79	24.29	
1 & 2	Anorectal squeeze pressure	0.93	0.83	0.97	−4.73	12.07	.37	−0.21	.35	36.17	
	Endurance	0.61	0.58	0.84	−1.51	6.08	.22	0.52	.01	−7.49	12.06
	Average squeeze pressure	0.83	0.59	0.93	−6.39	9.44	.69	−0.23	.32	34.08	
	Gradient	0.45	−0.38	0.78	−22.82	40.66	.56	−0.17	.45	136.68	
	Area under curve	0.88	0.71	0.95	−715.03	309.73	.41	−0.01	.96	2206.23	

Abbreviations: CC, correlation coefficient; CI, confidence interval; ICC, intraclass correlation; LOA, limit of agreement; MDC_{95}, 95% minimal detectable change.

standing was 0.95, 0.91, 0.96, and 0.92 in for maximum voluntary contraction, respectively, whereas relatively lower ICC values were found in endurance and resting pressure.[5] Intra- and interrater reliability of manometery (Camtech AS Sandvika, Oslo) were almost perfect, with values of more than 0.91 for vaginal resting pressure, maximum voluntary contraction, and area under curve during 10-second PFM contraction.[4] High ICC values of Peritron between-days were 0.88 for maximum voluntary contraction and 0.83 for endurance in women aged 22 to 50 years (mean 29.5).[21] In elderly incontinent women (mean age 62 ± 8 years), the ICC of Peritron was 0.95 for maximum contraction.[20] Inter-rater reliability of Myomed 932 (Enraf-Nonius, Delft, The Netherlands) was 0.97 with a coefficient of variation of 11.09%.[23] In the present study, we found satisfactory reliability in resting pressure, anorectal squeeze pressure, and endurance in healthy male participants aged 26 to 51 years with no pelvic floor dysfunction. These findings correspond with the abovementioned studies that evaluated the reliability of vaginal pressure devices.

A manometer with an anorectal sensor was used to assess the levator ani muscle and anal sphincter muscle to determine PFM function in men. This approach is different from measurement through the vagina, which has a circular musculature. A previous study focusing on recovery from urinary incontinence after radical prostatectomy reported that PFM strength measured by manometry and digital examination was associated with a greater decrease in urinary incontinence.[19,24] The modified Oxford scale is widely used as a grading system for digital examination. Findings consist of 6 grades, from 0 to 5, as follows: 0 = *no contraction*, 1 = *flicker*, 2 = *weak*, 3 = *moderate*, 4 = good, and 5 = *strong*.[3] Although male PFM assessment using anorectal squeeze pressure can include anal sphincter muscle contraction, we think that a manometer with an anorectal sensor could be used to refer to levator ani muscle contraction, which contributes to urinary continence.[2] To maintain the high accuracy of PFM assessments in this study, all participants were instructed regarding proper methodology. Thus, PFM functional assessment with a manometer can be applied to men.

Our results show a relatively high intra- and interrater reliability in most parameters. In terms of a standardized protocol, we followed verbal orientation instructions for women, including a standardized protocol including exact instructions to contract their PFM, and implementation of consistent voice volume to obtain reproducible data, as previously reported.[4,5] Male participants in this study were placed in a lateral position with their knees bent at a 45° angle during assessments. In a previous study, women were placed in a supine position or a bent-knee supine position with the head supported with a pillow; they used the examiner's leg to stabilize the lower extremities.[4,5] The reason we chose a lateral position was because it was difficult to insert the transrectal prove in the supine position and immobilize the probe at the same angle throughout the assessment. In addition, some subjects complained about discomfort and/or pain around the anus.

Our results showed the mean value of anorectal squeeze pressure in healthy men and can be used to compare with male patients with urinary incontinence after prostatectomy. A study assessing PFM function using the Peritron in patients with postprostatectomy, aged 45 to 75 years, reported that the mean maximal squeeze pressure was 92.4 cm H_2O before surgery, 100.7 cm H_2O at 1 month, and 126.2 cm H_2O 6 months after surgery.[19] Thus, compared to the value of squeeze pressure of middle-aged to elderly postprostatectomy patients, values in healthy men tend to be higher.

There are no numeric data to compare normal values of PFM function in a healthy male population. Therefore, we reviewed the following previous studies on PFM function, which measured by using the Peritron 9300V perineometer with the vaginal probe in female subjects. In the vaginal pressure among different age groups, continent women younger than 40 years showed 45.5 cm H_2O (range 31.0 to 51.5), and those aged 40 and older showed 36.0 cm H_2O (range 25.8 to 46.3).[22] Vaginal squeeze pressure with the Peritron was 19.3 ± 12.0 cm H_2O (mean age 41.2 ± 8.2) in incontinent women.[25] Thompson assessed vaginal squeeze pressure in both continent and incontinent women and found values of 33 ± 14 and 26 ± 19 cm H_2O for vaginal squeeze pressure, and 15 ± 11 and 7 ± 7 seconds for endurance in continent and incontinent women, respectively.[26] In our preliminary data of vaginal and anorectal squeeze pressure in continent women with a median age of 33.5 years (range 28-37) years, we showed a resting pressure of 45.7 ± 15.3 and 53.8 ± 18.7 cm H_2O, squeeze pressure of 45.1 ± 15.9 and 60.7 ± 17.6 cm H_2O, and endurance of 13.8 ± 2.2 and 14.1 ± 2.5 seconds in vaginal and anorectal squeeze pressure, respectively (unpublished data). We observed even higher anorectal squeeze pressure in a continent male population compared to a continent female population. However, the comparison of a normal valued of anorectal squeeze pressure between female and male subjects may be considerably different due to anatomical differences. Further studies would be required to clarify the difference between sexes. In addition, we will need future studies to determine quantitative data of PFM function in male patients with urinary incontinence.

We conducted Bland-Altman analysis to describe the absolute reliability of measuring anorectal squeeze pressure using manometory between 2 quantitative measurements. Anorectal squeeze pressure and resting pressure in the first session were not significantly associated with those in the second session within each examiner, which suggests there was no proportional error of those parameters. The 95% confidence interval of resting pressure, anorectal squeeze pressure, and endurance contained the null value, indicating the absence of any consistent error. Regarding proportional error, it is considered that the statistical results were substantially affected by the highest outlier of each examiner in the Bland Altman graph, and other plots were obviously arrayed parallel to the mean line. Because of the small number of participants in this study, more participants are required to reach a firm conclusion regarding proportional errors.

There was no significant association between the first and second sessions between examiners, and 95% confidence intervals for resting pressure and anorectal squeeze pressure contained the null value, demonstrating the absence of a systematic error in the inter-rater reliability of each examiner. Minimal detectable change (MDC) was provided for those parameters. Based on the results of MDC, 24.29 cm H_2O for resting pressure and 36.17 cm H_2O for anorectal squeeze pressure were considered within the bounds of measurement deviations. If the values were higher than the MDC, it is considered a true change due to the intervention, which can offer threshold change values to assist decision making in terms of the changing status of male PFM function.

There was a limitation in this study. The highest value of area under curve during PFM voluntary contraction is 9999.0 cm $H_2O{\cdot}s$. Of 21 participants who completed reliability tests, 20 men reached 9999.0 cm $H_2O{\cdot}s$. This means the manometer did not monitor accurate of area under curve values because area under curve values possibly exceeded the maximum limit in most participants.

5 | CONCLUSION

This is the first prospective study indicating the reliability of anorectal squeeze pressure measurements using a manometer in healthy men. Our findings suggest that manometry can provide both reliable and reproducible data regarding PFM function.

ACKNOWLEDGMENTS

The authors express their sincere thanks to all volunteers in this study. Also, the authors are grateful to all members of the Department of Renal and Urogenital Surgery for advice and constructive criticism of this project. This study was supported by the Japan Society for the Promotion of Science KAKENHI Grant Number 18K17648.

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS

MO: Protocol, data collection, management, analysis, and manuscript writing/editing. TK: protocol, project development, data collection, and manuscript writing/editing. TT: protocol, project development, and manuscript writing/editing. HC, MH, and MT: manuscript editing. NS: manuscript editing and project development.

ORCID

Mifuka Ouchi http://orcid.org/0000-0001-9535-1185
Takeya Kitta http://orcid.org/0000-0003-2870-9225
Hiroki Chiba http://orcid.org/0000-0001-7042-8211

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How to cite this article: Ouchi M, Kitta T, Takahashi Y, et al. Reliability of manometry for assessing pelvic floor muscle function in healthy men. *Neurourology and Urodynamics*. 2020;39:1464–1471. https://doi.org/10.1002/nau.24374