The Journal of Sexual Medicine, 2024, **21**, 44–53
https://doi.org/10.1093/jsxmed/qdad133
Advance access publication date 27 November 2023
Original Research

Acceptability, reliability, and validity of a vaginal insert for the self-assessment of endometriosis-associated deep dyspareunia: a cross-sectional study

Rebecca G.K. MacLeod, MMus[1], Gurkiran Parmar, BSc[1], Sandy Zhang, MD[1], Heather Noga, MA[2], Catherine Allaire, MD[1,3], Arianne Albert, PhD[2], Ryan Flannigan, MD[4], Lori A. Brotto, PhD[1,2], Natasha L. Orr, PhD[1], Kate Wahl, MSc[1], Paul J. Yong, MD, PhD[1,2,3,*]

[1]Department of Obstetrics and Gynecology, University of British Columbia, Vancouver, BC, V6Z 2K8, Canada
[2]Women's Health Research Institute, British Columbia Women's Hospital and Health Centre, Vancouver, BC, Canada
[3]British Columbia Women's Centre for Pelvic Pain and Endometriosis, British Columbia Women's Hospital and Health Centre, Vancouver, BC, Canada
[4]Department of Urology, University of British Columbia, Vancouver, BC, V5Z 1M9, Canada

*Corresponding author: University of British Columbia, F2-4500 Oak Street, Vancouver, BC, V6H 3N1. Email: paul.yong@vch.ca

R.G.K.M. and G.P. contributed equally as joint first authors.
N.L.O, K.W., and P.J.Y. contributed equally as joint last authors.

Abstract

Background: Approximately half of people with endometriosis experience deep dyspareunia; however, there is no means of objective self-testing of endometriosis-associated deep dyspareunia.
Aim: The aim of this study was to assess the acceptability, test–retest reliability, and validity of a vaginal insert for a self-assessment of endometriosis-associated deep dyspareunia.
Methods: Participants were recruited from a tertiary endometriosis center. Inclusion criteria were: 19 to 49 years of age, self-reported deep dyspareunia of ≥4 of 10, and surgically confirmed endometriosis. Participants completed 2 self-assessments using the vaginal insert to self-assess tenderness at the right and left pelvic floor, bladder, cervix-uterus, and posterior cul-de-sac (vaginal fornix). The participants recorded tenderness at each pelvic site and completed a questionnaire regarding the acceptability of the vaginal insert to assess deep dyspareunia. Test–retest reliability was assessed by correlating the tenderness scores between the 2 assessment dates. Over a 4-week period, the participants also recorded deep dyspareunia severity at each penetrative vaginal sex encounter. Validity was assessed by correlating vaginal insert tenderness to deep dyspareunia severity, and also to tenderness reported on a prior gynecologic pelvic examination.
Outcomes: The main outcome measures were the acceptability index score, tenderness (0-10) at each pelvic site, and prospective deep dyspareunia scores (0-10) over 4 weeks.
Results: There were 19 participants (mean age 34 ± 7 years) who completed the study. The majority identified as female (94.7%), heterosexual (89.5%), and white (89.5%). The median acceptability index score was 0.72 (interquartile range, 0.66-0.81). For test–retest reliability, the intraclass correlation coefficients were 0.79 ($P = .001$) for the left pelvic floor, 0.82 ($P < .001$) for the right pelvic floor, 0.54 ($P = .07$) for the bladder, 0.89 ($P < .001$) for the cervix-uterus, and 0.77 ($P = .003$) for the cul-de-sac. The correlation between the highest self-assessed mean tenderness in each participant and self-reported deep dyspareunia over 4 weeks was $r = 0.32$, but correlations for each pelvic site varied significantly. Tenderness at each site on prior gynecologist pelvic exam was associated with higher self-assessed mean tenderness with the vaginal insert in each participant (effect sizes = 0.42-0.88).
Clinical Implications: The vaginal insert is acceptable and reliable for the objective self-assessment of endometriosis-associated deep dyspareunia, with initial evidence of validity.
Strengths and Limitations: A strength was the inclusion of participants who were avoiding sexual activity and a limitation was the small sample size.
Conclusion: Future studies with larger sample sizes are required to further establish the validity of the vaginal insert for the self-assessment of endometriosis-associated deep dyspareunia.

Keywords: endometriosis; deep dyspareunia; self-management; gynecological exam.

Introduction

Endometriosis is a common condition defined by the growth of endometrial-like tissue in anatomical areas outside the uterus.[1] This condition affects approximately 10% of assigned female at birth individuals and is characterized by an array of symptoms including pelvic pain, dysmenorrhea, dyspareunia.[1,2] People with endometriosis have 9 times increased risk for dyspareunia compared with the general population.[3] Dyspareunia can be further divided into superficial dyspareunia (pain at the vaginal opening) and deep dyspareunia (pain with deep vaginal penetration).[4] Deep dyspareunia can be directly caused by endometriosis, though up to half of individuals with endometriosis may have both types of dyspareunia (with superficial dyspareunia

Received: March 7, 2023. **Revised:** September 1, 2023. **Accepted:** September 12, 2023

related to other pain mechanisms).[5,6] Deep dyspareunia has a widespread impact on individuals' quality of life, sexual satisfaction, and intimate partner relationships,[7,8] and is a predictor of decreased sexual quality of life.[9-13]

Deep dyspareunia is currently assessed using clinician-performed pelvic examination and questionnaires.[14,15] These assessment modalities have limitations. Some individuals, including those with a history of intimate partner violence and sexual abuse,[16] may find pelvic exams to be uncomfortable, painful, or traumatic.[17,18] Questionnaires are limited by recall bias[19] and are often not applicable to patients who have not recently been sexually active (eg, the Female Sexual Function Index asks, "Over the past 4 weeks, how often did you experience discomfort or pain during vaginal penetration?").[20]

Self-assessment of deep dyspareunia may help address the limitations of clinician examinations and questionnaires. For example, the tampon test is a validated, objective measure of superficial dyspareunia, in which the patient inserts and removes a tampon.[21] These types of self-assessment can integrate principles of trauma-informed gynecologic and pelvic examination, including patient choice in timing of their exam, having a support person present, and self-insertion of instruments.[22] In addition, self-assessment of dyspareunia may have good ecological validity and limit recall bias.

The aim of this study was to assess a vaginal insert used for the self-assessment of deep dyspareunia in subjects with endometriosis, with the hypothesis that the vaginal insert would be an acceptable, reliable, and valid tool.

Methods

Participants

Participants were recruited from the EPPIC (Endometriosis and Pelvic Pain Interdisciplinary Cohort) registry for subjects seen between January 2018 and December 2020 at a tertiary care clinic for endometriosis and pelvic pain in British Columbia. This data registry has previously been described in detail.[23] This study was embedded within a separate pilot randomized controlled trial (NCT04370444).

Inclusion criteria were as follows: (1) 19 to 49 years of age, (2) assigned female at birth, (3) monogamous sexual relationship, (4) sexually active or not currently sexually active due to deep dyspareunia, (5) self-reported deep dyspareunia score $\geq$4 of 10, (6) sexual partner who consents to participate, and (7) willing to engage in penetrative sex at least once during the study period. Exclusion criteria were as follows: (1) superficial dyspareunia score $\geq$4 of 10; (2) severe anxiety or depression symptoms in the last 2 weeks, defined as a General Anxiety Disorder 7[18] or Patient Health Questionnaire-9[19] score $\geq$15; (3) yes to the question, "In the last 2 weeks, have you had intense fear/anxiety in anticipation of, during or as a result of vaginal intercourse?"; (4) current use of a device to reduce depth of penetration; and (5) inability to complete English language questionnaires. The full methodology was previously described in the study protocol.[24]

Procedure

Following informed consent, all participants completed a demographic survey, the Female Sexual Function Index,[20] Female Sexual Distress Score–Revised,[25] the General Anxiety Disorder 7, and the Patient Health Questionnaire-9 for depression.

Participants were then asked to follow instructions detailed in a booklet and use a vaginal insert (Soul Source Rigid Plastic Vaginal Dilator Size #P1) to self-assess tenderness at 5 anatomical pelvic sites using an 11-point numeric rating scale (0-10).[24] Participants began the self-assessment from a home position (insertion of insert as deep as feels comfortable and marker at the 12 o'clock position) and then assessed left pelvic floor (levator ani), right pelvic floor (levator ani), bladder, cervix/uterus, and posterior cul-de-sac (vaginal fornix). Participants also assessed depth of insertion using the number of dots (0-5) visible on the exterior of the insert. Details about using the insert and the complete instruction booklet given to participants can be found in the study protocol.[24]

Tenderness was assessed on 2 separate occasions at an interval of 1 week apart to assess test–retest reliability. Participants completed an 18-item acceptability feedback questionnaire, modified from a questionnaire used for the female condom[26] using a 5-point Likert scale (eg, "how easy was it to follow the instructions?"), as well as 3 open-ended questions (eg, "What did you like about using the purple insert to self-assess your pelvic pain?"). In addition to the vaginal insert, participants were given a diary to prospectively record deep dyspareunia scores (using a 11-point numeric rating scale) at each sexual encounter over the course of the subsequent 4 weeks. The instructional booklet, acceptability questionnaire, and the diary to record deep dyspareunia scores are included in the study protocol.[24] We also obtained data from the prior gynecologist pelvic exam (at entry into the EPPIC registry) for tenderness at each anatomic site.

Analysis

Demographic characteristics of the sample are reported as mean $\pm$ SD or proportions.

Acceptability of the vaginal insert was assessed by calculating a median acceptability index score, such that each close-ended item in the feedback questionnaire was assigned a rank (1-5, from least to most favorable), then all responses were added and divided by the total possible score of 75, for a proportion from 0 (least favorable) to 1.00 (most favorable). Responses to the open-ended items were grouped using qualitative description.[27]

Test–retest reliability was evaluated by calculating the intraclass correlation coefficient between the tenderness scores (0-10) at the first and second assessment with the vaginal insert for each pelvic site.

We then conducted analyses in which self-assessed tenderness level (0-10) with the vaginal insert was averaged between the first and second assessments for each subject. We assessed for validity in 2 ways. First, we correlated the mean self-assessed tenderness level at each pelvic site (0-10) with the subject's mean self-report of deep dyspareunia (0-10) over the subsequent 4 weeks recorded in the daily diary (Spearman's correlation). We also correlated the highest mean self-assessed tenderness level across anatomic sites in each participant (0-10) with the participant's mean self-report of deep dyspareunia (0-10) over the subsequent 4 weeks (Spearman's correlation). Second, we studied the association between the mean self-assessed tenderness level at each anatomic site (0-10) with the tenderness (yes/no) on the prior gynecologist pelvic exam at baseline entry into the EPPIC registry (ie, before recruitment into this trial).

To maximize all of the available data, we conducted pairwise deletion of select cases within each variable that had missing data on an analysis-by-analysis basis.

Ethics

The research presented in this study was approved by the Children's and Women's Research Ethics Board of the University of British Columbia (H19-00294).

Results

Study cohort

There were 31 participants recruited from an original potential pool of 1003 from the EPPIC registry that consented to participate in the pilot randomized controlled trial (Supplementary Figure 1), of which 19 participants completed this study. The demographic characteristics of the sample that completed the study can be found in Table 1. The mean age of the sample was 34 years and the majority identified as female (94.7%), heterosexual (89.5%), and white (89.5%).

Acceptability

The results from the acceptability questionnaire are shown in Table 2. Out of the 19 participants, 18 completed the acceptability questionnaire. The median acceptability index score was 0.72 (interquartile range, 0.66-0.81). The majority of participants found it very easy to follow the instructions of the vaginal insert (66.7%) as well as to insert (55.6%) and remove (88.9%) the vaginal insert. When asked about the overall comfort level during the entire process of using the vaginal insert, 50.0% reported the process being somewhat or very comfortable, 33.3% reported the process being uncomfortable, and 16.7% were neutral. There were mixed responses when participants were asked about ability to self-assess pain at home or whether they preferred self-assessment vs clinician examination (Table 2).

There were 3 open-ended questions in the acceptability questionnaire. The full list of responses for these questions can be found in Supplementary Table 1. First, we asked participants what they liked about the vaginal insert to self-assess deep dyspareunia. Common responses were similar to that of participant 10, and included that the vaginal insert provided the participants the convenience of assessing deep dyspareunia at the time of their choosing, of completing the assessment at their own pace and with the privacy and comfort of their own home.

Participant 10: "I was able to do it on my own time and at certain dates after my menstrual period as my dr [sic] appointments don't always line up."

Second, we asked participants what they disliked about the vaginal insert to self-assess deep dyspareunia. Although 50% of participants reported being confident that they completed the assessment correctly (Table 2), in the open-ended responses 8 (44.0%) participants reported being uncertain. Some questioned if they used the correct depth and pressure during the self-assessment, especially if they were anticipating pain.

Table 1. Demographic characteristics of the sample (N = 19).

Age, y	34 ± 7
Sex category	
Female	18 (94.7)
Nonbinary/genderqueer	1 (5.3)
Sexual orientation	
Heterosexual	17 (89.5)
Bisexual	2 (10.5)
Race	
White	17 (89.5)
Mixed race	2 (10.5)
Highest level of education	
High school (completed grade 12)	2 (10.5)
2-y college or university program	5 (26.3)
4-y college or university program (including professional degrees)	8 (42.1)
Graduate program	4 (21.1)
Relationship status	
Dating	3 (15.8)
Common law	8 (42.1)
Married	8 (42.1)
Length of current relationship	
Not in a relationship	1 (5.3)
Between 2 and 5 mo	2 (10.5)
Between 6 and 12 mo	2 (10.5)
Between 1 and 2 y	1 (5.3)
Between 3 and 5 y	5 (26.3)
More than 5 y	8 (42.1)
Most recent engagement in penetrative vaginal sex	
Within the last week	14 (73.7)
Within the last 3 mo	3 (15.8)
Within the last year	2 (10.5)
Mean number of times the participant engaged in penetrative vaginal sex in the past month	5.5 ± 4.5
Mean deep penetrative pain score during sexual activity in the 3 mo prior to most recent clinical assessment	6.5 ± 2.4
Mean deep dyspareunia score over the 4-wk period of this study	4.9 ± 1.9

Values are mean ± SD or n (%).

Table 2. Participant perspectives on the use of the vaginal insert (n = 18).

Variable[a]	Very difficult	Somewhat difficult	Neutral	Somewhat easy	Very easy
Difficulty level of following instructions	0 (0)	0 (0)	0 (0)	6 (33.3)	12 (66.7)
Difficulty level of handling the vaginal insert	0 (0)	0 (0)	2 (11.1)	6 (33.3)	10 (55.6)
Difficulty level of inserting vaginal insert into vagina	0 (0)	2 (11.1)	2 (11.1)	4 (22.2)	10 (55.6)
Difficulty level of moving the vaginal insert after applying lubricant	0 (0)	2 (11.1)	0 (0)	7 (38.9)	9 (50.0)
Difficulty level in removing the vaginal insert	0 (0)	0 (0)	2 (11.1)	0 (0)	16 (88.9)
	Very uncomfortable	**Somewhat uncomfortable**	**Neutral**	**Somewhat comfortable**	**Very comfortable**
Comfort level during the insertion of the vaginal insert	0 (0)	9 (50.0)	1 (5.6)	5 (27.8)	3 (16.7)
Feel of the lubricant during insertion	0 (0)	1 (5.6)	4 (22.2)	7 (38.9)	6 (33.3)
Feel of the material of the vaginal insert	0 (0)	2 (11.1)	4 (22.2)	8 (44.4)	4 (22.2)
Overall comfort level during the entire process of using the vaginal insert	0 (0)	6 (33.3)	3 (16.7)	7 (38.9)	2 (11.1)
	Too short	**Somewhat short**	**Neutral**	**Somewhat long**	**Too long**
Length of the vaginal insert	0 (0)	1 (5.6)	7 (38.9)	9 (50.0)	1 (5.6)
	Too narrow	**Somewhat narrow**	**Neutral**	**Somewhat wide**	**Too wide**
Width of the vaginal insert	0 (0)	4 (22.2)	14 (77.8)	0 (0)	0 (0)
	Much better in the clinic	**Somewhat better in the clinic**	**Neutral**	**Somewhat better at home**	**Much better at home**
Ability to self-assess pelvic pain at home compared with in the clinic	2 (11.1)	5 (27.8)	4 (22.2)	5 (27.8)	2 (11.1)
	Strongly prefer the clinician	**Somewhat prefer the clinician**	**Neutral**	**Somewhat prefer myself**	**Strongly prefer myself**
How the participant felt after performing the assessment compared with having it done by the clinician	3 (16.7)	4 (22.2)	5 (27.8)	5 (27.8)	1 (5.6)
	Very not confident	**Somewhat not confident**	**Neutral**	**Somewhat confident**	**Very confident**
Confidence in having correctly performed the self-assessment	1 (5.6)	6 (33.3)	1 (5.6)	10 (55.6)	0 (0)
	Definitely choose clinician	**Probably choose clinician**	**Neutral**	**Probably choose to do it myself**	**Definitely choose to do it myself**
If self-assessment of pelvic pain was an option, would the participant rather use the vaginal insert to self-assess pain or would the participant rather have it done in the clinic by a clinician	2 (11.1)	8 (44.4)	3 (16.7)	5 (27.8)	0 (0)
	Very difficult	**Somewhat difficult**	**Neutral**	**Somewhat easy**	**Very easy**
Difficulty level of following instructions	0 (0)	0 (0)	0 (0)	6 (33.3)	12 (66.7)
Difficulty level of handling the vaginal insert	0 (0)	0 (0)	2 (11.1)	6 (33.3)	10 (55.6)
Difficulty level of inserting vaginal insert into vagina	0 (0)	2 (11.1)	2 (11.1)	4 (22.2)	10 (55.6)
Difficulty level of moving the vaginal insert after applying lubricant	0 (0)	2 (11.1)	0 (0)	7 (38.9)	9 (50.0)
Difficulty level in removing the vaginal insert	0 (0)	0 (0)	2 (11.1)	0 (0)	16 (88.9)
	Very uncomfortable	**Somewhat uncomfortable**	**Neutral**	**Somewhat comfortable**	**Very comfortable**
Comfort level during the insertion of the vaginal insert	0 (0)	9 (50.0)	1 (5.6)	5 (27.8)	3 (16.7)
Feel of the lubricant during insertion	0 (0)	1 (5.6)	4 (22.2)	7 (38.9)	6 (33.3)
Feel of the material of the vaginal insert	0 (0)	2 (11.1)	4 (22.2)	8 (44.4)	4 (22.2)

(*Continued*)

Table 2. Continued.

Overall comfort level during the entire process of using the vaginal insert	0 (0)	6 (33.3)	3 (16.7)	7 (38.9)	2 (11.1)
	Too short	**Somewhat short**	**Neutral**	**Somewhat long**	**Too long**
Length of the vaginal insert	0 (0)	1 (5.6)	7 (38.9)	9 (50.0)	1 (5.6)
	Too narrow	**Somewhat narrow**	**Neutral**	**Somewhat wide**	**Too wide**
Width of the vaginal insert	0 (0)	4 (22.2)	14 (77.8)	0 (0)	0 (0)
	Much better in the clinic	**Somewhat better in the clinic**	**Neutral**	**Somewhat better at home**	**Much better at home**
Ability to self-assess pelvic pain at home compared with in the clinic	2 (11.1)	5 (27.8)	4 (22.2)	5 (27.8)	2 (11.1)
	Strongly prefer the clinician	**Somewhat prefer the clinician**	**Neutral**	**Somewhat prefer myself**	**Strongly prefer myself**
How the participant felt after performing the assessment compared with having it done by the clinician	3 (16.7)	4 (22.2)	5 (27.8)	5 (27.8)	1 (5.6)
	Very not confident	**Somewhat not confident**	**Neutral**	**Somewhat confident**	**Very confident**
Confidence in having correctly performed the self-assessment	1 (5.6)	6 (33.3)	1 (5.6)	10 (55.6)	0 (0)
	Definitely choose clinician	**Probably choose clinician**	**Neutral**	**Probably choose to do it myself**	**Definitely choose to do it myself**
If self-assessment of pelvic pain was an option, would the participant rather use the vaginal insert to self-assess pain or would the participant rather have it done in the clinic by a clinician	2 (11.1)	8 (44.4)	3 (16.7)	5 (27.8)	0 (0)
	Very difficult	**Somewhat difficult**	**Neutral**	**Somewhat easy**	**Very easy**
Difficulty level of following instructions	0 (0)	0 (0)	0 (0)	6 (33.3)	12 (66.7)
Difficulty level of handling the vaginal insert	0 (0)	0 (0)	2 (11.1)	6 (33.3)	10 (55.6)
Difficulty level of inserting vaginal insert into vagina	0 (0)	2 (11.1)	2 (11.1)	4 (22.2)	10 (55.6)
Difficulty level of moving the vaginal insert after applying lubricant	0 (0)	2 (11.1)	0 (0)	7 (38.9)	9 (50.0)
Difficulty level in removing the vaginal insert	0 (0)	0 (0)	2 (11.1)	0 (0)	16 (88.9)
	Very uncomfortable	**Somewhat uncomfortable**	**Neutral**	**Somewhat comfortable**	**Very comfortable**
Comfort level during the insertion of the vaginal insert	0 (0)	9 (50.0)	1 (5.6)	5 (27.8)	3 (16.7)
Feel of the lubricant during insertion	0 (0)	1 (5.6)	4 (22.2)	7 (38.9)	6 (33.3)
Feel of the material of the vaginal insert	0 (0)	2 (11.1)	4 (22.2)	8 (44.4)	4 (22.2)
Overall comfort level during the entire process of using the vaginal insert	0 (0)	6 (33.3)	3 (16.7)	7 (38.9)	2 (11.1)
	Too short	**Somewhat short**	**Neutral**	**Somewhat long**	**Too long**
Length of the vaginal insert	0 (0)	1 (5.6)	7 (38.9)	9 (50.0)	1 (5.6)
	Too narrow	**Somewhat narrow**	**Neutral**	**Somewhat wide**	**Too wide**
Width of the vaginal insert	0 (0)	4 (22.2)	14 (77.8)	0 (0)	0 (0)
	Much better in the clinic	**Somewhat better in the clinic**	**Neutral**	**Somewhat better at home**	**Much better at home**
Ability to self-assess pelvic pain at home compared with in the clinic	2 (11.1)	5 (27.8)	4 (22.2)	5 (27.8)	2 (11.1)

(*Continued*)

Table 2. Continued.

	Strongly prefer the clinician	**Somewhat prefer the clinician**	**Neutral**	**Somewhat prefer myself**	**Strongly prefer myself**
How the participant felt after performing the assessment compared with having it done by the clinician	3 (16.7)	4 (22.2)	5 (27.8)	5 (27.8)	1 (5.6)
	Very not confident	**Somewhat not confident**	**Neutral**	**Somewhat confident**	**Very confident**
Confidence in having correctly performed the self-assessment	1 (5.6)	6 (33.3)	1 (5.6)	10 (55.6)	0 (0)
	Definitely choose clinician	**Probably choose clinician**	**Neutral**	**Probably choose to do it myself**	**Definitely choose to do it myself**
If self-assessment of pelvic pain was an option, would the participant rather use the vaginal insert to self-assess pain or would the participant rather have it done in the clinic by a clinician	2 (11.1)	8 (44.4)	3 (16.7)	5 (27.8)	0 (0)

Values are n (%). The acceptability index score was median 0.72 (interquartile range, 0.66-0.81).

Table 3. Test–retest reliability between the first and second assessments.

Anatomic site	**Total**	**Intraclass correlation coefficient**	***P* value**
Left pelvic floor	18 (94.7)	0.79	.001
Right pelvic floor	18 (94.7)	0.82	<.001
Bladder	17 (89.5)	0.54	.07
Cervix-uterus	18 (94.7)	0.89	<.001
Cul-de-sac	17 (89.5)	0.77	.003

Values are n (%).

Participant 16: "I wasn't always sure I was inserting it far enough or if the pressure I was using was right."

Participant 19: "The only concern I have is that because it can be painful I might have not pushed as hard as a clinician would have, some people might be more weary due to pain and not fully assess properly, but I think I did it to best to my ability knowing it would hurt in some spots."

Third, we asked participants what they would change about using the vaginal insert to self-assess deep dyspareunia. Among the responses, there were 8 (44.0%) participants that would not change anything about the vaginal insert. There was one participant who asked for more instructions on what depth and pressure to use. Another participant mentioned that it would be helpful to have a clinician assist them in finding the different pelvic sites correctly for future use.

Participant 16: "Maybe a bit more instructions about how far and how much pressure to use."

Participant 6: "It would be helpful to do the first one at a clinic to have assistance in finding the right areas to know where to go for the next time."

Test–retest reliability

There were 19 participants that completed the first assessment and 18 participants that completed the second assessment. Individual self-assessment results of tenderness are detailed in Supplementary Table 2 and the median number of visible dots on the vaginal insert at each pelvic site are reported in Supplementary Table 3.

Test–retest reliability was demonstrated by intraclass correlation coefficients for tenderness level (0-10) between the first and second assessments, ranging from 0.54 for the bladder to 0.89 for the cervix-uterus (Table 3). Moreover, there were no systematic differences in the tenderness levels between the first and second assessments (Figure 1), whether as a score of 0 to 10 or when binarized into tenderness yes/no (Supplementary Table 4).

Validity

For each subject, the tenderness level between the 2 self-assessments were averaged for each pelvic anatomic site. Moderate correlations were observed between mean tenderness level at one pelvic site and mean tenderness levels at other pelvic sites in each subject (Supplementary Table 5).

Table 4 shows the correlations between the mean tenderness level at each pelvic site and mean self-reported deep dyspareunia scores prospectively reported over the subsequent 4 weeks. The highest level of tenderness for each participant (across the 5 pelvic anatomic sites) showed a correlation of 0.32 for prospectively self-reported deep dyspareunia scores (Table 4). Correlations for each anatomic site varied significantly, with the highest correlation of 0.35 for the cervix-uterus (Table 4).

We also explored the comparison between mean tenderness levels at each site, in comparison with the previous gynecologist pelvic examination (tenderness yes/no) at entry into the EPPIC registry (Table 5; Supplementary Figure 2). When tenderness had been previously identified at an anatomic site by the gynecologist pelvic exam, there was higher mean tenderness with self-assessment with the insert (effect sizes = 0.42-0.88), although none reached statistical significance.

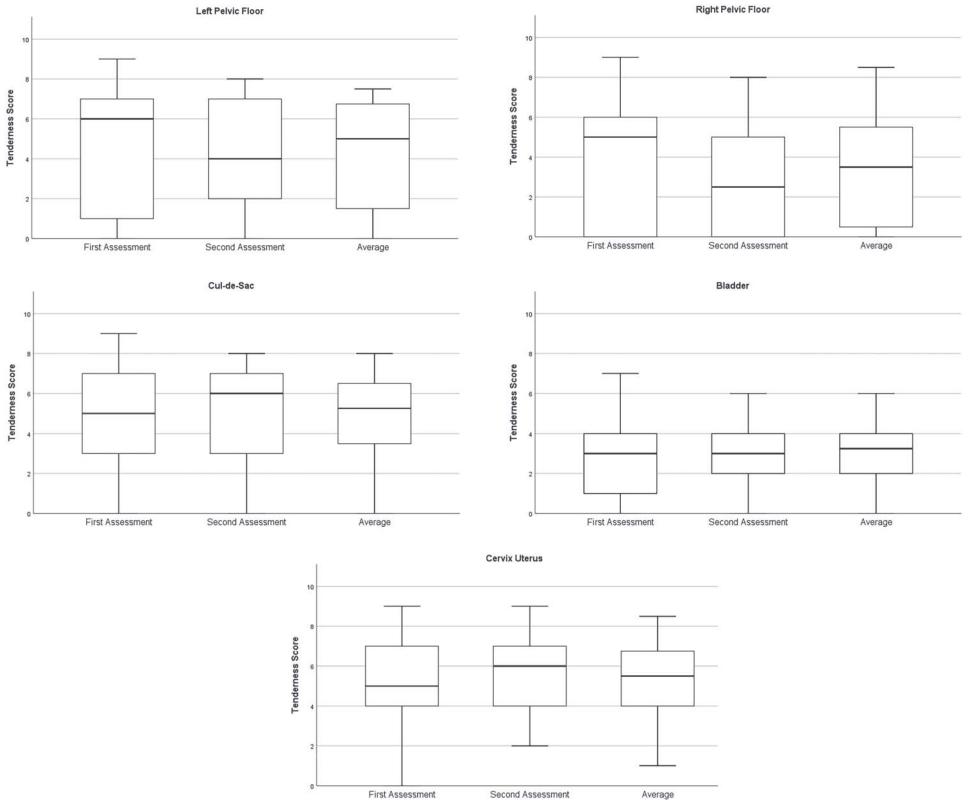

Figure 1. Distribution of tenderness scores at each pelvic site from the first assessment and second assessment and the average scores between the 2 assessments. The bars indicate the range of scores, the box indicates the interquartile range, and the black line indicates the median score.There were no differences in tenderness scores between the two assessments at each site (Wilcoxon Signed Rank test).

Table 4. Spearman's rank correlation test results between mean self-reported deep dyspareunia scores and the mean self-assessed tenderness scores at each anatomic location.

Anatomic site	Total	Correlation (Spearman ρ)	*P* value
Left pelvic floor	19 (100)	0.17	.49
Right pelvic floor	19 (100)	0.13	.59
Cul-de-sac	19 (100)	−0.07	.79
Bladder	18 (94.7)	−0.14	.58
Cervix-uterus	18 (94.7)	0.35	.14
Highest tenderness score across the 5 anatomic sites	19 (100)	0.32	.18

Values are n (%).

Table 5. Mean self-assessed tenderness scores in participants with and without tenderness on the prior gynecologist pelvic examination.

	Tenderness at prior gynecologist pelvic exam		Effect size	*P* value
	Yes	No		
Left pelvic floor	5.17 ± 2.16 (6)	3.92 ± 2.97 (13)	0.45	.37
Right pelvic floor	5.10 ± 3.15 (5)	2.82 ± 2.41 (14)	0.88	.11
Cul-de-sac	5.80 ± 2.17 (5)	4.62 ± 2.21 (13)	0.54	.32
Bladder[a]	—	—	—	—
Cervix	5.92 ± 1.32 (6)	5.12 ± 2.13 (13)	0.42	.41

Values are mean ± SD (n). [a]Comparison could not be done, as only 1 subject had bladder tenderness on the gynecologist exam

Discussion

We conducted a study to investigate the acceptability, test–retest reliability, and validity of a vaginal insert for an at-home self-assessment of deep dyspareunia in individuals with endometriosis. Overall, participants found the vaginal insert to be acceptable. As well, the vaginal insert tenderness levels were found to have strong test–retest reliability between the two assessment time points. Initial evidence for validity was obtained by comparing self-assessment tenderness with prospective deep dyspareunia scores and the prior gynecologist pelvic exam.

Notably, the acceptability index of the insert (0.72) was similar to that of 2 types of female condoms, latex (acceptability index: 1 – 0.37 = 0.63) and polyurethane (acceptability index: 1 – 0.40 = 0.60),[26] in which a higher index indicates greater acceptability. Participants described benefits of

self-assessment including privacy and autonomy, but many were concerned about the accuracy of this approach and preferred clinician assessment. This is consistent with a 2017 systematic review and meta-analysis of self-sampled human papillomavirus (HPV) screening studies that demonstrated good acceptability of self-sampling across 37 studies.[28] Another study of 45 individuals found that self-administration of an intravaginal gel for pelvic magnetic resonance imaging was acceptable to study participants.[29] The most common reasons for liking self-sampling techniques were increased ease and increased privacy. The authors found that the most common reason for disliking self-sampling was the uncertainty of collecting correctly.[28] Open-ended feedback in our study demonstrated similar findings, in which participants expressed that they liked the increased privacy and ease of scheduling the self-assessment on their own time.

Despite the acceptability of the vaginal insert, just over half of the participants in our study preferred to have their pain assessed by a clinician. A potential explanation is that there was no in-person demonstration of use of the insert, as the trial was completed during the COVID pandemic; instead, participants received instructions in a study handbook. A similar preference for clinician exam was identified in one study of tampon self-collection test for high-risk HPV, which suggested that the most preferred option may be self-collection under clinical guidance. The study found that 55% of participants preferred clinician collection; however, 82% were willing to perform the tampon collection at home, but 65% preferred this self-collection in clinic when given this option.[30] The reason participants preferred clinician assessment to self-assessment was related to concern with accuracy. In the systematic review and meta-analysis, the authors found that the most common reason for disliking self-sampling was the uncertainty of collecting correctly.[28] Given existing evidence showing increased acceptability of self-assessment under physician supervision,[30] this could provide an alternative option for the patient to have increased autonomy and privacy, while allowing for more confidence in accuracy. Alternatively, an initial demonstration could be done with the clinician, before patients perform self-assessment at home. A demonstration would provide insight into understanding any barriers or concerns to patients, as well provides the opportunity to offer reassurance and knowledge correction to empower them to do the self-assessments at home. Supporting patients to self-assess deep dyspareunia under the guidance of a clinician or at home following a clinician demonstration may be particularly important when seeking to increase patient control, choice, and dignity as part of trauma-informed gynecologic care.[22] For a future study, it would be important to consider an in-person demonstration by a clinician as it may address some of the participants' concerns about accuracy, while maintaining the trauma-informed aspects of self-assessment.

Our results suggested that the vaginal insert may have similar psychometric properties to the tampon test, which the objective self-assessment used to evaluate superficial dyspareunia. In terms of test–retest reliability, we observed intraclass correlation coefficients ranging from 0.54 to 0.89 for each anatomic site between the first and second assessment with the vaginal insert. Moreover, there were no differences in tenderness level between the two assessments. This supports the reliability of self-assessment with a vaginal insert for pain with deep insertion/penetration. The test–retest reliability of the vaginal insert is also comparable to the intraclass correlation coefficient for the tampon test for superficial dyspareunia due to provoked vestibulodynia was 0.74.[21] In terms of validity, the maximum self-assessed tenderness with the vaginal insert for each participant had a correlation of 0.32 for prospectively recorded self-reported deep dyspareunia, whereas correlations of 0.35 were reported for pain with tampon insertion and intercourse pain.[21] It should be noted that in our results, there was significant variability in this correlation with deep dyspareunia when individual anatomic sites were studied, which is likely related to the complexity of deep dyspareunia. For example, a patient with 10 of 10 reported deep dyspareunia, could have 10 of 10 tenderness at the cul-de-sac and 0 of 10 tenderness at the pelvic floor, resulting in a strong correlation of deep dyspareunia with cul-de-sac tenderness but no correlation with pelvic floor tenderness. For this reason, we utilized the highest level of self-assessed tenderness across anatomic sites in each subject.

The primary limitation of our study was the sample size, which affected the representativeness of our sample as well as our ability to detect statistically significant associations and control for additional variables (eg, depth of insertion). Recruitment and retention of participants was affected by our strict mental health exclusion criteria, which we put in place to maximize participant safety, as well as additional eligibility criteria related to the randomized controlled trial in which this study was embedded (eg, monogamous sexual relationship, sexual partner who consents to participate). Additionally, the relationship between self-assessed level of tenderness and the presence/absence of tenderness at the prior pelvic exam was likely attenuated by the duration of time between the two events (which could be on the order of months/years). A more ideal comparison would be if the gynecologist performed palpation of the pelvic structures with the vaginal insert in the clinic, immediately followed by the patient performing the self-assessment with the insert. This protocol would also provide the opportunity to help guide the patient on the technique for self-assessment, which was identified as a patient need in the qualitative data.

Among the strengths of this study was inclusion of participants who were currently avoiding sexual activity due to severity of deep dyspareunia, which serves to reduce bias and to include those who may be most in need of this type of intervention.[4] We also repeated the vaginal insert over 2 occasions for test–retest reliability and utilized prospective deep dyspareunia scores for the initial evaluation of validity.

Our findings have clinical and research implications. Clinically, self-assessment of deep dyspareunia may present an opportunity to integrate trauma-informed principles (ie, patient choice in timing of their exam, having a support person present, self-insertion of instruments) into the assessment of this symptom. Compared with clinical examination, self-assessment may also allow for more frequent assessment (eg, to monitor progression, response to treatment). Compared with questionnaires used in clinical practice and research, self-assessment may have greater ecological validity, may be less susceptible to recall bias, and can be used by patients who are not currently sexually active.

Conclusion

This study found that a vaginal insert for self-assessment of deep dyspareunia in individuals with endometriosis was

acceptable to use and demonstrated good test–retest reliability. Future research with larger samples is required to further evaluate validity. This research is important to expand the clinical and research tools for deep dyspareunia and to provide a trauma-informed self-assessment option for people with endometriosis.

Author contributions

R.G.K.M. (Data curation-Equal, Investigation-Equal, Project administration-Equal, Writing – original draft-Lead, Writing – review & editing-Equal), G.P. (Data curation-Equal, Formal analysis-Lead, Investigation-Equal, Project administration-Equal, Visualization-Lead, Writing – original draft-Lead, Writing – review & editing-Equal), S.W. (Data curation-Equal, Investigation-Equal, Project administration-Equal, Writing – review & editing-Equal), H.N. (Data curation-Equal, Writing – review & editing-Equal), C.A. (Methodology-Supporting, Writing – review & editing-Supporting), A.A. (Formal analysis-Supporting, Methodology-Supporting, Writing – review & editing-Supporting), R.F. (Methodology-Supporting, Writing – review & editing-Supporting), L.A.B. (Methodology-Supporting, Writing – review & editing-Equal), N.L.O. (Conceptualization-Equal, Funding acquisition-Equal, Investigation-Equal, Methodology-Equal, Project administration-Equal, Resources-Equal, Software-Equal, Supervision-Equal, Validation-Equal, Visualization-Equal, Writing – review & editing-Equal), K.J.W. (Conceptualization-Equal, Funding acquisition-Equal, Investigation-Equal, Methodology-Equal, Resources-Equal, Software-Equal, Supervision-Equal, Validation-Equal, Visualization-Equal, Writing – review & editing-Equal), P.J.Y. (Conceptualization-Equal, Methodology-Equal, Supervision-Equal, Writing – review & editing-Equal).

Supplementary material

Supplementary material is available at *The Journal of Sexual Medicine* online.

Funding

This research was funded by a Scholars in Women's Sexual Health Research Grant from the International Society for the Study of Women's Sexual Health.

Conflict of interest

None declared.

References

1. Giudice LC, Kao LC. Endometriosis. *Lancet*. 2004;**364**(9447):1789–1799.
2. Howard FM. Endometriosis and mechanisms of pelvic pain. *J Minim Invasive Gynecol*. 2009;**16**(5):540–550.
3. Vercellini P, Meana M, Hummelshoj L, Somigliana E, Viganò P, Fedele L. Priorities for endometriosis research: a proposed focus on deep dyspareunia. *Reprod Sci*. 2011;**18**(2):114–118.
4. Orr N, Wahl K, Joannou A, *et al*. Deep dyspareunia: review of pathophysiology and proposed future research priorities. *Sex Med Rev*. 2020;**8**(1):3–17.
5. Ferrero S, Esposito F, Abbamonte LH, Anserini P, Remorgida V, Ragni N. Quality of sex life in women with endometriosis and deep dyspareunia. *Fertil Steril*. 2005;**83**(3):573–579.
6. Yong PJ. Deep dyspareunia in endometriosis: a proposed framework based on pain mechanisms and genito-pelvic pain penetration disorder. *Sex Med Rev*. 2017;**5**(4):495–507.
7. Fritzer N, Haas D, Oppelt P, *et al*. More than just bad sex: sexual dysfunction and distress in patients with endometriosis. *Eur J Obstet Gynecol Reprod Biol*. 2013;**169**(2):392–396.
8. Jones G, Kennedy S, Barnard A, Wong J, Jenkinson C. Development of an endometriosis quality-of-life instrument: the Endometriosis Health Profile-30. *Obstet Gynecol*. 2001;**98**(2):258–264.
9. van Poll M, van Barneveld E, Aerts L, *et al*. Endometriosis and sexual quality of life. *Sex Med*. 2020;**8**(3):532–544.
10. Yang X, Xu X, Lin L, *et al*. Sexual function in patients with endometriosis: a prospective case-control study in China. *J Int Med Res*. 2021;**49**(4):030006052110043.
11. Pluchino N, Wenger JM, Petignat P, *et al*. Sexual function in endometriosis patients and their partners: effect of the disease and consequences of treatment. *Hum Reprod Update*. 2016;**22**(6):762–774.
12. Shi C, Xu H, Zhang T, Gao Y. Endometriosis decreases female sexual function and increases pain severity: a meta-analysis. *Arch Gynecol Obstet*. 2023;**307**(1):195–204.
13. Pérez-López FR, Ornat L, Pérez-Roncero GR, López-Baena MT, Sánchez-Prieto M, Chedraui P. The effect of endometriosis on sexual function as assessed with the female sexual function index: systematic review and meta-analysis. *Gynecol Endocrinol*. 2020;**36**(11):1015–1023.
14. Alimi Y, Iwanaga J, Oskouian RJ, Loukas M, Tubbs RS. The clinical anatomy of dyspareunia: a review. *Clin Anat*. 2018;**31**(7):1013–1017.
15. Seehusen DA, Baird DC, Bode DV. Dyspareunia in women. *Am Fam Physician*. 2014;**90**(7):465–470.
16. Weitlauf JC, Finney JW, Ruzek JI, *et al*. Distress and pain during pelvic examinations: effect of sexual violence. *Obstet Gynecol*. 2008;**112**(6):1343–1350.
17. Leeners B, Stiller R, Block E, Görres G, Imthurn B, Rath W. Effect of childhood sexual abuse on Gynecologic care as an adult. *Psychosomatics*. 2007;**48**(5):385–393.
18. Ackerson K. A history of interpersonal trauma and the gynecological exam. *Qual Health Res*. 2012;**22**(5):679–688.
19. Schmier JK, Halpern MT. Patient recall and recall bias of health state and health status. *Expert Rev Pharmacoecon Outcomes Res*. 2004;**4**(2):159–163.
20. Rosen R, Brown C, Heiman J, *et al*. The Female Sexual Function Index (FSFI): a multidimensional self-report instrument for the assessment of female sexual function. *J Sex Marital Ther*. 2000;**26**(2):191–208.
21. Foster DC, Kotok MB, Huang LS, *et al*. The tampon test for vulvodynia treatment outcomes research: reliability, construct validity, and responsiveness. *Obstet Gynecol*. 2009;**113**(4):825–832.
22. Gorfinkel I, Perlow E, Macdonald S. The trauma-informed genital and gynecologic examination. *CMAJ*. 2021;**193**(28):E1090.
23. Yosef A, Allaire C, Williams C, *et al*. Multifactorial contributors to the severity of chronic pelvic pain in women. *Am J Obstet Gynecol*. 2016;**215**(6):760.e1–760.e14.
24. Zhang SXJ, MacLeod R, Parmar G, *et al*. Ohnut vs. waitlist control for the self-management of endometriosis-associated deep dyspareunia: a pilot randomized controlled trial protocol. *JMIR Res Protoc*. 2023;**12**:e39834.
25. Derogatis L, Clayton A, Lewis-D'Agostino D, Wunderlich G, Fu Y. Validation of the female sexual distress scale-revised for assessing distress in women with hypoactive sexual desire disorder. *J Sex Med*. 2008;**5**(2):357–364.

26. Latka M, Joanis C, Glover L. Acceptability of the reality female condom and a latex prototype. *J Urban Health Bull N Y Acad Med*. 2001;**78**(4):614–626.
27. Sandelowski M. Whatever happened to qualitative description? *Res Nurs Health*. 2000;**23**(4):334–340.
28. Nelson EJ, Maynard BR, Loux T, Fatla J, Gordon R, Arnold LD. The acceptability of self-sampled screening for HPV DNA: a systematic review and meta-analysis. *Sex Transm Infect*. 2017;**93**(1):56–61.
29. Hughes NJ, Kalkur S, Zhang J, Liyanage SH. Patient acceptability and quality of self-administered intravaginal gel for pelvic MRI. *J Endometr Pelvic Pain Disord*. 2022;**14**(1):6–13.
30. Adamson PC, Huchko MJ, Moss AM, Kinkel HF, Medina-Marino A. Acceptability and accuracy of cervical Cancer screening using a self-collected tampon for HPV messenger-RNA testing among HIV-infected women in South Africa. *PLoS One*. 2015;**10**(9):e0137299.