

# Validity & Reliability of Vlosum (Het's Device - to Instantly Test Vaginal Opening) Test the Vaginal Opening

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## ABSTRACT

Spasmodic pelvic floor muscles can occur due to multiple reasons like stress, anxiety, recurrent urinary tract infection. The pelvic floor dysfunctions due to hypertonus pelvic floor muscles can be Vaginismus, dyspareunia, chronic pelvic pain, urinary symptoms like dysuria, incomplete voiding, lower abdominal pain associated with bladder filling, hypertonic pelvic floor muscles can also lead to issues with constipation, pelvic dyssynergia etc. The prevalence of Vaginismus and dyspareunia is very high. Yet there is no single tool which is designed to assess the pelvic floor relaxation ability. Vlosum is the world's first device which can test and improve vaginal opening (through relaxation of pelvic floor muscles). The outcome measure taken are FSFI – Female Sexual Function Index, NPRS – Numeric Pain Rating Scale, self-reported question for anxiety about first time penetration and Vlosum. The study duration was of 18 months and 1184 women were evaluated. The participants were divided into 3 groups Group A – Vaginismus, Group B – Dyspareunia and Group C – Anxiety of first-time penetration. The data of all the outcome measure were analyzed. It can be

concluded that Vlosum is a reliable and valid tool to test vaginal opening.

**Keywords:** Vaginismus, Dyspareunia, First-time Anxiety, Vlosum

## INTRODUCTION

Spasmodic pelvic floor muscles can occur due to multiple reasons like stress, anxiety, recurrent urinary tract infection. The dysfunction due to hypertonus pelvic floor muscles can be Vaginismus, dyspareunia, chronic pelvic pain, urinary symptoms like dysuria, incomplete voiding, lower abdominal pain associated with bladder filling, hypertonic pelvic floor muscles can also lead to issues with constipation, pelvic dyssynergia etc.

Pelvic muscles are commonly known as vaginal muscles also. There are very scanty evidences and research studies done for the causes and management of spasmodic or hypertonic pelvic floor (vaginal muscles).

Vaginismus is the functional spasm of the outer one third of the vaginal orifice. The outer one third of the vaginal orifice are guarded by pelvic floor muscles. Female

with Vaginismus has severe pain while inserting anything inside the vagina. It can be a sexual penetration while having a sexual activity or sexual intercourse or it can be a non-sexual penetration like inserting tampon or menstrual cup. Vaginismus can be primary Vaginismus in which from the very beginning the female is unable to penetrate anything inside the vagina. Or it can be secondary Vaginismus in which earlier the female had a pain free vaginal penetration but after a particular incidence or surgery or trauma or some pathology she develops Vaginismus. Many mothers as well as postmenopausal female also presents with Vaginismus the cause being scar tissue formed as a result of episiotomy or perineal tear during vaginal delivery or hormonal imbalance and dryness of vagina.

Many young females, who never had a vaginal penetration earlier can have apprehension related to vaginal penetration, which causes anticipatory spasm of pelvic floor muscles that lead to sexual dysfunction, like Vaginismus.

Dyspareunia is a term used to describe painful sexual intercourse. Females with dyspareunia finds it very difficult to relax and let the vaginal penetration happen. There is a vaginal penetration possible but it is with severe pain and discomfort.

Dyspareunia can be superficial or deep dyspareunia. The causes of superficial dyspareunia are tightness at the superficial layer of pelvic floor muscles, vaginal dryness, scar related to episiotomy or perineal tear etc. The deep dyspareunia can be due to cervical pathology, endometriosis, spasm in the deep layer of pelvic floor muscles, chronic pelvic pain, interstitial cystitis, or any pathology of the pelvic organs, etc.

The prevalence of Vaginismus and dyspareunia is very high. Around 5-17% female suffers from vaginismus and around 28% females suffers from dyspareunia.<sup>[1,2]</sup> Yet there is no single tool which is designed to assess the pelvic floor relaxation ability

## **MATERIALS & METHODS**

### **Study Design:**

Observational Study – Validity and Test – Retest Reliability of Vlosum.

An Observational study conducted at a private hospital, Ahmedabad. The study duration was 18 months. The study was done on 1184 participants.

This study was conducted at the OPD of a Private Hospital. Ethical clearance was obtained from Institutional Ethical Committee of IIPRE – International Institute of Pelvic Floor Research, Rehab and Education – Recognized by Central Government of India.

### **Participants:**

This is a validity and reliability study of a device; an experienced examiner was recruited for the study. The participants above the age of 18 years and were following the inclusion criteria were recruited in the study.

### **Inclusion Criteria:**

- Female who reported symptoms of painful vaginal penetration,
- No vaginal penetration,
- First time anxiety about vaginal penetration.
- Female having no complaints of either weak or spasmodic pelvic floor. (Normal pelvic floor functioning)

### **Exclusion Criteria:**

- Females with weak pelvic floor,
- Urine leakage,
- Pelvic organ prolapses,
- Fecal incontinence,
- Sexual dysfunction due to weak pelvic floor,
- Not willing to sign the consent
- Not able to understand English.
- Any other neuro muscular, cardio pulmonary etc. condition which limits the participation.

In total, 1349 women were approached out of which 1184 women over the time period of 18 months were evaluated. Participants

were divided into 4 groups Group A females having Vaginismus- inability to having vaginal penetration, Group B females having dyspareunia – painful sexual intercourse, Group C females having first time anxiety of penetration (sexual penetration) and Group D females having no complaint of either weak or spasmodic pelvic floor muscles.

Participants were divided according to symptoms

Group A: Vaginismus<sup>3</sup>

Group B: Dyspareunia<sup>3</sup>

Group C: Anxiety of first time penetration

Group D: No complaints of either weak or spasmodic pelvic floor muscles.

### **Outcome Measure:**

#### **FSFI**<sup>4</sup>

Female Sexual Function Index, is the self-reported scale consisting of 19 questions. The score is between 2 to 36. Higher the score better the sexual function. The scale has sub-headings as Desire, Arousal, Lubrication, Orgasm, Satisfaction and Pain.

#### **Self-reported question**

A self-reported question was asked to measure the symptoms of first-time penetration anxiety.

The females were asked the following question

On a rate of 10 how much anxiety do you feel for first-time sexual penetration?

0 means no anxiety, and 10 means maximum anxiety.

#### **NPRS**<sup>5</sup>

Numerical Pain Rating Scale

NPRS is a subjective measurement of pain perceived during palpation. This scale has 0 to 10 numbers which reflects the intensity of the pain experienced by the patient. 0 being the no pain and 10 being worst possible pain.

#### **Vlosum (Het's Device to instantly test vaginal opening)**<sup>6</sup>

It is the first of its kind, unique, innovative and revolutionary device which is used to

assess the vaginal opening ability, vaginal dilation or relaxation of pelvic floor muscles.

Pain free vaginal opening can be categorized in 3 grades by Vlosum.

Grade C – Extremely spasmodic pelvic floor muscle.

Grade B – Spasmodic pelvic floor muscles

Grade A – Completely relaxed pelvic floor muscles.

For an easy analysis the grades are compared with numbers 1, 2 and 3 on Likert scale. Where Grade A is 3, Grade B is 2 and Grade C is 1.

#### **Procedure:**

Participants were asked to fill the FSFI scale, NPRS, Self-reported questionnaire for first time anxiety.

Testing of Vlosum was done by the participants alone there wasn't any examiner present at the time of testing as it is a self-use device. The whole procedure of testing was explained to the participants.

Participants were instructed to test pelvic floor muscle relaxation (pain free vaginal opening) in supine position with hips and knees bent and abducted in a quiet, private and comfortable place. Special instructions were given to make sure that the test is done in an environment which was relaxing, as anxiety and nervousness can interfere with the findings.

First the penetration (insertion) of the narrow end was assessed, instructions were given to use condom over the Vlosum for testing. To test with narrow end, condom tip covered the narrow end of Vlosum and water-based lubrication was advised to use. Participants were instructed to insert the narrow end of Vlosum inside the vagina. And note the findings, after that the testing with broad end should be done.

For broad end penetration fresh condom should be used, such that the tip of the condom covers the broad end. Broad end penetration should be checked in the same way like the narrow end.

The results of test are as follows:

Description	Vlosum	Interpretation
If both the narrow and broad end cannot get inserted inside vagina due to extreme pain or discomfort, it suggests extremely spasmodic pelvic floor muscles.	C	Extremely spasmodic pelvic floor muscle.
If both the narrow and broad end can get inserted inside vagina but with pain or discomfort during insertion it suggests spasmodic pelvic floor muscles.	B	Spasmodic pelvic floor muscles
If both the narrow and broad end gets inserted inside the vagina easily without pain or discomfort, it indicates a healthy vaginal opening with relaxed pelvic floor muscles	A	Completely relaxed pelvic floor muscles



Figure 1: Vlosum

To assess the validity of Vlosum, the data of NPRS, FSFI, Self-reported questionnaire for anxiety of first-time penetration and Vlosum were analyzed.

To assess the test and retest reliability of Vlosum, the test was repeated after 2 hours on the same day. And the data of test and retest were analyzed.

## RESULT

The statistical analysis was done using Microsoft excel. The data were analyzed to check the distribution. As the data was not having a normal distribution for NPRS, FSFI and self-reported anxiety for first time questionnaire non-parametric test of correlation coefficient Spearman's Coefficient Correlation test was used to analyze the data of Vlosum with FSFI, Vlosum with NPRS, Vlosum with self-reported questionnaire.

The data of test and retest followed a normal distribution so an intraclass correlation coefficient was used to assess the reliability of Vlosum.

Serial No	Parameters	Findings
1	Age	27.4 ± 10
2	BMI	20.2 ± 2.4
3	Parity	1 ± 1.4
3	FSFI-19	15.24 ± 4.97
4	NPRS	5.42 ± 2.65
5	SELF REPORTED QUESTIONNAIRE	8.12 ± 1.86
6	Vlosum	1 - C 60.47 % 2 - B 33.43 % 3 - A 6.1 %
7	Vaginismus	368 (31.08%)
8	Dyspareunia	329 (27.78%)
9	Anxiety of first-time penetration	287 (24.23%)
10	No complaints of weak or spasmodic pelvic floor	200 (16.91%)

The table of test and retest – Vlosum

Groups	ICC (Intraclass correlation Coefficient)	95% Confidence Interval
A – Vaginismus	0.94	0.86-0.97
B – Dyspareunia	0.92	0.85-0.91
C - Anxiety of first-time penetration	0.90	0.83-0.91
D – No complaint of weak or spasmodic pelvic floor muscles	0.91	0.84-0.92

### For Group A Vaginismus

Vlosum and FSFI measurement showed a significantly strong correlation with  $r = 0.87$  ( $p < 0.001$ ).

Vlosum and NPRS measurement showed a significantly strong correlation with  $r = 0.88$  ( $p < 0.001$ ).

Vlosum and Self-reported questionnaire measurement showed a significantly strong correlation with  $r = 0.92$  ( $p < 0.001$ ).

#### **For Group B Dyspareunia**

Vlosum and FSFI measurement showed a significantly strong correlation with  $r = 0.92$  ( $p < 0.001$ )

Vlosum and NPRS measurement showed a significantly strong correlation with  $r = 0.90$  ( $p < 0.001$ )

Vlosum and Self-reported measurement showed a significantly strong correlation with  $r = 0.87$  ( $p < 0.001$ )

#### **For Group C Anxiety for first time sexual penetration**

Vlosum and FSFI measurement showed a significantly strong correlation with  $r = 0.87$  ( $p < 0.001$ )

Vlosum and NPRS measurement showed a significantly strong correlation with  $r = 0.89$  ( $p < 0.001$ )

Vlosum and self-reported questionnaire measurement showed a significantly strong correlation with  $r = 0.93$  ( $p < 0.001$ )

#### **For Group D No complaint of weak or spasmodic pelvic floor muscles.**

Vlosum and FSFI measurement showed a significantly strong correlation with  $r = 0.93$  ( $p < 0.001$ )

Vlosum and NPRS measurement showed a significantly strong correlation with  $r = 0.86$  ( $p < 0.001$ )

Vlosum and self-reported questionnaire measurement showed a significantly strong correlation with  $r = 0.98$  ( $p < 0.001$ )

There was a significant correlation between FSFI and Vlosum, NPRS and Vlosum, Self-reported questionnaire and Vlosum.

The test and retest reliability of Vlosum has shown very high reliability.

## **DISCUSSION**

Present study was conducted to assess the validity and test-retest reliability of Vlosum

to test the opening ability of vaginal muscles (pelvic floor muscles).

The conditions like vaginismus, dyspareunia, painful sexual intercourse are very disturbing and do affect the interpersonal relations of the sufferer. Many females suffer from these conditions but they opt to not discuss it due to lack of awareness of the condition and also the available options.

Many a times the conditions like vaginismus develops due to various psychological barriers like fear of sexual penetration, bad past experience, history of sexual abuse etc.

In this study, 368 cases of vaginismus were included, these were the female having either primary or secondary vaginismus. 329 females had dyspareunia and 287 females were those who never had sexual intercourse earlier. And 200 females were having no complaint of weak or spasmodic pelvic floor muscles (they were sexually active with no reported sexual dysfunctions) On the self-reported questionnaire for anxiety for first time sexual penetration out of 287, around 236 females reported having high (8 on the scale of 0 to 10) anxiety related to first time sexual penetration. This anxiety if remained unaddressed can increase the odds of developing either dyspareunia or vaginismus. A literature review done by Reissing ED, Blink YM et al (1999) stated that female with vaginismus can have lack of sexual education and also the female can develop vaginismus due to an actual or imagined negative sexual experience.<sup>7</sup>

If proper sex education along with correct way of pelvic floor muscles relaxation (vaginal opening ability) if taught to the female can help in preventing these depressing conditions like vaginismus and dyspareunia.

The study had shown a significantly strong correlation between Vlosum and FSFI, Vlosum and NPRS, Vlosum and self-reported questionnaire. The female who has low score in FSFI and high score in NPRS and self-reported questionnaire also has shown that the findings for Vlosum were

either 1 or 2, these suggests either extremely spasmodic or spasmodic pelvic floor muscles and the female who had a low score of NPRS and self –reported questionnaire and high score of FSFI has a grade of 3 on Vlosum, these suggest completely relaxed pelvic floor muscles.

The scale present to diagnose the symptoms of hypertonus pelvic floor muscles (painful vaginal opening) are all subjective scale or are patient reported outcome measures they don't assess the hypertonus pelvic floor muscles objectively.

The possibility of having a functional vaginal spasm only with the thought of vaginal penetration or during vaginal penetration should not be overlooked. Many females can report easy usability of tampon and menstrual cups but they do experience a painful sexual intercourse, this is because a) size of tampon and menstrual cup b) during periods the pelvic floor muscles tone is less due to hormonal alteration<sup>8</sup> c) the psychosocial aspect of female during sexual penetration.

The early and objective evaluation of spasmodic pelvic floor muscles (vaginismus and dyspareunia) can greatly help in preventing and managing these conditions. This study has opened a new dimension to objectively diagnose the spasmodic pelvic floor muscles.

## CONCLUSION

The above study showed a significantly strong correlation between Vlosum and FSFI, Vlosum and NPRS, Vlosum and self-reported questionnaire. The test- retest reliability of Vlosum also had shown high reliability. It can be concluded from this study that Vlosum is a highly reliable and valid tool to assess the vaginal opening (relaxation or dilation) ability (pelvic floor muscles relaxation).

### Declaration by Authors

**Ethical Approval:** Approved

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