

## Vaginal Laxity Issues, Answers and Implications for Female Sexual Function



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### INTRODUCTION

Vaginal laxity and tissue architecture have often been overlooked as contributing etiologic factors to female sexual dysfunction. Vaginal laxity can lead to decreased physical sensation during intercourse. This decrease in sensation is often coupled with a decrease in sexual satisfaction, which can affect a woman's sense of sexual self-esteem and her relationship with her sexual partner. Indeed, physiologically, introital vaginal laxity is the key facet when discussing sexual function associated with vaginal laxity based on the positioning of the clitoral matrix. Subjective report of vaginal laxity, or looseness, might be suboptimal for defining the medical condition. However, vaginal laxity remains a patient self-reported condition, and thus far no objective measurement exists to quantify its severity or uniquely separate it from overall pelvic floor dysfunction.

In this article, vaginal laxity is defined as "looseness" of the vaginal introitus. The simplest definition of vaginal laxity as it relates to intercourse can be found in a pilot study published by Millheiser et al.<sup>1</sup> Women were asked, "How would you rate your current level of vaginal laxity/looseness during intercourse?" and responses were assessed using a seven-point Likert scale ranging from "very loose" (1) to "very tight" (7). A woman was defined as having laxity if she scored no higher than 3 on this self-reported scale.

Vaginal laxity is differentiated from pelvic organ prolapse in that the vaginal tissue is loose, and the other organs are not displaced or pushing against the walls of the vagina as one sees with prolapse.

Vaginal laxity is rarely discussed in the clinical situation, yet most surveyed urogynecologists recognize that it is an underreported, yet bothersome, medical condition that affects personal happiness and sexual function.<sup>2</sup> Another survey of obstetricians-gynecologists found that vaginal laxity is the most frequent physical change seen or discussed after vaginal delivery.<sup>3</sup> In addition, in a survey of women 25 to 45 years of age who had experienced at least one vaginal delivery, approximately half expressed some degree of concern over "looseness" of the vaginal introitus.<sup>4</sup>

Inclusion of sexual health as a standard part of a medical history serves patients well because it can provide an opportunity

for the woman to raise concerns and for the physician to normalize the condition. Comprehensive medical history, physical examination, and psychosexual evaluation are the initial steps for appropriate patient selection for a vaginal laxity intervention. It is imperative that the woman herself is requesting evaluation and treatment for this medical condition. Appropriate relationship assessment and screening are critical to rule out potential coercion by the intimate partner.

### AVAILABLE TREATMENTS

Treatments for vaginal laxity range from surgery to self-prescribed over-the-counter medications, with varying degrees of clinical evidence associated with each.

#### Surgical Intervention

Of the women who are candidates for a vaginal laxity intervention, some also have more significant prolapse issues. In these situations, restoration of the pelvic floor foundation could be a critical component before moving on to "non-invasive" treatments. Surgical intervention to improve the integrity of the vaginal tissue has been clinically proved to be an effective approach for "reshaping" and/or improving sexual function. A recent review by Moore et al<sup>5</sup> outlined existing data on surgical vaginal rejuvenation and linked this intervention with an improvement in sexual function. Specific examples include two randomized controlled trials in which women receiving pelvic organ prolapse repair showed significant improvement in sexual function.<sup>6,7</sup> However, surgery is an invasive approach, can include a substantial recovery period, and has potential for serious adverse effects (eg, suburethral trauma).

#### Beyond Surgery: Non-Invasive Treatments

For evidence supporting treatments beyond surgical intervention, a review of PubMed and ClinicalTrials.gov using the terms *vagina*, *laxity/loose*, and *sexual function* or *vaginal relaxation syndrome* produced only five studies, one for behavioral modification and four for energy-based devices, which are discussed in more detail below.

#### Over-the-Counter Vaginal Tightening Products

There are different non-prescription topical vaginal tightening products; however, these products are not subject to the same levels of regulatory oversight associated with prescription products. This is concerning because topical vaginal tightening products can severely disrupt the vaginal ecosystem, and they can cause

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**Table 1.** Comparison of non-surgical evidence for vaginal laxity (publications and clinicaltrials.gov)

	Kolberg Tennfjord et al, <sup>8</sup> 2016	Millheiser et al, <sup>1</sup> 2010	Sekiguchi et al, <sup>12</sup> 2013	Lee, <sup>10</sup> 2014	NCT02261974 <sup>9</sup>
Vaginal indication	Loose or lax	Laxity of introitus	Laxity of introitus	Relaxation syndrome	Laxity of introitus
Treatment	Muscle training	RF with cooling	RF with cooling	Erbium:YAG laser	RF with cooling
Subjects, n	175	24	30	30	155
Follow-up (mo)	6	6	12	2	6
Randomized	✓			✓	✓
Sham-controlled	✓				✓
Validated sexual function end point	✓ (ICIQ-VS, ICIQ-FLUTSsex)	✓ (mv-FSFI, FSDS-R)	✓ (FSFI, FSDS-R)		✓ (FSFI, FSDS-R)

FSDS-R = Female Sexual Distress Scale, revised; FSFI = Female Sexual Function Index; ICIQ-FLUTS = ICIQ (International Consultation on Incontinence Modular Questionnaire)—Female Urinary Tract Symptoms; ICIQ-VS = International Consultation on Incontinence Modular Questionnaire—Vaginal Symptoms; mv-FSFI = Female Sexual Function Index, modified version; RF = radiofrequency.

significant harm, including, but not limited to, severe vaginal mucosa erosion, discharge, and/or infections. No randomized controlled trials could be identified for this category of products.

### Behavioral Modification

There have been many published studies of behavioral modification (eg, pelvic floor physical therapy, Kegel exercises) that support its potential viability as a non-invasive treatment for different indications. However, the one randomized controlled study in PubMed on “vaginal symptoms” that evaluated the effect of postpartum pelvic floor muscle training using a validated sexual function end point found no difference between the training and control groups for sexual dysfunction 6 months postpartum.<sup>8</sup> In addition, behavioral modification for vaginal laxity is time consuming, has poor patient compliance, and has a minimal effect on soft tissue integrity, which contribute to limited effectiveness in a “real-world” population.

### Energy-Based Devices

Currently, there are many energy-based devices being used for vaginal rejuvenation, but not necessarily for treating vaginal laxity, in an office-based setting in some areas of the world (eg, CO<sub>2</sub> laser, erbium laser, unipolar radiofrequency, and monopolar radiofrequency with cooling). There are significant differences among the different energy-based devices, which include whether the outcome is oriented toward esthetic genital appearance or toward underlying sexual function. If oriented toward function, then the devices are delineated further between an improvement in laxity and sexual sensation and other applications. For instance, lasers and unipolar radiofrequency could be limited to treating superficial issues such as atrophic changes, but deeper, more extensive volumetric delivery of heat, to the introitus specifically, might be more appropriate for the treatment of underlying vaginal laxity. Of the four studies for energy-based devices treating vaginal laxity on PubMed or ClinicalTrials.gov, three were for treatment of vaginal tissue to improve laxity and sexual function using a targeted radiofrequency device with controlled cooling<sup>5,7,9</sup> and one was for the treatment of

“vaginal relaxation syndrome” using an erbium:YAG laser.<sup>10</sup> Of these studies, there was only one that was randomized, blinded, and placebo-controlled, and this was using the targeted radiofrequency device with controlled cooling. This study showed significant increases in subjects reporting no vaginal laxity and overall improvement in vaginal laxity with no increased safety risk.<sup>11</sup>

### WHAT QUALIFIES AS PROOF OF EFFICACY?

What type of evidence should we, as health care professionals, be looking for when counseling our patients about the various treatment options? Study design and outcome data (especially efficacy and safety) should mimic those seen in sexual pharmacology, the most recent of which are the three flibanserin phase 3 studies. These studies were randomized, blinded, and placebo-controlled, with a full 6 months of follow-up. In addition, patient-reported outcome measurements and validated sexual instruments such as the Female Sexual Function Index questionnaire seem reasonable end points given the inability to accurately and objectively measure vaginal laxity. Multiple patient assessments have been developed; however, each assesses slightly different things. Selection for use should be dependent on which symptoms are the most troublesome for the patient. Additional examples of validated patient-reported assessments of vaginal laxity, sexual function, and sexual distress include the Female Sexual Distress Scale,<sup>12</sup> the International Consultation on Incontinence Modular Questionnaire—Vaginal Symptoms,<sup>13</sup> and the Prolapse-Urinary Incontinence Sexual Questionnaire-12.<sup>14</sup>

### WHAT IS THE EVIDENCE FOR NON-SURGICAL APPROACHES TO VAGINAL LAXITY?

As discussed earlier, although the publications on surgical approaches for vaginal laxity are numerous, a review of PubMed and Clinicaltrials.gov using the terms *vagina*, *laxity/loose*, and *sexual function* or *vaginal relaxation syndrome* produced only five studies related to non-surgical vaginal treatment to improve

sexual function (Table 1). Table 1 summarizes the paucity of rigorous clinical studies in this area, with currently only one randomized, placebo-controlled, blinded study on this subject.

## CONCLUSION

Vaginal laxity is a self-reported medical condition that can affect a woman's sexual enjoyment and satisfaction. It is my opinion that this impactful condition is underappreciated in the medical community and remains under-reported in the sexual literature. Further research is needed in a randomized, placebo-controlled fashion to assess efficacy and safety for therapeutic interventions. Should she seek medical intervention, a woman could be offered different therapeutic approaches. As clinicians discuss benefits and risks with patients for all potential treatments, they are encouraged to be aware of the latest innovative research on the subject to ensure the treatments they are advocating are safe and effective for the patient's specific, primary complaint.

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