

High Intensity Focal Ultrasound (HIFU) for Management of Vaginal Laxity with Impact on Sexual Satisfaction

¹Rania Ali Elrashidy, MD, Msc.

Department of Obstetrics and Gynecology, Tanta General Hospital, Tanta, Egypt.

Abstract

Introduction: Vaginal laxity drastically impairs women's quality of life, suggesting there is a need for effective noninvasive treatments.

Aim: The aim was to retrospectively assess the effectiveness and safety of the HIFU (High Intensity Focal Ultrasound) procedure for vaginal laxity in patients treated in our clinical practice during a one-year period.

Methods: patients presented to our clinic complaining of manifestation of vaginal laxity were offered HIFU treatment. Effectiveness was assessed using a Patient Satisfaction Questionnaire. The safety and tolerability of the procedure was monitored in all patients.

Results: As assessed by the Patient Satisfaction Questionnaire, we show that 93.3% and 95.5% of patients experienced improvement of sexual gratification after 1 and 3 months, respectively, of HIFU treatment. None of the patients had categorized their vagina as being loose anymore after treatment.

Conclusion: The results have confirmed that patients suffering from vaginal laxity can be effectively treated using HIFU procedure without adverse effects.

Introduction

A steady increase in patient demand for vaginal rejuvenation and reconstruction, colloquially termed "vajuvenation," has occurred over the past 10 years. In the context of female genitalia, "rejuvenation" is a broad term encompassing both aesthetic and medically indicated procedures for the treatment of laxity, genitourinary syndrome of menopause (GSM), vulvovaginal atrophy (VVA), and associated urinary incontinence.^{1,2}

Treatments for vaginal laxity and atrophy have previously ranged from noninvasive pelvic floor muscle (Kegel) tightening exercises, topical lubricants, topical and systemic hormone replacement, to invasive surgical procedures, such as labiaplasty and invasive vaginal tightening. Recently, minimally invasive energy-based devices for vaginal rejuvenation, such as radiofrequency (RF), laser and High Intensity Focal Ultrasound (HIFU) have grown in popularity because of reported effectiveness, high patient satisfaction, minimal downtime, and decreased side effects, compared with invasive treatment modalities.^{2,3}

Laser and radiofrequency work by creating superficial microablation zones on the mucosal surface that result in a healing response is triggered, resulting in new collagen formation. On contrary, HIFU is a noninvasive, nonionizing technique that focuses a high-intensity ultrasound waves onto a targeted area. The ultrasound wave propagates deeply through tissue, the energy is absorbed and converted to heat that results in tightening of the mucosa and stimulation of new collagen formation, without injuring the tissue surface. In this way, the risk of unwanted side effects, especially after multiple repeated treatments, is greatly reduced.⁴

For the aforementioned reasons, we have chosen the HIFU treatment as our noninvasive treatment of choice for vaginal laxity patients. In the present study, we have presented our experience with patients treated in our clinic, which included patients with vaginal laxity from our clinical practice who received the HIFU treatment during a one year period.

Patients and Methods:

This study was a prospective case series carried out on patients suffering from vaginal laxity, who were treated in a private aesthetic gynecological center, using a HIFU treatment (Chongqing Hifu Technology Co., Ltd. Chongqing, China) between January 2020 and February 2021.

Inclusion criteria included women older than 18 years who had complained from symptoms of vaginal looseness, which negatively impacted their QoL. Exclusion criteria included pregnant women, women with genitourinary infection and those with a sign of vaginal canal or introitus injuries.

All patients were subjected to complete gynecological examination and provided with detailed information about the treatment. Informed consent was obtained from all individual participants included in the study.

We used a HIFU (Chongqing Hifu Technology Co., Ltd. Chongqing, China) machine with two vaginal transducers. Focal depth 3 mm with frequency 7 MHz (0.4-1.2 J/mm²), and focal depth 4.5 mm with frequency 4 MHz (0.4-1.2 J/mm²). The number of shots (ultrasound pulses lines) was adjusted to 7 in all procedures. After application of 10% lidocaine, as a local anesthesia, the transducer was inserted into the vagina and operated. The auto-rotated head ensure 360° application of the ultrasonic waves through the whole vaginal circumference.

Telephone follow-ups were scheduled for all patients after 48 hours and at 1 and 3 months after the final treatment to obtain data on treatment safety and efficacy. The safety and tolerability of the treatment were monitored in all treated patients. The tolerability of the procedure was assessed by measuring patient discomfort data on a 0-10 VAS scale. Safety was measured by monitoring and documenting side effects during and after the procedure.

The efficacy of vaginal tightening was assessed using a subjective patient's evaluation of improvement. A Patient Satisfaction Questionnaire (Table 1) comprised of 2 questions was offered to all participants. The first question asking for information about improvement of sexual gratification after the HIFU treatment and the second question about the sensation of the degree of the tightness of the vagina after the treatment.⁴ Patients were also asked if their partner had commented on vaginal tightness. There is no standardized questionnaire of partner-reported vaginal laxity, so we asked patients "Has a partner ever commented on your vagina being tight or loose?" with answer options being "Never commented," "Tight" or "Loose."

All statistical analyses were done using SPSS v23 (IBM© Inc., Chicago, IL, USA). The Spearman correlation analysis was performed to detect association between continuous variables, and the differences of continuous variables between groups were assessed by T Test or Wilcoxon rank sum test depending on the distribution of data.

Results:

A total of 95 subjects were included in the study. The average age among subjects was 24.3 ± 13.18 years with an average parity of 2.12 ± 1.06 . Regarding the first question, five patients were excluded from the analysis, as they had marked 0 on the questionnaire, indicating that they had no sexual relations since the treatment. Of the remaining patients, at the first follow up after 1 month, 40% (n=36/90) reported a large improvement of sexual gratification after the treatment, 53.3% (n= 48/90) reported noticeable improvement, and only 6.7% (n= 6/90) reported no improvement. Together, 93.3% (n= 84/90) of patients reported improvement of sexual gratification after treatment (Figure 1).

At the second follow up after 3 months, two patients who had marked 3 on the questionnaire "indicating large improvement of sexual gratification" at the first follow-up, marked 2 on the questionnaire at the second follow-up. While 6 patients who had marked 2 on the questionnaire "indicating noticeable improvement of sexual gratification" at the first follow up, marked 3 at the second follow-up. Two patients who marked 1 on the questionnaire "indication no improvement" at the first follow-up have marked 2 at the second one. So, of the ninety patients, 44.4% (n=40/90) reported a large improvement of sexual gratification after treatment, 51.1% (n= 46/90) and only 4.5% (n= 4/90) reported no improvement. Together, 95.5% (n= 86/90) of patients reported improvement after treatment. (Figure 1).

Regarding the second question, before treatment, all patients reported their vagina as being loose (n=50/95) or very loose (n=45/95). At the first follow-up after 1 month, 60% (n= 57/95) evaluated their vaginal canal to be tight, and 40% (n= 38/95) evaluated it to be normal. After 3 months, two patients who had evaluated their vaginal canal to be tight at the first follow-up, evaluated it to be normal. While 8 patients who had evaluated their vaginal canal to be normal, evaluated it to be tight. So, of the ninety-five patients, 66.3% (n= 63/95) have evaluated their vaginal canal as being tight, and 33.7% (n= 32/95) have evaluated it as being normal. However, none of the patients considered it loose anymore at the follow-ups 1 month and 3 months after the treatment (Figure 2).

Most partners did not comment on laxity (62.1%; n= 59/95) and the rest (37.9%; n= 36/95) commented on the vagina being tight. Of these 36 patients who have commented on the vagina as being tight, 30 partners (83%) have commented on it as being loose before treatment. However, none of the partners considered it loose anymore at the follow-ups 1 month and 3 months after the treatment. Patient sensation of vaginal tightness as reported by questionnaire was correlated with partner commenting on vaginal tightness ($P < 0.001$).

Tolerability and safety of the treatment were evaluated for all treated patients (n= 95). HIFU procedure associated pain was estimated on average as 1 on a VAS 0-10 scale. No major adverse effects were reported.

Discussion:

Vaginal laxity significantly impairs patients' sexual function and reduces their QoL. Recently, different studies suggested promising short-term results with treating vaginal laxity using energy-based devices such as lasers, low-dose radiofrequency and HIFU.⁵⁻⁷

In the present study, we aimed to prospectively analyze the safety and efficacy of the HIFU procedure, as a treatment of vaginal laxity, performed in our clinical practice during a one-year period. Our results revealed that HIFU treatment produced favorable results without serious adverse effects. The effect on sexual gratification was assessed using a Patient Satisfaction Questionnaire. The results have shown that 93.3% and 95.5% of the patients experienced an improvement of sexual gratification after receiving HIFU treatment by 1 & 3 months respectively. Our results are in accordance with those reported by other published studies using other energy based devices. Gaviria and Lanz have shown improvement in vaginal laxity and high patient satisfaction after laser treatment.^{8,9} Pardo and Dalenz evaluated sexual satisfaction before and after Laser treatment and also the patient's satisfaction with the procedure. They found that the mean level of improvement in sexual satisfaction was 70% and the mean level of satisfaction with the laser vaginal tightening procedure was 75%.¹⁰

Our results strongly indicated that HIFU improved the sexual gratification of the treated patients; however, it was recorded only using a self-reported questionnaire. Owing to the absence of a control group, other factors that might have influenced sexual gratification in women may have been overlooked. These may include higher motivation for sexual intercourse of the patients and their partners because of the received treatment.

Vaginal laxity was estimated using a modified 4-point vaginal laxity scale.⁴ Patients had reported significantly improved symptoms of vaginal laxity at the 1- and 3-month follow-ups after receiving the HIFU treatment. None of the patients had categorized their vagina as being very loose or loose. The results of our study are in accordance with other studies that used other energy based devices, where the improvement of vaginal laxity symptoms assessed by patients was in a range of 80-95%.⁸⁻¹¹ This level of effectiveness is comparable with that of surgical procedures.¹²

All 95 treated patients were asked about tolerability and side effects, which were mild and rare. Although our results indicate a high effectiveness of the HIFU treatment for treating vaginal laxity, these would have to be further confirmed in a randomized controlled trial setting

Partners rarely commented on vaginal laxity, and more often commented on tightness rather than laxity, despite women reporting some spectrum of vaginal laxity. In our study Partner comment was not used as an objective measure of laxity but rather a potential independent variable which might affect patient perception of laxity. Asking partners directly about perceptions of laxity may have provided different information as only about 38% of patients reported that partners had commented. Asking patients for information on partner comment rather than asking partners directly resulted in imperfect data on true partner perception but did provide data on patient views of partner perception.

Microablative fractional CO₂ laser, which produces laser light in the wavelength of 10.6 mm, works by creating microablation zones on the surface of the mucosa. In these zones, microscopic punctures with coagulated edges are created; these stimulate the regenerative response in the skin/mucosal surface, increasing the synthesis of collagen, the formation of new vessels, and tightening of the tissue.¹³ Even though CO₂ treatments have been shown effective in treating some genitourinary conditions, there is concern about the side effects of long-term repetitive microwounding of the mucosa, as the laser treatments need to be repeated to maintain symptom free results. There were several reported cases of pain and burning sensation lasting up to 5 days after fractional CO₂ laser treatment.¹⁴ Contrary to fractional microablative CO₂ laser, High-intensity focused ultrasound (HIFU) is a noninvasive, nonionizing procedure with bioeffects created by high-intensity ultrasound. The bioeffects is achieved by two mechanisms: thermal and nonthermal. The thermal biologic effects are created by tightly focusing the high-intensity ultrasound waves onto the targeted area. The ultrasonic wave propagates through the mucosa to the submucosa causing heating of the deep mucosa without surface overheating. The treatment results in shrinkage of collagen fibers and the induction of neocollagenesis. The nonthermal effect is known as cavitation. When HIFU is applied to specific tissue, micro-bubbles of gas within the tissue begin to oscillate rapidly. This rapid oscillation causes the gas bubbles to collapse, creating inertial cavitation. The force from the collapse will in turn stimulate healing in the form of fibrosis and neocollagenesis with stimulation of the subepithelial muscular layer contraction⁷

This distinction is important to understand considering the Food and Drug Administration (FDA) warning letter of July 2018, which was sent to 7 energy-based device manufacturers its indications for vaginal rejuvenation. In contrast to ablative lasers, HIFU is a nonionizing and non-invasive device that does not physically harm the tissue surface but creates only controlled heating of the submucosal surface. It therefore does not pose any of the safety risks that relate to tissue ablation, such as scarring or infection.

The major limitation of this study is that it is not a randomized controlled trial, but a prospective case-series, without a control group. In order to confirm the effect of the HIFU on vaginal laxity with the highest level of clinical evidence, randomized controlled trials should be performed.

Conclusion:

Vaginal laxity is detrimental to quality of life and may be an early or a concurrent symptom in more conditions related to pelvic dysfunction. Our data indicates that HIFU is an effective and safe method for treating vaginal laxity symptoms, with our results being comparable to other treatment modalities. Randomized controlled trials are necessary to confirm these results with highest level of clinical evidence.

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Patient Satisfaction Questionnaire

Q1. How do you assess improvement of sexual gratification after HIFU treatment?

0 = No sexual relations since treatment

<p>1 = No improvement 2 = Noticeable improvement 3 = Large improvement</p> <p>Q2. How do you assess the tightness of your vagina? 1 = very loose 2 = loose 3 = normal 4 = tight</p>
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Table 1

Question 1 was used to assess improvement of sexual gratification, whereas question 2 was used to assess vaginal tightness by patients who have undergone the HIFU procedure

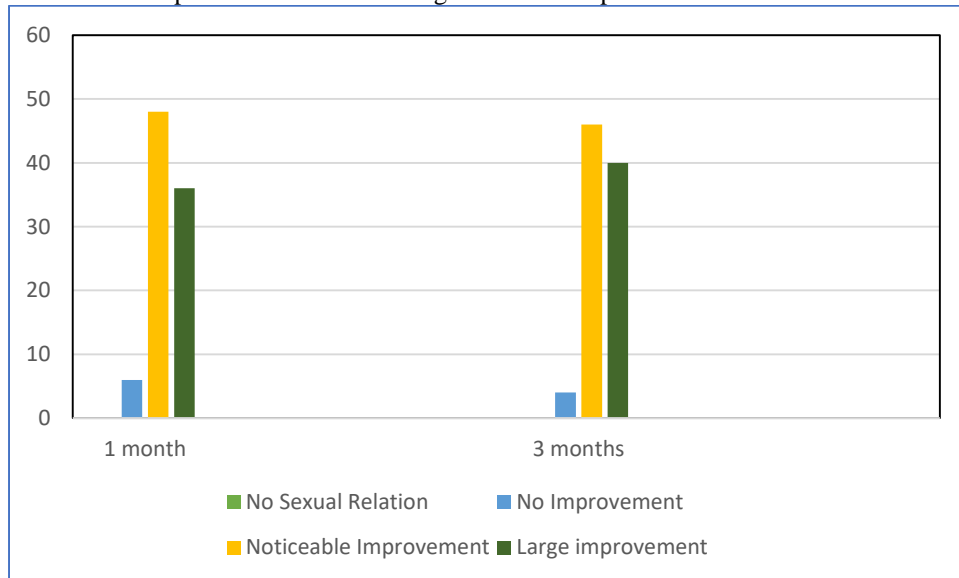


Figure 1

Patients' improvement in sexual satisfaction after the vaginal HIFU tightening as assessed by question 1 from the Patient Satisfaction Questionnaire after 1, 3 months of treatment.

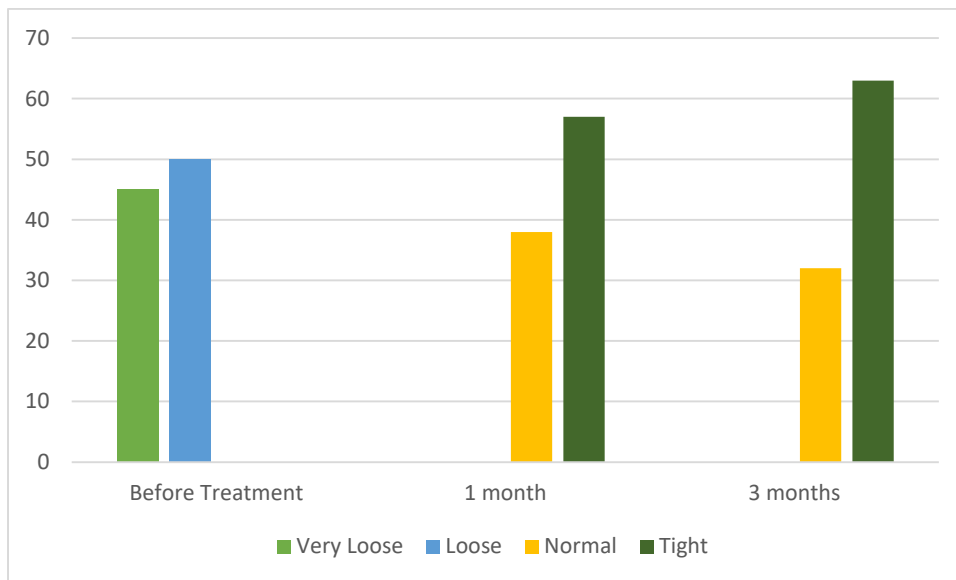


Figure 2

Patients' sensation of vaginal tightness as assessed by question 2 from the Patient Satisfaction Questionnaire before and after 1, 3 months of treatment.