# STUDY OF CLINICAL CASES IN VULVOVAGINAL REJUVENATION

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## Introduction

In recent years aesthetic gynecology has brought about a revolution from the clinical and technological point of view since it deals with various gynecology pathologies in an integral way, solving both morphological and functional alterations. The percentage of women seeking for non-invasive treatments to correct and restore the shape and function of the vulva and vagina is increasing enormously. "Enygma X- Orbital" proposes a non-surgical alternative for the treatment of vulvaginal hyperlaxity syndrome and the associated symptoms such as sexual dysfunction, stress urinary incontinence and atrophic vulvovaginitis

## Objetives

The objective of the present case study is to evaluate the efficacy of the treatment protocol to treat vulvovaginal laxity using the new technology developed by Body Health, "Enygma X-Orbital".

## Materials and methods:

Fueron sometidas a tratamiento 6 Patients (n =6; rango de Age 36-53 años, con una media de 46 años, 2 premenopaúsicas, una perimenopaúsica y 3 postmenopaúsicas) presentando un grado leve a moderado de laxitud vulvovaginal con y sin síntomas asociadas ( disfunción sexual, incontinencia de esfuerzo, vulvovaginitis atrófica). Los criterios de exclusión: Patients con antecedente de cirugía pélvica menor a 5 años, Patients cursando o planificando embarazo, Patients con alteraciones en últimos resultados ginecológicos, Patients con lesiones vulvares, Patients bajo terapia de reemplazo hormonal (6 meses previos) y uso de geles lubricantes en el último mes. El consentimiento informado fue obtenido de todas las participantes.

## Results:

Six patients were treated (n = 6, age range 36-53 years, with a mean of 46 years, 2 premenopausal, one perimenopausal and 3 postmenopausal) presenting a mild to moderate degree of vulvovaginal laxity with and without associated symptoms ( sexual dysfunction, stress incontinence, atrophic vulvovaginitis). Exclusion criteria: Patients with a history of pelvic surgery younger than 5 years, patients studying or planning pregnancy, patients with alterations in latest gynecological results, patients with vulvar lesions, patients undergoing hormone replacement therapy (6 months prior) and using gels lubricants in the last month. Informed consent was obtained from all participants.

## Conclusions:

The use of "Enygma X-Orbital" has shown to generate a remarkable tissue retraction from the first session caused by the increase of the temperature (> 40 ° C) inside the vulvar and vaginal submucosa. The effects are sustained in the time given to the induced neocolagenogenesis, responsible for the lasting tensioning. Additionally, the increase in microcirculation on the one hand stimulates glandular production, giving a marked improvement in the symptoms caused by atrophy vulvovagina and on the other hand raise nervous sensitivity, reversing sexual dysfunction.

## INTRODUCTION

During vaginal delivery there is an inevitable stretch of the dense connective tissue that forms the vaginal walls, introitus, labia majora and minor, which regenerates in a variable way and also it worsens with each new birth. Additionally, the hormonal and neuroendocrine changes associated with menopause and physiological aging contribute to a decrease in connective tissue quality leading to vulvovaginal hyperlaxity and atrophy.

This syndrome has a great impact on the perception of body image, on self-esteem and directly on the quality life of women. This is due to the discomfort and irritation perceived when wearing tight clothes caused by laxity and hypertrophy of the vulvar lips, to the negative impact on sexuality consequence on one hand by the vulvovaginal atrophy that causes dyspareunia and on to the loss of tone of the vaginal walls that the sensation diminishes during intercourse. These situations determine a variable degree of sexual dysfunction that affects the sexual health of women and the relationship with their partners

According to a multinational survey conducted by the International Urogynecological Society (IUGA) 4 out of 5 respondents recognized vulvovaginal laxity as the main change perceived after vaginal delivery, aggravated by natural aging, and accepting it as a condition that generates a great impact on the sexual relationship with their partners. Nowadays, due to cultural and social advances, vaginal rejuvenation has ceased to be a taboo subject reflected by the increase on the demand for treatments that seek to give results to the aforementioned functional problems.

The aim of the present study is to evaluate the efficacy of the treatment protocol to treat vulvovaginal laxity using the new technology developed by Body Health, "Enygma X-Orbital".

The following is a study aimed to women whose quality life is affected by genitourinary signs and symptoms associated with vulvovaginal hyperlaxity. The main focus of the study is aimed at evaluating the efficacy of "Enygma X-Orbital" as the new technology of choice for the treatment of said pathology.

## MATERIALS AND METHODS

This is a private study carried out to test the effectiveness of the innovative development created by Body Health, "Enygma X-Orbital" that uses electromagnetic energy emitted in an orbital way as a non-surgical alternative for vaginal rejuvenation in women with vulvovaginal hyperlaxity and symptoms associated (stress urinary incontinence and sexual dysfunction).

All the patients involved in the study were correctly informed about the therapy to be performed and gave their consent for the procedure and the publication of the collected data. The selected candidates were women between 36 and 53 years old who currently have a negative pregnancy test and previous gynecological examination with normal pap smear, no evidence of pelvic organ prolapse, no bleeding or injury to the vaginal canal, introitus or lobby. Sexually active heterosexual women were included (at least 2 sexual intercourse per month).

In patients who are taking medication such as psychotropics, antidepressants and antihypertensive drugs that could affect sexuality, they should have been taken constant doses of medication in the last 3 months. Patients taking medication that could affect collagen metabolism or healing, such as non-steroidal anti-inflammatory drugs, glucocorticoids, immunosuppressants or biological agents, were excluded.

The study participants had a complete physical examination, including gynecological examination with cytology using the Papanicolau method and colposcopy. The writing of a complete clinical history was made with special emphasis on gynecological and obstetric history. The exclusion criteria were patients with a history of pelvic surgery less than 6 months, the presence of pregnancy or pregnancy planning, patients with alterations in the latest gynecological results, patients with vulvar lesions, patients undergoing hormone replacement therapy 6 months prior to the study, patients with acute or recurrent genitourinary tract infections, patients with chronic pelvic pain, patients with vulvovaginal lesions, patients with psychological / psychiatric disorders that prevent correct compression of the patient when making the decision to participate in the study and therefore signing the informed consent.

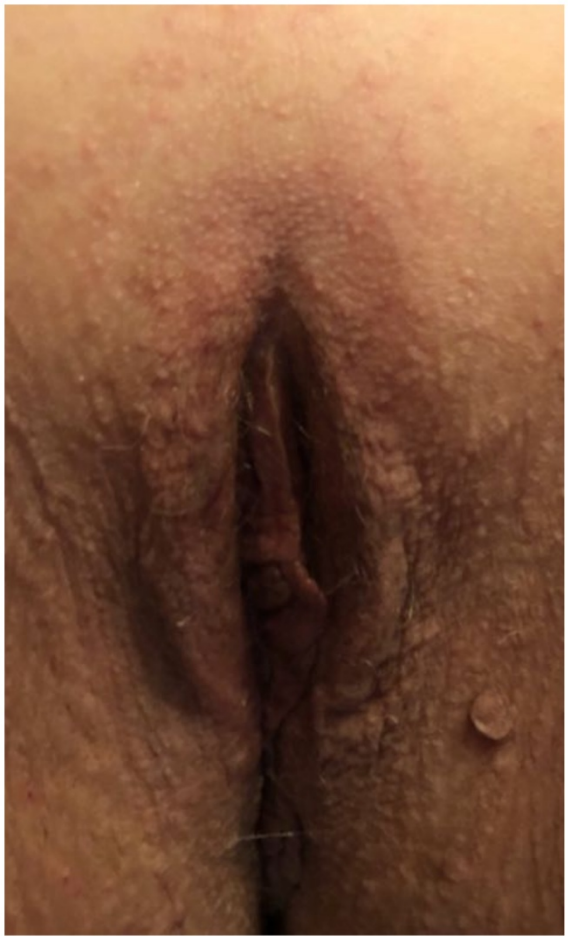
It is a necessary condition for the correct application of the procedure 48 hours of sexual abstinence before and after the session.

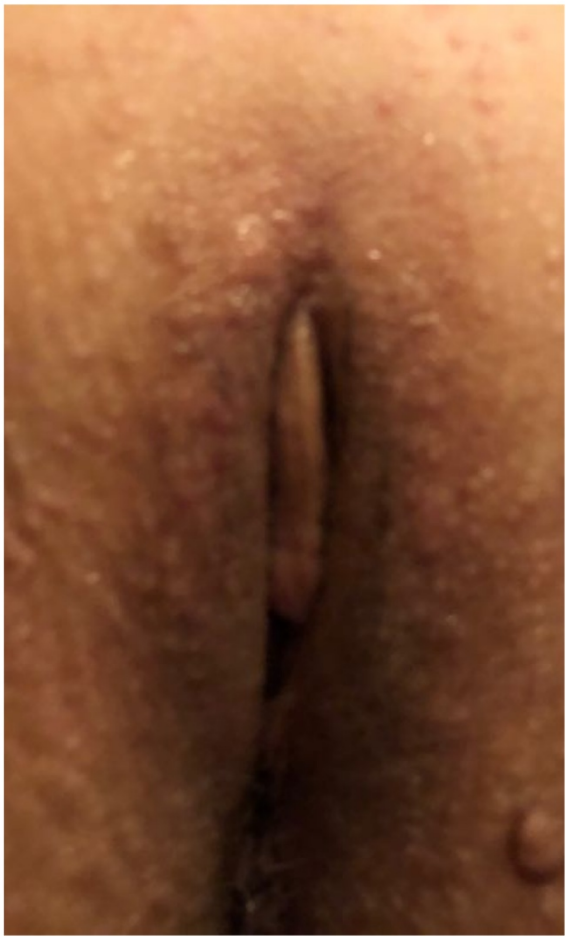
The treated patients had a medical appointment prior to the first session where they were clinically evaluated and photographed. Before and after the

session, photographs of the vulvar region and vaginal introitus were taken to evaluate the degree of tissue retraction obtained. In the course of the session were evaluated vital signs and the presence of adverse effects with special reference to feeling pain or discomfort. In addition, 24 hours after each session, a telephone follow-up was carried out investigating the presence of similar adverse effects.

6 cases of patients who received one session of "Enygma X-Orbital" are shown below. Each case has before and after session photographs and tables that resumes the main characteristics of each patient and treatment. The 6 treated patients were evaluated clinically throughout the session evaluating tolerance and the presence of adverse effects. The treatment power was selected based on the tolerance of each patient. The time was selected based on the pathology each patient present and the intra-treatment tissue retraction.

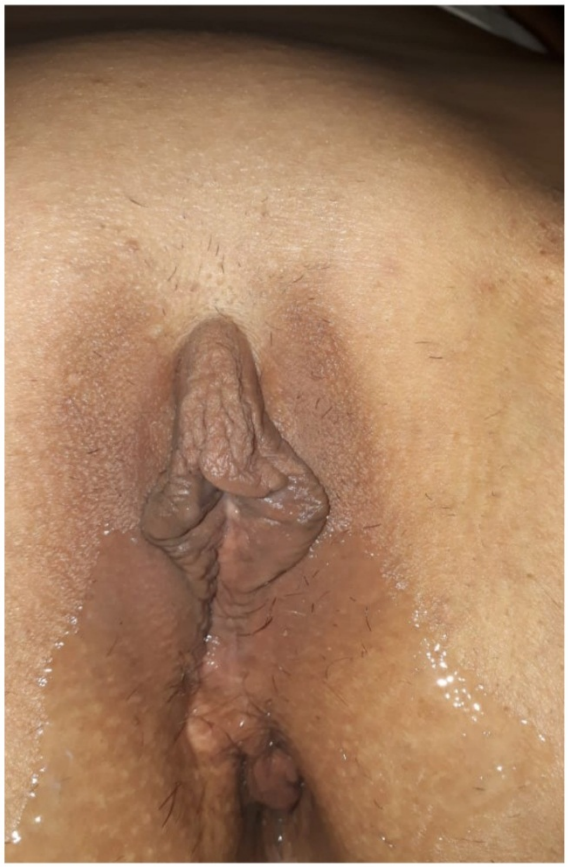
## Patient 1:

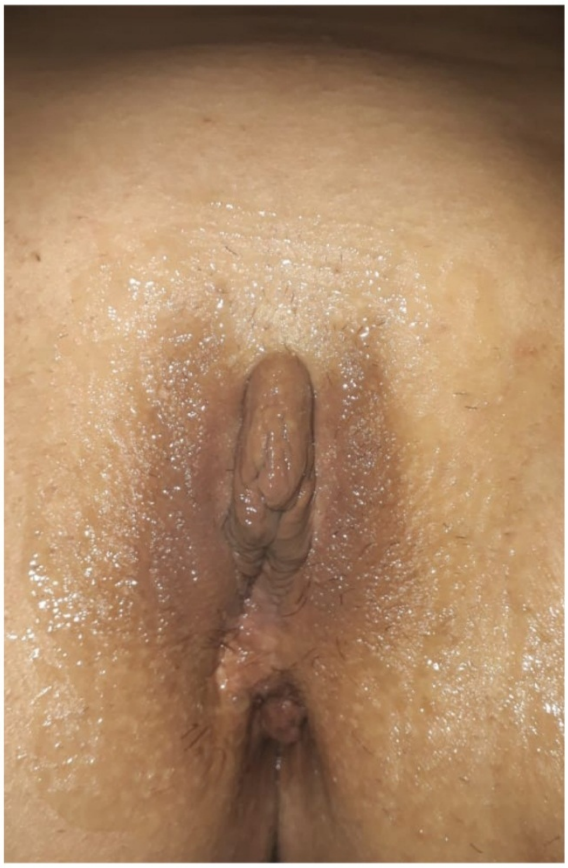




| Age | 50 years |
|---|---|
| Hormonal Stage | Postmenopause |
| Pregnancies | 2 |
| Vaginal births | - |
| Cesareans | 2 |
| Internal application time | 6 |
| Internal power | 60% |
| External application time | 8 |
| External power | 70% |
| Frequency | HIGH |

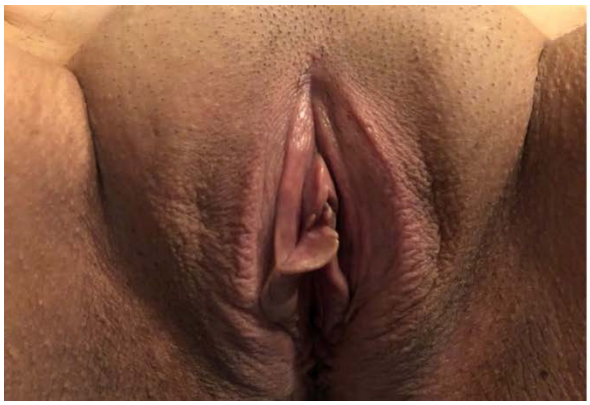
## Patient 2:

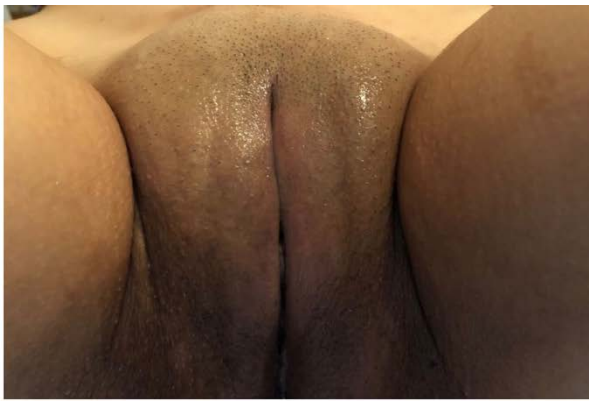




| Age | 53 years |
|---|---|
| Hormonal Stage | Postmenopause |
| Pregnancies | 2 |
| Vaginal births | 2 |
| Cesareans | - |
| Internal application time | 8 |
| Internal power | 60% |
| External application time | 8 |
| External power | 60% |
| Frequency | HIGH |

## Patient 3:

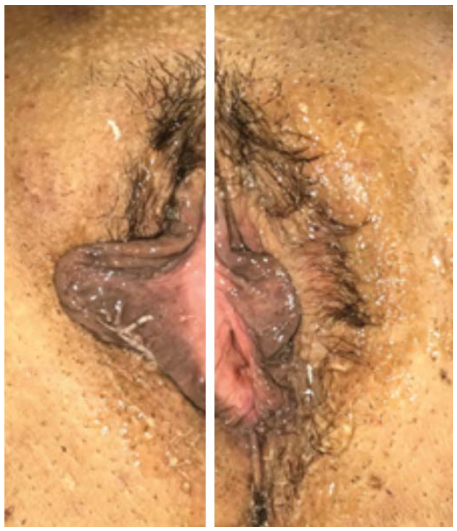




| Age | 36 year |
|---|---|
| Hormonal Stage | Premenopause |
| Pregnancies | 2 |
| Vaginal births | 2 |
| Cesareans | - |
| Internal application time | 10´ |
| Internal power | 60% |
| External application time | 6´ |
| External power | 60% |
| Frequency | HIGH |

## Patient 4:

Untreated area

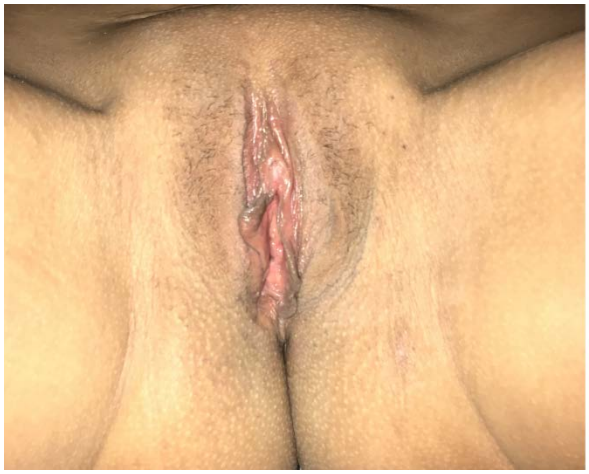


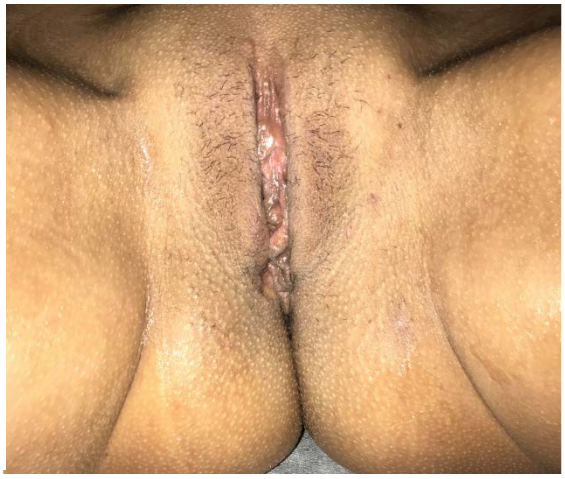
Treated area

Intra-treatment photo, the endocavitary treatment and the external application of the left upper and lower lip were performed to the patient.

| **Age** | **48 years** |
|---|---|
| **Hormonal Stage** | Perimenopause |
| **Pregnancies** | - |
| **Vaginal births** | - |
| **Cesareans** | - |
| **Internal application time** | 13´ |
| **Internal power** | 60% |
| **External application time** | 8´ |
| **External power** | 60% |
| **Frequency** | HIGH |
| **Urinary stress incontinence** | YES |

## Patient: 5





| Age | 36 years |
|---|---|
| Hormonal Stage | Premenopause |
| Pregnancies | 4 |
| Vaginal births | 2 |
| Cesareans | 2 |
| Internal application time | 8´ |
| Internal power | 70% |
| External application time | 6´ |
| External power | 70% |
| Frequency | HIGH |

## Patient: 6

| Age | 53 years |
|---|---|
| Hormonal Stage | Postmenopause |
| Pregnancies | 2 |
| Vaginal births | 2 |
| Cesareans | - |
| Internal application time | 15´ |
| Internal power | 60% |
| External application time | 8´ |
| External power | 70% |
| Frequency | HIGH |
| Urinary stress incontinence | YES |
| Prolapse | Grade 1 |

## Results

Previously to the session, the patients self-assessed the degree of laxity of the introitus, vaginal canal and labia vulva, classifying the perception of the degree of vulvovaginal relaxation they presented.

Clinical benefits with "Enygma-X orbital" were perceived by patients themselves and evidenced change immediately after the session, the 6 patients mentioned a change in the perception of the degree of vaginal laxity, making special reference to the narrowness of the vaginal canal and the retraction of the vulvar lips.

We will make special reference to the sixth patient who presents prolapse of the pelvic floor of grade 1 associated with urinary stress incontinence. With a "Enygma X-Orbital" session a certain degree of retraction of the introitus and the prolapsed floor was achieved as evidenced in the photograph, improving the discomfort presented by the patient caused by the prolapse, especially a remarkable improvement in the urinary incontinence was obtained .

All the Patients referred to the treatment as a pleasant procedure with the perception of a slight heat throughout the session. None of the patients reported the presence of adverse effects during or after the session.

## Conclusions

Based on the clinical experience obtained, we can say that the technology of "Enygma X-Orbital" as a non-surgical method for vaginal rejuvenation in women with vaginal laxity and / or associated symptoms is a safe and well tolerated treatment with an excellent profile of tracking security. Other minimally invasive therapies on the market frequently have adverse effects such as bleeding, pain and burning that limit adherence to treatment. "Enygma X- Orbital" offers greater safety over other radiofrequencies and lasers by generating a radiated and gradual tissue warming giving greater safety by minimizing the risk of thermal injuries.