ASSESSMENT OF FEASIBILITY ON VAGINAL LASER APPLICATION:
Vaginal Photo Restructuring

The **MIXTO-PRO V-LASE** system was evaluated with a basic "setting" which provided an output power of 13w CW with only one spot repetition and with a CCS of 150. With this basic setting, interesting results were achieved through a safe outpatient procedure and without the ablation of the vaginal tissues or visible carbonization elements. On this basis, the improvement of the results was subsequently evaluated in cases of advanced atrophy, with or without USI (urinary stress incontinence) symptoms.
The **V-LASE** procedures were performed in an outpatient clinical environment (Althea Day Surgery Centre), without pharmacological preparation, without any local anaesthesia and post-treatment medication.
Before the procedure, all the patients were studied and the degree of atrophy of the mucous membranes was determined; this made it possible to subsequently evaluate the result according to the type of treatment performed in an attempt to customize the protocol (essential condition for the success of the treatment from the first application).

The procedure. After installation of the patient on the gynaecological table, a disposable speculum was used and the vagina was cleaned with a disinfecting solution (H2O2 at 2% or ready chlorhexidine solution) and then dried with a gauze pad. With the help of a vulvar washer, the gynaecological device was introduced (previously prepared according to prior indications). The laser application always started from the front vaginal wall and using the graduated scale present in the device and in the vulvar washer, following the path through the vagina proved easy. More specifically, starting from the rear-vaginal fornix, a clockwise rotation was performed, emitting the laser spot every 30 degrees. After completing the rotation, back to square one, the device was retracted, according to the graduated scale, by about 7mm, before repeating the procedure as described. After terminating the vaginal procedure, having reached the introitus, the device was removed and replaced by the defocalizing spacer vulvar insert before proceeding with the irradiation of the introitus mucous, starting from the fork as far as the paraclitoris region, bilaterally.
The procedure was thus terminated and the patient immediately resumed her activities, without any supportive therapy.

Patient management. The patients were treated with three laser applications (T1, T2, T3) every 30 days, with a screening visit two weeks before the first laser treatment (baseline or T0) and follow-up visits after 2 weeks from the laser application. During the baseline visit (T0) a swab was performed for common germs and fungi.
After treatment, the patients were advised to avoid sexual intercourse for 2-3 days.
The majority of postmenopausal women also suffer from urinary stress incontinence (USI), and this also affected the group of patients selected for the assessment in question. The degree of incontinence was assessed by means of the international questionnaire Incontinence-Short Form (ICIQ-UI SF), where a maximum score of 21 points means permanent incontinence and therefore a "not indicated" for treatment.
For the study group, none of the patients had a pelvic organ prolapse higher than stage II. These patients, during V-Lase procedures, were also subjected to additional laser treatment of the front vaginal wall, "designed" for urinary incontinence (USI setting).

Inclusion of patients. At the first visit, the suitability of the patients was checked, the written informed consent deposited and socio-demographic and clinical characteristics were noted in data collection forms. The subjective symptoms (vaginal dryness, dyspareunia, essential pruritus, dysuria) were assessed by a visual analogue scale (VAS) at each visit (range 1-10, 1 total absence of symptom and 10 maximum symptoms). In addition, at each visit during the gynaecological examination, the vaginal physiological condition was evaluated with the Vaginal Health Score Index (VHI). The VHI assesses the appearance of the vaginal mucous (elasticity, pH, vaginal discharge, the integrity of the mucous and moisture). Each parameter was rated from 1 to 5. If the total score was at least 15 (or less), the vagina was considered atrophic.

Device management (protocols). The laser parameters used were based on a fluence of 1,000 mJ/cm^2, with the VA mode in CW and 13w power; the vestibule and introitus were irradiated with a defocalized 10 mm spot with VA mode and 13w power and CCS 90. A second protocol in the event of marked atrophy (VHI below 10) was set up with a VA in CW mode and power 13w CCS 100 with RIP 2 (double repetition of single point). In case of confirmed or reported USI, after vaginal treatment, the protocol was set to provide a passage on the front vaginal wall with USI mode at 13w and CCS 150.

Summarizing the applied initial protocols, we can distinguish:
mild to moderate atrophy protocol ---- VA 13W CW mode CCS 150
severe atrophy protocol ---- VA 13W CW mode CCS 100 RIP 2
USI protocol ---- USI CW 13W mode CCS 150 on the front wall after complete vaginal treatment

Device management (sterilization). With regard to the sterilization of the device, after treatment rapid cleansing was applied with H2O to remove organic residues with a soft brush, followed by a bath in the enzyme solution for 10 min, then washing with saline solution and drying by means of the compressed air system in the operating theatres; the device was then placed in a double sealed bag and sterilized in a short cycle to 136 degrees for 20 min.

Results. V-LASE was well tolerated, with less than 3% of patients discontinuing treatment due to adverse events: one patient described the procedure unacceptable, saying she felt a burning sensation from the start which lasted a couple of days. One patient left the study for personal reasons. 22 patients completed treatment with the three applications. 18 patients (82%) defined the result of the procedure as excellent-good, 3 patients (13.6%) as acceptable, and 1 patient (4.4%) as an annoying experience which failed to improve symptoms.

These results indicate that the **V-LASE** treatment is able to induce a fast and efficient improvement of the signs and symptoms of vaginal atrophy in menopause.

A significant subjective and objective improvement becomes apparent after the first laser application; a more pronounced effect is evident after the second and third laser application.
The long term effects should be evaluated with follow-up after 4 months from the **V-LASE** application.

V-LASE *is easy to perform*, especially after the first laser application, and the insertion of the probe in the vaginal canal is also well tolerated in cases of reduced compliance.

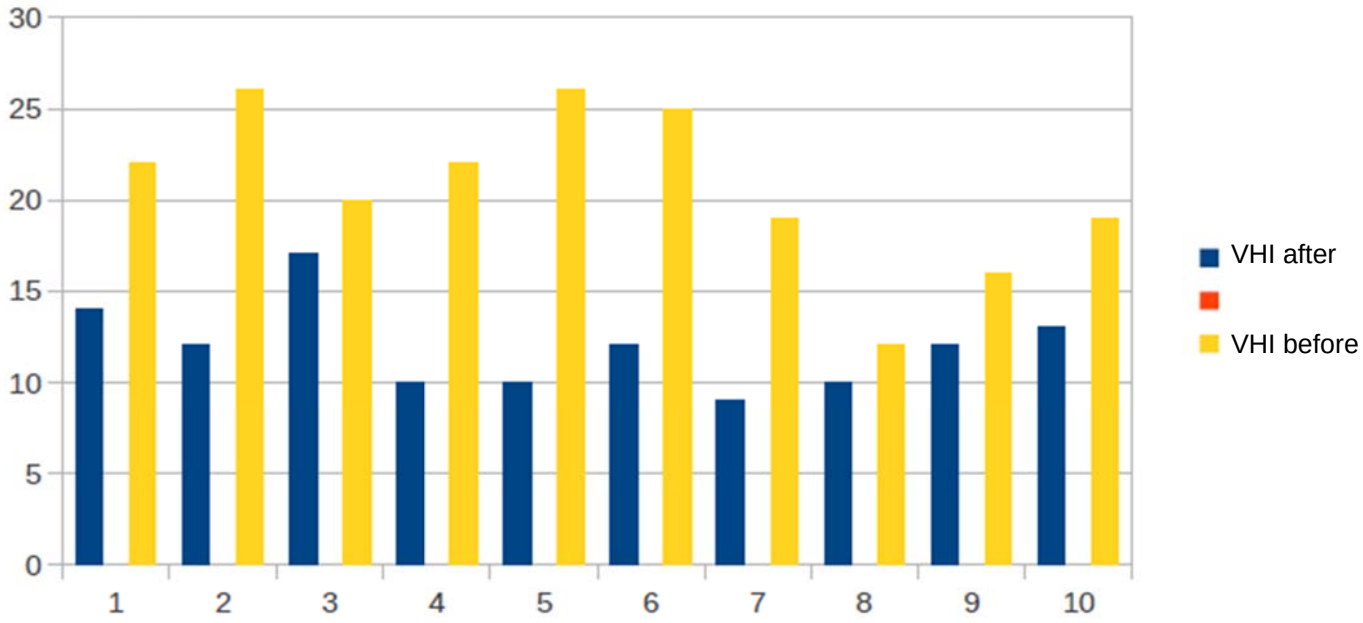
In the feasibility study in question, the **V-LASE** treatment was performed in postmenopausal women suffering from GSM without any previous or concomitant treatment with oestrogens or even non-hormonal vaginal creams. Therefore, this evaluation suggests that the effects of **V-LASE** are independent of any pre-treatment, which permits suggesting treatment to postmenopausal women who cannot be treated with hormone replacement therapy.

Furthermore, the data collected suggest that the V-Lase treatments can be helpful in postmenopausal women with mild to moderate USI. In fact, in women suffering from postmenopausal GSM and even mild to moderate USI, **V-LASE** improved the ICIQ-SF scores. The effect of **V-LASE** on USI is of particular interest. Urinary incontinence is a common and major health problem which is underestimated, little diagnosed, and therefore not treated in post climacteric women. The non-surgical treatment of USI is a major challenge for health and the psychological well-being of menopausal women.

Clinical Manager: Dott. Antonio Castelli

Annex: evaluation of results of first 10 patients with complete follow up after 4 months

Schematic assessment of VHI grading score of vaginal atrophy before and after treatment



Symptom assessment with VAS scale before and after treatment