

ASSESSMENT OF FEASIBILITY ON VAGINAL LASER APPLICATION: *Vaginal Photo Restructuring*

System evaluation. The **MiXto Pro V-Lase** system was evaluated with a baseline "setting" which provided an output power of 13 W (average CW power) with spot repetition set at 1 and with a pulse width (designated "**CCS**" [**CW Chopped Sequence**]) of 150 ms. With this basic setting, interesting results were achieved via a safe outpatient procedure without ablation of the vaginal tissues or visible elements of carbonization. On this basis, the results of the improvement were subsequently evaluated in cases of advanced atrophy, with or without SUI (Stress Urinary Incontinence) symptoms.

The **V-Lase** procedures were performed in an outpatient clinical environment (Althea Day Surgery Centre), without pharmacological preparation, local anaesthesia or post-treatment medication. Before the procedure, all patients were evaluated and the degree of mucous membrane atrophy was determined; this made it possible to subsequently evaluate the results according to the type of treatment performed in an attempt to customize the protocol (essential requirement in order to obtain treatment success from the first application).

The procedure. After placing patient on the gynaecological table, a disposable speculum was used to clean the vagina with a disinfecting solution (H_2O_2 at 2% or ready chlorhexidine solution) and then dried with a gauze pad. With the help of an insertion ring, the gynaecological device was then inserted vaginally. The laser application always started from the front (upper) vaginal wall at the 12 o'clock position using the graduated scale marked on the device and on the insertion ring. Following the path through the vagina proved easy. More specifically, starting from the anterior-vaginal fornix, a 360° clockwise rotation was performed, emitting the laser spot every 45°. After completing the rotation, back to square one, the device was retracted 1 cm at a time, according to the graduated scale, by about 7 mm, before repeating the procedure a second time as described. After terminating the vaginal procedure, having reached the introitus (vaginal opening), the gynaecological device and insertion ring were removed. The vaginal probe's long mirror extension was separated (unscrewed) from the collimating (defocalizing) lens assembly which is directly attached and remains connected to the end of the laser arm. Laser radiation is now applied to the introitus mucous, starting from the fork (frenulum of the labia minora) as far as the paraclitoris region, bilaterally, using the same laser settings as described above. 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 2 weeks after each laser application. During the baseline visit (T0) a swab was performed for common germs and fungi.

After each treatment, the patients were advised to avoid sexual intercourse for 2-3 days. The majority of postmenopausal women also suffer from stress urinary incontinence, 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 "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 an additional laser treatment of the front (upper) vaginal wall, using the stress urinary incontinence (SUI) setting.

Inclusion of patients. During the first visit, the suitability of the patients was checked, the written informed consent signed, and socio-demographic and clinical characteristics were noted in data collection forms. The subjective symptoms (vaginal dryness, dyspareunia, essential pruritus, and 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/cm², VA mode, and power of 13 W in CW; the vestibule and introitus were irradiated with a defocalized (collimated) 10 mm spot in VA mode, 13 W of power and a CCS of 90 ms. A second protocol in the event of marked atrophy (VHI below 10) was set up with VA mode, power of 13 W, and a CCS of 100 ms in repeat mode set at 2 (double repetition of a single point). In case of confirmed or reported SUI, after vaginal treatment, the protocol was set to provide a passage on the front (upper) vaginal wall in SUI mode, power of 13 W, and a CCS of 150 ms.

Summarizing the applied initial protocols, we can distinguish:

- mild to moderate atrophy protocol ---- VA mode, 13 W CW, CCS of 150 ms
- severe atrophy protocol ---- VA mode, 13 W CW, CCS of 100 ms, repeat set at 2
- SUI protocol ---- SUI mode, 13 W CW, CCS of 150 ms on the front (upper) 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° 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

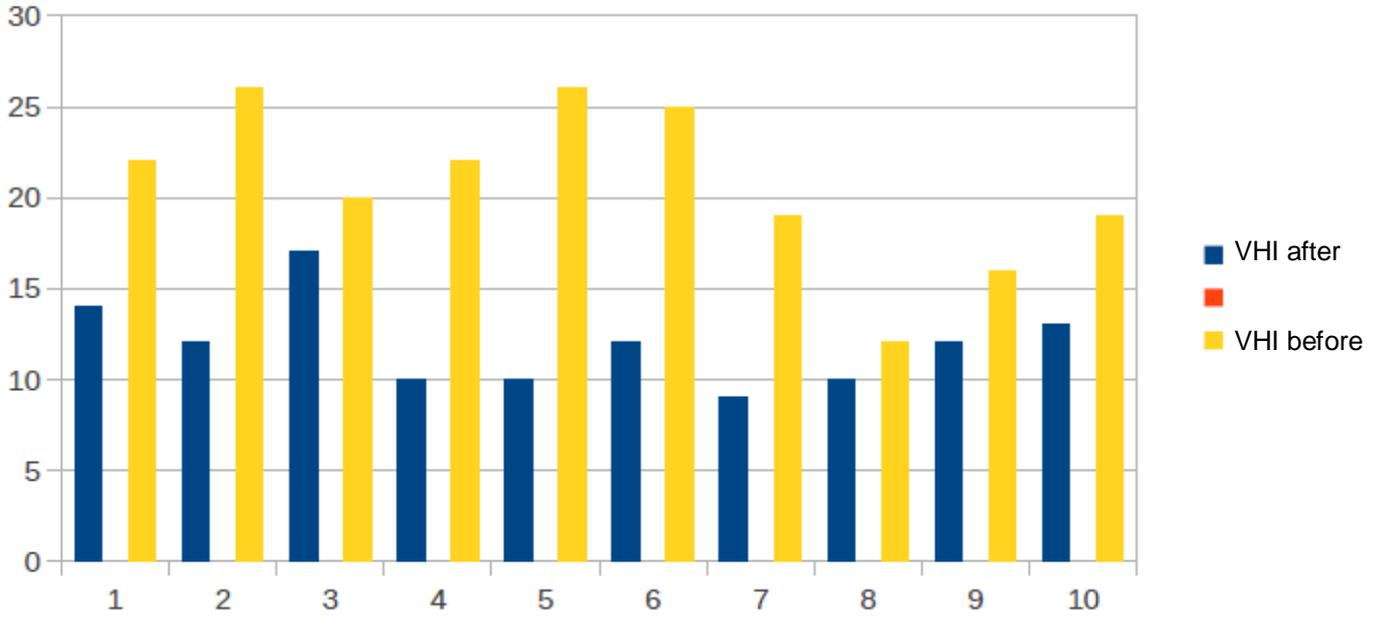
V-LASE are independent of any pre-treatment, which permits suggesting treatment to postmenopausal women who cannot be treated with hormone replacement therapy.

Furthermore, the data collected suggest that the **V-LASE** treatments can be helpful in postmenopausal women with mild to moderate SUI. In fact, in women suffering from postmenopausal GSM (genitourinary syndrome of menopause) and even mild to moderate SUI, **V-LASE** improved the ICIQ-SF scores. The effect of **V-LASE** on SUI 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 SUI is a major challenge for health and the psychological well-being of menopausal women.

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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

