

Clinical Evaluation:
Using the fractional CO2 laser, FRAXIS
GYNOLASER for female disorder



GYNOLASER

VAGINAL REJUVENATION FOR ULTIMATE
CONFORT AND CONFIDENCE



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Evaluation of using the fractional CO2 laser, FRAXIS GYNOLASER for female disorder

Abstract :



The aim of our study was to describe the possibility of using the FRAXIS laser with the GynoLaser applicator in a gynecologist's office.

The consequences of childbirth and hormonal changes accompanied by aging or fluctuations in weight can lead to reduced elasticity of the vaginal tissue, collagen loss and muscle weakness. These anatomical changes then often lead to occurrence of stress incontinence, vaginal drying and insufficient or even a painful sensation during sexual intercourse, which negatively affects the quality of life of women.

The FRAXIS GYNOLASER offers a fast, safe and highly effective non-invasive procedure, which solves the above-mentioned broad variety of female disorders. The FRAXIS GYNOLASER provides a comprehensive treatment that can be performed on an outpatient basis without the necessity of anesthesia, pain or a long recovery period.

Introduction :

Stress Incontinence



Stress incontinence is leakage of urine without detrusor contraction with a simple increase in the intra-abdominal pressure. It is caused by an insufficient functioning of the urethra closing mechanism. When the intra-abdominal pressure increases pathologically, there is no compression of the urethra (the normal mechanism), on the contrary, the urethra moves freely (hypermobility) and the pressure pushes the urine into the urethra through the wall of the bladder. Patients suffer from stress incontinence during various activities, which increase the intra-abdominal pressure, e.g. coughing, sneezing, laughing or lifting heavy objects. The problem of stress incontinence is usually solved by means of pelvic floor exercises or surgery (surgery for urinary incontinence using a sling). However, like any surgery, this invasive method has its complications (about 13%), which are usually associated with bleeding, pain in the groins spreading into the lower extremities and disturbances of micturition, which occurs for several days after surgery.

Stress incontinence



Sagging and weakness of the bladder neck.
Urine leaks during a cough or movement

Serious complications may also include thrombosis, bleeding during surgery or an injury to the uterus/surrounding organs. If the procedure is performed under general anesthesia, there is an even higher possibility of complications and risks.

The FRAXIS laser with the GynoLaser applicator offers a new safe treatment of grade-I stress incontinence. Requirements on laser technology, which would be capable of solving problems of incontinence, include a high thermal effect and higher penetrability of laser beams into the tissue. These conditions for treatment of stress incontinence can be met only by the CO2 laser technology, which - unlike Er: YAG systems –fulfils the requirement of high penetrability into the tissue and high thermal efficiency.

The result of the use of the laser is remodeling and new collagen synthesis in the area under the urethra and under the bladder, which reinforces the key stress area of the closure of the bladder.

Vaginal Weakness

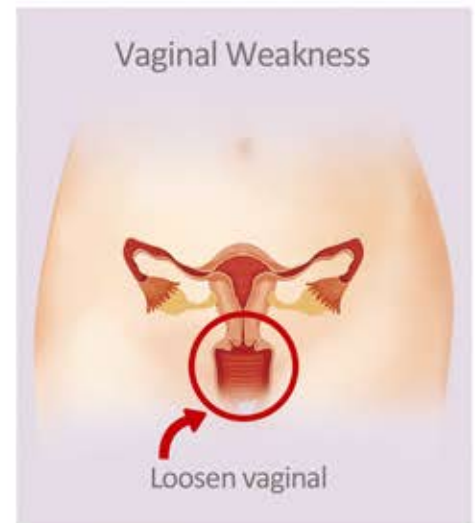


A certain type of vaginal weakness probably occurs in all women after giving birth naturally, but it turns out to be a serious restriction for approximately 20% of them. Vaginal laxity may lead to reduced tightness and sensitivity in the vaginal area, resulting in lower satisfaction during sexual intercourse for both partners.

Laser vaginal-plastic is a classic solution, which is used to solve significant degrees of vaginal weakness, and it performed under general anesthesia, which involves several weeks of convalescence in addition to certain health risks.

Unlike surgery, the FRAXIS laser with the GynoLaser applicator restores and rejuvenates the vaginal wall in a safe, quick and non-invasive way, and moreover, it also results in the formation of new blood vessels (a better blood flow) and an increase in the sensitivity of receptors.

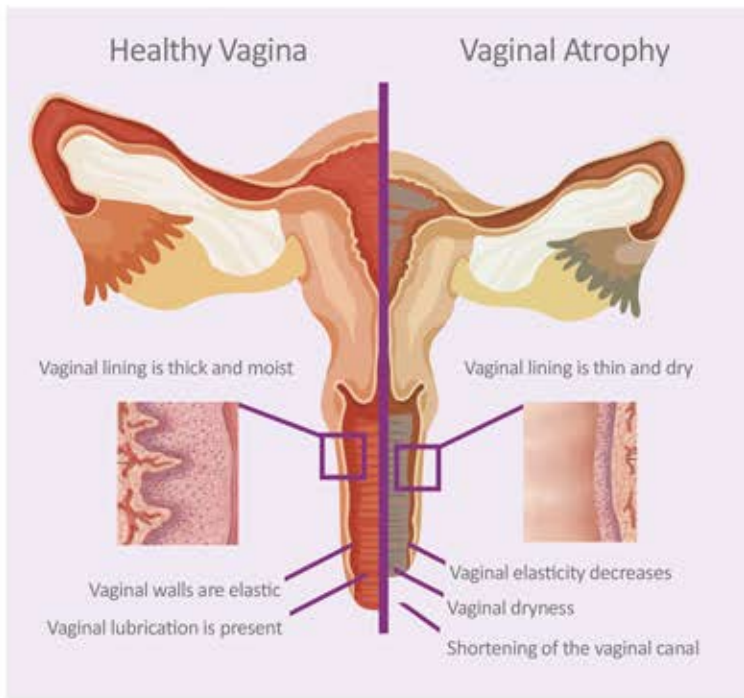
A concentrated thermal effect and micro ablation is applied along the entire inner layer of the vaginal wall, so that it stimulates collagen regeneration and contraction of elastin fibres. This leads to vaginal rejuvenation and a reduction in the diameter of the vagina.



Vaginal Atrophy



Symptoms of atrophic vaginitis usually appear 5 years after menopause and they may affect up to 61% of women at this stage of their life. A patient with vaginal atrophy may suffer from a variety of symptoms ranging from itching, decreased vaginal secretion, dyspareunia, bleeding during intercourse, polyuria etc.



These symptoms may deteriorate over the years and they may have a significant impact on sexuality and the overall quality of life, but only about 3% patients decide to seek medical help in order to solve this problem.

Topical estrogen therapy acts only on the surface of the vaginal mucosa and it results in only a temporary improvement of the condition of the patient, not to mention its potential negative side effects. The treatment with the use of the FRAXIS laser with the GynoLaser applicator improves the insufficient vaginal secretion and treats dyspareunia. Positive side effects include anti-inflammatory effects thanks to the resumption of glycogen production in the vagina, which balances the PH level.

Treatment Methods using the FRAXIS laser with the Gynolaser Applicator



The study was conducted over 6 months. Inclusion criteria were: patients, who will benefit from treatment with the CO₂ laser in a continuous, pulsed or fractional mode for indications that have been verified in at least one publication. Patients, who were excluded from the study:

- patients with urinary or genital infections
- patients, who have undergone reconstructive surgery
- patients with malignant tumours
- patients with epilepsy
- patients taking photosensitive drugs
- patients with poor cytology results
- patients with anticoagulation therapy and bleeding diathesis

Technology and indications:

The laser used was the FRAXIS fractional, gynecological and surgical CO₂ laser, model FRX-C1, with RF laser tube from the manufacturer Synrad USA with the patented Gynolaser applicator including the I-Slide applicators.



The study included 17 patients with 4 different indications in total. The indications and treatment parameters were the following:

Using the surgical head - pulsed or continuous mode



- Three patients with the indication of vulvar warts and 1 patient with a vulvar fibroma were treated. The values used for the treatment were the following: pulse mode (50 ms on, 50 ms off), power: 0.5 - 5 W depending on the size of the problem, 1-3 transitions, the endpoint: disappearance of the lesion.

Surgical head



SmartSurgi™

- The main advantage of the surgical SmartSurgi applicator of the FRAXIS laser lies in its fast setting options for the surgical spot size at seven different positions from 0.2 mm to 1.3 mm, when the spot size of 0.2 mm is suitable for precision surgery, as opposed to spot sizes approaching 1.3 mm, which are ideal for evaporation of larger areas.

Using the fractional head



- Three patients were treated for the purpose of rejuvenating the vulva
- The labia majora, which showed laxity and increased pigmentation: fractional mode, power: 70 to 105 mJ, 2 transitions, the spacing between the spots 0.8 - 1 mm.

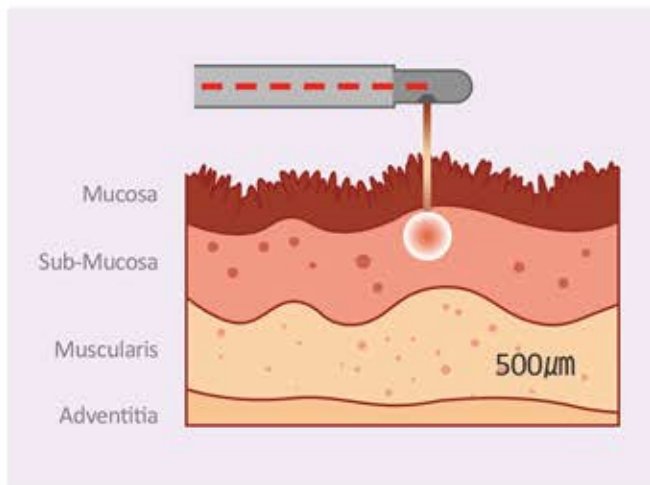


Using the gynecological head



- The study included 10 cases, of which, 5 patients for treatment of urethra for SIM I, power: 66-99 mJ, the spacing between the spots: 0.8 mm, overlap 1x.
- 5 patients for vaginal rejuvenation – size reduction of the vagina and treatment of vaginal atrophy: power 60 to 99 mJ, 1 transition, the spacing between the spots was 0.8 mm.

The treatment procedure for vaginal rejuvenation/stress incontinence:

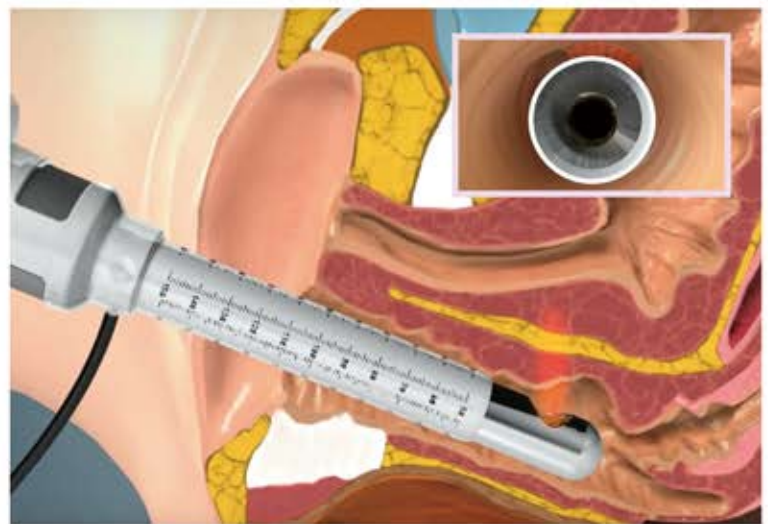


The GynoLaser Applicator supplies energy to the tissue in the fractional mode with the surface area of 8 x 8 mm. The thermal effect is achieved in microscopic columns, thereby reducing thermal damage to the surrounding tissue. This causes contraction of collagen fibres and stimulates neocollagenesis.

Treatment with the Gynolaser applicator was conducted without general or local anesthesia, Emla was used in the other cases. Before treatment, the vaginal canal was cleaned and dried, in order to avoid reduction in the penetrability of the tissue by laser beams.

Vaginal treatment consisted in the use of the innovated GynoLaser applicator with the patented I-Slide applicator, which effectively prevents attachment of the vaginal wall to the metal body of the applicator. Another advantage is an increased precision of the treatment, when the applicator contains a total of 8 positions, owing to which the entire vaginal wall can be treated with sufficient spacing between the treated spots.

Benefits also include weak airflow to the applicator, which improves penetrability of the beam through any undesirable vaporised tissue. The values used for the treatment were the following: 66 to 90 mJ, the spacing between the spots 0.8 mm.



Treatment with the Gynolaser applicator

The applicator was introduced as far as the uterine cervix, and after performing the rotation of 360° once (8 positions in total), the applicator was extended by 1 cm out of the vagina. Subsequently, this system was used to treat the whole vaginal canal as far as half of the vagina, when the applicator was removed (I-Slide remains) and the mirror on the end of the applicator is checked for possible secretions. Subsequently, the applicator was inserted back into the I-Slide in the vagina and the entire treatment was performed as far as the vaginal opening.

During the treatment of stress incontinence, the urethral region was treated at the position 10 to 2 hours under the urethra (position of the Gynolaser degree 7-1). The maximum set energy was 99 mJ with a 0.8 mm spacing between the spots.

In order to achieve a long-term vaginal rejuvenation effect, it was necessary to repeat the procedure at least 4 weeks after the first treatment. The patients introduced vaginal suppositories Cicatridina with hyaluronic acid for the purpose of improved healing after intravaginal treatment with the GynoLaser applicator. Sexual intercourse was prohibited for 7 days after surgery.

During the medical check-up after the last treatment, more than 90% of patients reported high satisfaction with the results and 100% absence of adverse effects.

Discussion and Conclusion

The laser treatment brought very promising early results in treating symptoms of stress incontinence, vaginal laxity and atrophic vaginitis, without adverse effects. The potential benefits of this outpatient treatment include improved patient tolerance with a high safety profile. Further studies are needed to assess the effect in the long term. As far as I am concerned, this procedure is suitable for all post-partum women, and especially for those, who are not satisfied with the volume of their vagina, with impacts on their sexual life, and those who suffer from milder forms of stress incontinence and vaginal atrophy.

In terms of comfort and safety, the FRAXIS CO2 laser is suited for treating various benign indications, as well as aesthetic indications. FRAXIS CO2 laser with the GynoLaser applicator is a versatile tool, which can be used in the pulse or fractional mode, and which is a reliable and very useful tool for obstetrics and gynecology aesthetics.





SPECIFICATIONS

LASER	Fraxis Fractional CO2 Laser with Gynolaser
WAVELENGTH	10,600 nm
LASER POWER	Up to 30 W (RF metal tube)
PULSE DURATION	20 - 5,000 us
i-STACK	1 - 10
TREATMET AREA	1X1 - 20X20 mm
REPETITION	0.2 - 2 sec / Single
HANDPIECES & OPTICS	Probe with 90 reflecting gold-coated mirror and MicroZone Optic 8 mm Round i - SLIDE for easy operation, comfort and rotation i - SPOT distance gauge 2- 20 mm

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