# New promise in correction of vulvovaginal laxity syndromes.

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# JETT PLASMA For Her


***...the only direct current plasma device for gynaecological rejuvenation in the world!***

***CERTIFIED MEDICAL DEVICE***

- 8 intensities
- 3 types of applicators
- controlled with a footswitch
- portable

# Applicators for JETT PLASMA For Her

G-Applicator 30 mm

G-Applicator Wave

Flat applicator 10 mm

# Vulvovaginal laxity

Weakening of pelvic muscles, the syndrome of weakened vaginal walls occurs in vulvovaginal area. Vulvovaginal laxity is caused particularly by vaginal delivery, excessive physical strain, ageing or due to hormonal changes during or after menopause. It is influenced by insufficient vaginal wetness, burning and itching in vaginal orifice, yeast infections and inflammations. Consequence of the changes in woman's intimate parts is also incontinence and, last but not least, worsening of sexual life due to vaginal dryness and irritation, decreased tightness, elasticity and sensitivity. This is closely connected with woman's mental issues. After menopause, ovaries stop producing hormone oestrogen and concurrently vaginal mucosa and submucosal structures begin to atrophy due to aging.

# Vulvovaginal laxity

Vaginal mucosa consists of multi-layer squamous epithelium. Due to ageing and gradual hormone oestrogen loss, epithelium thins, and vaginal elasticity end wetness loss occur gradually. Tissue dries out and regenerates insufficiently. Dried and thinned mucosa of vagina and vulva are more susceptible to bruising that occurs during sexual intercourse or during sport activities, e.g., riding a bicycle. Sensations of pain during sexual intercourse are more intensive. Vaginal environment changes its natural pH from acidic to more alkaline, thus mucosa is more susceptible to infections. Thin atrophied vulvovaginal mucosa cannot produce moisturizing secretion in sufficient quantity, the feeling of dry vagina and vulva occurs.

# Vulvovaginal laxity

Vulvovaginal laxity worsens also due to vaginal delivery where occurrence of stress incontinence is among the most frequent negative consequences. During vaginal delivery pelvic floor is exposed to the pressure of the adjacent part of foetus and the pressure of mother's force out which can lead to anatomical and functional changes of fibrous tissue. After a certain period, post-partum, the incontinence condition is adjusted in a large group of women. Other factors are collagen changes, reduction in its tensile strength.

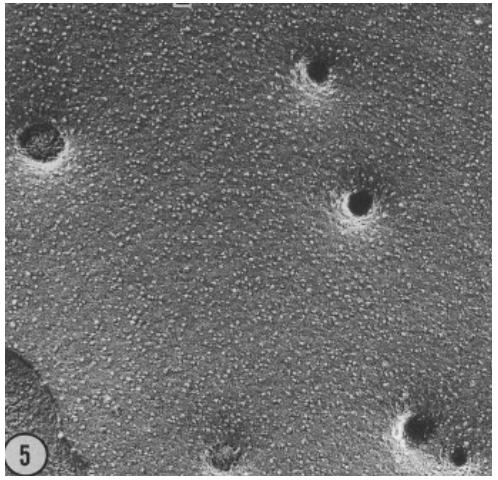
# JETT PLASMA For Her treatment

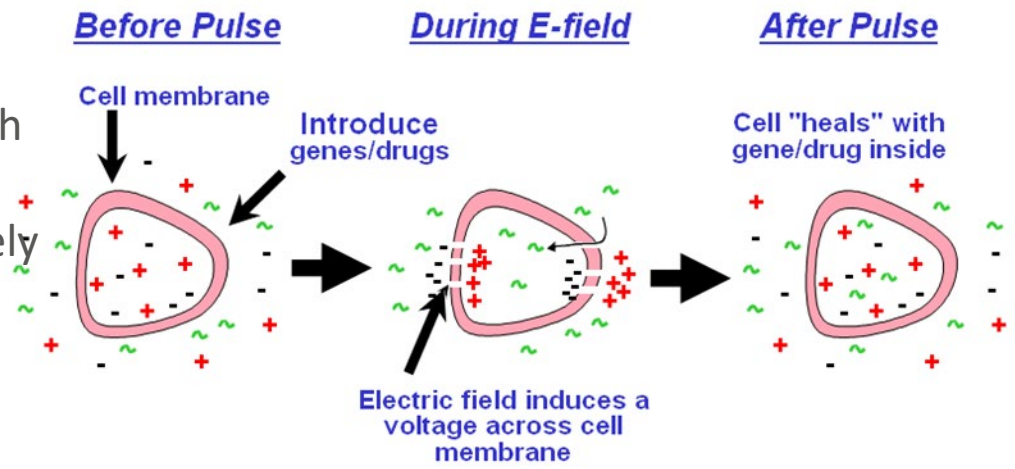
Therapeutic effects are achieved using direct current that provides membrane depolarization and reversible electroporation and thermal stimulation. Direct current as well as other heat sources start collagen activation, tissue structure is strengthened.

The procedure is painless, it does not require application of local anaesthetic, it solves rejuvenation of atrophied vaginal mucosa. It is suitable also in cases when local oestrogen vaginal creams cannot be applied (condition after oncological diseases) with oestrogen-dependent tumours. After treatment using this device, patients report significant improvement in intimate area. Spontaneous leakage of urine mitigates or nearly ceases, patient's sexual life improves, and the treatment is generally well tolerated and positively assessed for its comfort and painlessness.

# What is reversible electroporation?

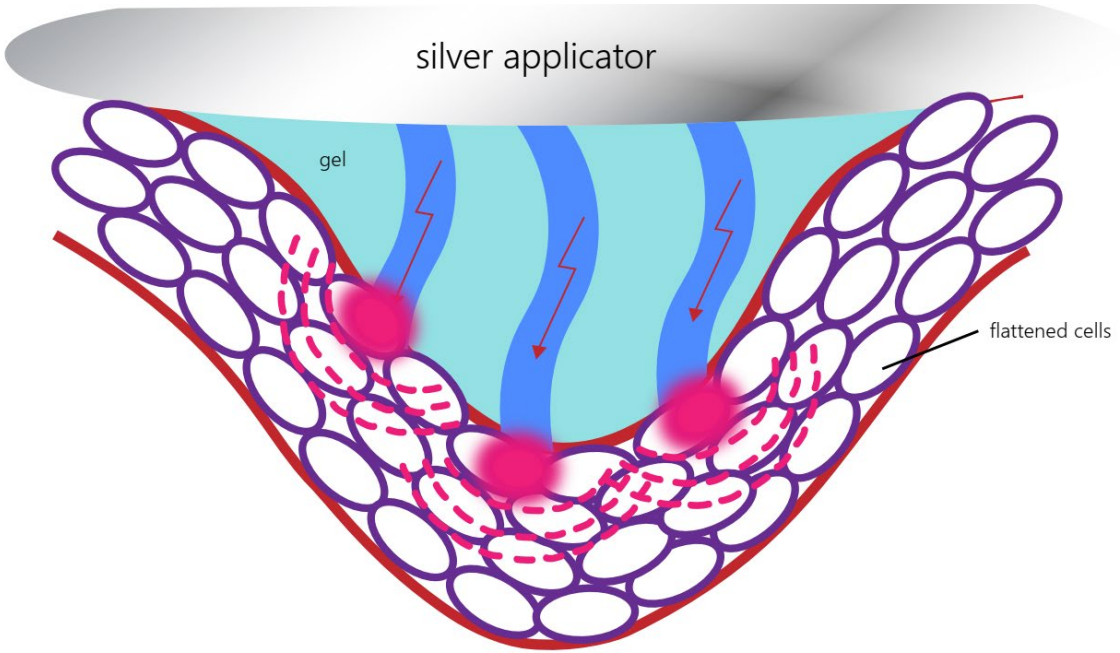
- **Electroporation** is a phenomenon observed after application of a high-voltage electrical pulse to the cell membrane.
- As a result, small temporary nanopores are formed in the plasma membrane.
- These **nanopores** allow macromolecules and other ions to pass through the membrane in both directions.
- This type of electroporation is widely used in biomedical engineering, electrochemotherapy, electro-genetherapy and **cosmetic treatments**.



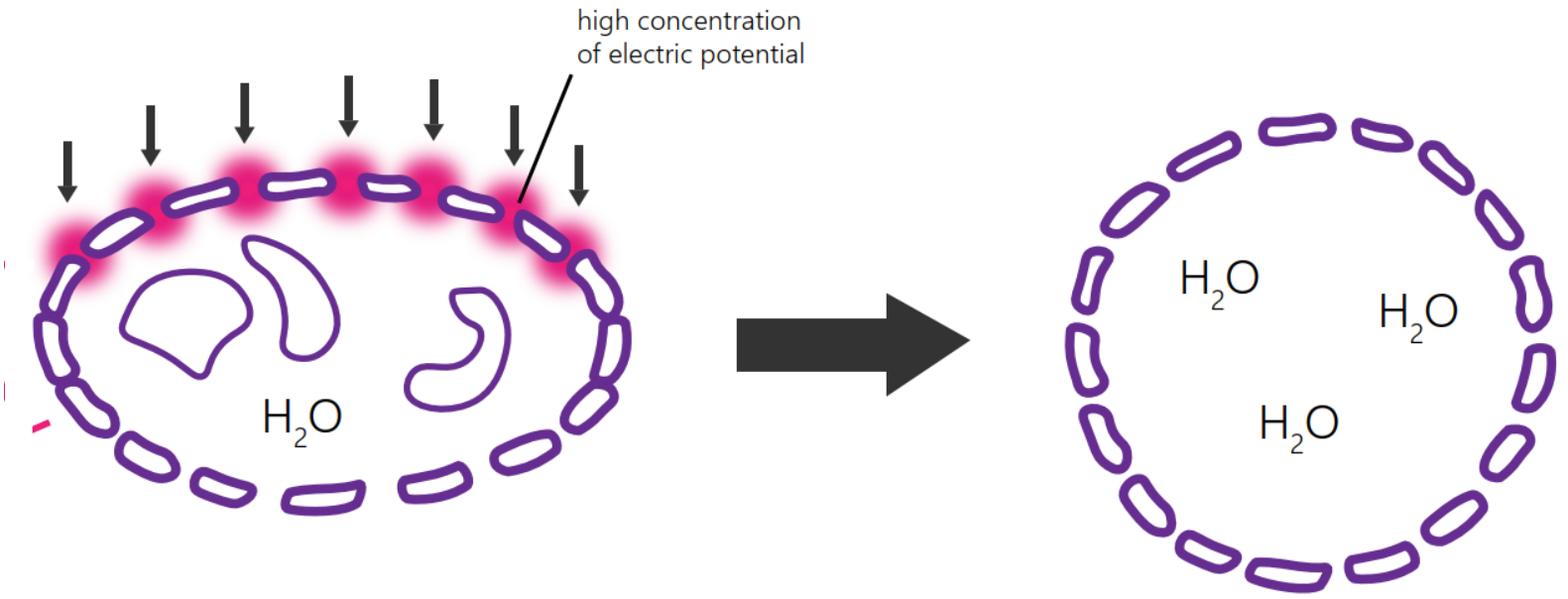
# The vulvovaginal treatment principle

- Small micro-discharges occur in the gel between the applicator and the tissue.
- Micro-discharges causes local increase of electric intensity.
- When this intensity reaches certain threshold value, the electroporation appears.
- Micro-discharges randomly arise and disappear in huge numbers, which ensures desired effect in the treated area.



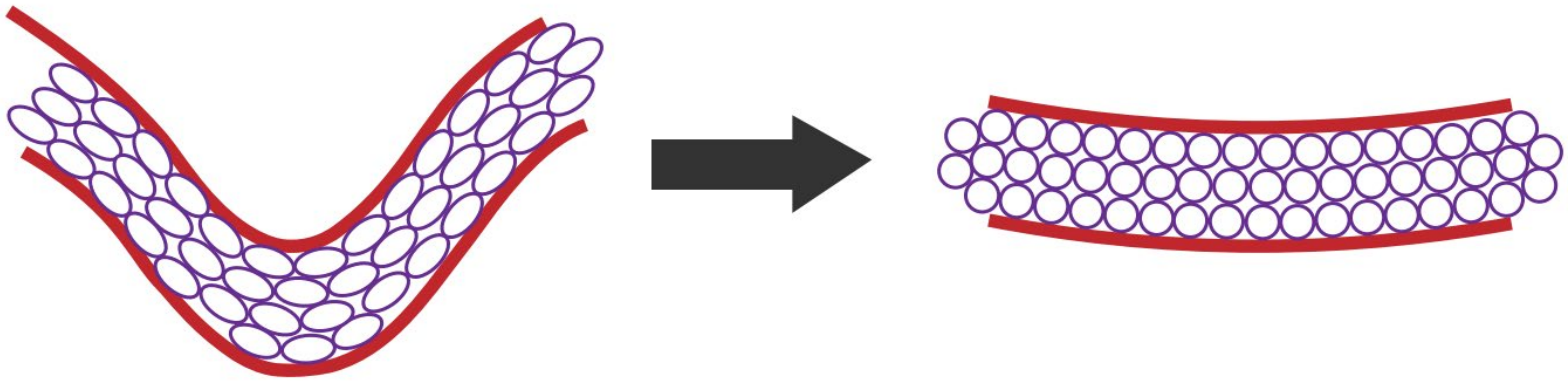
# The vulvovaginal treatment principle

- Local increase of electric intensity causes nanopore formation in the cell membrane.
- Macromolecules and ions can easily get into the cell through these pores.



# The vulvovaginal treatment principle

- The cells are refreshed and increase its volume
- The atrophy of vaginal mucosal and submucosal tissue decrease
- The cohesion between mucosal and submucosal tissue is improved
- The vulvovaginal laxity is improved



# PMCF Study – JETT PLASMA for Her

**IN PROCESS**

## Study design:

- A prospective, multi-center, controlled (single blind placebo) and randomized Post Marketing Surveillance Study Evaluating the Safety and Efficacy of the JETT PLASMA for Her for vaginal laxity treatment.

## Randomization:

- From 1-140 will be randomly assigned to either the active treatment (90 occurrences) or the placebo treatment (50 occurrences).
- If the patient agrees to the biopsy, she is assigned the number 141-150 and all of these patients undergo active treatment.

## Monitoring plan:

- An entrance examination is performed before the treatment itself. After the initial examination, the treatment takes place, which will be performed 3 times. Between the treatments, there should be a time interval of 10-14 days. After the last treatment, a check-up will be performed after 1 month, 3 months, 6 months and 12 months.

# PMCF Study – JETT PLASMA for Her

**Primary endpoints:**

- To evaluate the efficacy of JPH II for the treatment of vaginal laxity using the VLQ.

**Secondary endpoints:**

- To evaluate:
  - side effects and adverse events
  - patient satisfaction using 5 point scale
  - urinary Incontinence symptoms using UDI-6, IIQ-7, and stress test
  - sexual function symptoms using FSFI, SSQ
  - formation of new collagen fibers by biopsies

# PMCF Study – results so far

Now we have results from 30 patients with active treatment and all patients have good results.

We can show the improvement using VLQ:

- 1 point is very loose vagina
- 2 points are moderately loose vagina
- 3 points are slightly loose vagina
- 4 points are neither loose nor tight vagina
- 5 points are slightly tight vagina
- 6 points are moderately tight vagina
- 7 points are very tight vagina

The improvement of the score is following:

- VLQ 5,16 before first treatment
- VLQ 4,52 before second treatment
- VLQ 4,42 before third treatment
- VLQ 4,13 1 month after 3rd treatment

# PMCF Study – results so far

We also used IIQ7 – this questionnare has 7 questions and each has 4 possible answers and points are for each answer following:

- 1 point is for no effect at all
- 2 points are for slightly effect
- 3 points are for moderate effect
- 4 points are for great effect

Minimum score is 7 points and maximum 28 points.

The improvement of the score is following:

- IIQ7 score 14,6 before first treatment
- IIQ7 score is 10,1 1 month after 3rd treatment

# Biopsy examples

First collection of samples for biopsy took place before the first treatment. The second sample was taken 1 month after the 3rd treatment, which corresponds to the 1st control.

Expected effects:

- increase in epithelial thickness (increase in the number of cell layers)
- improving epithelial maturation
- strengthening of the stratum granulosum
- rete ridges extension
- increase of collagen in the submucosal ligament (strengthening of the vaginal wall)
- fibroblast proliferation
- increase in vascularity (and consequent increase in water transudation into the vaginal environment and decrease in vaginal dryness)

In none of the cases in the samples evaluated so far were signs of physical damage to the mucosa observed.

# Biopsy examples – patient 1

*47 years*

*2 pregnancies*

*2 vaginal births*

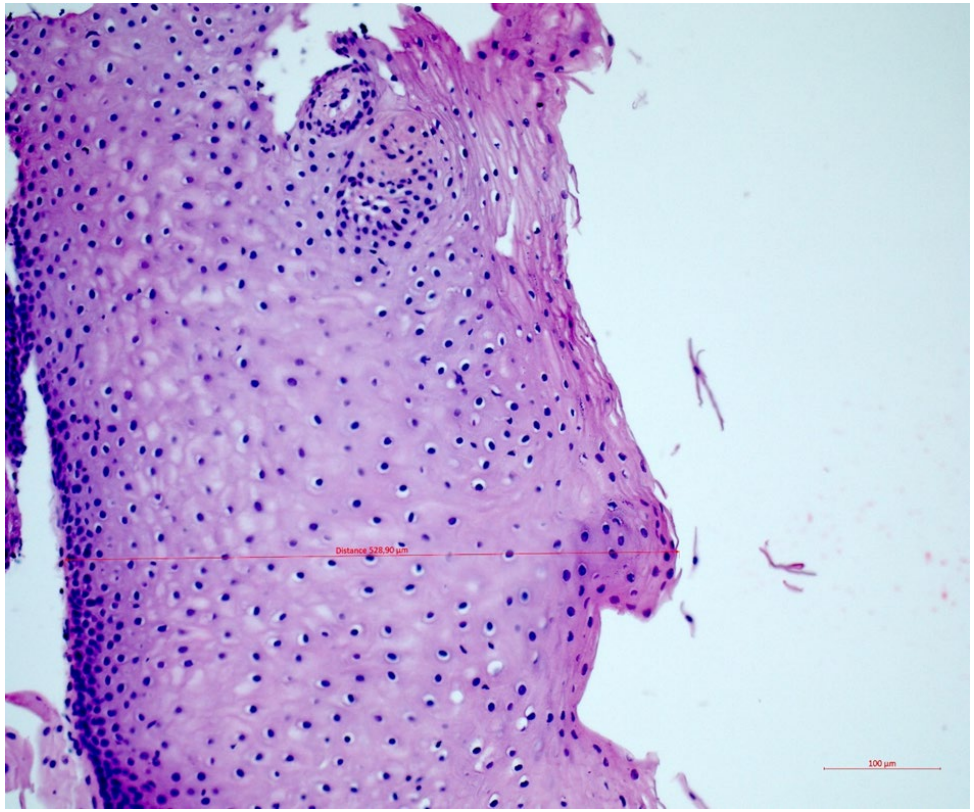
*288 months since last birth*

The pre-treatment epithelial thickness of the patient was 226.86 µm, see obr. 1. After the third treatment, the biopsy was taken again and the epithelial thickness increased to 528.90 µm. Thus, there was an almost 100% increase in the epithelial layer, see obr. 2.

# Biopsy examples – patient 1

**Before**

**After 3rd treatment**



# Biopsy examples – patient 2

*45 years*

*4 pregnancies*

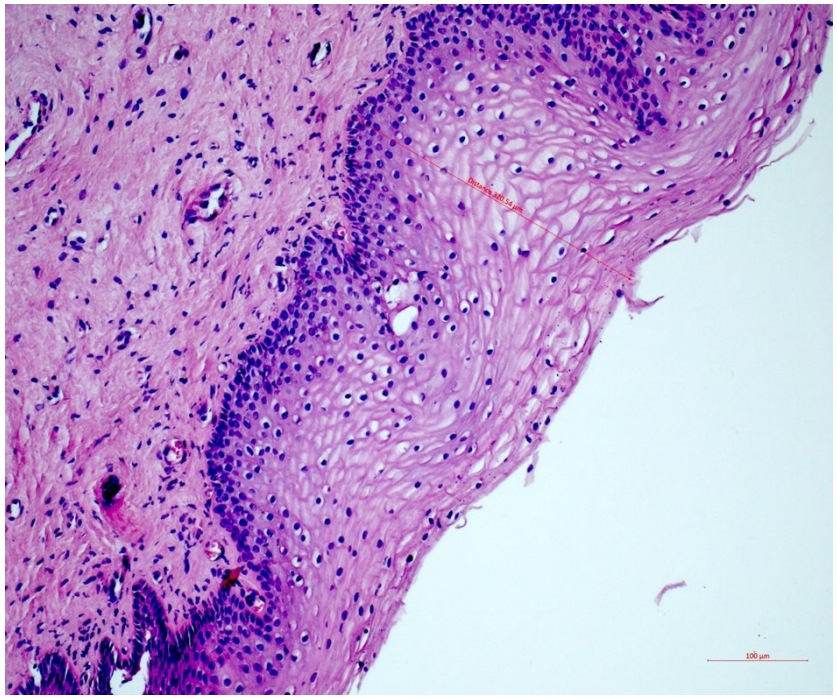
*4 vaginal births*

*48 months after the last birth*

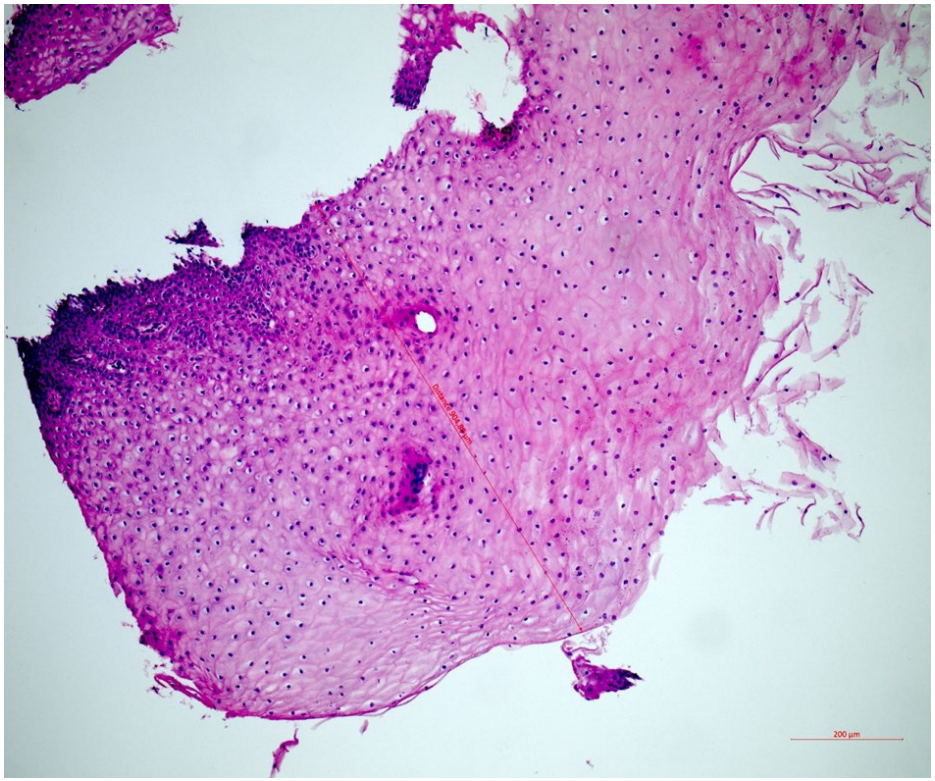
The patient's pre-treatment epithelial thickness was 320.54 µm, see obr 3. After the third treatment, the biopsy was taken again and the epithelial thickness increased to 904.86 µm. Thus, there was an almost 300% increase in the epithelial layer, see obr. 4

# Biopsy examples – Patient 2

**Before**



**After**



# Conclusion

JETT PLASMA For Her seems to be great promise in the treatment of vulvovaginal laxity or improvement of sexual function and incontinence.

Treatment with the device JETT PLASMA For Her device may be an alternative to existing treatment methods in the treatment of mild pelvic floor descents and stress incontinence.

# Authors

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**Thank you for your attention!**