



New Promise in Correction of Vulvovaginal Laxity Syndromes

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Vulvovaginal Laxity

- The **weakened vaginal walls syndrome** 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. When ovaries stop producing hormone estrogen and concurrently vaginal mucosa and submucosal structures begin to atrophy due to aging. 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.

Vulvovaginal Laxity

- Vaginal mucosa consists of multi-layer squamous epithelium.
- Due to ageing and gradual loss of hormone estrogen, epithelium thins and **vaginal elasticity and 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 also **worsens due to vaginal delivery** where occurrence of **stress incontinence and over active bladder (OAB)** 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 muscles and 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

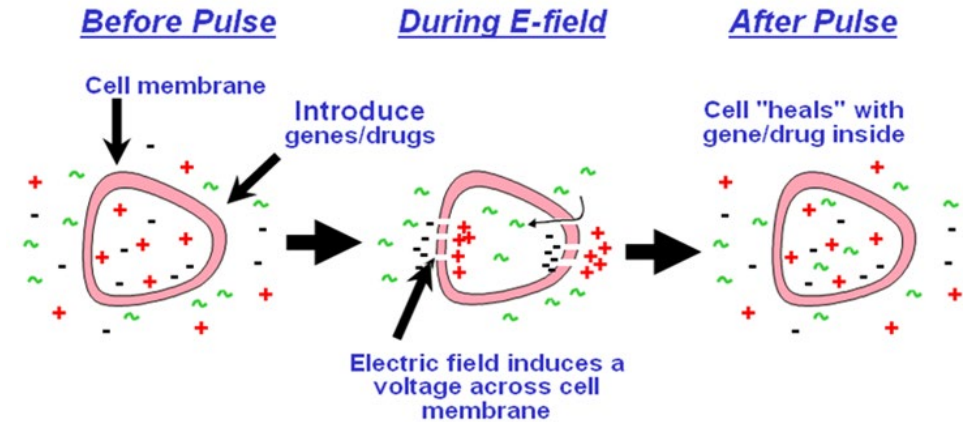
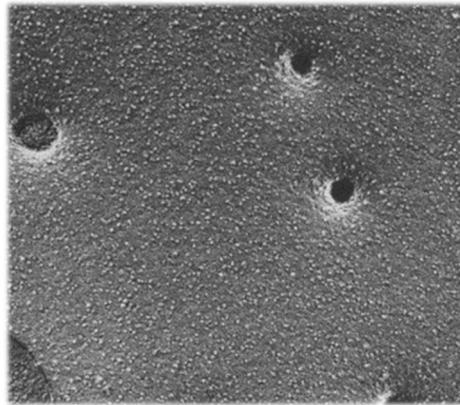


- Therapeutic effects are achieved using direct current that provides membrane depolarization, **reversible electroporation**, **thermal stimulation**, as well as **collagen activation** and strengthening of tissue structure.
- The procedure is **painless**, well tolerated and it does not require local anaesthetic application. It solves **rejuvenation** of atrophied vaginal mucosa. It is suitable also in cases when local estrogen vaginal creams cannot be applied (condition after oncological diseases) with estrogen-dependent tumours.
- After treatment using JPH, **patients report significant improvement** in sexual life quality and symptoms in intimate area like spontaneous leakage of urine.



Reversible Electroporation

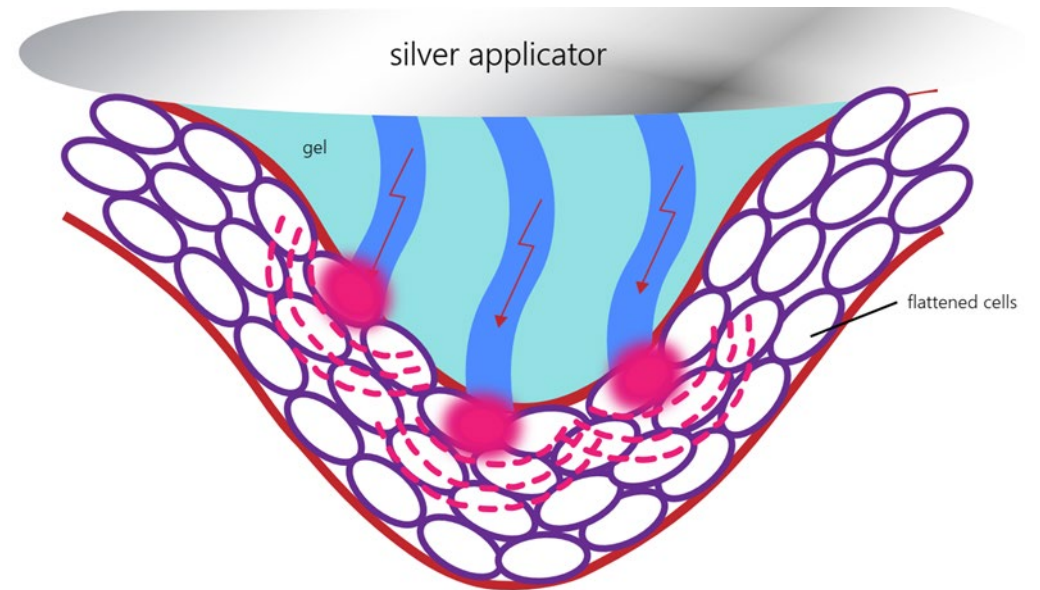
- **Electroporation** is a phenomenon observed after application of a high-voltage electrical pulse to the cell membrane.
 - As a result, small temporary nanopores are formed in the plasma membrane.



- 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**.

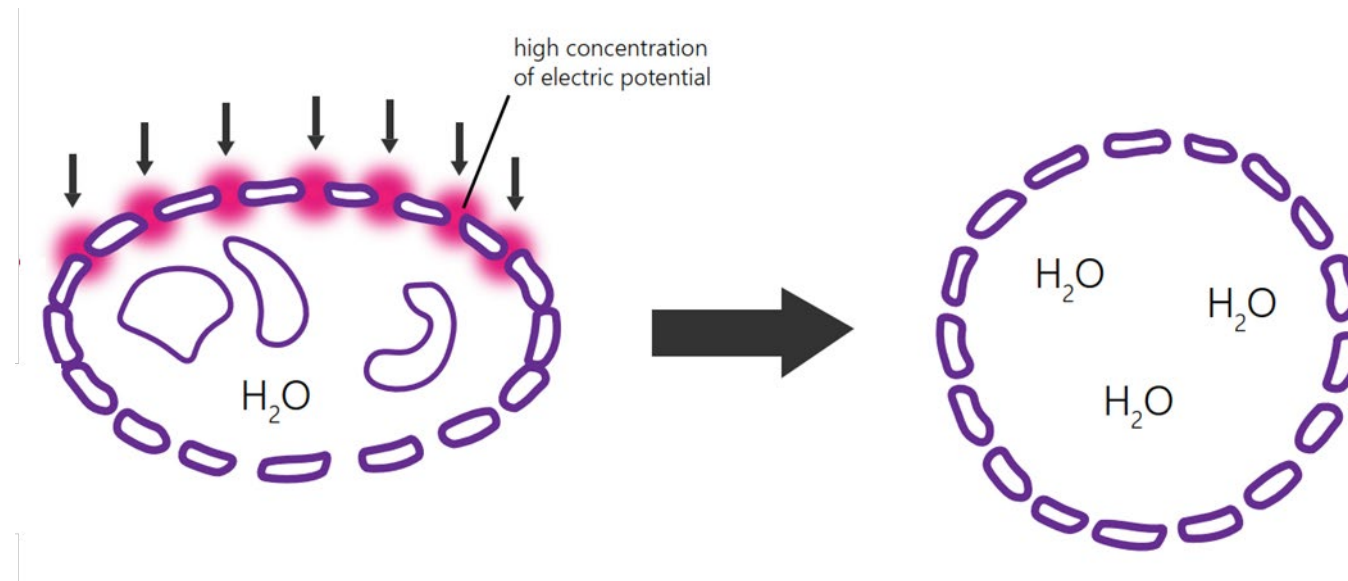
Vulvovaginal Treatment Principle

- **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.



Vulvovaginal Treatment Principle

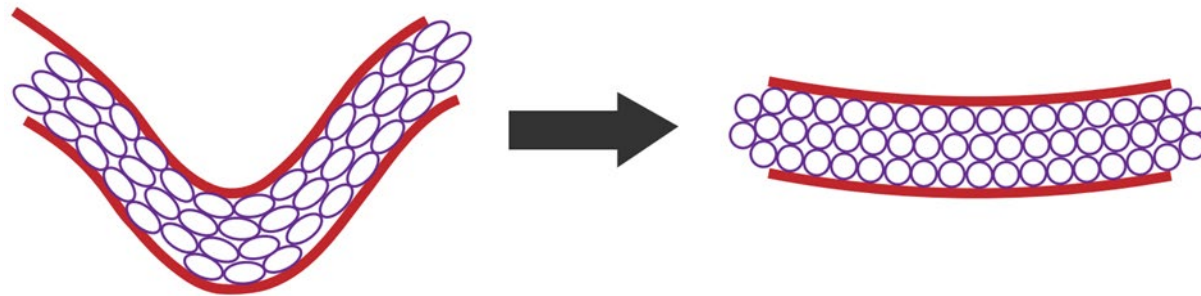
- Local increase of electric intensity causes **nanopore** formation in the cell membrane
 - **Macromolecules and ions** can easily get into the cell through these pores



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



Mechanism of Action Animation





PMCF Study – JETT PLASMA For Her

IN PROCESS

STUDY DESIGN

- A prospective, multi-centered, 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 **1-150 patients** will be randomly assigned to either the active treatment (100 occurrences) or the placebo treatment (50 occurrences).
- If the patient agrees to the biopsy, the number 141-150 is assigned (all of these patients undergo an 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 **checkup** 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 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 **biopsy**



PMCF Study – Preliminary Results

Comparison of subjective vaginal laxity symptoms in **group of 17 patients** with active JPH treatment and **placebo group of 4 patients** as a negative control (underwent all checkups).

(52 patients enrolled in the study so far)

Each patient's satisfaction was recorded by **QUESTIONNAIRES** at the beginning of study and then gradually over the course of the study using:

- **VLQ** Vaginal Laxity questionnaire – 7 questions, 1 - 7 points scale
- **UDI-6** Urogenital Distress questionnaire – 6 questions, 6 – 24 points scale
- **IIQ-7** Incontinence Impact questionnaire - 7 questions, 7- 28 points scale
- **FSFI** Sexual function questionnaire – 19 questions, 19 – 36 points scale
- **SSQ** Sexual Satisfaction questionnaire – 6 questions, 1 – 6 points scale

Also, **biopsy samples of 20 patients** before and after active treatment were taken and comparison of samples were made.

Excellent results with significant improvement of patient's vaginal laxity symptoms!



VLQ – Vaginal Laxity Questionnaire

1-7 POINTS – SUBJECTIVE EVALUATION OF THE PATIENT

7 Very loose

6 Moderately loose

5 Slightly loose

4 Neither loose nor tight

3 Slightly tight

2 Moderately tight

1 Very tight

UDI-6 – Urogenital Distress Inventory (Short Form)



6 QUESTIONS AND 4 POSSIBLE ANSWERS

(not at all, slightly, moderately and greatly)

1. Frequent urination?
2. Urine leakage related to the feeling of urgency
3. Urine leakage related to physical activity, coughing, or sneezing
4. Small amounts of urine leakage (drops)
5. Difficulty emptying your bladder
6. Pain or discomfort in the lower abdominal or genital area



IIQ7 - Incontinence Impact Questionnaire

7 QUESTIONS AND 4 POSSIBLE ANSWERS

(not at all, slightly, moderately and greatly)

1. Your ability to do household chores (cooking, housekeeping, etc.)?
2. Your physical recreation such as walking or other exercise?
3. Your ability to attend entertainment activities (movie, concerts, etc.)?
4. Your ability to travel by car more than 30 minutes from home?
5. Your participation in social activities outside your home?
6. Your emotional health (nervousness, depression, etc.)?
7. Made you feel frustrated?

FSFI - Female Sexual Function Index

19 QUESTIONS

6 FIELDS OF QUESTIONS

Domain	Questions	Score Range	Factor	Minimum Score	Maximum Score	Score
Desire	1, 2	1 – 5	0.6	1.2	6.0	
Arousal	3, 4, 5, 6	0 – 5	0.3	0	6.0	
Lubrication	7, 8, 9, 10	0 – 5	0.3	0	6.0	
Orgasm	11, 12, 13	0 – 5	0.4	0	6.0	
Satisfaction	14, 15, 16	0 (or 1) – 5	0.4	0.8	6.0	
Pain	17, 18, 19	0 – 5	0.4	0	6.0	
Full Scale Score Range				2.0	36.0	

SSQ - Sexual Satisfaction Questionnaire

SUBJECTIVE EVALUATION OF THE PATIENT WITH HER
SEXUAL SATISFACTION FROM VAGINAL INTERCOURSE

None sexual satisfaction

Poor sexual satisfaction

Fair sexual satisfaction

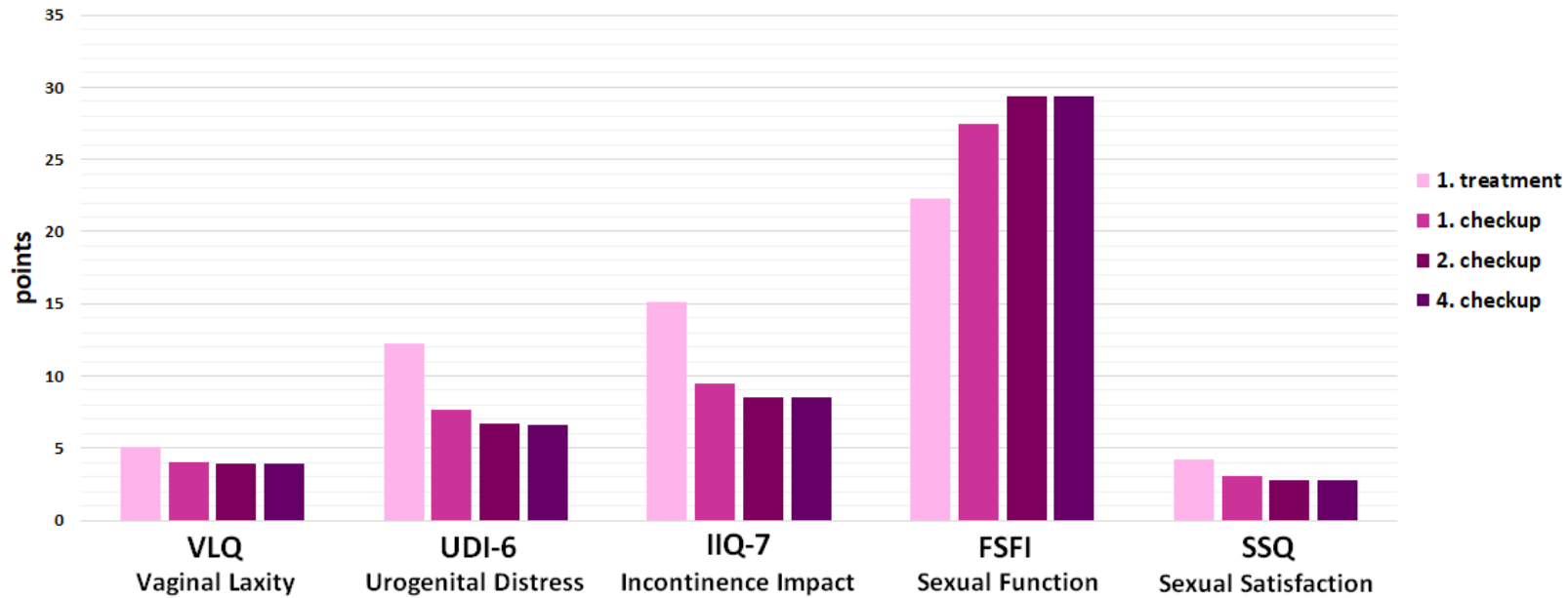
Good sexual satisfaction

Very good sexual satisfaction

Excellent sexual satisfaction

PMCF Study – Preliminary Results

Patient satisfaction improvement



Graph 1

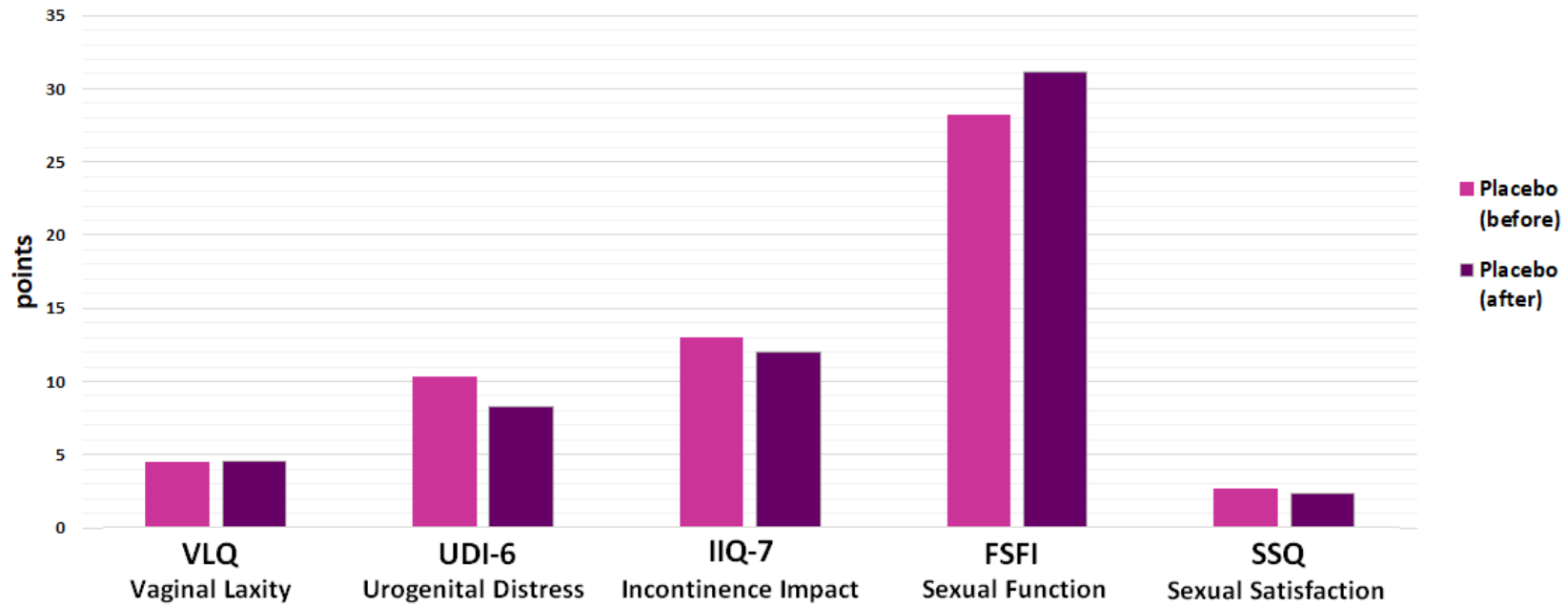
Comparison of subjective vaginal laxity symptoms improvement in group of patients with active treatment
 Average points difference before treatment compared to after 1.,2. and 4. checkup
 (after 1 month, 3 months and 12 months)



Overall **31 %** vaginal laxity, **85 %** urogenital distress, **78 %** incontinence impact, **24 %** sexual function and **50 %** sexual satisfaction improvement!

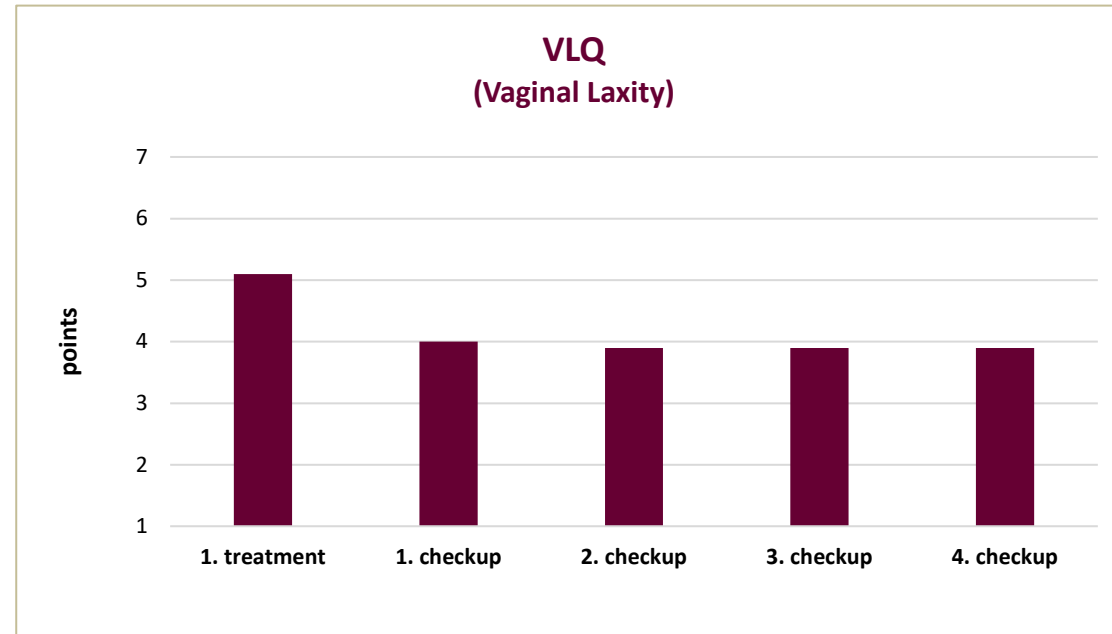
PMCF Study – Preliminary Results

Patient satisfaction improvement



Overall placebo 0 % vaginal laxity, 24 % urogenital distress, 8 % incontinence impact, 9 % sexual function and 17 % sexual satisfaction improvement!

PMCF Study – Preliminary Results



Graph 3

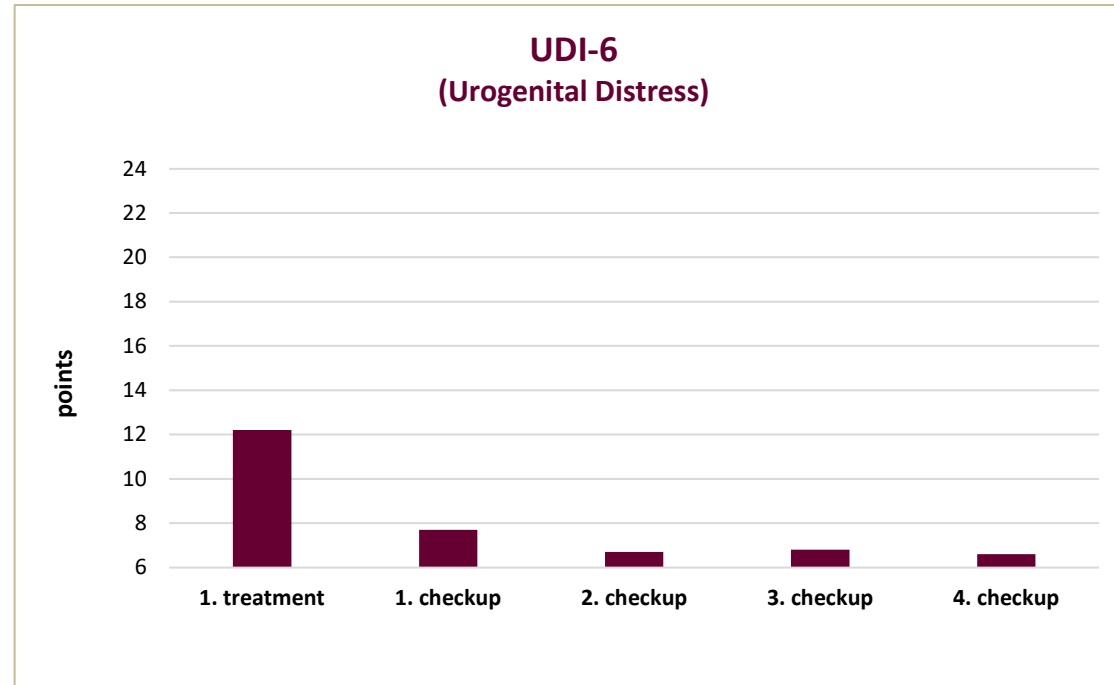
Comparison of subjective vaginal laxity improvement in group of patients with active treatment
Average points difference before 1.treatment compared to after 1., 2., 3. and 4. checkup.

Checkups after 1 month, 3 months, 6 months and 12 months.



Compared to the state of patient before treatment, overall
31 % vaginal laxity symptoms improvement average!

PMCF Study – Preliminary Results



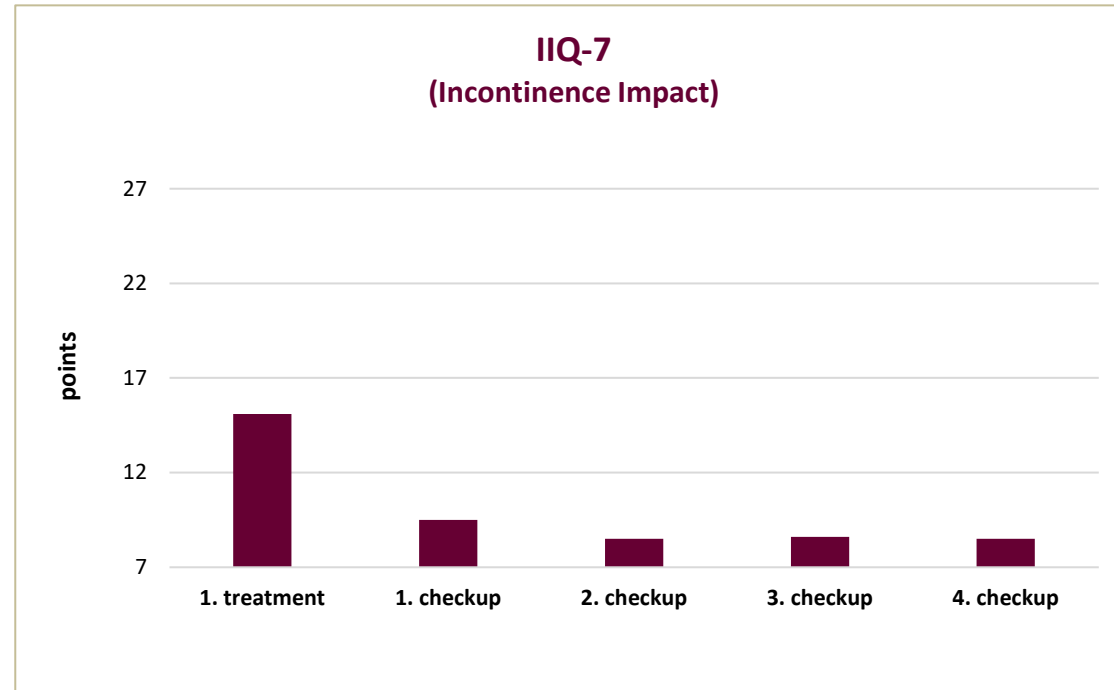
Graph 4

Comparison of subjective vaginal laxity improvement in group of patients with active treatment
 Average points difference before 1.treatment compared to after 1., 2., 3. and 4. checkup.
 Checkups after 1 month, 3 months, 6 months and 12 months.



Compared to the state of patient before treatment, overall
85 % urogenital distress symptoms improvement average!

PMCF Study – Preliminary Results

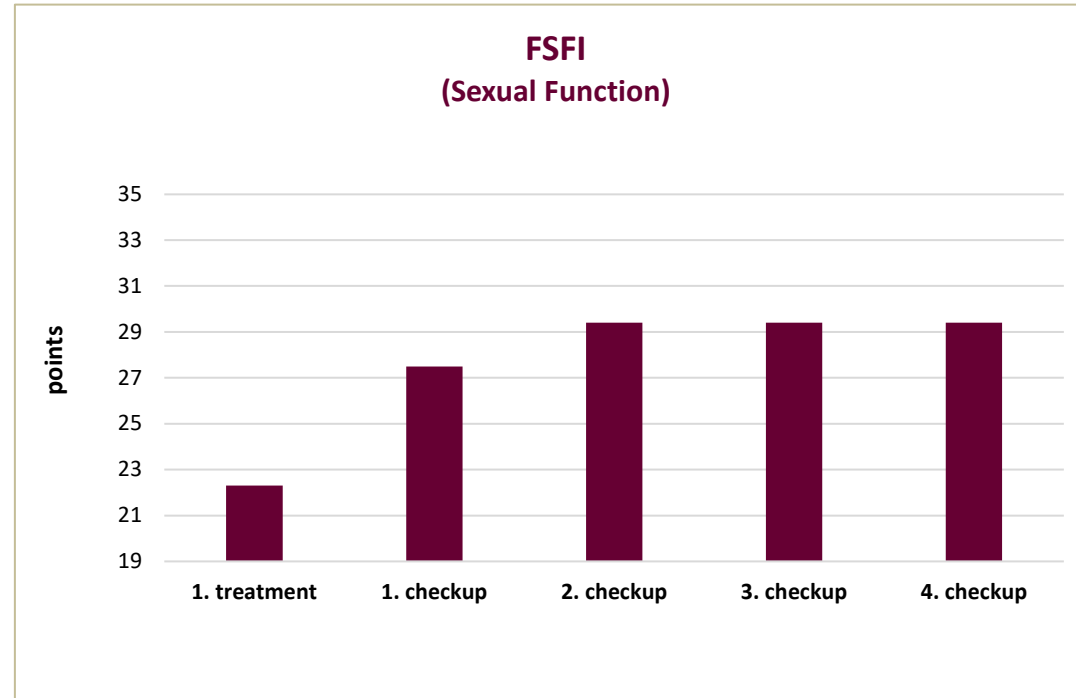


Graph 5

Comparison of subjective vaginal laxity improvement in group of patients with active treatment
 Average points difference before 1.treatment compared to after 1., 2., 3. and 4. checkup.
 Checkups after 1 month, 3 months, 6 months and 12 months.

➔ Compared to the state of patient before treatment, overall **78 % incontinence impact symptoms improvement average!**

PMCF Study – Preliminary Results



Graph 6

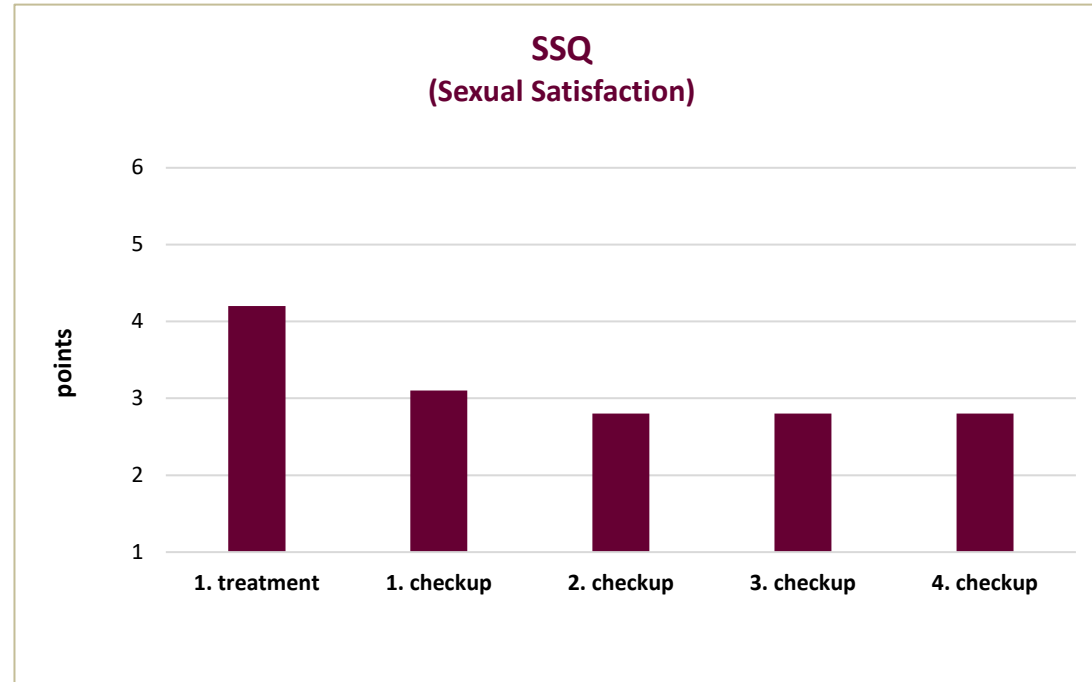
Comparison of subjective vaginal laxity improvement in group of patients with active treatment
Average points difference before 1.treatment compared to after 1., 2., 3. and 4. checkup.

Checkups after 1 month, 3 months, 6 months and 12 months.



**Compared to the state of patient before treatment, overall
24 % sexual function symptoms improvement average!**

PMCF Study – Preliminary Results



Graph 7

Comparison of subjective vaginal laxity improvement in group of patients with active treatment
 Average points difference before 1.treatment compared to after 1., 2., 3. and 4. checkup.
 Checkups after 1 month, 3 months, 6 months and 12 months.



**Compared to the state of patient before treatment, overall
 50 % sexual satisfaction symptoms improvement average!**

Biopsy

First collection of samples for biopsy took place before the first treatment.

Then, the second sample was taken 3 months after the 3rd treatment (which corresponds with the 2nd control).

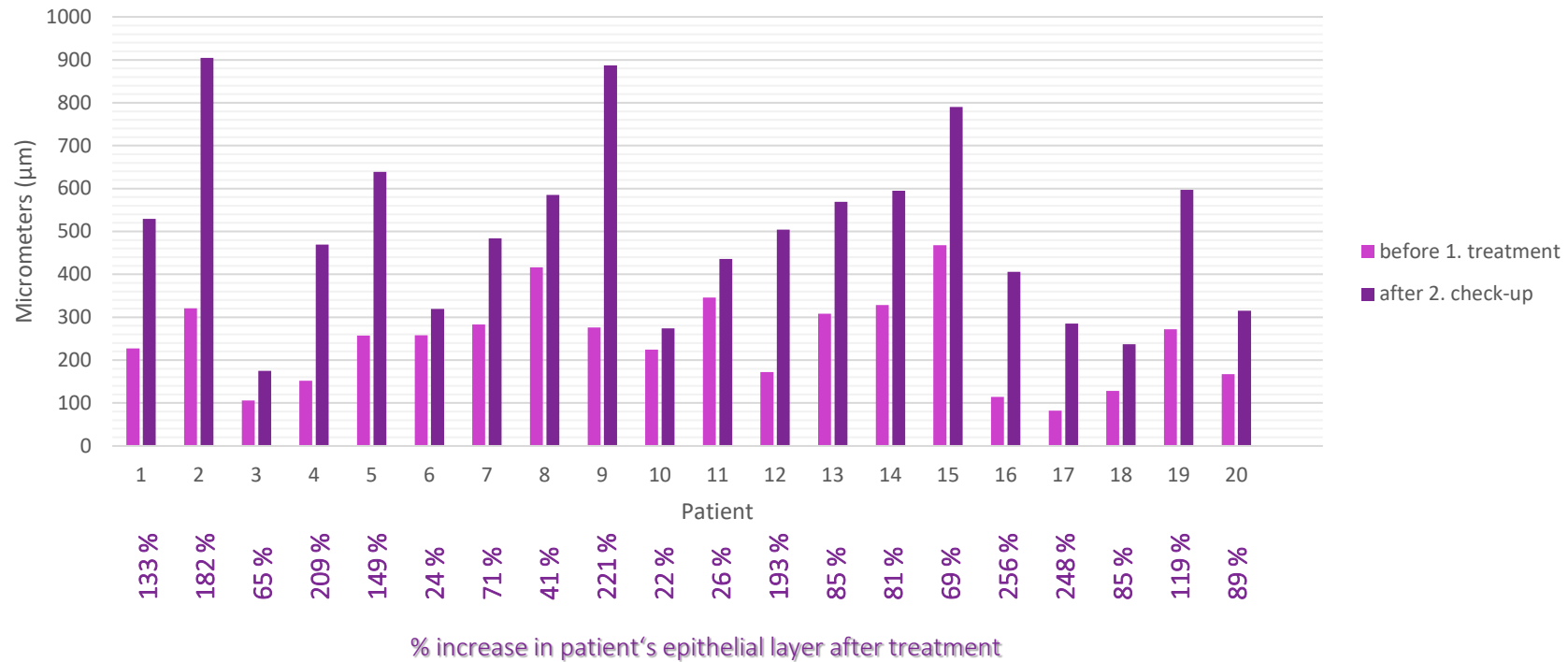
EXPECTED EFFECTS

- 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)

None of the biopsy samples evaluated so far **showed signs of physical damage** to the mucosa.

PMCF Study – Preliminary Results

BIOPSY



Graph 8

Comparison of biopsy samples in group of patients with active treatment (20 patients).
Overall difference before 1.treatment and after 2.check-up.

118,4 % increase average in the epithelial layer!

Biopsy Example – Patient no. 1

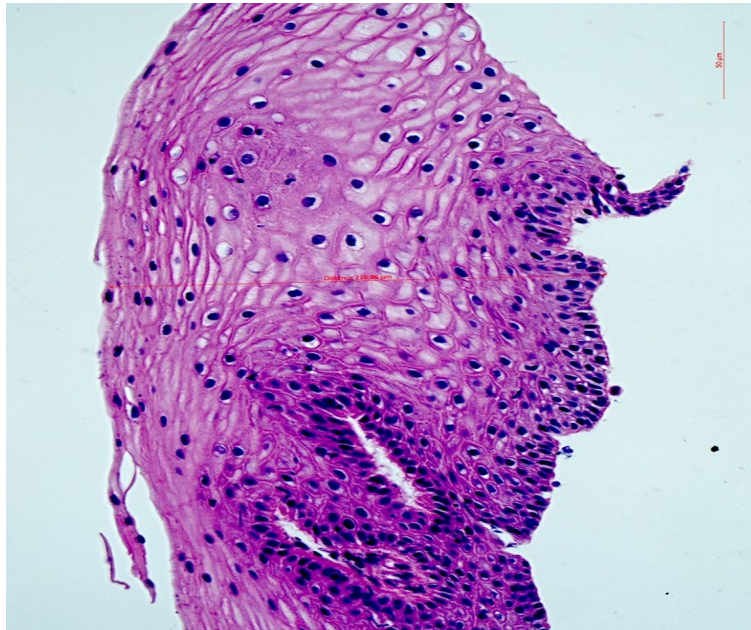
45 years

4 pregnancies

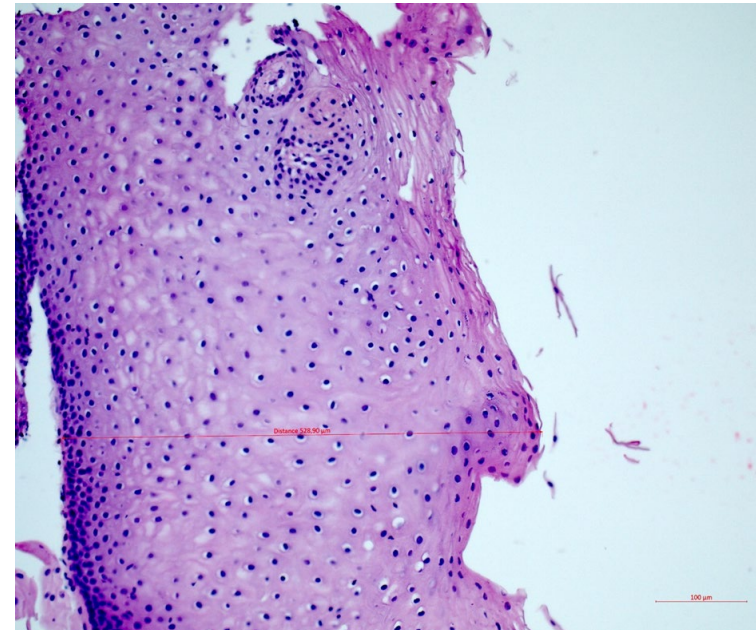
4 vaginal births

48 months after the last birth

Before



After



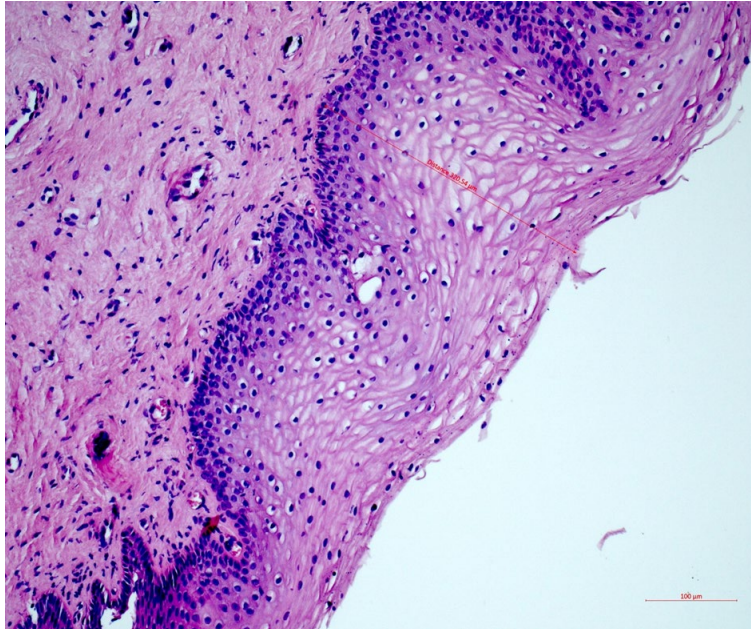
The pre-treatment epithelial thickness of the patient was **226.86 μm** . After the second
checkup, the biopsy samples showed increased epithelial thickness up to **528.90 μm** .

➔ **133 % increase of epithelial layer**

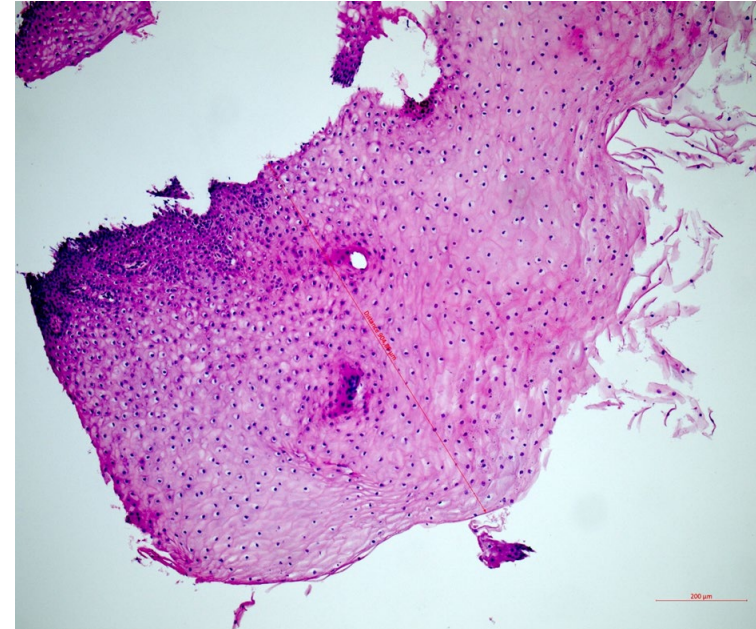
Biopsy Example – Patient no. 2

47 years
 2 pregnancies
 2 vaginal births
 288 months since last birth

Before



After



The patient's pre-treatment epithelial thickness was **320.54 μm**. After the second check-up, the biopsy samples showed increased epithelial thickness up to **904.86 μm**.

➔ **182 % increase of epithelial layer**

Biopsy Example – Patient no. 4

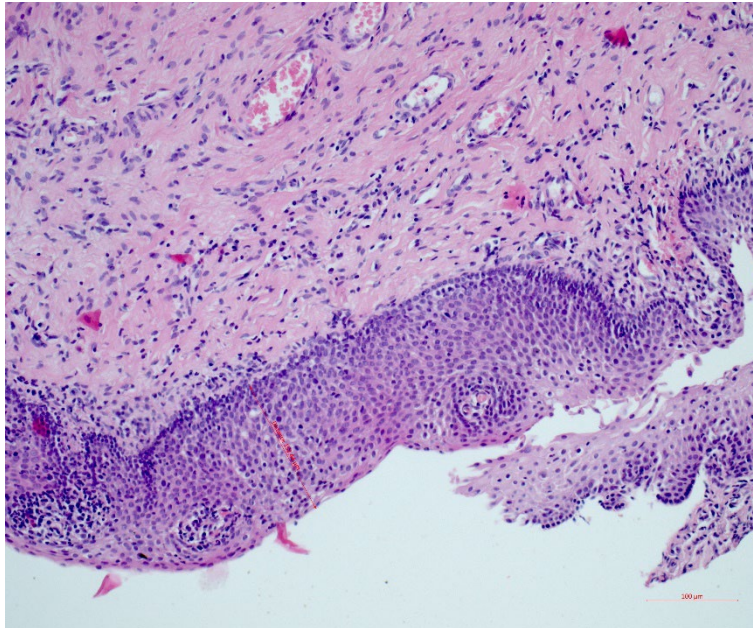
53 years

3 pregnancies

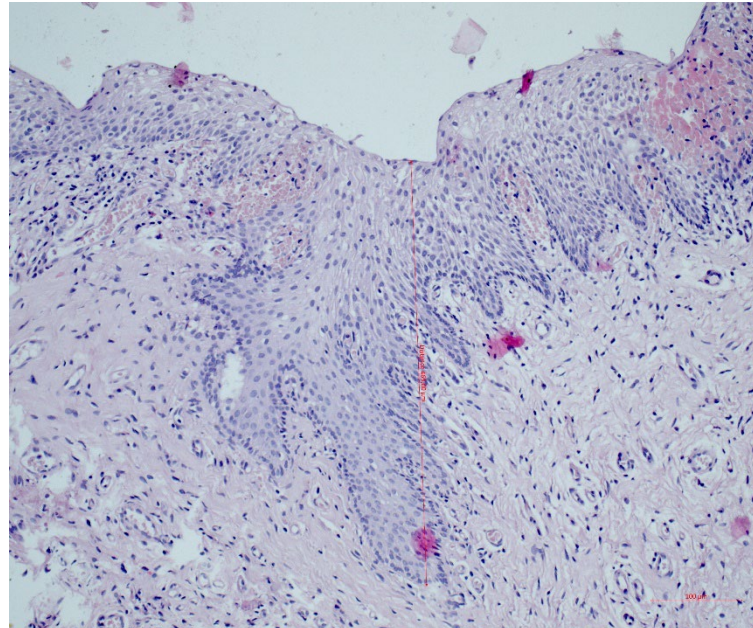
3 vaginal births

204 months since last birth

Before



After



The patient's pre-treatment epithelial thickness was **152 μm** . At the 2nd checkup, the biopsy was taken again and epithelial thickness increased to **469 μm** .

➔ Up to **209 %** increased epithelial layer

Biopsy Example – Patient no. 5

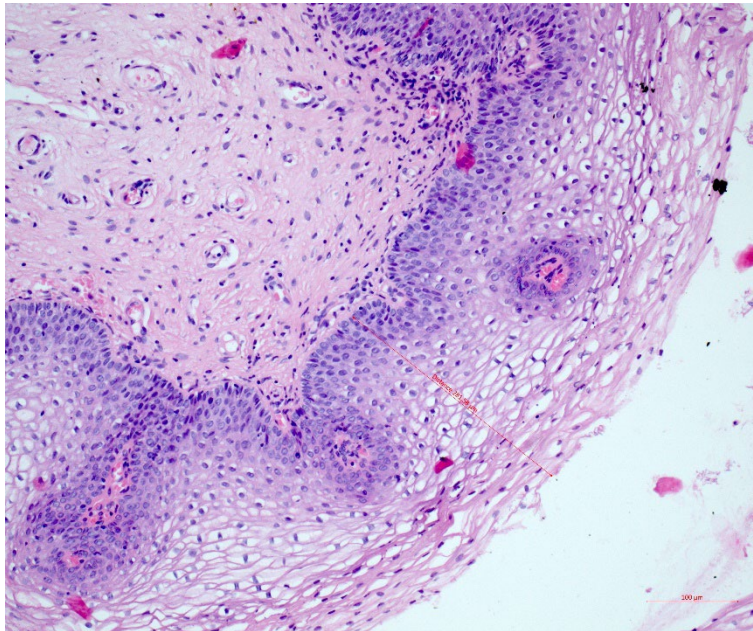
42 years

3 pregnancies

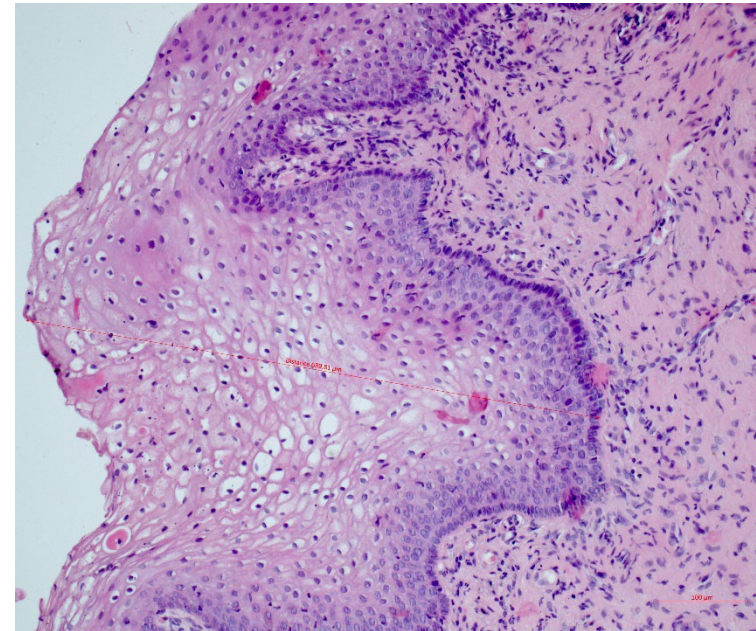
3 vaginal births

252 months since last birth

Before



After



The patient's pre-treatment epithelial thickness was **257 μm**. At the 2nd checkup, the biopsy was taken again and epithelial thickness increased to **639 μm**.

➔ Up to **149 %** increased epithelial layer

Biopsy Example – Patient no. 16

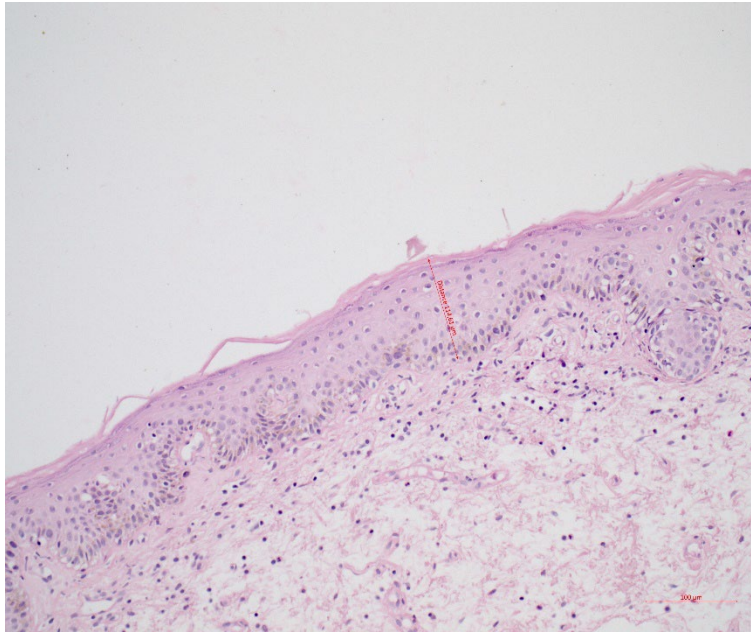
62 years

2 pregnancies

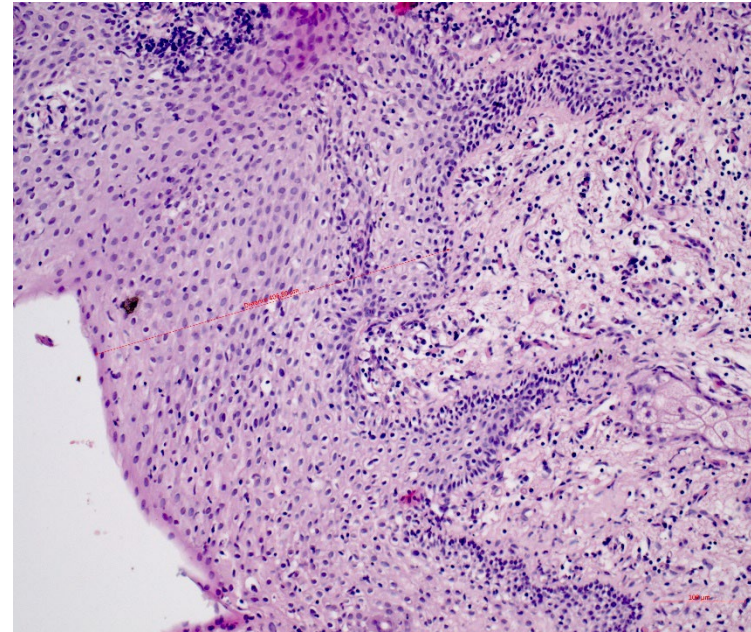
2 vaginal births

468 months since last birth

Before



After



The patient's pre-treatment epithelial thickness was **114 μm**. Three months after 3rd treatment, the biopsy was taken again and epithelial thickness increased to **406 μm**.

➔ **256 % increase in epithelial layer**

Biopsy Example – Patient no. 17

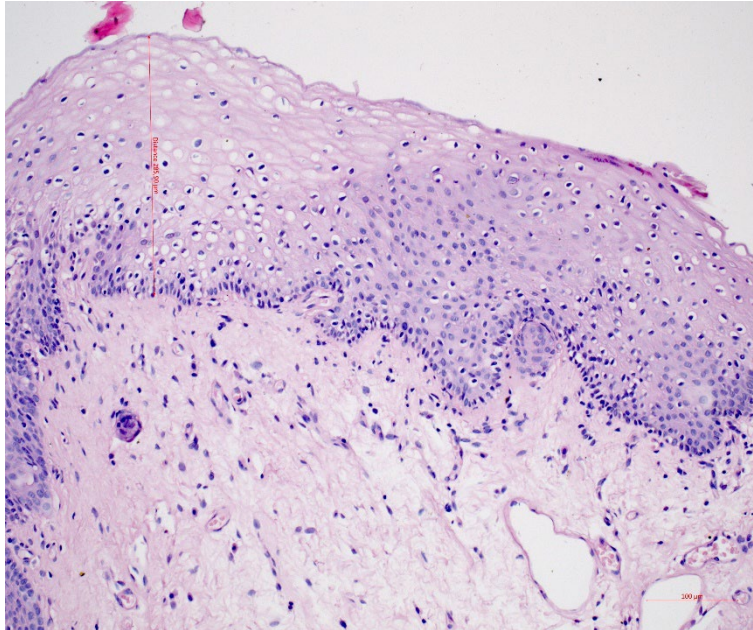
64 years

3 pregnancies

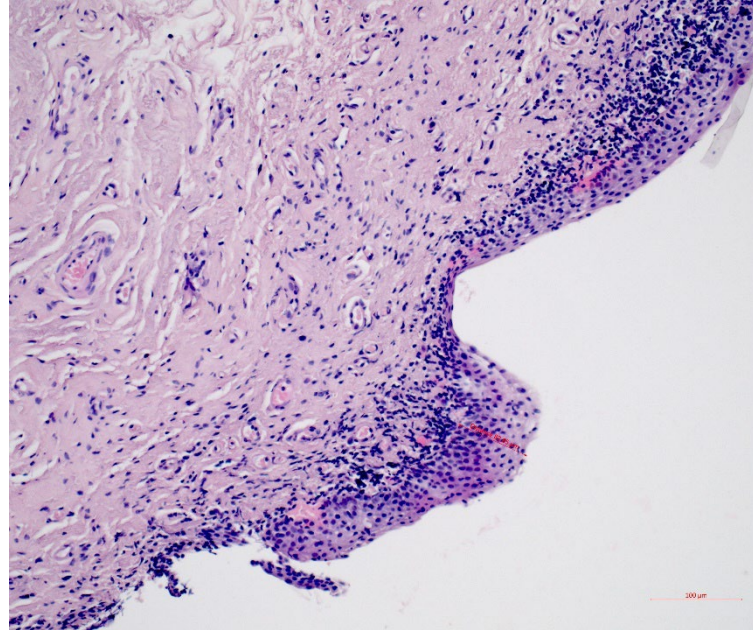
2 vaginal births

384 months since last birth

Before



After



The patient's pre-treatment epithelial thickness was **82 μm** . Three months after 3rd treatment, the biopsy was taken again and epithelial thickness increased to **285 μm** .

➔ **248 % increase in epithelial layer**

Conclusion

JETT PLASMA For Her seems to show a great promise in:

- Treatment of vulvovaginal laxity
- Improvement of incontinence
- Improvement of sexual life

Treatment with JETT PLASMA For Her may be a good alternative to existing methods of:

- Treatment of mild pelvic floor descents
- Treatment of stress incontinence



In Cooperation with

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MD Helena Maskova



“The best effect, according to my observation, is on over active bladder, where the improvement is about 60 – 80 %, and relief is very high. Treating stress incontinence is also very successful, with improvement about 40 – 60 %. It is important to combine the JETT PLASMA For Her treatment with physiotherapy and concentrate to strengthen pelvic floor muscles. Ladies refer that they perceive muscles much better during exercises than without plasma treatment, effect is dueling to stimulation and rejuvenation.

Duration of effect is more than a year as I use the device for approximately 15 months and all treated ladies are satisfied till now.

Vulvovaginal laxity is improved too, narrowing of vagina is objectively about 30 %. Treatment of atrophy brings great relief for ladies, not only post menopausal but also for young ladies after surgical castration.

Unfortunately duration is not so long compared with the treatment of incontinence, sometimes we have to repeat it after 6month, especially when atrophy is severe.

Usually one session is enough but sometimes 3 sessions must be performed again.

Using gel with hyaluronic acid is helpful, could potentiate effect.

Lowering the numbers of acute urine bladder infections was observed as positive side effect after treatment.”

MD Lukas Pasnisin

“As we are still working on the study, we don’t have the final results yet, but I can already see that our patients are very satisfied with the treatment and recommend it to their friends and acquaintances. Patients themselves have subjectively experienced significant changes in their quality of life, especially in terms of significantly improved incontinence or the complete disappearance of stress or urge incontinence.

Furthermore, they also experience an improvement in their sexual life. I can observe these changes in 60 % of patients after first treatment, after the second or third treatment it is up to 98 % of patients.

Patients highly praise the ease of the treatment without any daily-life disrupt and the painlessness of the treatment.”



MD Sona Pankova



“According to my experience, patients are dealing mainly with vaginal dryness, discomfort, and recurrent inflammations, which occurs in connection, for example, with swimming in the pool or Whirlpool. All patients claim that they are satisfied after the treatment with JETT PLASMA For Her. Some patients report a slight improvement, others 100 % improvement.

In my opinion, younger women are more satisfied with the treatment.”

MD Miroslav Müller

“I spent about a year looking for a treatment to help women with urinary incontinence. I had two CO2 lasers but later on, I started to treat the patients with JETT PLASMA For Her device.

The patients are satisfied after the treatment and I haven't noticed any adverse reactions or complications.

The overall evaluation is very positive. The treatment is very simple and undemanding to the staff and the client.

The performance lasts a maximum of 45 minutes. Eventually, additional time is required when treating labia and external genitalia.

According to the patients' reports, there is 60 – 90 % improvement in urinary incontinence. The patients don't need to get up at night, nocturia disappears, and they also don't have to urinate so often and keep urine during physical activity.“





MD Jan Pistek & MD Martina Pistkova



“JETT PLASMA For Her is an unique, simple and effective device, well tolerated by our patients. We are very happy that we bought it for our practice. It brings new possibilities for solving the problems that the gynaecologist encounters every day at work. Among the most common indications in which we see the greatest improvement belongs reducing the laxity and elasticity of the vagina after childbirth, with the incipient incontinence of these young women, in their sports and work activities, deterioration of their sexual functions and often dyspareunia, chronic vaginal discomfort after recurrent vaginitis, problems with vaginal wall weakening, reduced lubrication and incontinence associated with menopause.

Of course, the communication and trust of patients who are able to confide in their sensitive intimate complaints in time are important. During our participation in this study, we gradually became aware of the limitations of this method, which are advanced conditions of vaginal wall relaxation and descent, and chronic advanced conditions arising in connection with long-term estrogen deficiency. Furthermore, conditions that are potentiated by comorbidities such as psychological and psychiatric diseases, as well as systemic, often autoimmune diseases or diseases with unclear etiology. It is therefore important to critically assess in individual cases the expected effectiveness of the indication of this method on the basis of a detailed history and knowledge female patient.

A pleasant surprise was the treatment of a 70-year-old woman who subsequently postponed her urinary incontinence medication. In any case, we are extremely satisfied that we have this device in our equipment portfolio of our gynaecological clinic.“



MD Martin Stepan

“JETT PLASMA For Her is a unique device in the treatment of incontinence and mild vaginal wall descents.

Patients report an improvement in subjective difficulties of up to 50 % after the first treatment.

The main advantage of the method is the high effectiveness of the treatment with zero invasiveness of the method.”



Literature Reference

Cooper, Geoffrey M., and Hausman, Robert E. "A molecular approach." *The Cell*. 2nd ed. Sunderland, MA: Sinauer Associates (2000).

JETT PLASMA LIFT MEDICAL. Instructions for Use. COMPEX, spol. s r.o.

JETT PLASMA For Her. Instrucions for Use. COMPEX, spol. s r.o.

THANK YOU FOR YOUR ATTENTION



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