New Promise in Correction of Vulvovaginal Laxity Syndromes

in cooperation with

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JETT PLASMA For Her II

For Gynaecology

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

Certified medical device!

JETT PLASMA For Her II

For Gynaecology

JETT PLASMA For Her II with Plasma Pen III/G

+

Flat applicator 10 mm (2x)

+

G-Applicator 30 mm

+

G-Applicator Wave

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. 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 estrogen 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 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** 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 II

Treatment

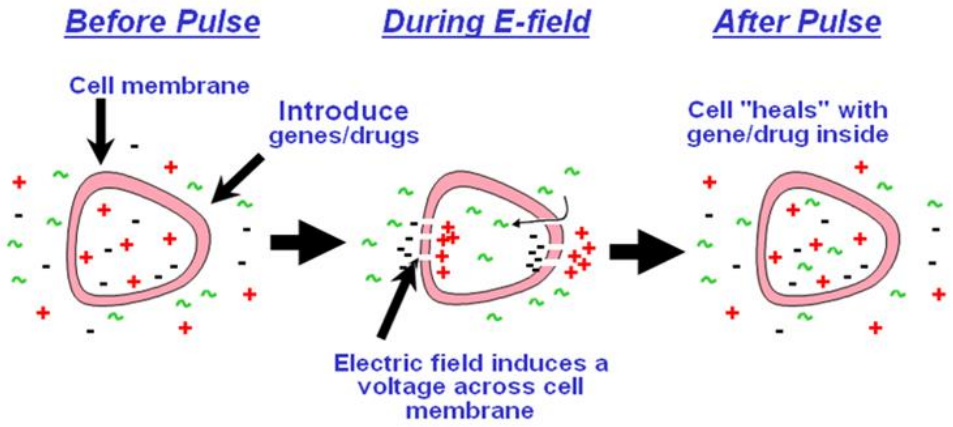
- Therapeutic effects are achieved using direct current that provides membrane depolarization, **reversible electroporation, thermal stimulation**, as well as **collagen activation** and strengthening of tissue structure.

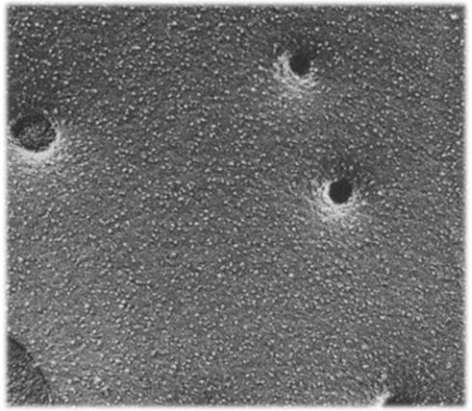
- The procedure is **painless**, well tolerated and it does not require local anaesthetic application. It solves **rejuvenation** of atrophied vaginal mucosa. It is suitable also in cases when local estrogen vaginal creams cannot be applied (condition after oncological diseases) with estrogen-dependent tumours.

- After treatment using JPHII, **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.

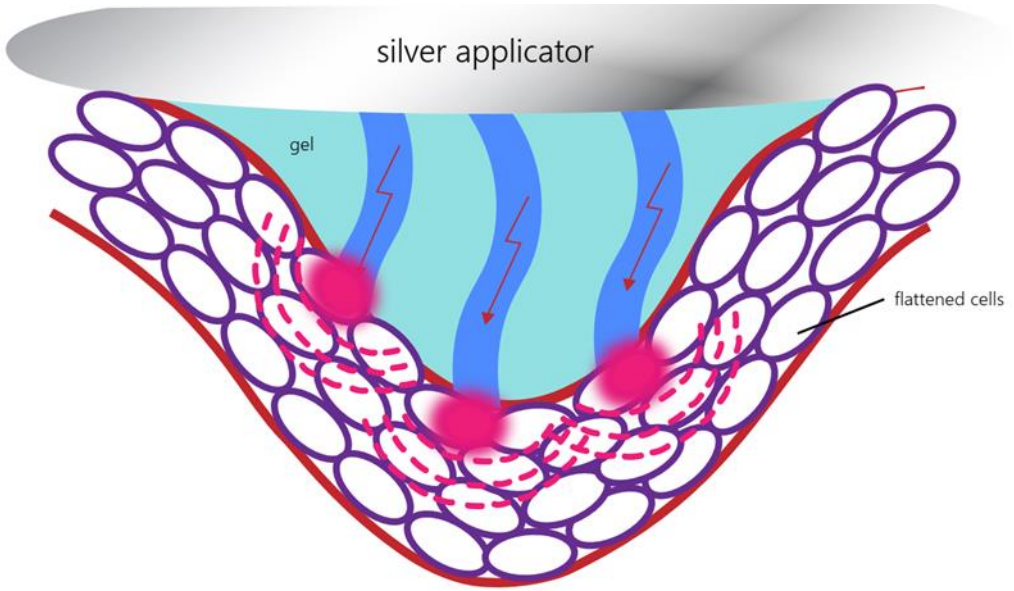




- These **nanopores** allow macromolecules and other ions to pass through the membrane in both directions.
- This type of electroporation is widely used in biomedical engineering, electrochemotherapy, electro-genetherapy and **cosmetic treatments**.

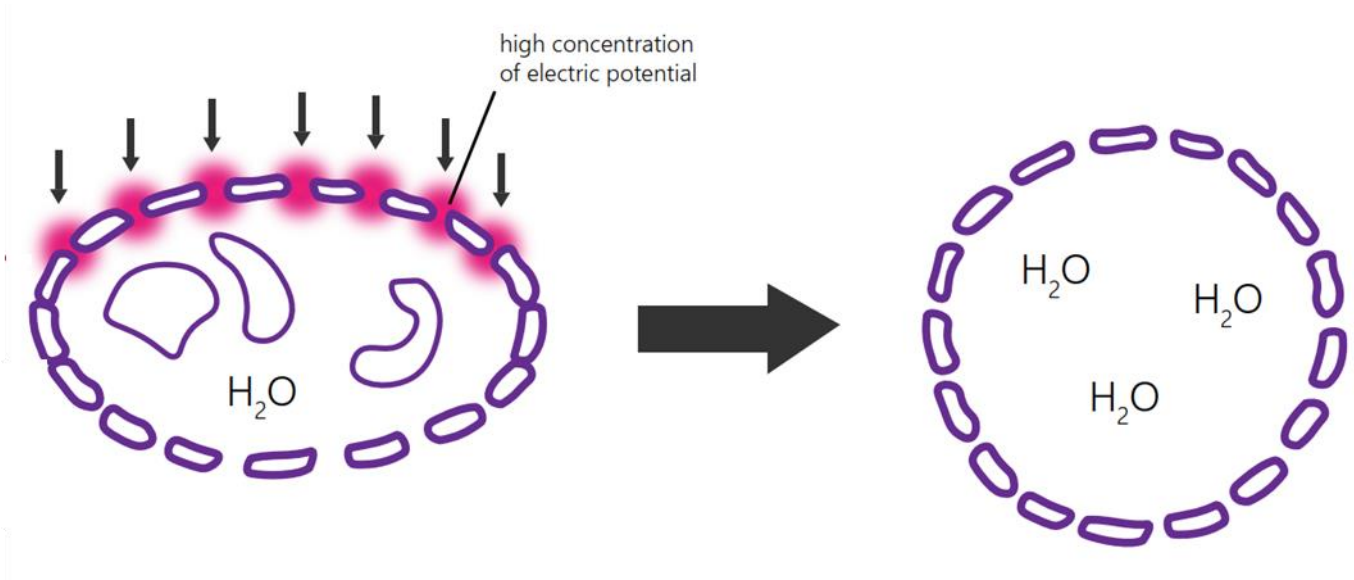
Vulvovaginal Treatment Principle

- **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

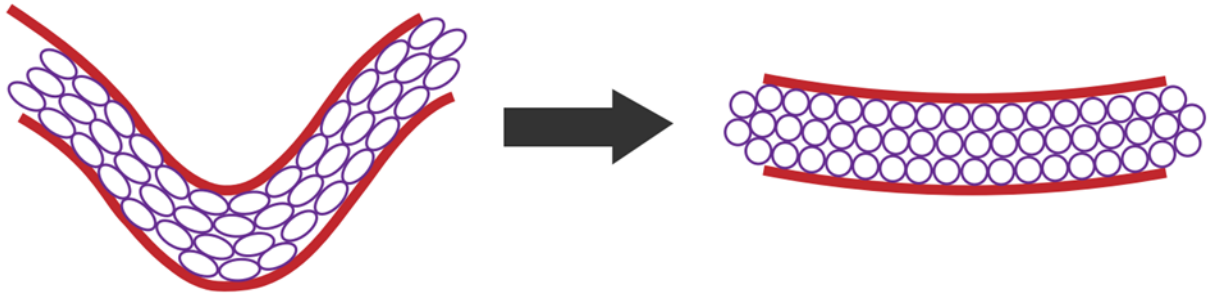
- Local increase of electric intensity causes **nanopore** formation in the cell membrane
  - **Macromolecules and ions** can easily get **into the cell** through these pores



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



PMCF Study – JETT PLASMA For Her II

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 II 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 II

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 **biopsy**

PMCF Study – Preliminary Results

Comparison of subjective vaginal laxity symptoms in **group of 65 patients** with active JPH II treatment and **placebo group of 9 patients** as a negative control.

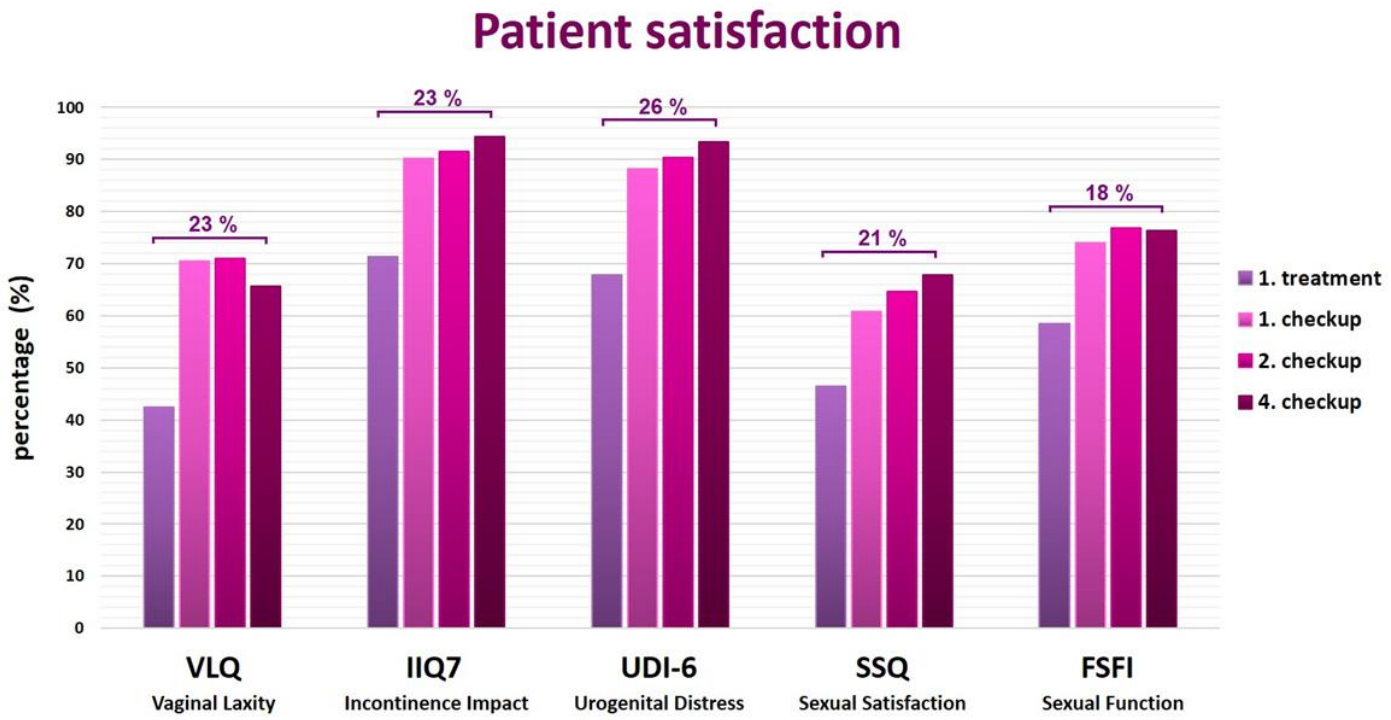
Each patient's satisfaction was recorded by **QUESTIONNAIRES** at the beginning of study and then gradually over the course of the study using:

- 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, 2 – 36 points scale
- SSQ **Sexual Satisfaction** questionnaire – 6 questions, 1 – 6 points scale

Also, **biopsy samples of 24 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!

PMCF Study – Preliminary Results

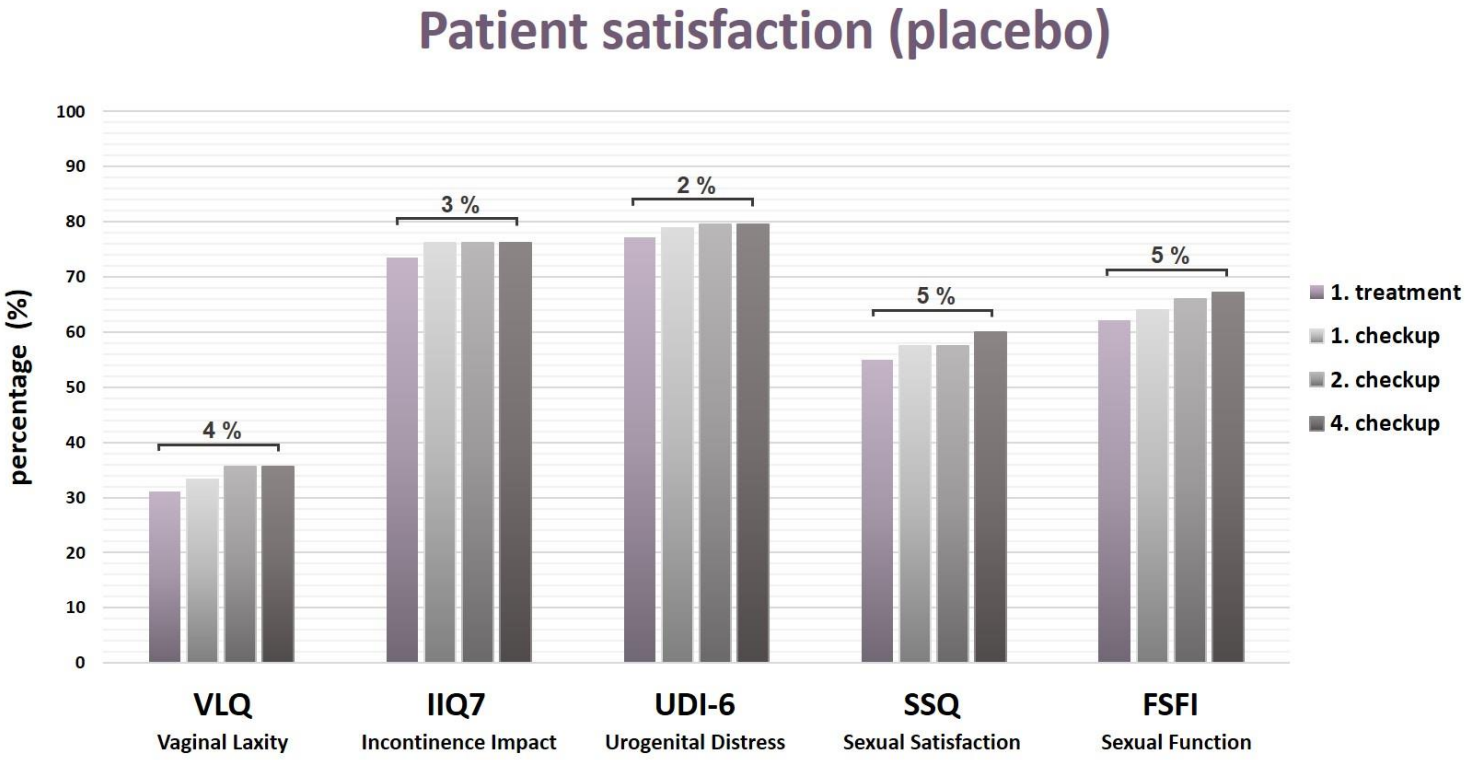


Graph 1

Comparison of subjective vaginal laxity symptoms improvement in group of patients with active treatment (65 patients)
General difference before 1. treatment and after check-ups

Overall 90 % average patient satisfaction with treatment!

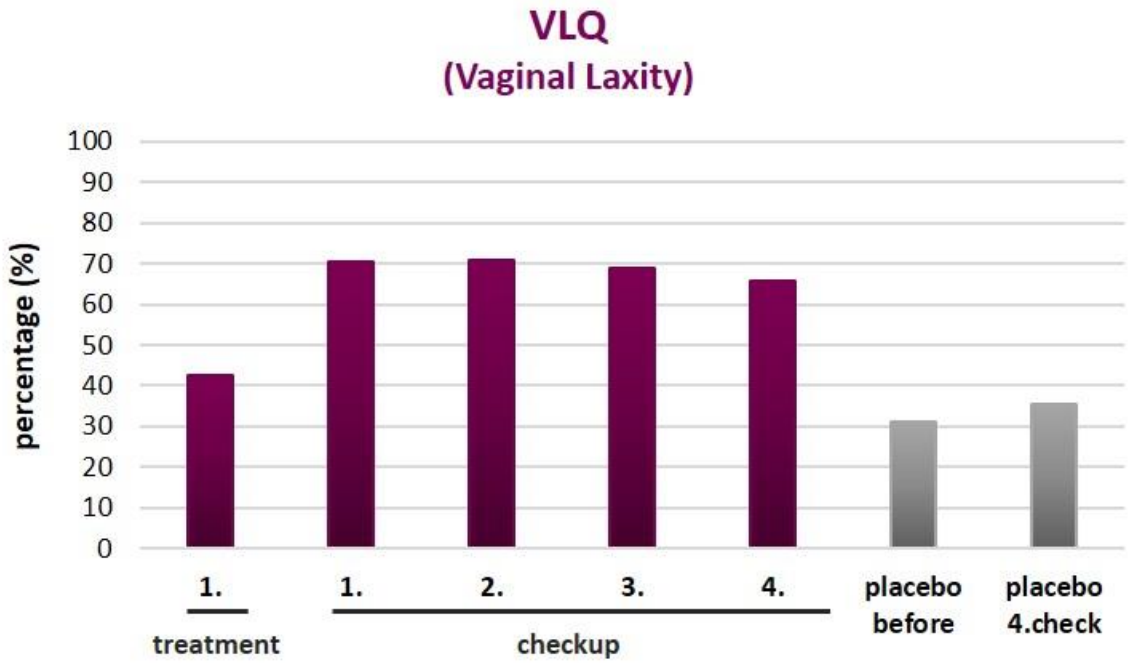
PMCF Study – Preliminary Results



Graph 2

Comparison of subjective vaginal laxity symptoms improvement in placebo group as a negative control (9 patients)
General difference before 1. treatment and after check-ups

PMCF Study – Preliminary Results

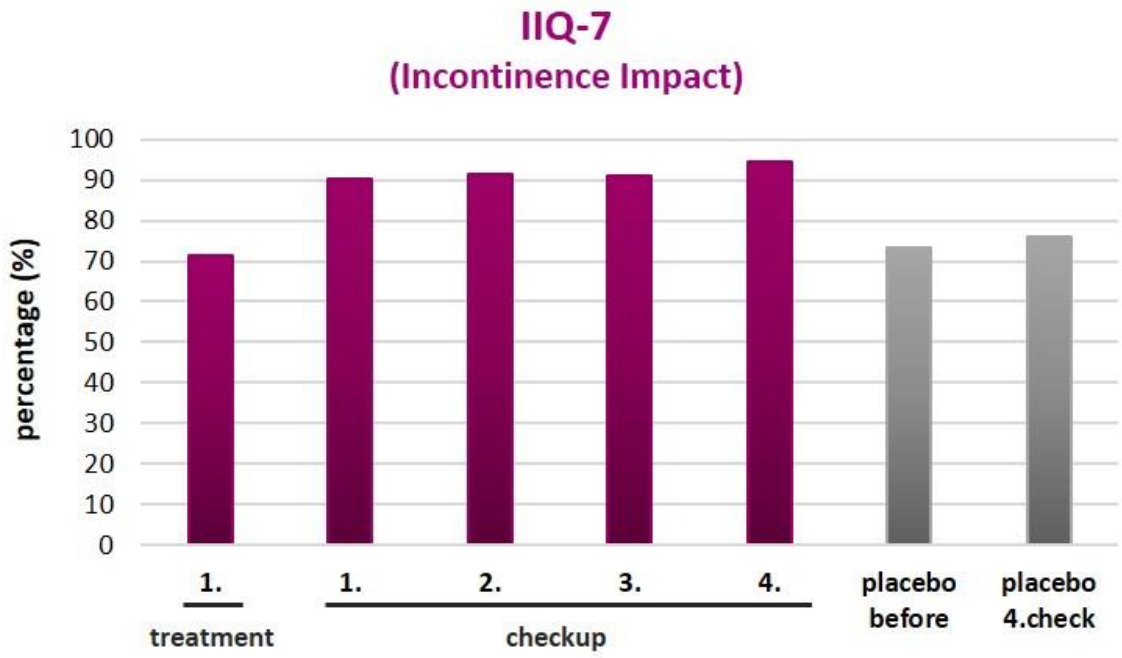


Graph 3

Comparison of subjective vaginal laxity symptoms improvement in group of patients with active treatment (65 patients) and placebo group as a negative control (9 patients)
General difference before 1.treatment and after 1., 2., 3. and 4. checkup in VLQ questionnaire

Final average vaginal laxity symptoms improvement of 23 %!

PMCF Study – Preliminary Results

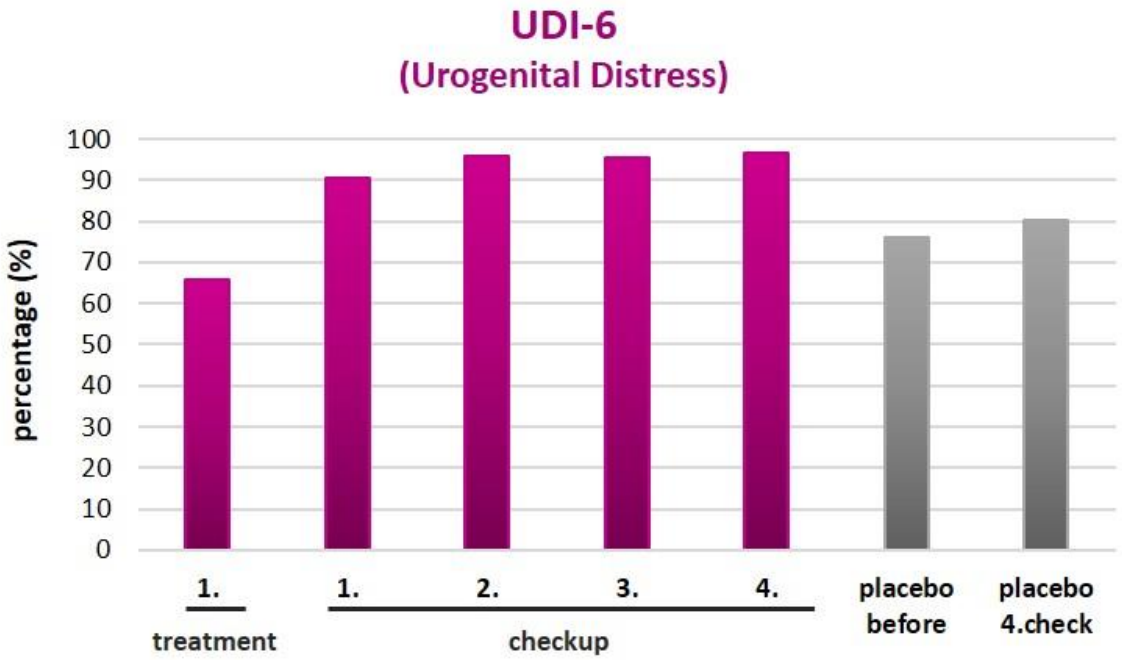


Graph 4

Comparison of subjective incontinence symptoms improvement in group of patients with active treatment (65 patients) and placebo group as a negative control (9 patients)
General difference before 1.treatment and after 1., 2., 3. and 4. checkup in IIQ7 questionnaire

Final average incontinence symptoms improvement of 23 %!

PMCF Study – Preliminary Results

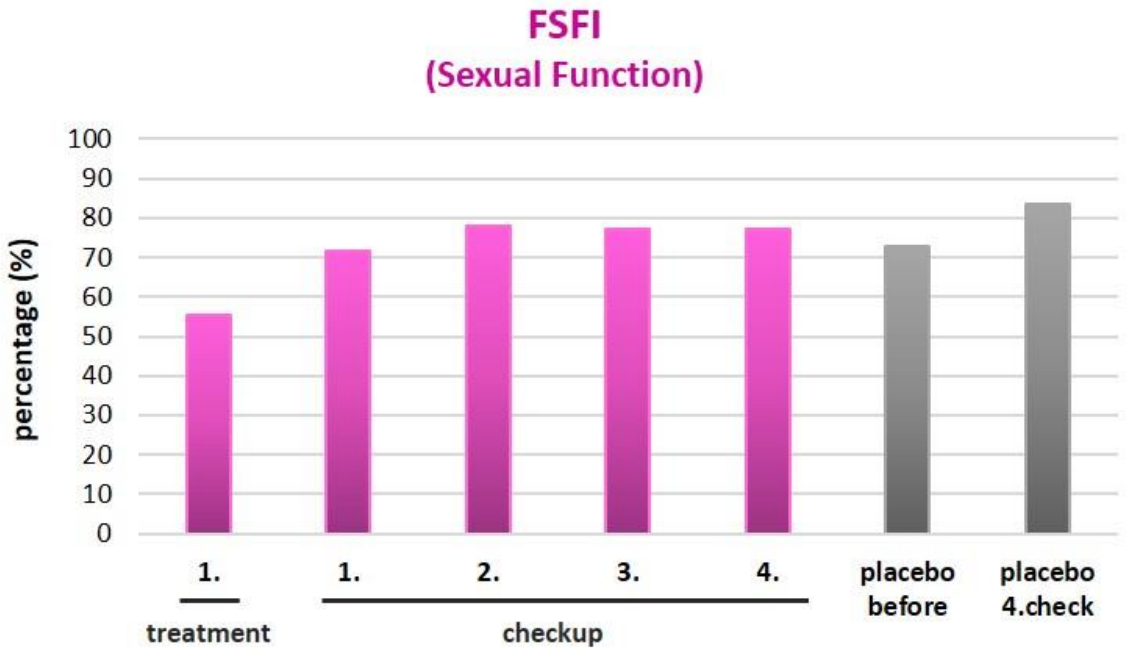


Graph 5

Comparison of subjective urogenital distress symptoms improvement in group of patients with active treatment (65 patients) and placebo group as a negative control (9 patients)
General difference before 1.treatment and after 1., 2., 3. and 4. checkup in UDI-6 questionnaire

Final average urogenital distress symptoms improvement of 26 %!

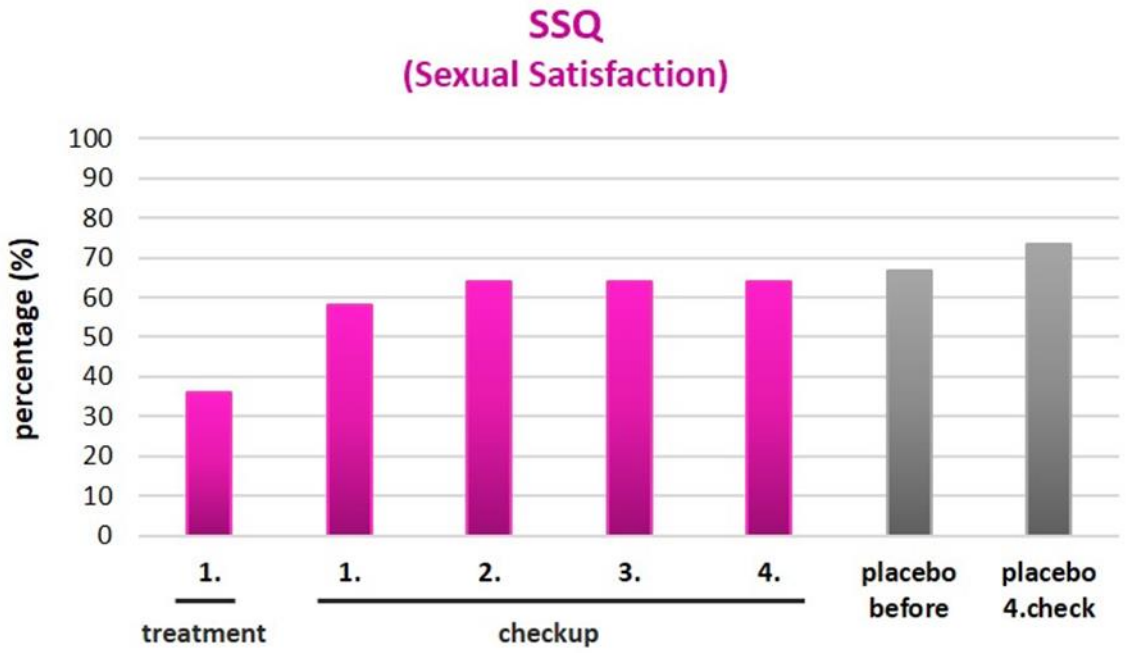
PMCF Study – Preliminary Results



Graph 6
Comparison of subjective sexual function symptoms improvement in group of patients with active treatment (45 patients) and placebo group as a negative control (8 patients)
General difference before 1.treatment and after 1., 2., 3. and 4. checkup in FSFI questionnaire

Final average sexual function symptoms improvement of 18 %!

PMCF Study – Preliminary Results



Graph 7

Comparison of subjective sexual satisfaction symptoms improvement in group of patients with active treatment (55 patients) and placebo group as a negative control (9 patients)
General difference before 1.treatment and after 1., 2., 3. and 4. checkup in SSQ questionnaire

Final average sexual satisfaction symptoms improvement of 21 %!

Biopsy

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

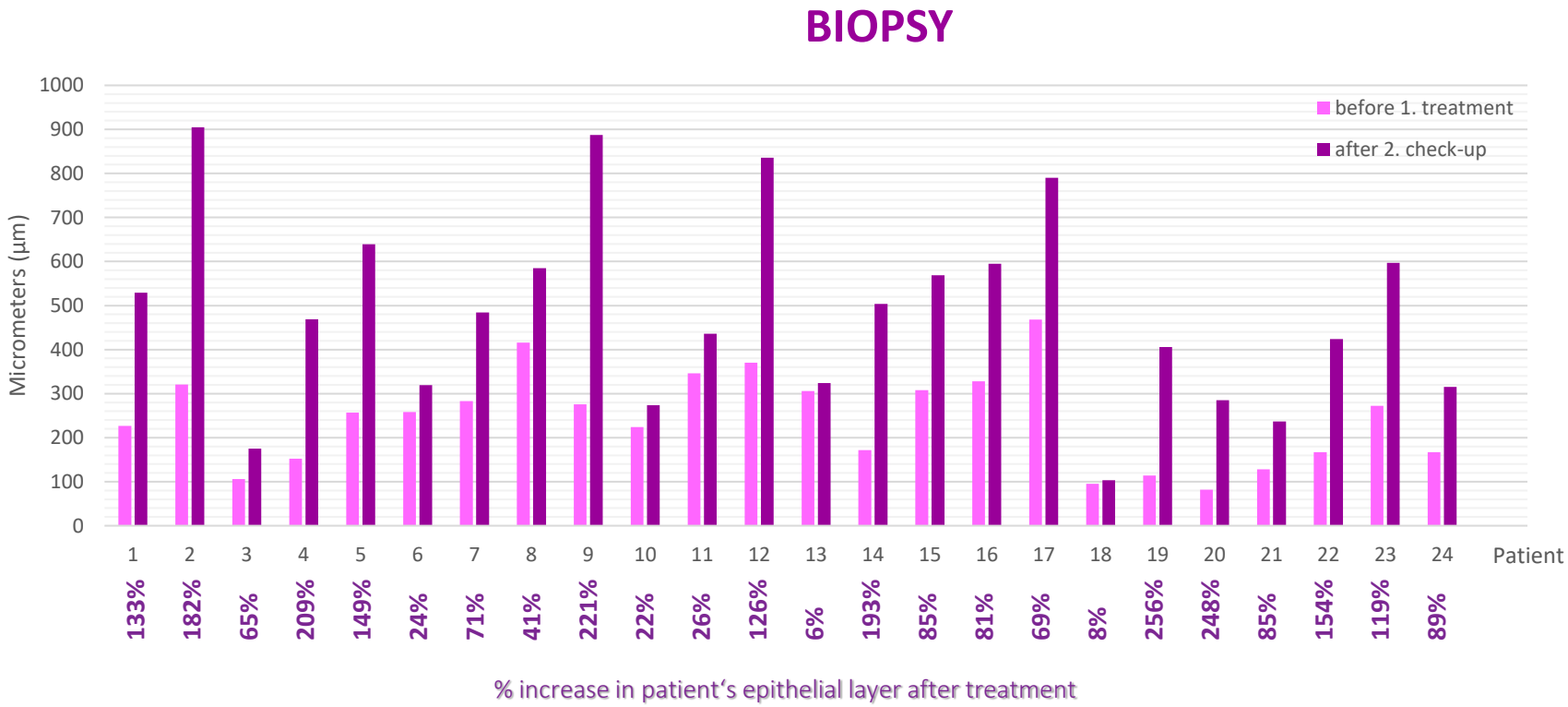
Then, the second sample was taken 3 months after the 3rd treatment
(which corresponds with the 2nd control).

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



Graph 8

Comparison of biopsy samples in group of patients with active treatment (24 patients)

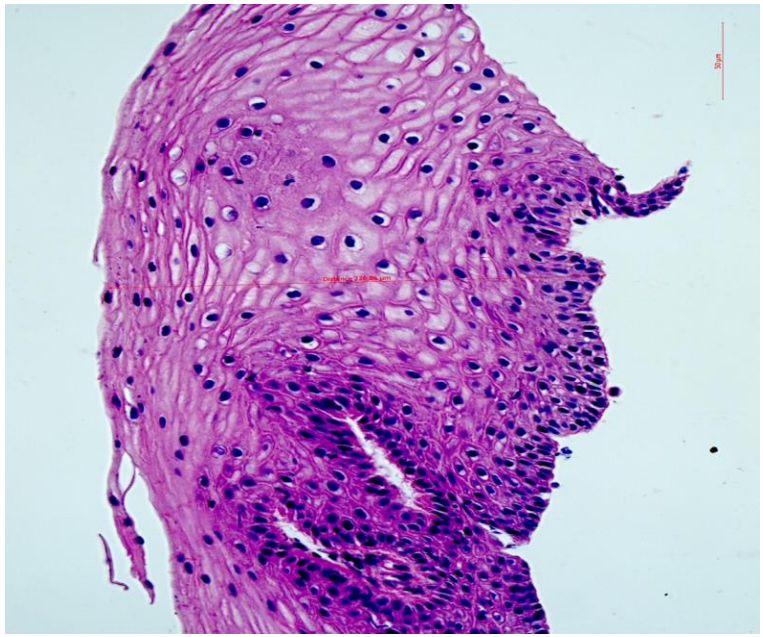
Overall difference before 1.treatment and after 2.check-up

111 % increase average in the epithelial layer!

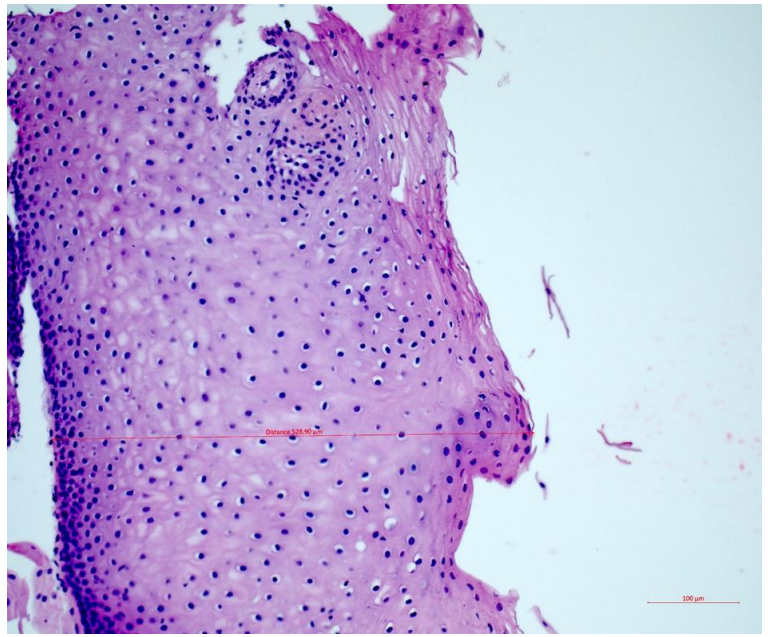
Biopsy Example – Patient no. 1

45 years
4 pregnancies
4 vaginal births
48 months after the last birth

Before



After



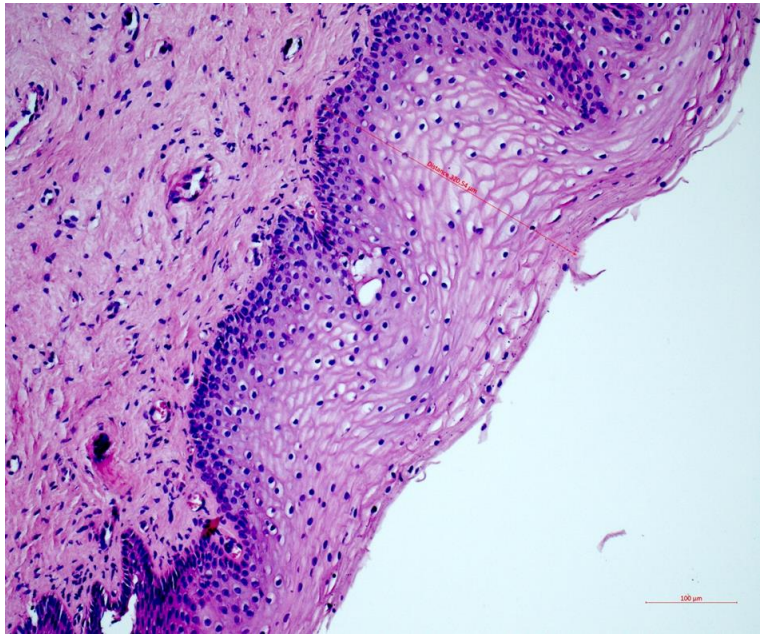
The pre-treatment epithelial thickness of the patient was **226.86 µm**. After the second check-up, the biopsy samples showed increased epithelial thickness up to **528.90 µm**.

133 % increase in epithelial layer

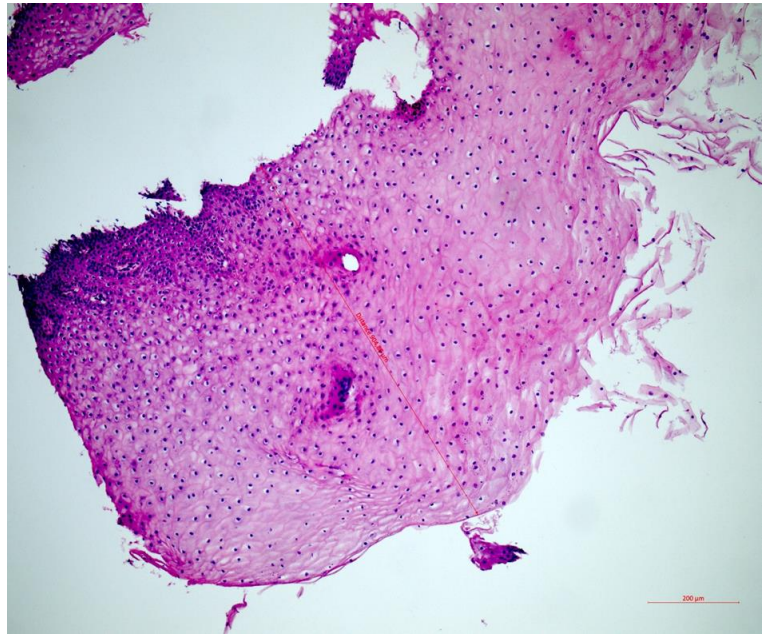
Biopsy Example – Patient no. 2

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

Before



After



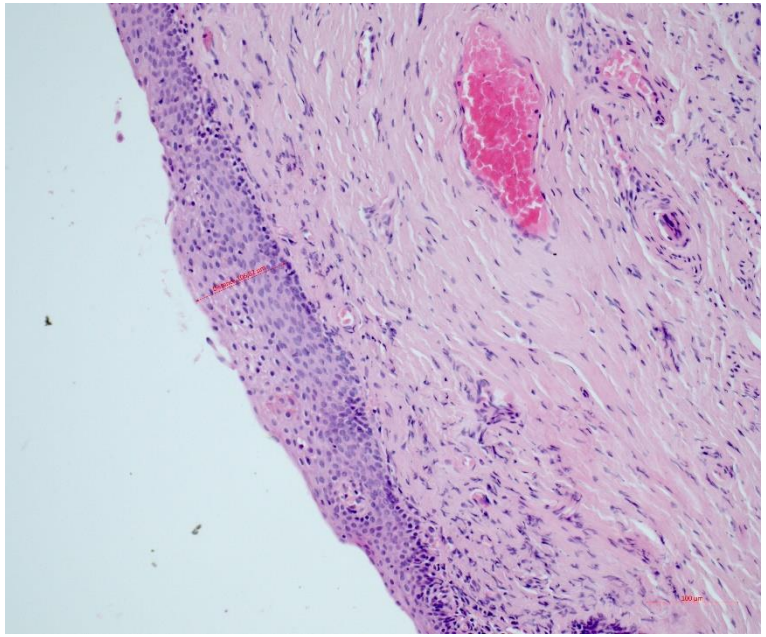
The patient's pre-treatment epithelial thickness was **320.54 µm**. After the second check-up, the biopsy samples showed increased epithelial thickness up to **904.86 µm**.

182 % increase in epithelial layer

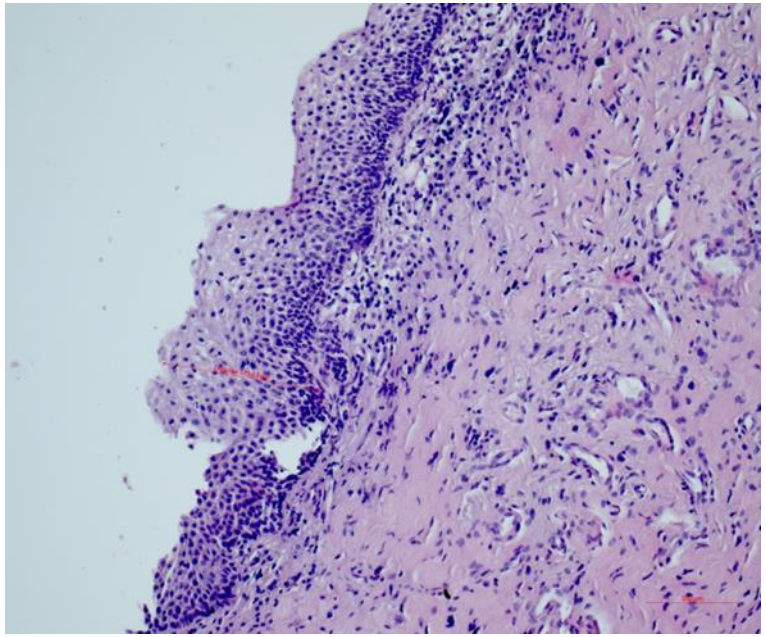
Biopsy Example – Patient no. 3

63 years
2 pregnancies
2 vaginal births
444 months since last birth

Before



After



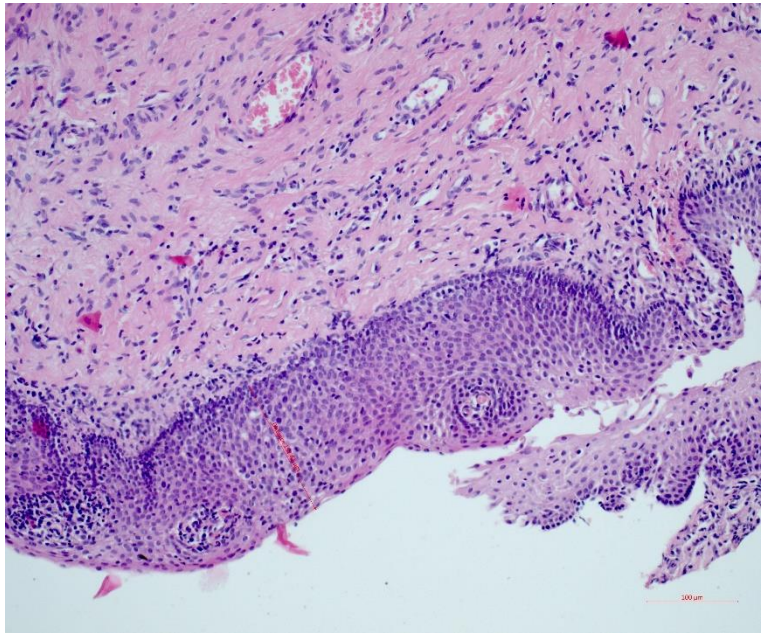
The patient's pre-treatment epithelial thickness was **106 µm**. After the second check-up, the biopsy samples showed increased epithelial thickness up to **175 µm**.

65 % increase in epithelial layer

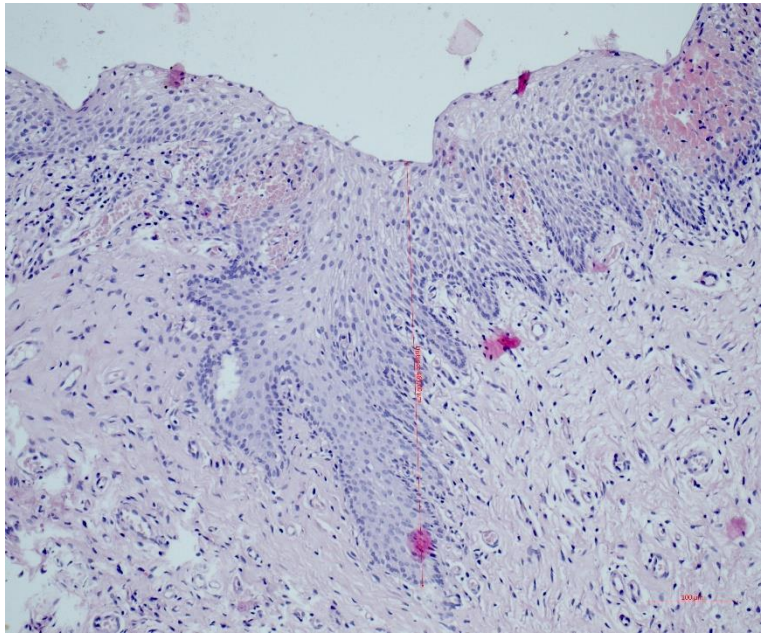
Biopsy Example – Patient no. 4

53 years
3 pregnancies
3 vaginal births
204 months since last birth

Before



After



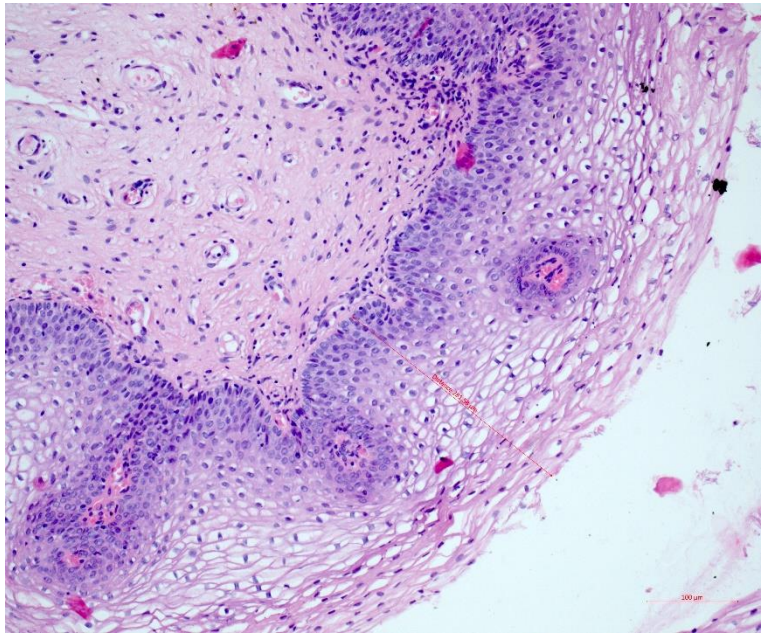
The patient's pre-treatment epithelial thickness was **152 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **469 µm**.

➡ **209 % increase in epithelial layer**

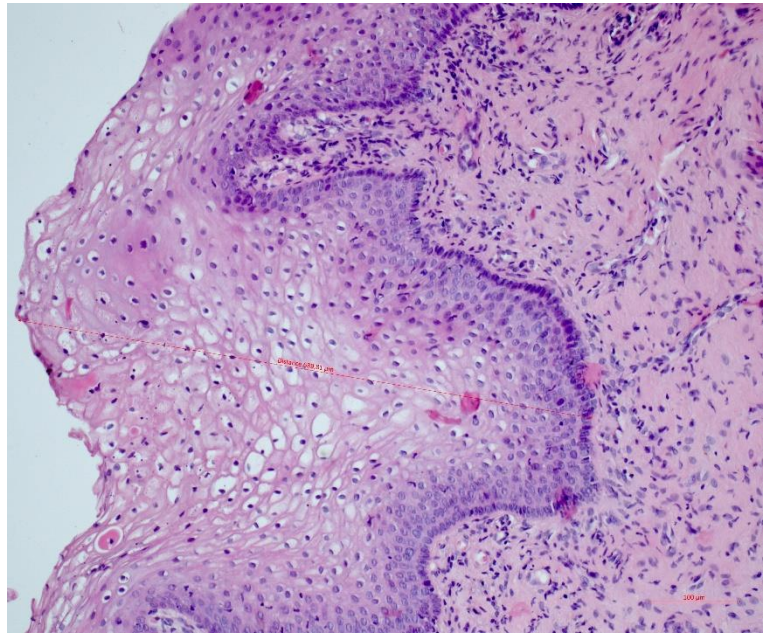
Biopsy Example – Patient no. 5

42 years
3 pregnancies
3 vaginal births
252 months since last birth

Before



After



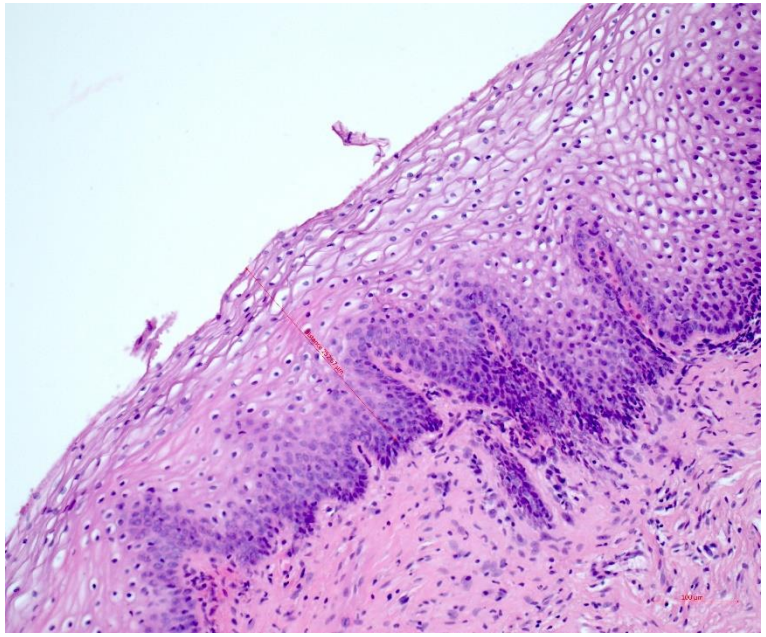
The patient's pre-treatment epithelial thickness was **257 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **639 µm**.

149 % increase in epithelial layer

Biopsy Example – Patient no. 6

39 years
2 pregnancies
2 vaginal births
96 months since last birth

Before



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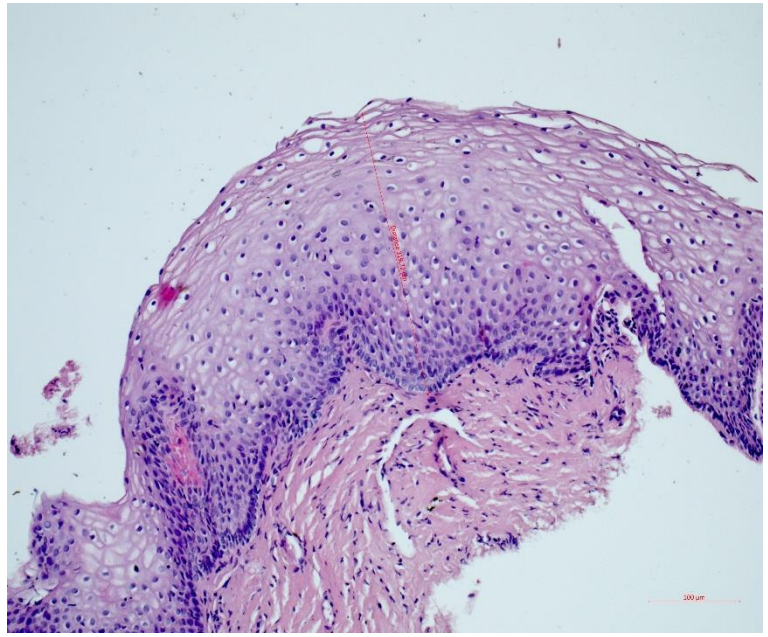


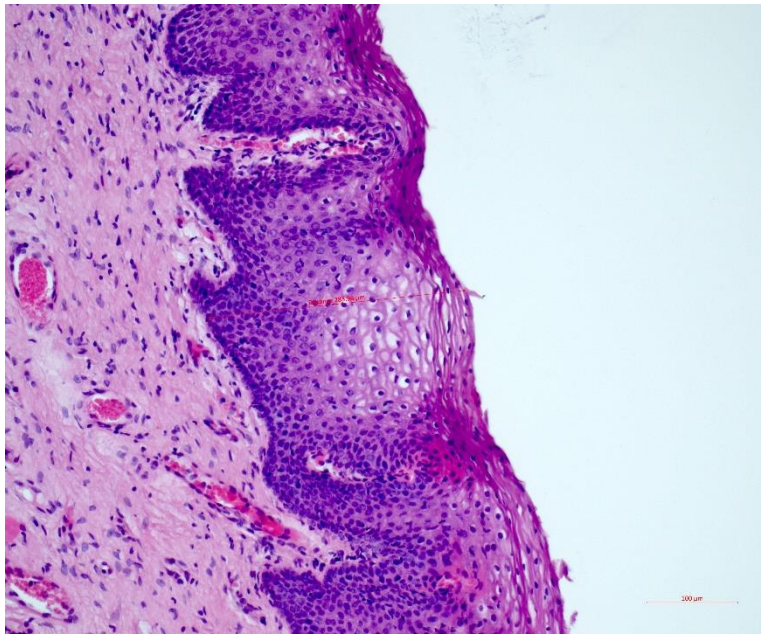
The patient's pre-treatment epithelial thickness was **258 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **319 µm**.

➡ **24 % increase in epithelial layer**

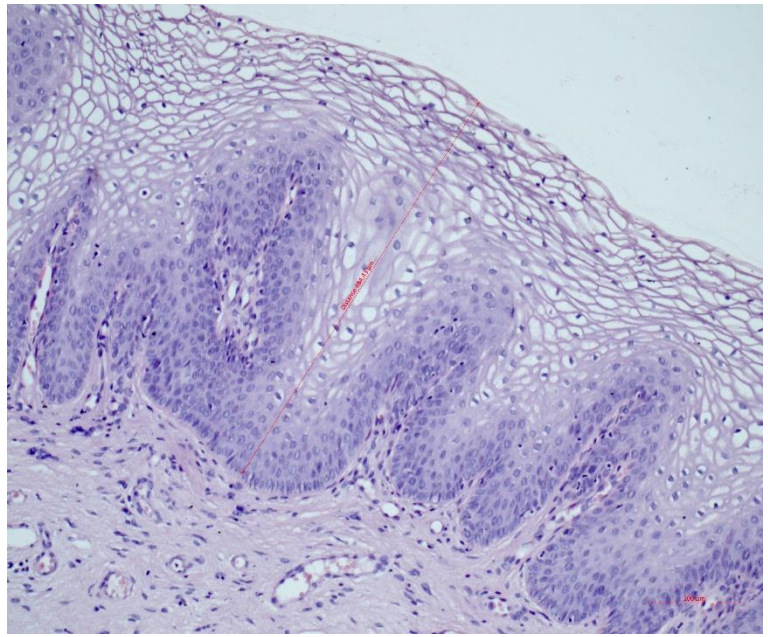
Biopsy Example – Patient no. 7

38 years
2 pregnancies
1 vaginal births
74 months since last birth

Before



After



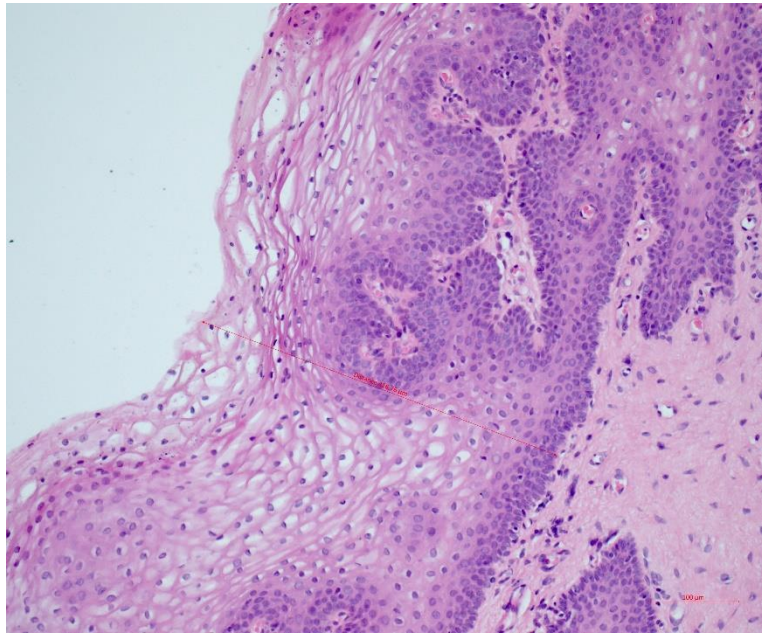
The patient's pre-treatment epithelial thickness was **283 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **484 µm**.

➡ **71 % increase in epithelial layer**

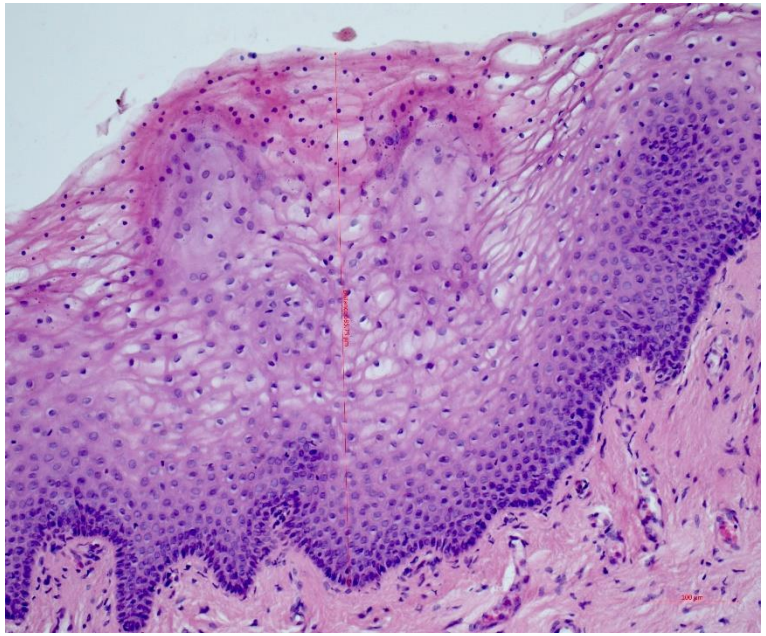
Biopsy Example – Patient no. 8

42 years
3 pregnancies
2 vaginal births
63 months since last birth

Before



After



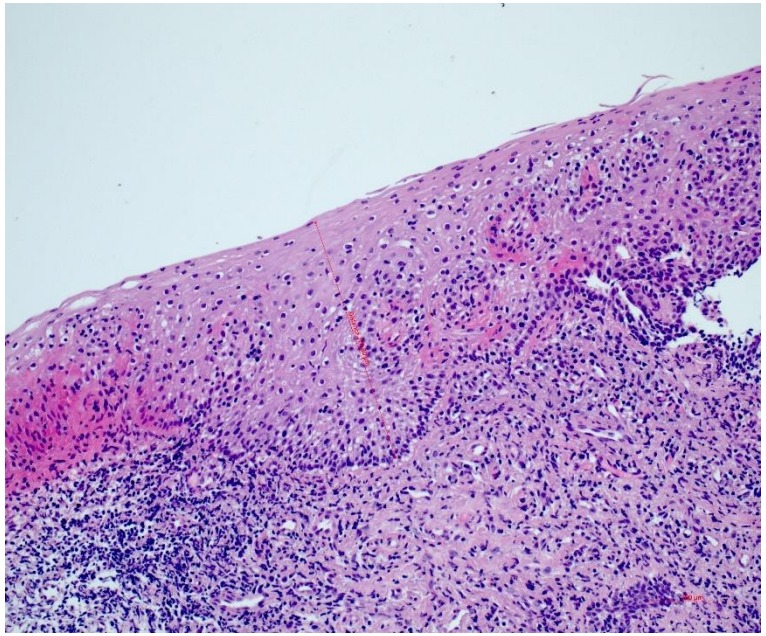
The patient's pre-treatment epithelial thickness was **416 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **585 µm**.

➡ **41 % increase in epithelial layer**

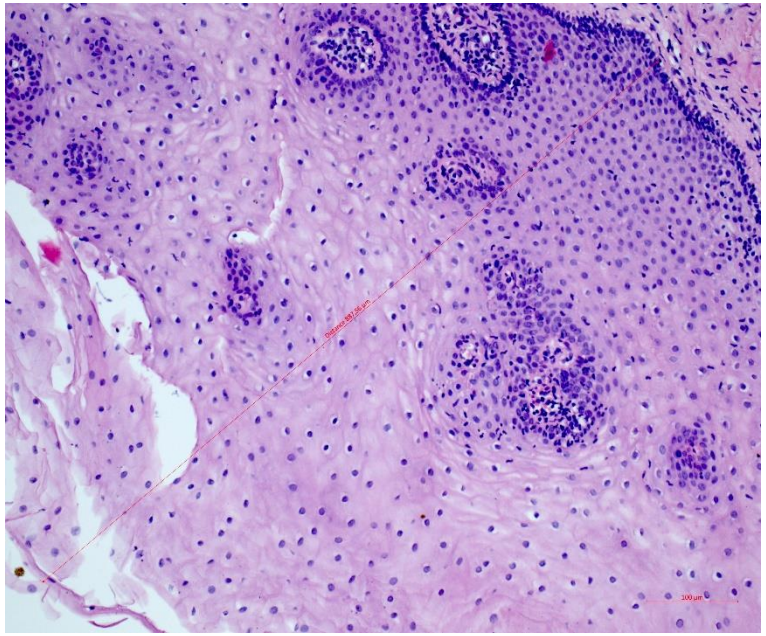
Biopsy Example – Patient no. 9

39 years
2 pregnancies
2 vaginal births
96 months since last birth

Before



After



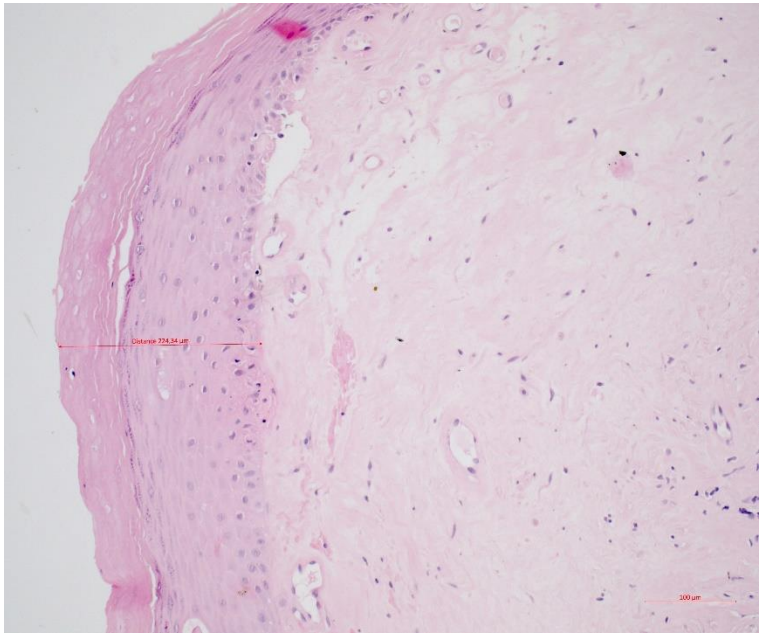
The patient's pre-treatment epithelial thickness was **276 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **887 µm**.

➡ **221 % increase in epithelial layer**

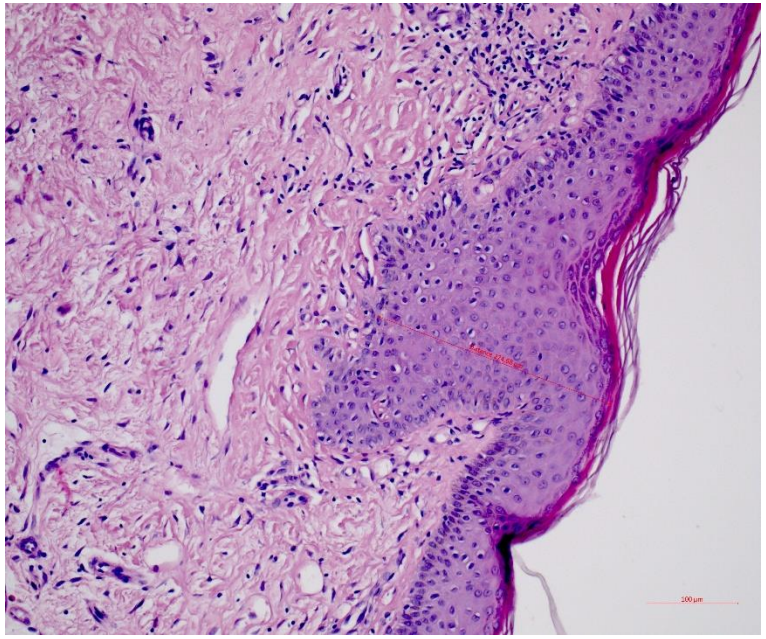
Biopsy Example – Patient no. 10

72 years
7 pregnancies
3 vaginal births
504 months since last birth

Before



After



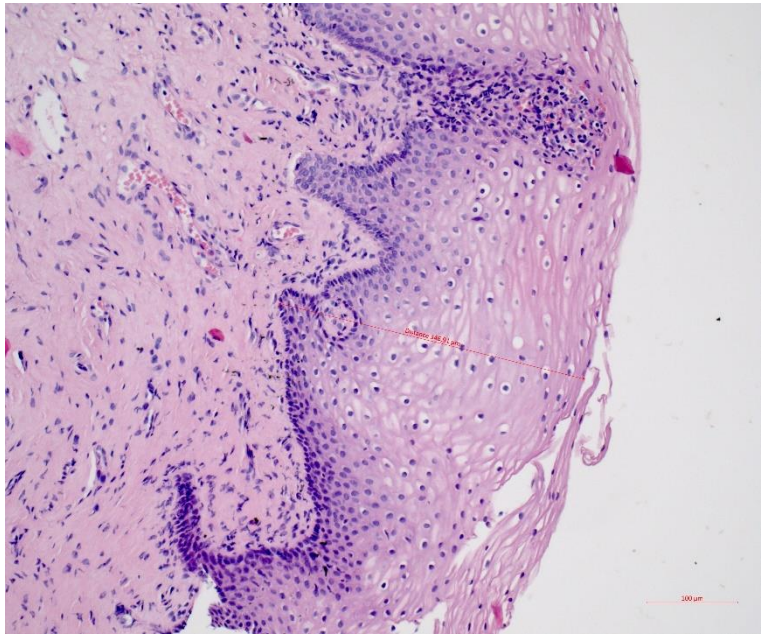
The patient's pre-treatment epithelial thickness was **224 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **274 µm**.

➡ **22 % increase in epithelial layer**

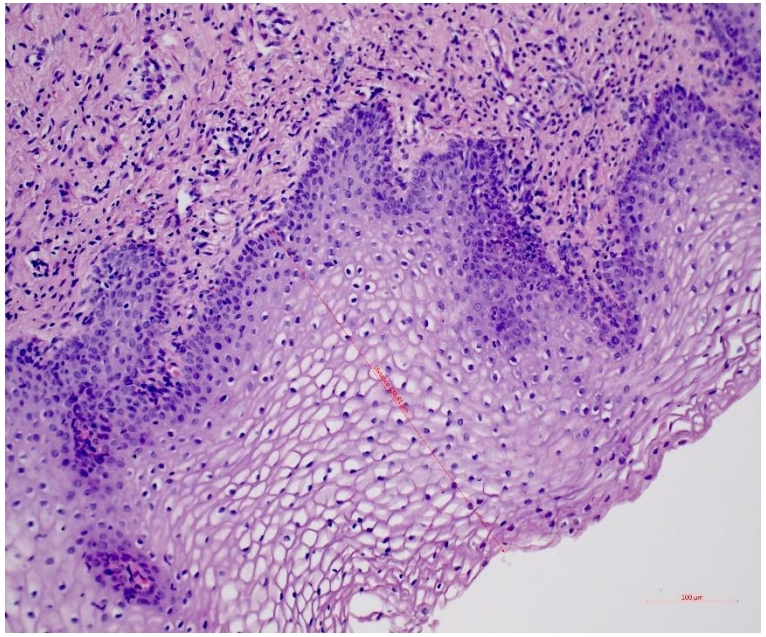
Biopsy Example – Patient no. 11

48 years
3 pregnancies
3 vaginal births
168 months since last birth

Before



After



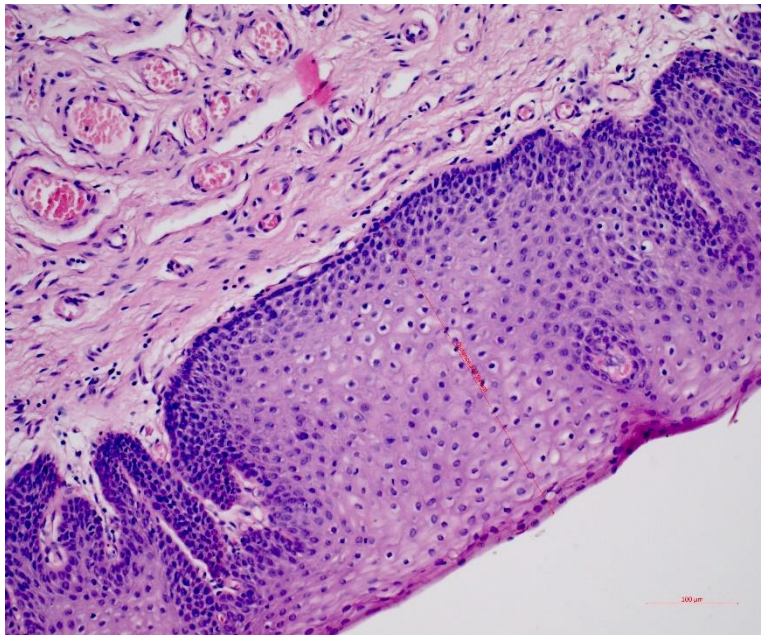
The patient's pre-treatment epithelial thickness was **346 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **436 µm**.

➡ **26 % increase in epithelial layer**

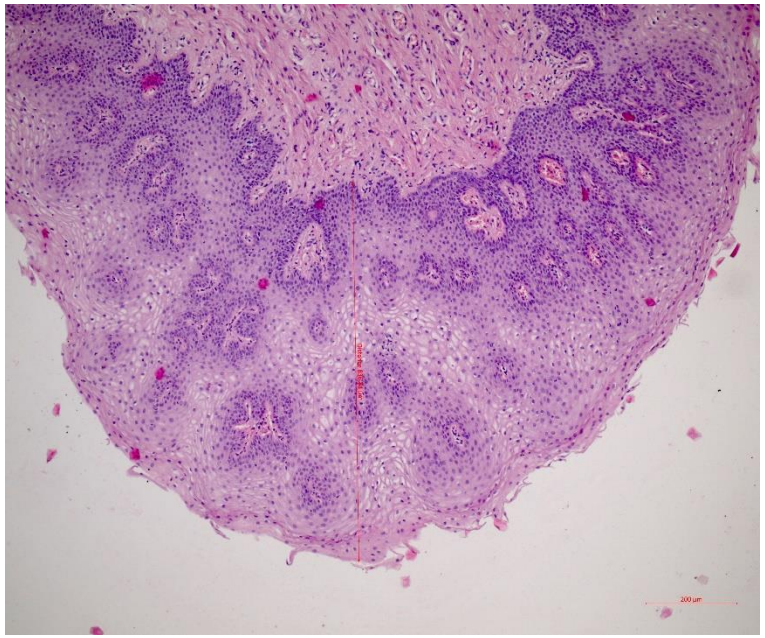
Biopsy Example – Patient no. 12

36 years
3 pregnancies
1 vaginal birth
57 months since last birth

Before



After



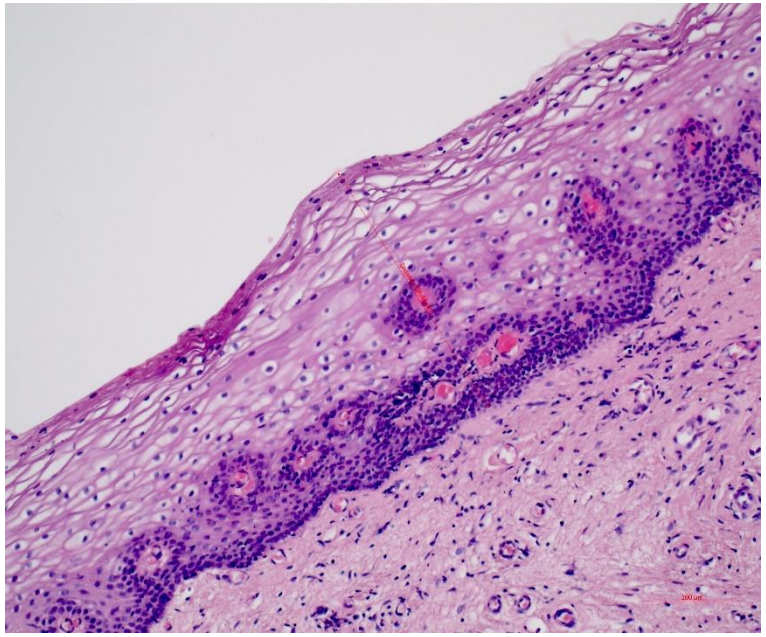
The patient's pre-treatment epithelial thickness was **370 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **836 µm**.

126 % increase in epithelial layer

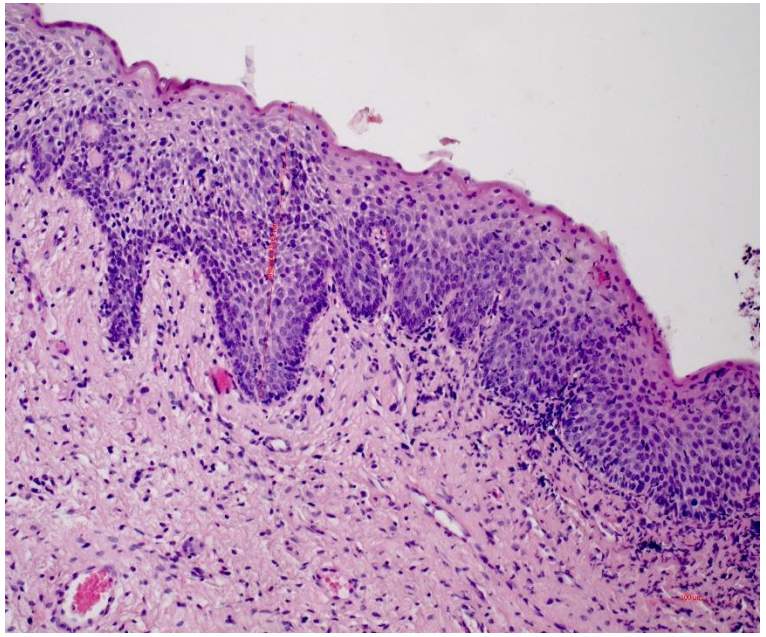
Biopsy Example – Patient no. 13

52 years
2 pregnancies
2 vaginal births
324 months since last birth

Before



After



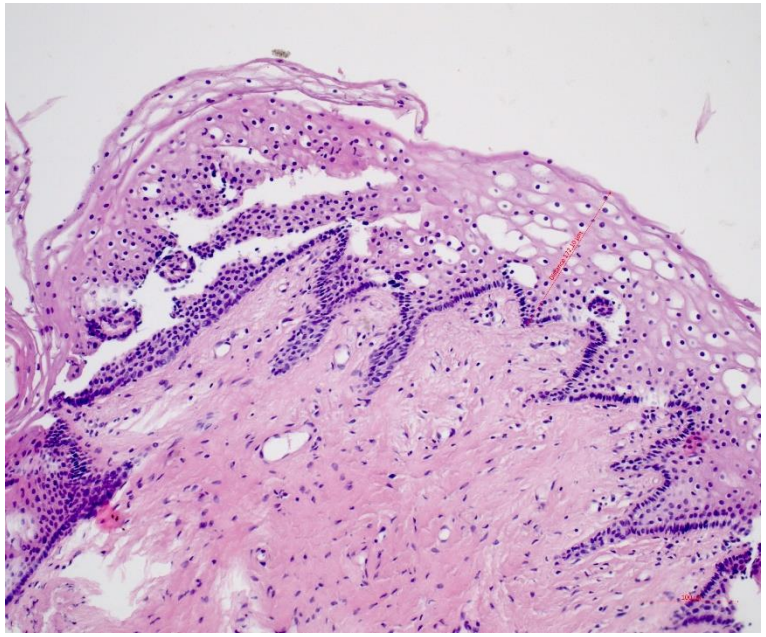
The patient's pre-treatment epithelial thickness was **306 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **324 µm**.

➡ **6 % increase in epithelial layer**

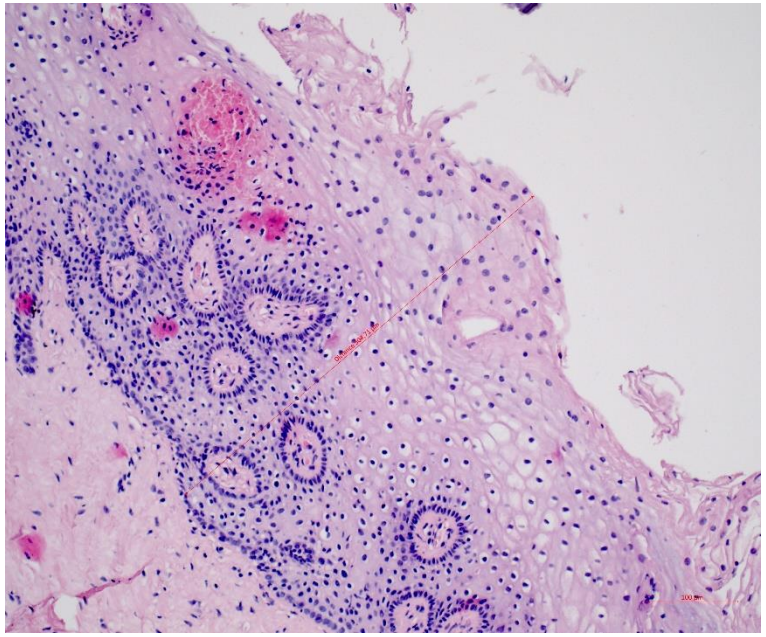
Biopsy Example – Patient no. 14

57 years
1 pregnancies
1 vaginal birth
408 months since last birth

Before



After



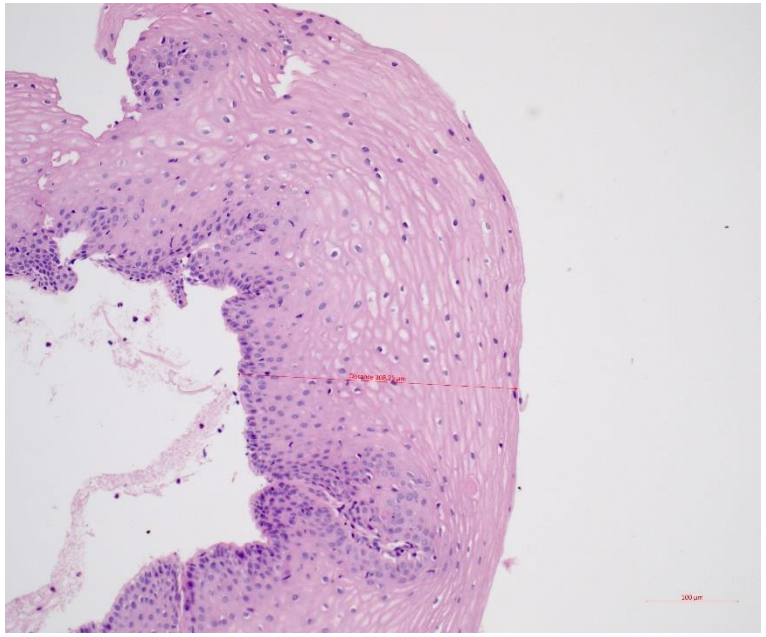
The patient's pre-treatment epithelial thickness was **172 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **504 µm**.

➡ **193 % increase in epithelial layer**

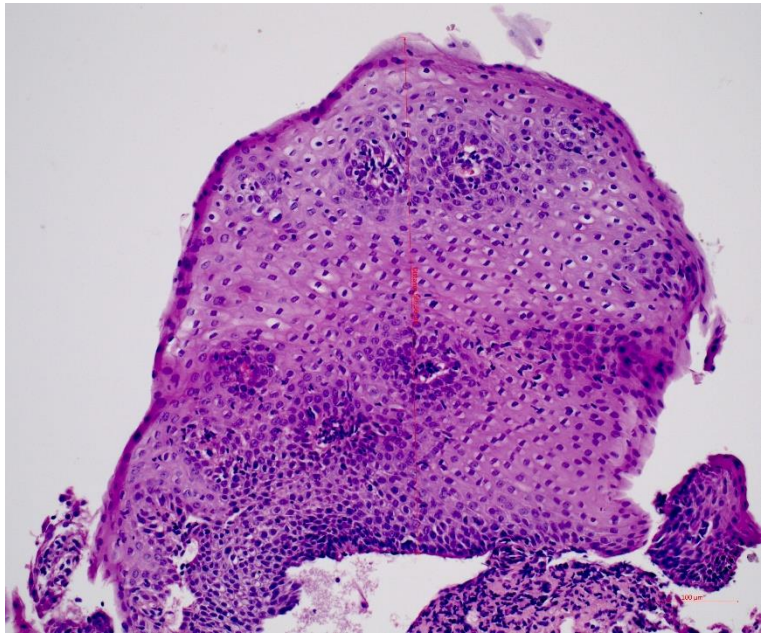
Biopsy Example – Patient no. 15

50 years
7 pregnancies
3 vaginal births
148 months since last birth

Before



After



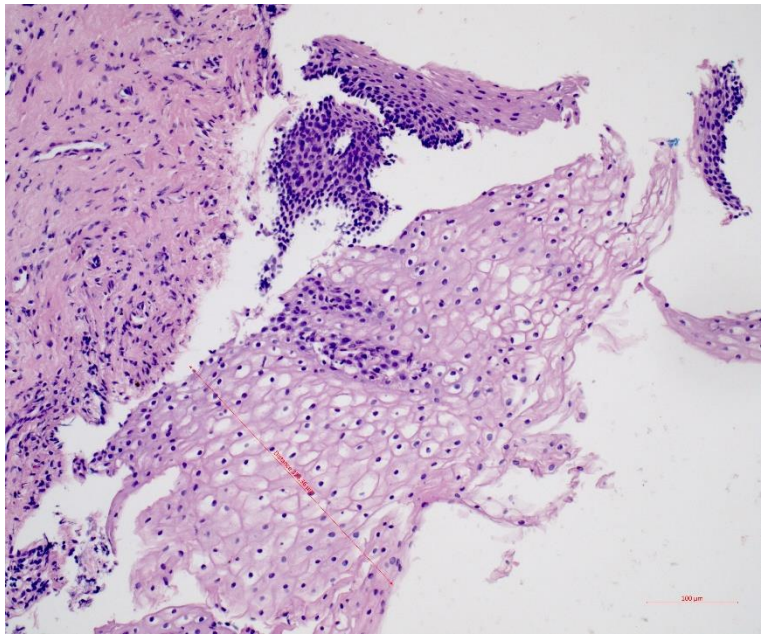
The patient's pre-treatment epithelial thickness was **308 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **569 µm**.

85 % increase in epithelial layer

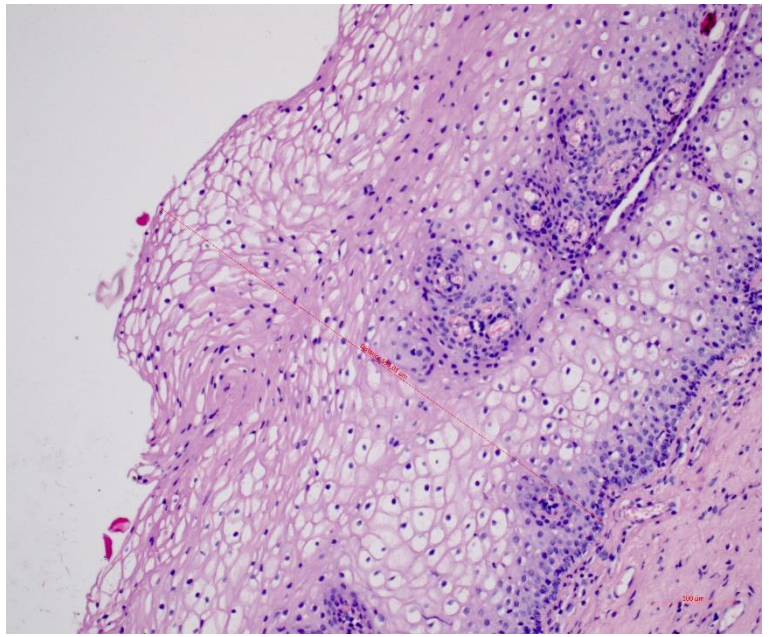
Biopsy Example – Patient no. 16

46 years
2 pregnancies
2 vaginal births
156 months since last birth

Before



After



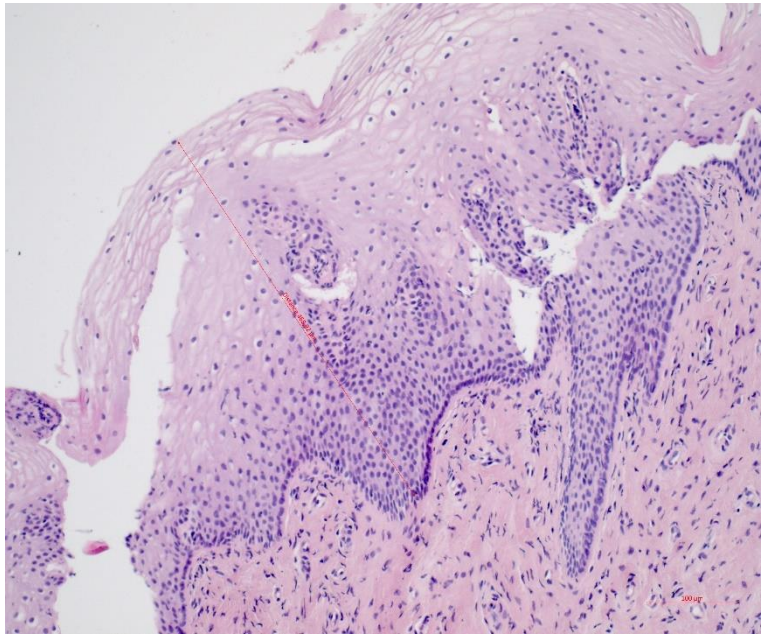
The patient's pre-treatment epithelial thickness was **328 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **595 µm**.

➡ **81 % increase in epithelial layer**

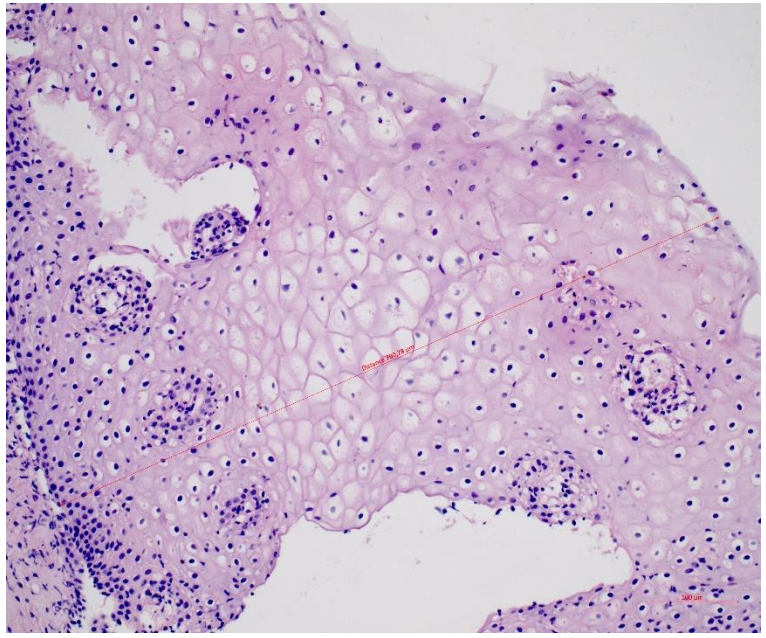
Biopsy Example – Patient no. 17

35 years
3 pregnancies
3 vaginal births
48 months since last birth

Before



After



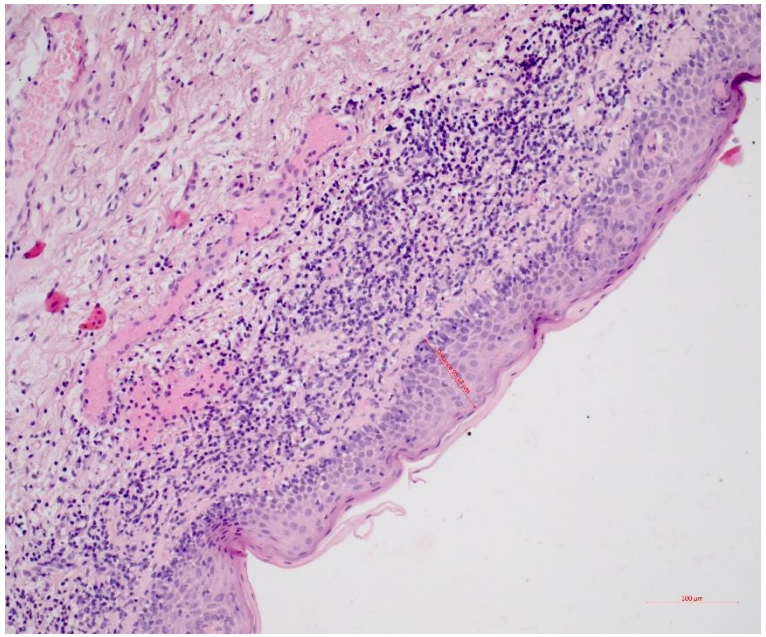
The patient's pre-treatment epithelial thickness was **468 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **790 µm**.

69 % increase in epithelial layer

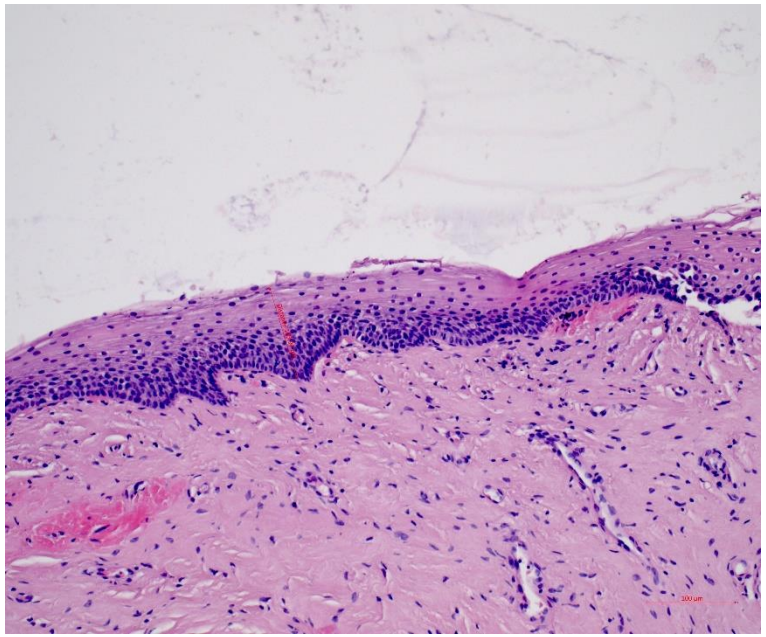
Biopsy Example – Patient no. 18

67 years
2 pregnancies
2 vaginal births
492 months since last birth

Before



After



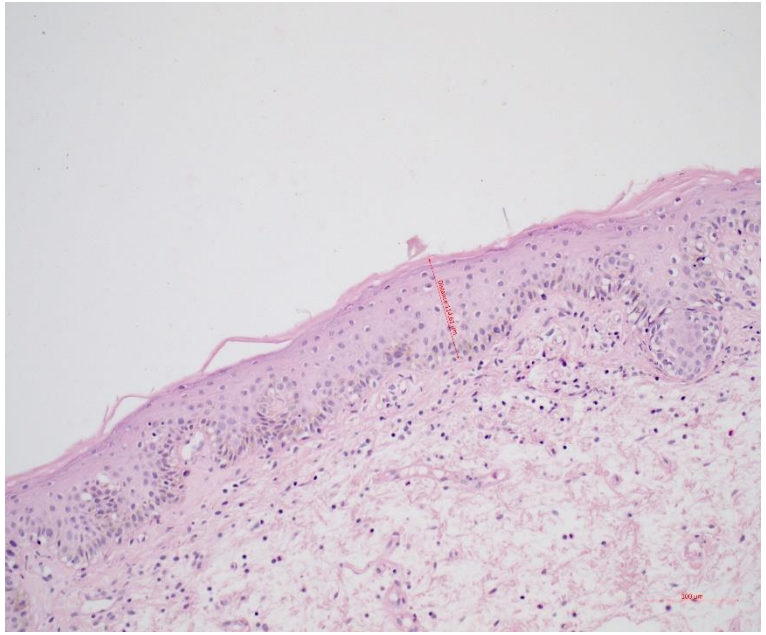
The patient's pre-treatment epithelial thickness was **95 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **103 µm**.

8 % increase in epithelial layer

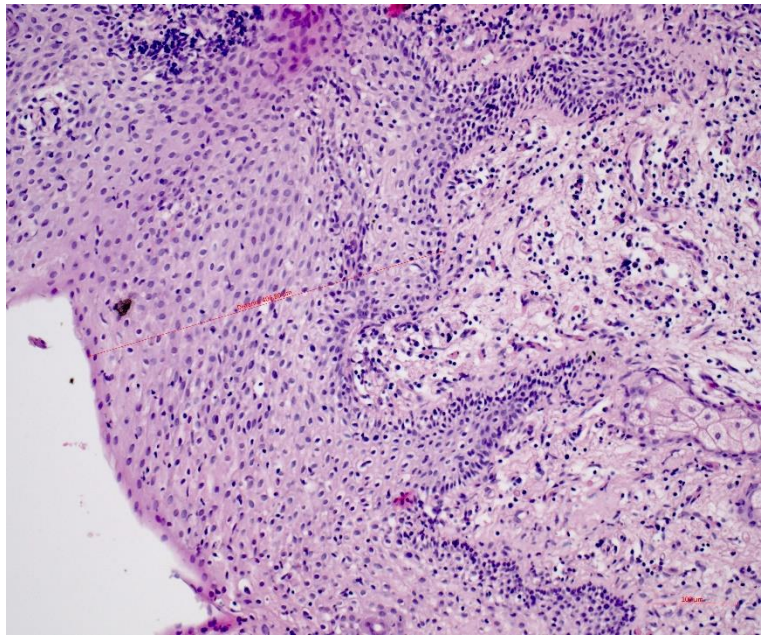
Biopsy Example – Patient no. 19

62 years
2 pregnancies
2 vaginal births
468 months since last birth

Before



After



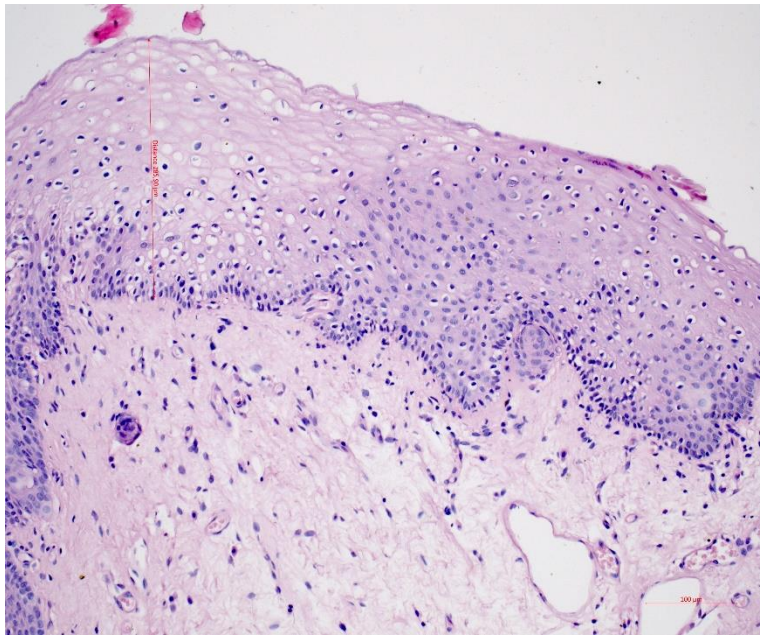
The patient's pre-treatment epithelial thickness was **114 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **406 µm**.

256 % increase in epithelial layer

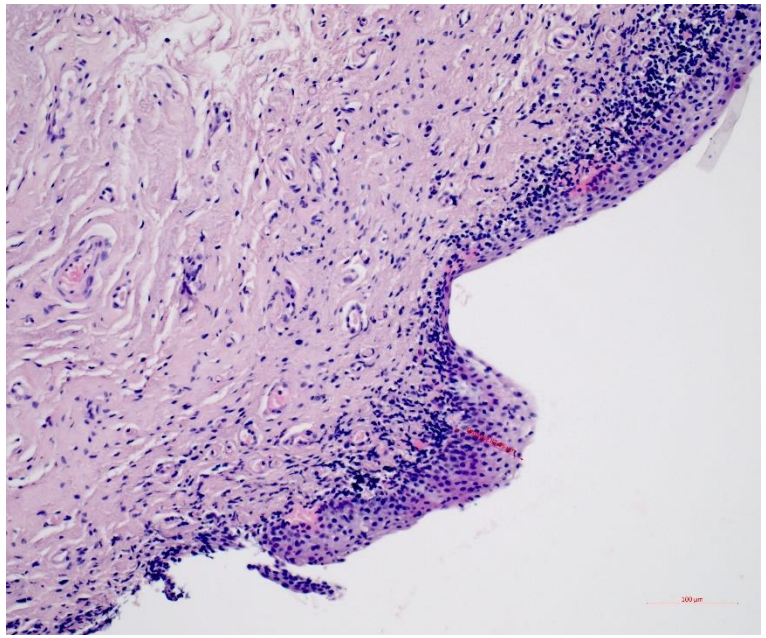
Biopsy Example – Patient no. 20

64 years
3 pregnancies
2 vaginal births
384 months since last birth

Before



After



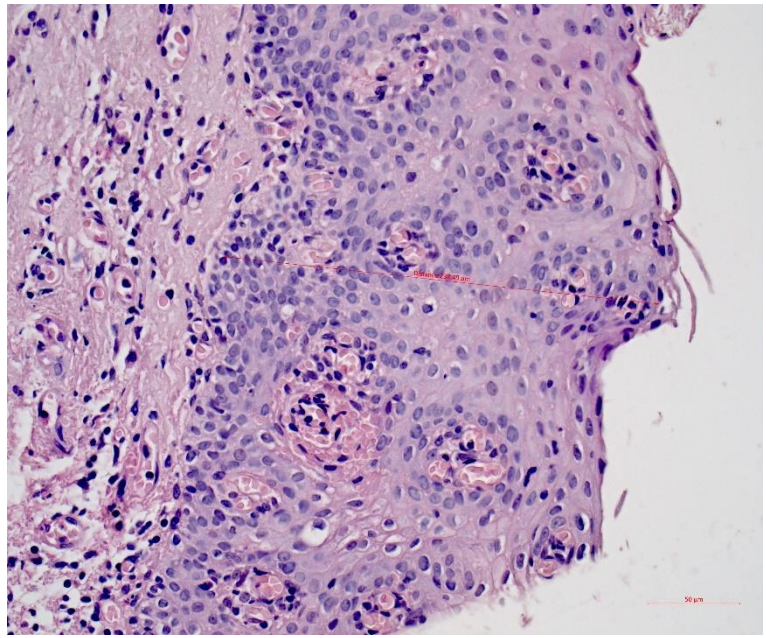
The patient's pre-treatment epithelial thickness was **82 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **285 µm**.

248 % increase in epithelial layer

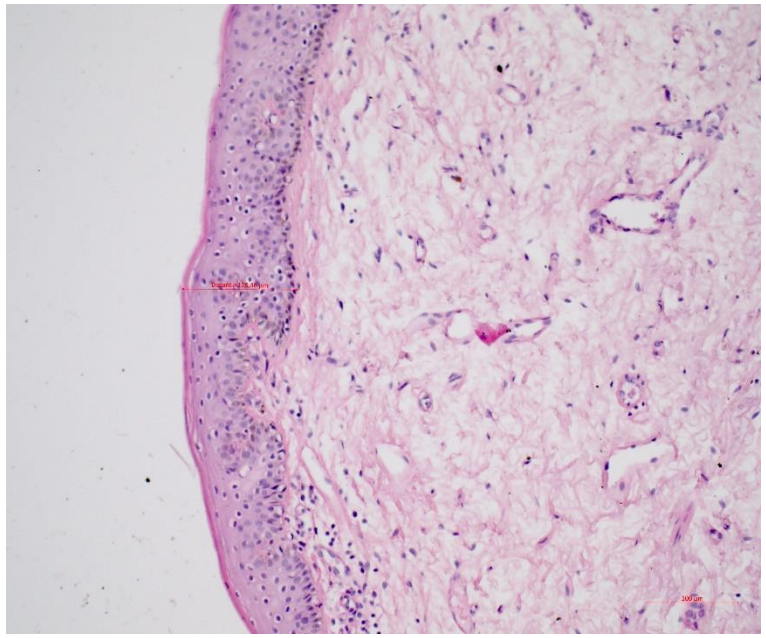
Biopsy Example – Patient no. 21

64 years
2 pregnancies
2 vaginal births
480 months since last birth

Before



After



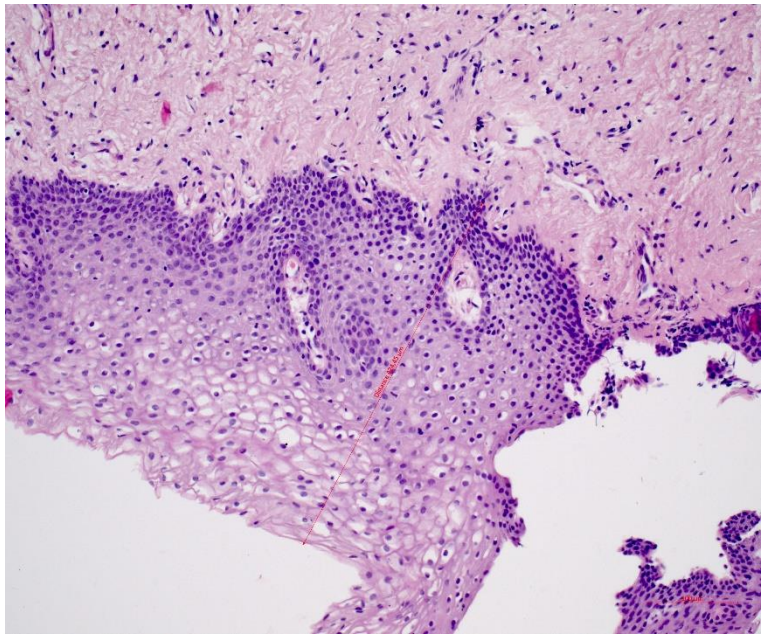
The patient's pre-treatment epithelial thickness was **128 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **237 µm**.

➡ **85 % increase in epithelial layer**

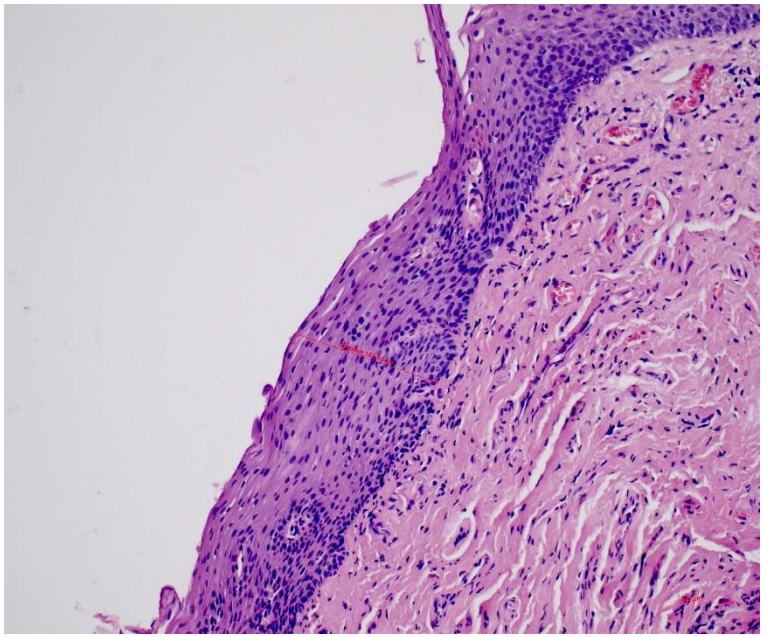
Biopsy Example – Patient no. 22

49 years
2 pregnancies
2 vaginal births
324 months since last birth

Before



After



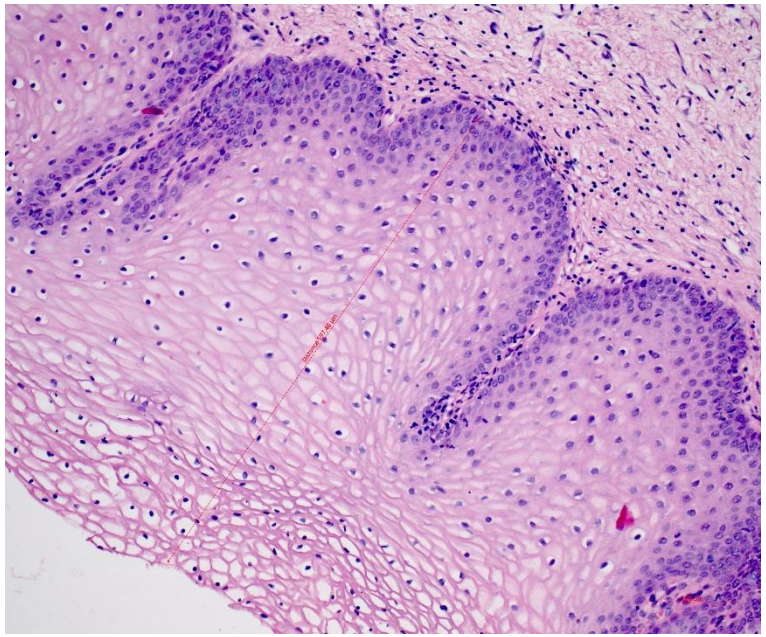
The patient's pre-treatment epithelial thickness was **167 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **424 µm**.

154 % increase in epithelial layer

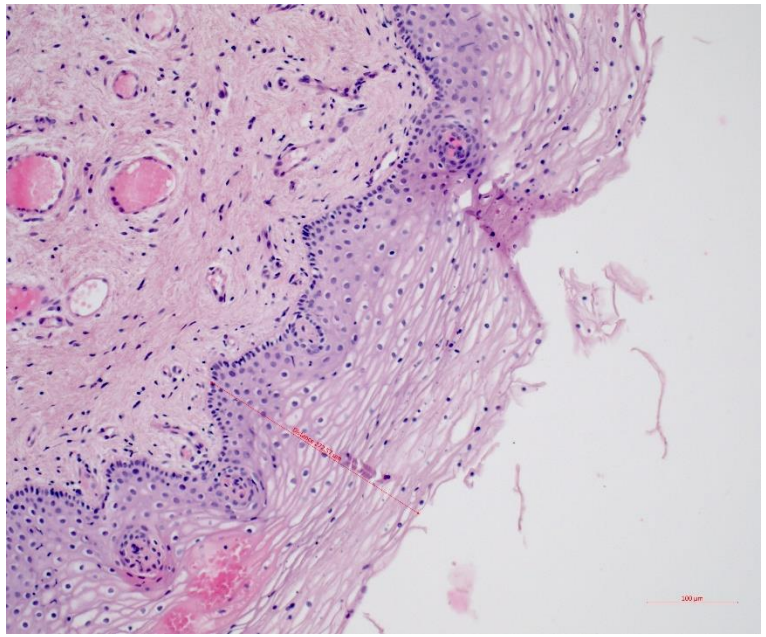
Biopsy Example – Patient no. 23

37 years
3 pregnancies
3 vaginal births
50 months since last birth

Before



After



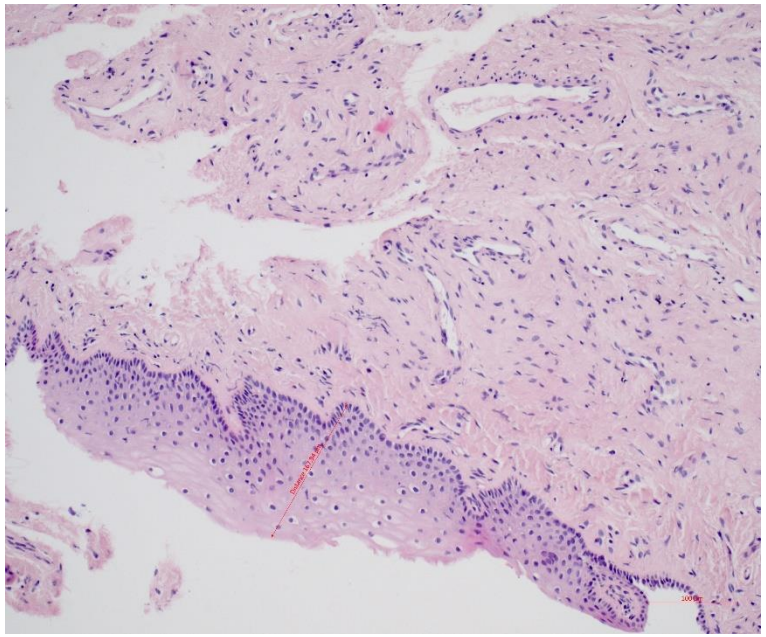
The patient's pre-treatment epithelial thickness was **272 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **597 µm**.

119 % increase in epithelial layer

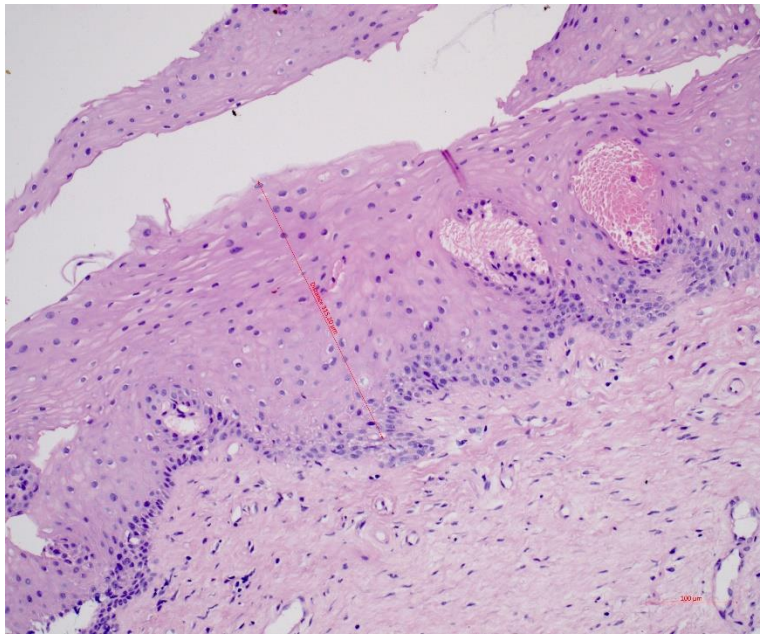
Biopsy Example – Patient no. 24

42 years
2 pregnancies
2 vaginal births
96 months since last birth

Before



After



The patient's pre-treatment epithelial thickness was **167 µm**. After the second check-up, the biopsy was taken again and epithelial thickness increased to **315 µm**.

89 % increase in epithelial layer

Conclusion

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

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

Treatment with JETT PLASMA For Her II 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 II 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."

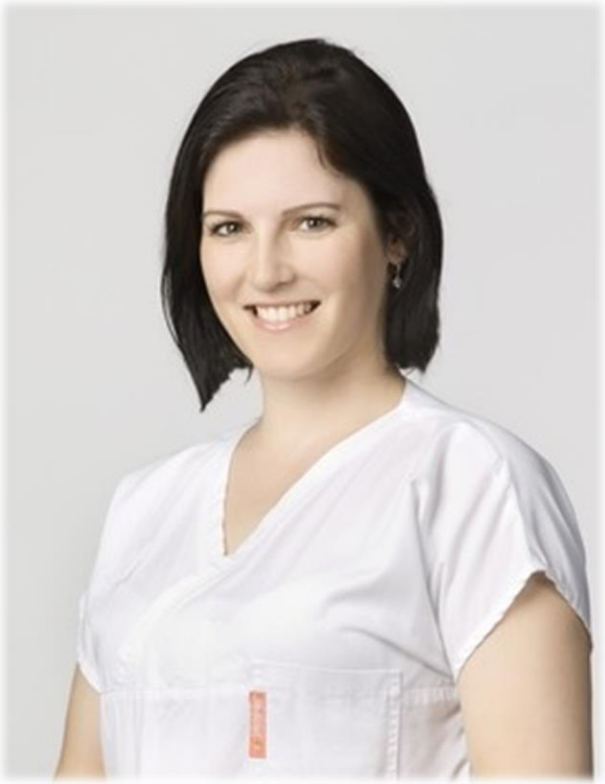
MD Lukas Pasnisin

“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 II. 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 II 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 II 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."