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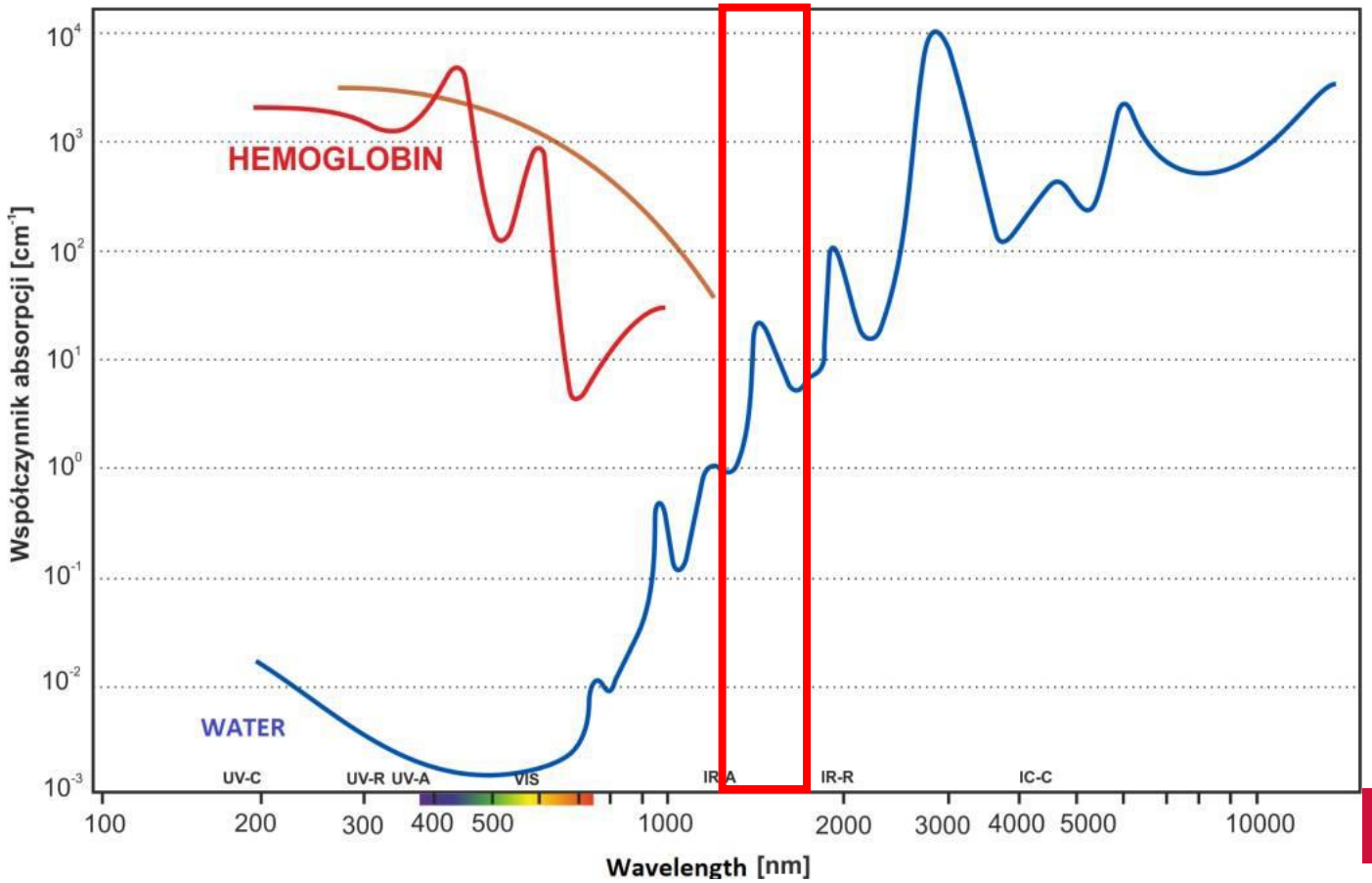
LASER WAVELENGTH AND WATER ABSORPTION

- MOST COMMON NON-ABLATIVE WAVELENGTHS:
  - 1.064 nm
  - 1.320 nm
  - 1.410 nm
  - 1.440 nm
  - 1.470 nm
  - 1.540 nm
  - 1.550 nm

- MOST COMMON SEMI-ABLATIVE (?!) WAVELENGTHS
  - 1.927 nm

- MOST COMMON ABLATIVE WAVELENGTHS
  - 2.940 nm
  - 10.600 nm



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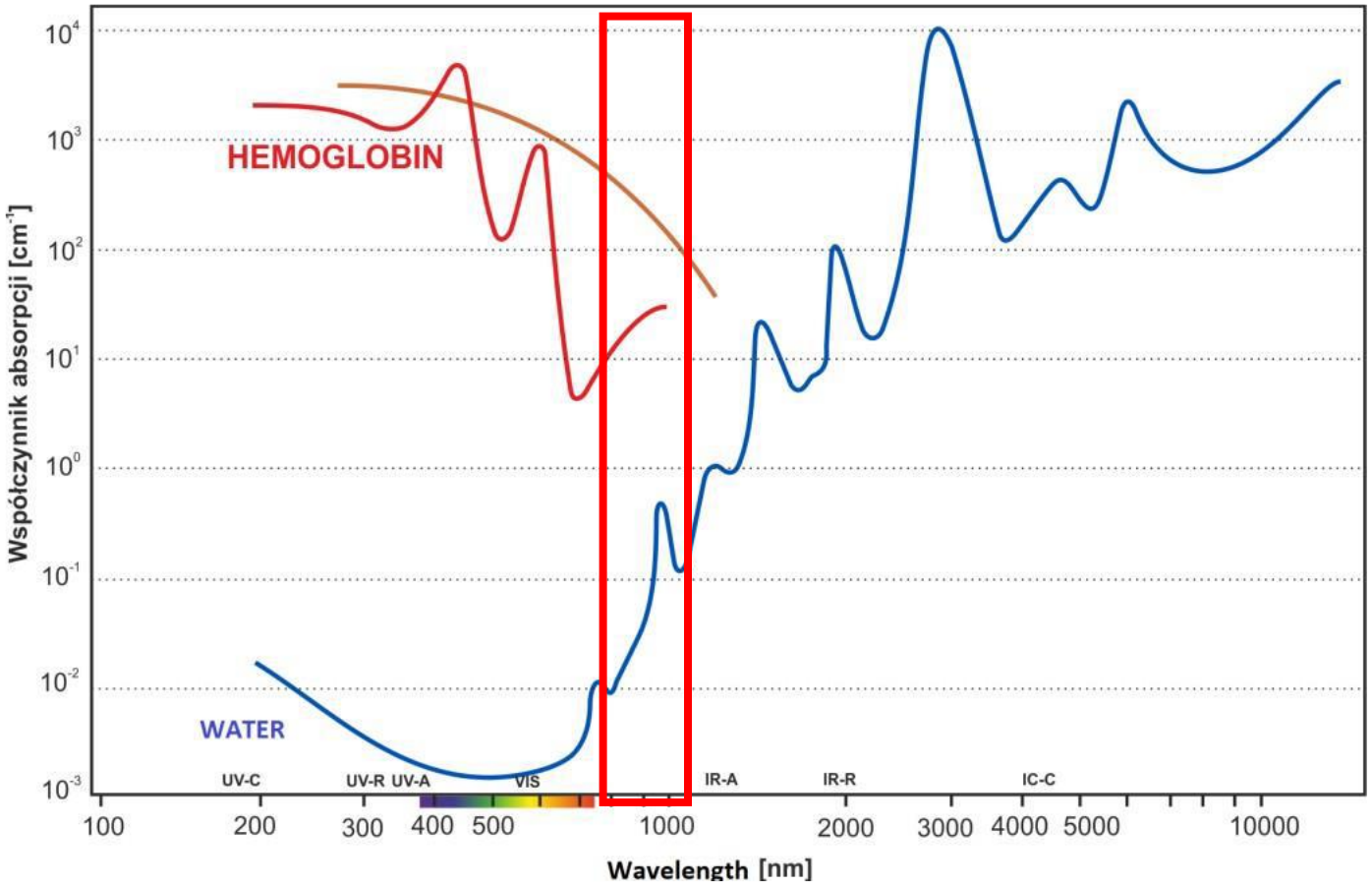
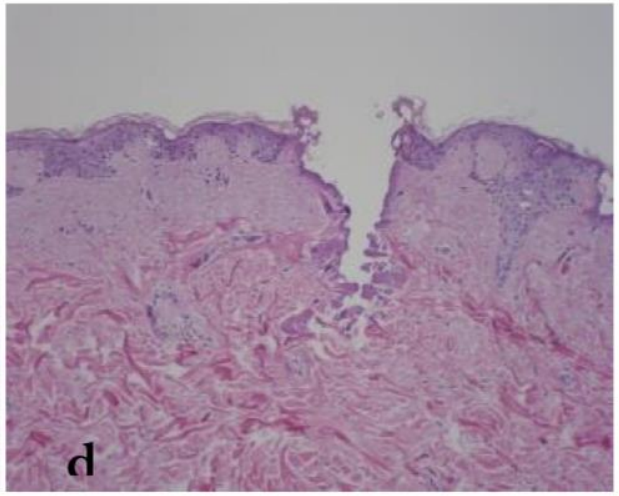
LASER WAVELENGTH AND WATER ABSORPTION

- MAIN DIFFERENCE BETWEEN ABLATIVE & NON-ABLATIVE LASERS:
- ABLATION IS FEW MICRONS AND HEATING EFFECT; NON-ABLATIVE IS COAGULATING DEEPER WITH HEATING EFFECT
- WITH ABLATION AND COAGULATION, THE CYTOKIN CASCADE IS COMPLETELY DIFFERENT FROM THE COAGULATION ONLY OF THE NON-ABLATIVE
- MORE RISKS OF SIDE EFFECT WITH ABLATIVE LASERS, ESPECIALLY IN SUNNY COUNTRIES
- ABLATIVE LASERS HAVE DIFFERENT INDICATIONS IN COMPARISON WITH ABLATIVE: KELOID SCARS FOR INSTANCE



LASER WAVELENGTH AND WATER ABSORPTION



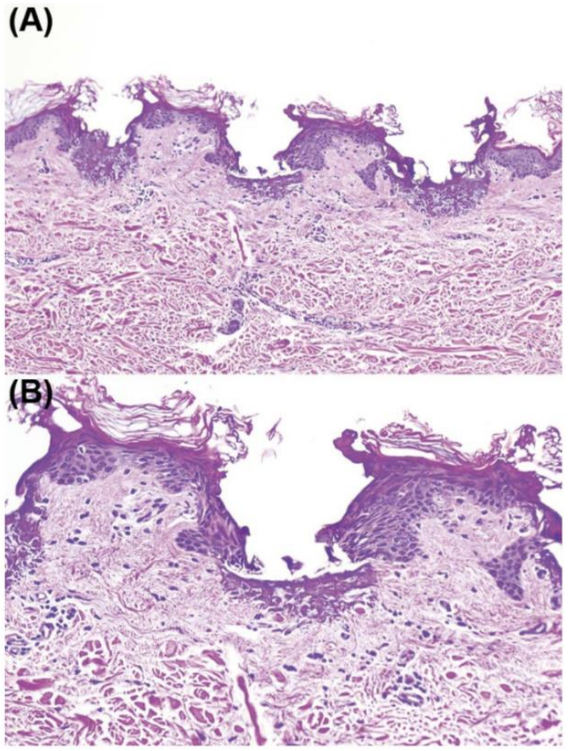


Figure 4. Fractional ablative CO_2 laser. (A) Focal vaporization of the epidermis and dermis (H&E ×100). (B) Magnified (H&E ×200).

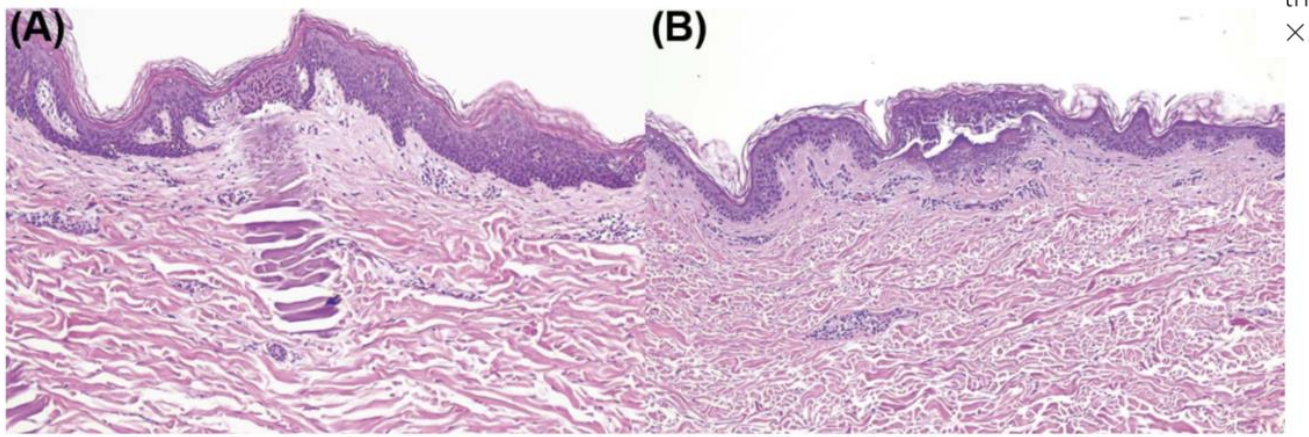
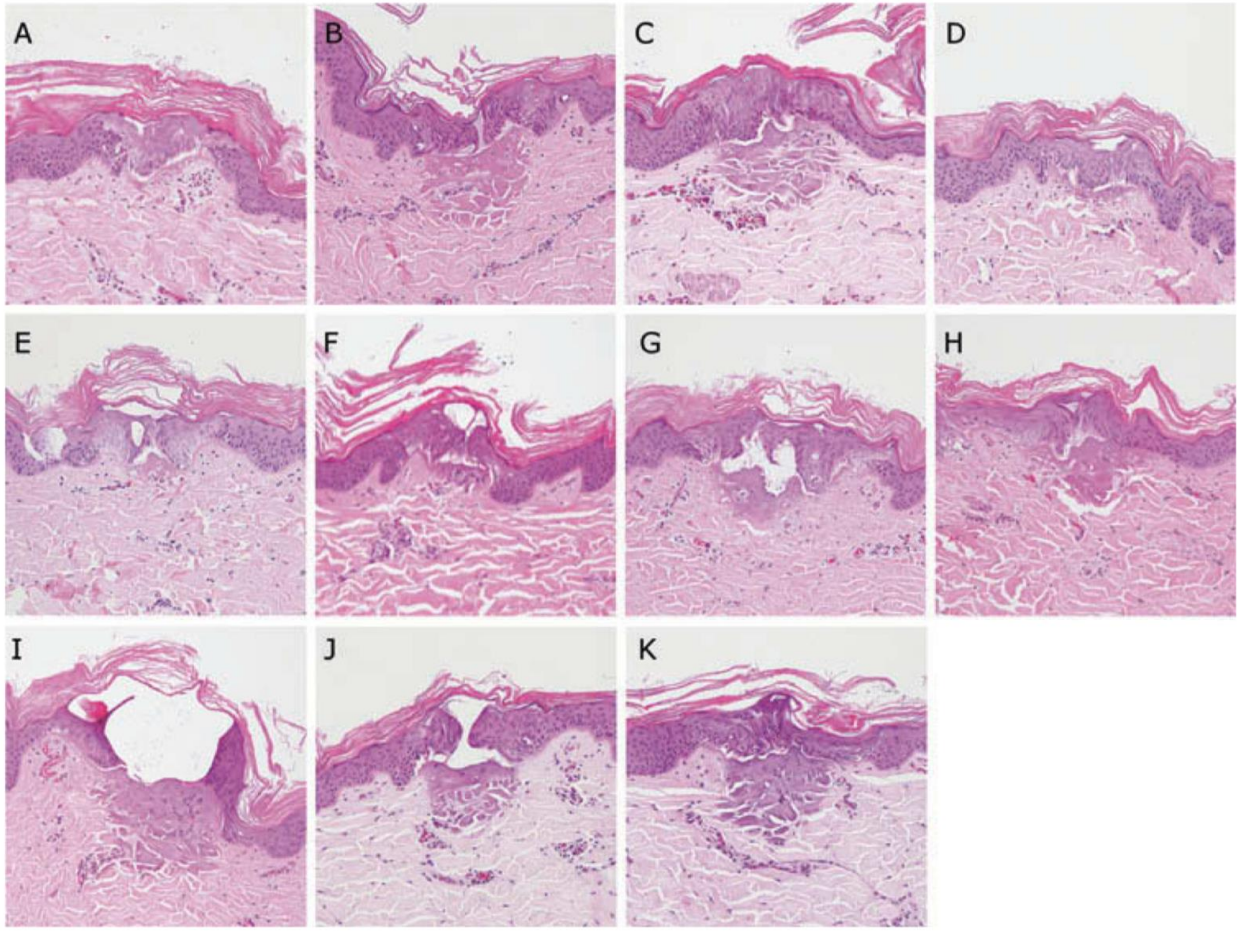


Figure 3. Fractional nonablative laser. (A) Focal coagulation of the epidermis and dermis with preservation of the stratum corneum after fractional 1,540 nm laser (H&E ×100). (B) Focal coagulation of the epidermis and papillary dermis with preservation of the stratum corneum after fractional 1,927 nm laser (H&E ×100).

LASER WAVELENGTH AND WATER ABSORPTION



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Histologic analyses on the response of the skin to 1,927-nm fractional thulium fiber laser treatment

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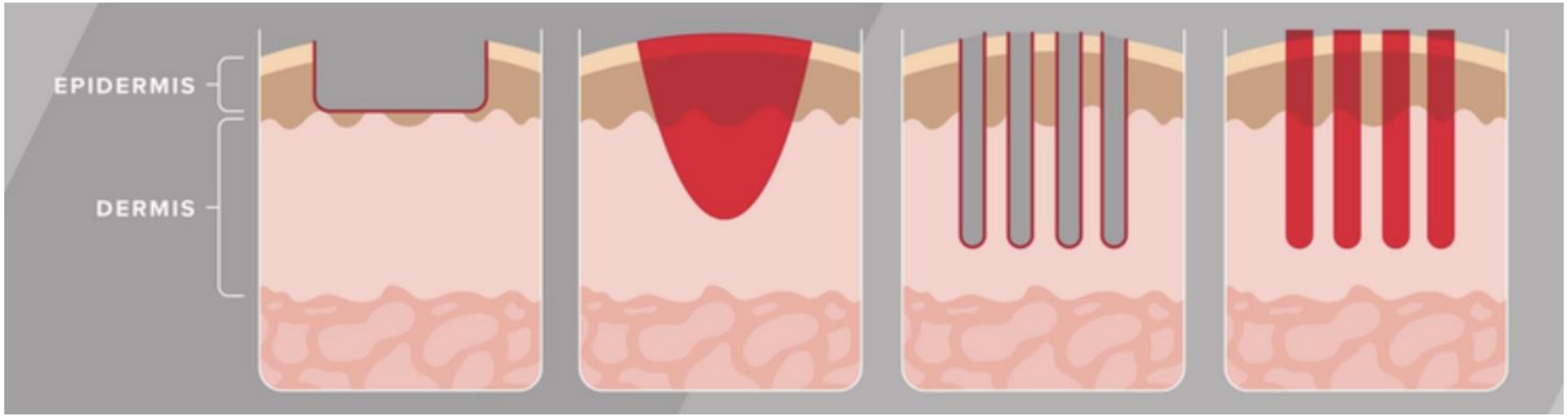
Thus, the stratum corneum remains relatively intact, and the dermal penetration is limited within the superficial dermis (15,16,18). Consistent with these characteristics, this study also showed that the 1,927-nm fractional thulium fiber laser induces the epidermal necrosis sparing the stratum corneum and collagen denaturation at the upper dermis within the depth of 200 μm.

OBJECTION

- HOW DOES LASERME OR A NON ABLATIVE FRACTIONAL LASER WORK?

- SCANNER IS FRACTIONATING THE BEAM INTO MICROBEAMS (200μm)
- MICROSCOPIC TREATMENT ZONES OF CONTROLLED WIDTH, DEPTH, AND DENSITIES ARE CREATED IN THE SKIN
- ONLY FRACTIONS OF SKIN ARE TREATED INDUCING SMALL 3-DIMENSIONAL ZONES OF THERMAL DAMAGE KNOWN AS “MICROSCOPIC THERMAL ZONES” (MTZs)



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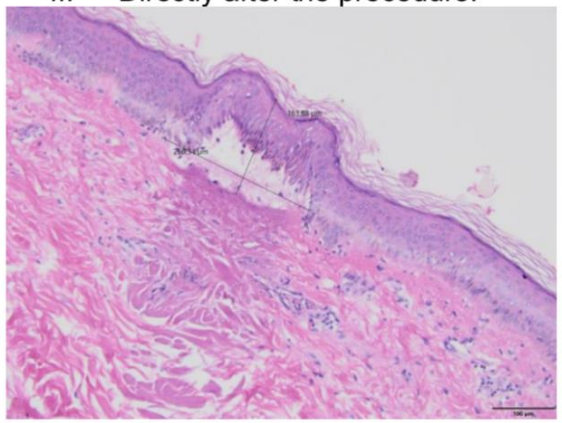
LASERME

NEAUVIA – LASERME HISTOLOGIES

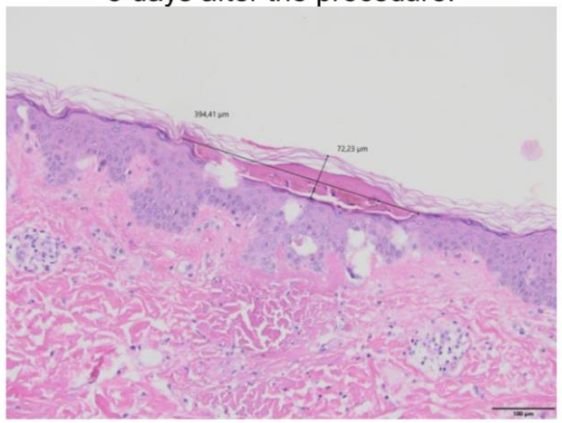
LASERME BY NEAUVIA

HISTOLOGIES

II. Directly after the procedure:



3 days after the procedure:



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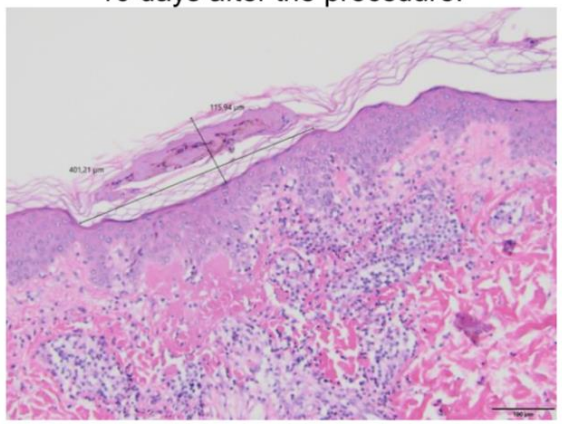

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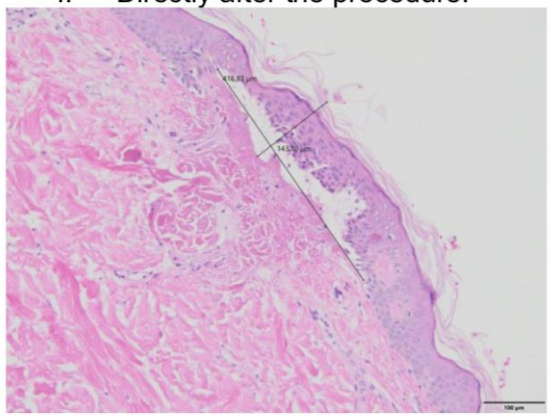

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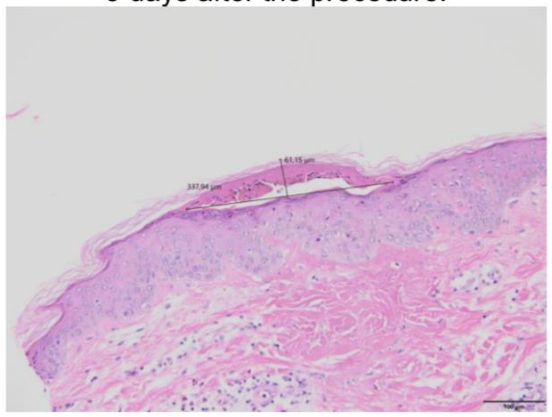
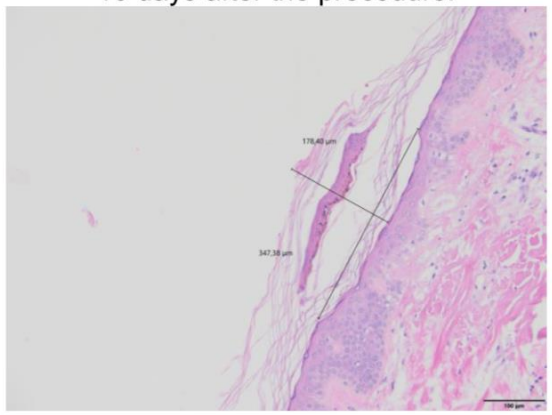


10 days after the procedure:



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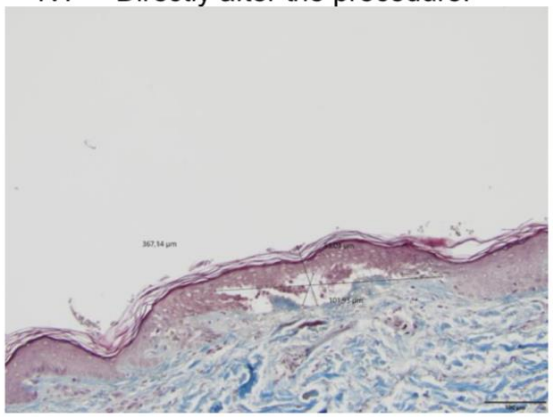
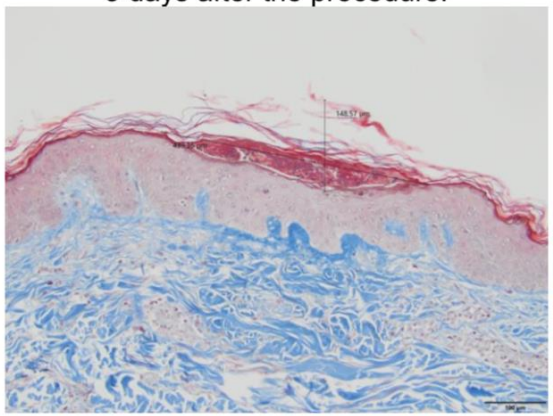
HISTOLOGIES

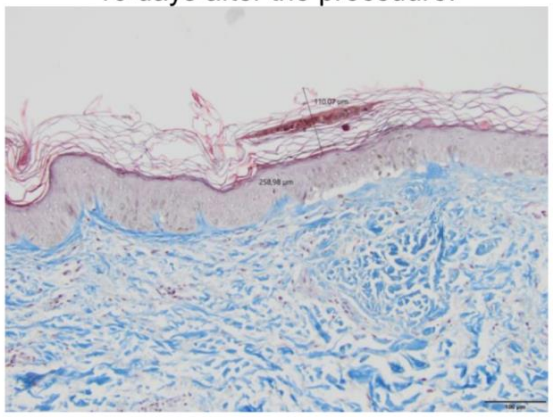
IV. Directly after the procedure:



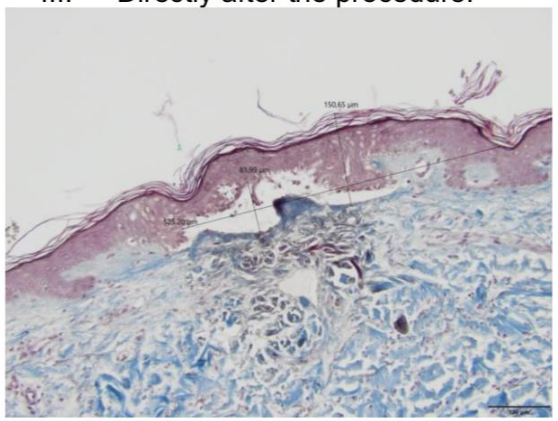
3 days after the procedure:



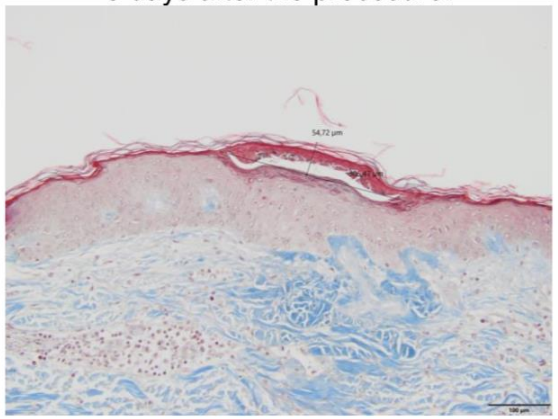
10 days after the procedure:



III. Directly after the procedure:



3 days after the procedure:



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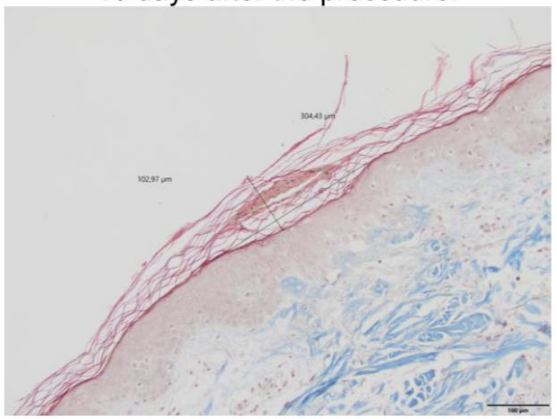

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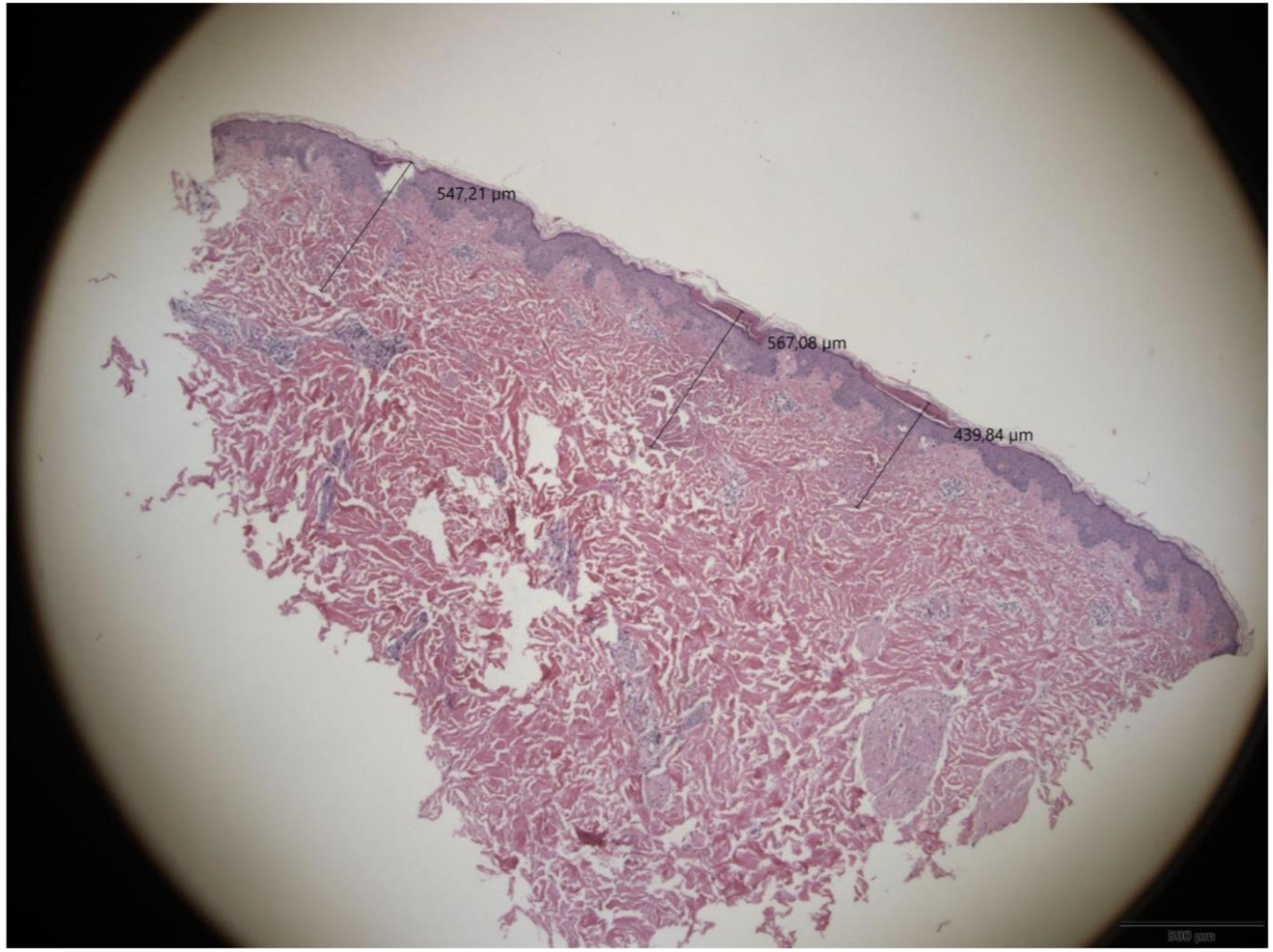
HISTOLOGIES

3 days after the treatment HA staining, 4x magnification:



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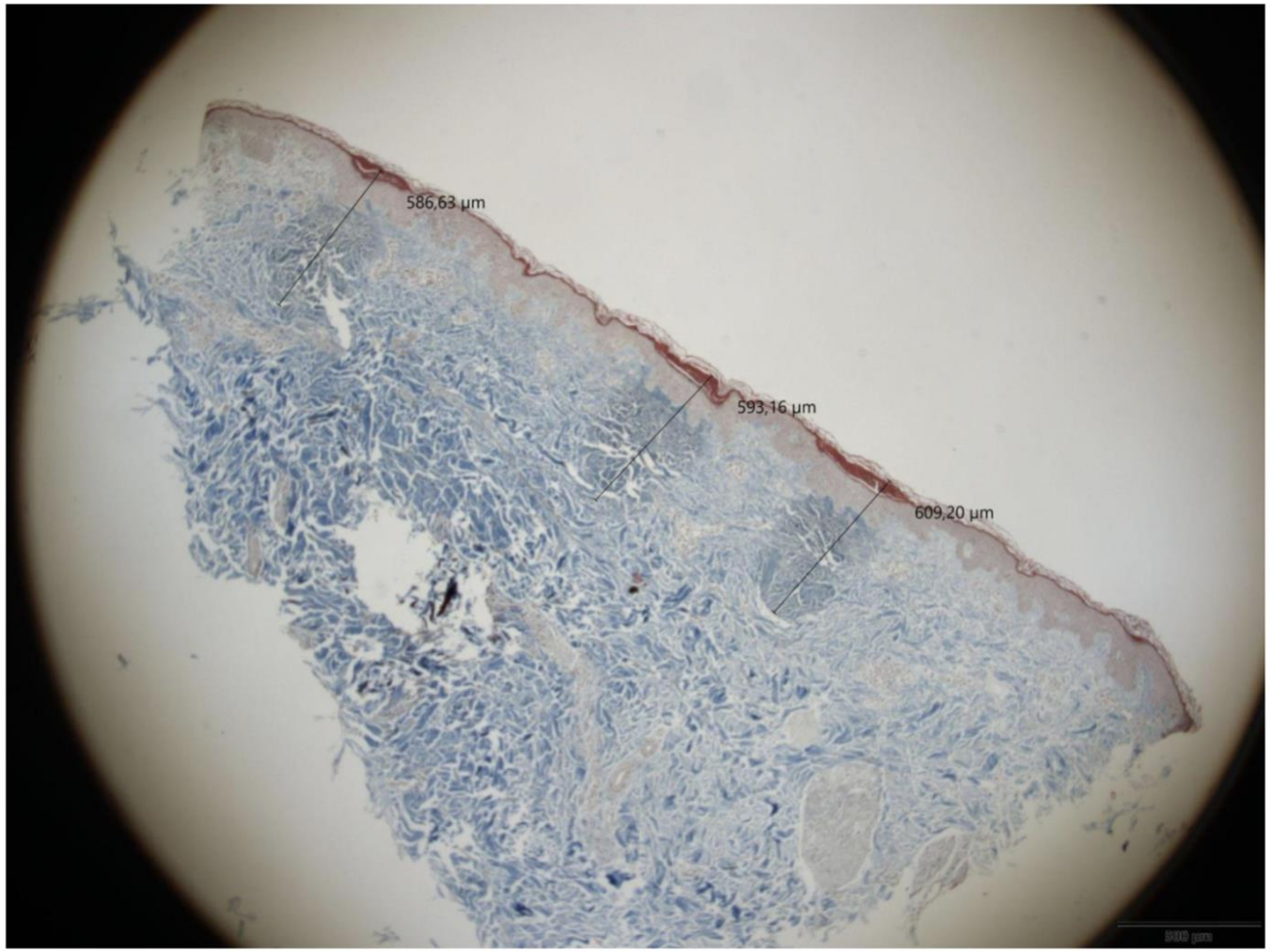
HISTOLOGIES

3 days after the treatment Trichrome-Masson staining, 4x magnification:



Description of the 2HL case: Analysis of the depth of the laser radiation impact three days after the procedure: the depth of the induced biological effect in the range between 439,84 µm and 609,20 µm, average 557,19 µm.

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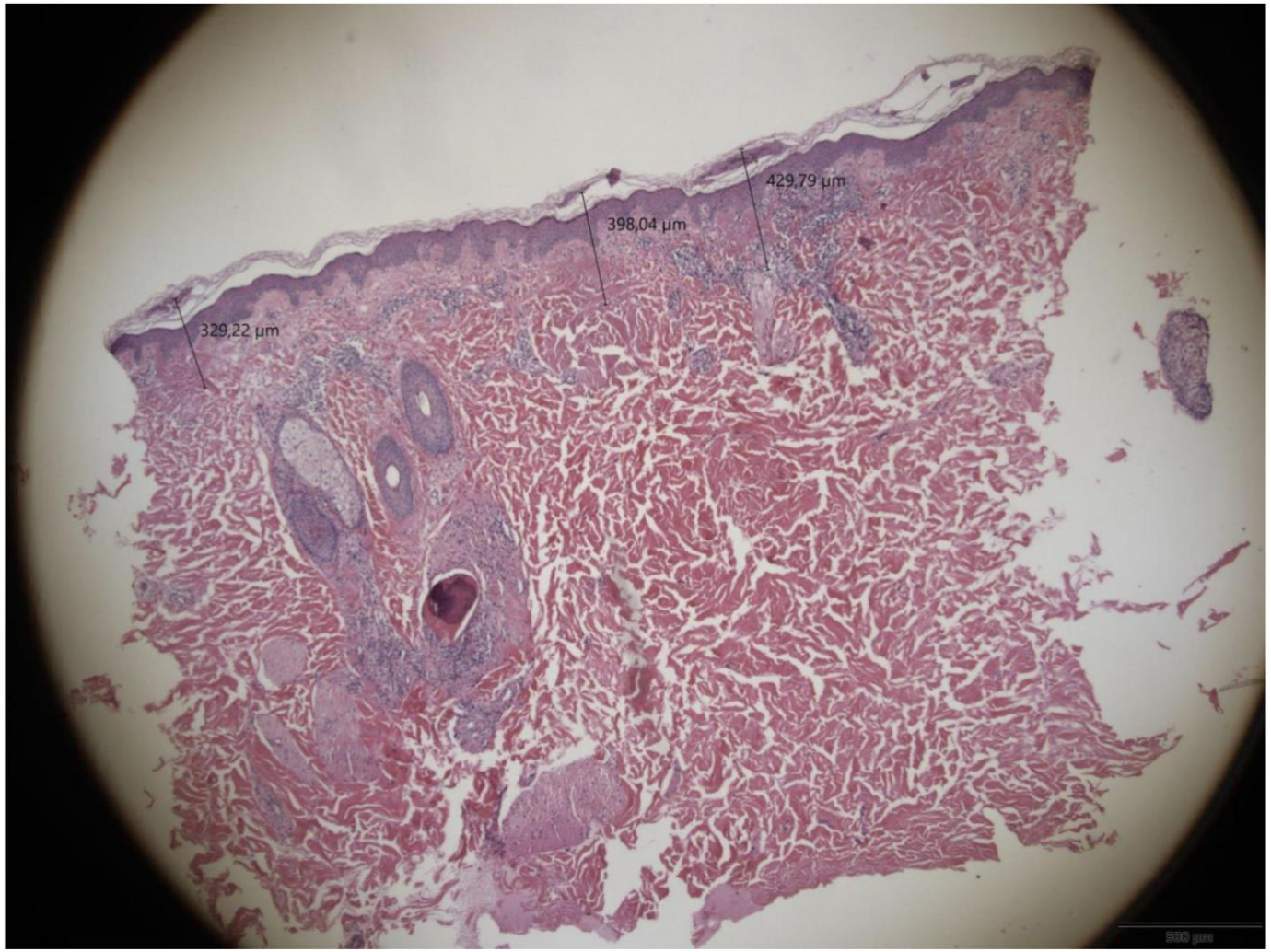
HISTOLOGIES

10 days after the treatment HA staining, 4x magnification:



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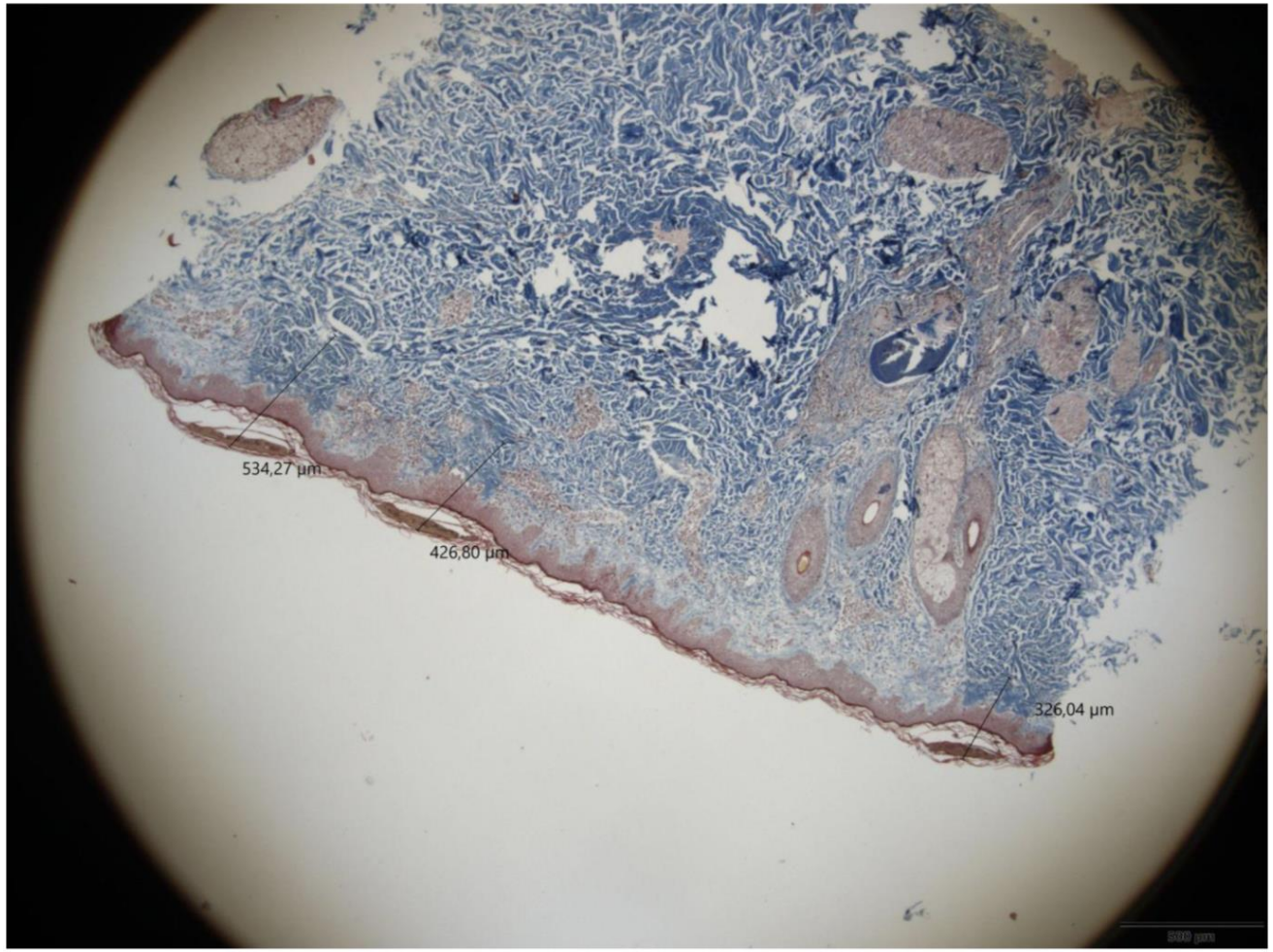
HISTOLOGIES

10 days after the treatment Trichrome-Masson staining, 4x magnification:



Description of the 2HL case: Analysis of the depth of the laser radiation impact ten days after the procedure: the depth of the induced biological effect in the range between 326,04 µm and 534,27 µm, average 407,36 µm.

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HISTOLOGIES - HEALING

In both groups with the lowest energy density parameters (5 mJ/point) no macroscopic signs of tissue healing were observed.

In the groups with moderate energy density parameters (28 mJ/point), the average time of complete healing was 19.6 days for a large spacing of laser impact points (4,0 mm) and 23 days for a dense spacing of laser impact points (1,0 mm). Features of skin redness and irritation were rare, poorly expressed and occurred only in the group with a dense spacing of laser exposure points (1,0 mm). The overall healing process consisted primarily of the presence of sub-/intra-epidermal damage points, which over time exfoliated without leaving visible traces.

In the case of groups in which the maximum possible energy density (50 mJ/point) was used, the average healing time for the group with a large spacing of laser exposure points (4,0 mm) was 23 days, while for the group with a dense spacing of laser exposure points (1,0 mm) it was 25 days. In both of these groups, apart from the subepidermal/intraepidermal lesion points that flaked off over time, there was also mild and moderate redness and irritation of the skin in the area of laser impact (with greater intensity for the group with a dense spacing of laser impact points (1,0 mm)) . Also in these groups, the dominant effect of healing was gradually exfoliating damage points which were gone without leaving visible traces .

In none of the groups, at any stage of healing, signs of skin disruption, such as bleeding or exudation, were observed. There were also no post-inflammatory hyperpigmentation changes or other ailments not described above.

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HISTOLOGIES - PENETRATION

Summary of the deep tissue effect observations

In depth to each of the observed limited, dermal-epidermal interfaces of damage, there is a discrete but distinct and repetitive change in collagen coloration and contraction - a "fractional column". It has a repeatable depth of an average of 350.56 micrometers when an energy of 28 mJ/point is applied and an average of 426.93 micrometers when an energy of 50 mJ/point is applied. This initially significant (21.7%) difference in the range of in-depth impact gradually disappears over time, reaching a ratio of 390.77 micrometers for groups with 50 mJ/point energy and 367.66 micrometers for groups with energy of 28 mJ/point, to almost equalize on the tenth day of observation reaching 374.47 micrometers for the groups with an energy of 50 mJ/point and 387.07 micrometers for the groups with an energy of 28 mJ/point. The greatest depth of the impact of the examined laser radiation observed in histopathological preparations was 626.47 micrometers and occurred in the group with the energy of 50 mJ/point.

From the perspective of the biophysical impact, the above phenomenon most likely results from the formation of a fluid-filled vesicle in the vicinity of the basement membrane at a certain time (in the range above 5 ms and below 16.8 ms) of tissue exposure to laser radiation emitted by the LaserMe device. Extending the exposure time does not enlarge this damage zone, but most likely its further heating, which translates into deeper transmission of thermal energy into the dermis (this relationship is non-linear and decreasing due to the volume effect of the tissue).

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HISTOLOGIES - EFFECT

The damage scheme is as follows:

1. The laser beam passes through the epidermis with almost no significant damage to the keratinocytes - discreet swelling and slight loosening of the connections between the cells are visible. The stratum corneum, granular layer and most of the spinous layer maintain integrity and intercellular connections.

2. Damage occurs at the level of the dermal-epidermal junction - the epidermis peels off at the level of the basement membrane. This suggests damage to the desmosomes or to the basement membrane itself with damage to only single cells. The preservation of the integrity of the basement membrane is also evidenced by the rapid regeneration at the site of damage. The regeneration process takes place by pushing out the damaged layer. By analogy with similar processes observed in cell cultures, the process of regeneration after producing a controlled damage with the tested medical device can be defined as the migration of cells from the side, undamaged parts of the epidermis, which corresponds to the physiological theoretical basis of regeneration after fractional skin damage.

3. Thickening/dehydration/coagulation of the superficial layer of the papillary dermis just below the blister, reproducible thickness of about 30 µm, is visible. At the same time, the lesion is the base and the widest place of the domed, slightly narrowing "fractional column" reaching the thread-like layer of the dermis.

4. During the healing process, along with pushing the damaged layer to the outer regions of the stratum corneum, the fractional column gradually blurs in the dermis.

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HISTOLOGIES

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No macroscopic or microscopic evidence of tissue damage was observed in the 5 mJ/point groups. There is no noticeable healing, but photobiomodulation effects are most likely present at these device settings, which could be of further interest, inter alia, by examining the presence of heat shock proteins, which was not the focus of the present study.

In groups exposed to both 28 mJ/point and 50 mJ/point, a repeating pattern was observed:

- macroscopically: the appearance of regular (coinciding precisely with the given density parameters of the distribution of laser radiation impact points), small, dark spots in the initial phase (about 3 days after the procedure) with a subepidermal location, then (about 10 days after the procedure) exfoliating with dead skin cells, disappearing completely within a maximum of 27 days after the procedure. These points in the treatment area were sometimes accompanied by weak and moderate signs of skin irritation and redness, with a clear advantage among the groups with a higher concentration of damage points (every 1,0 mm) and higher applied energy (50 mJ/point);

- microscopically: immediately after the procedure, each time at the dermal-epidermal border, small (about 112 x 375 micrometers) and shallowly located (about 180 micrometers) damage zones containing a bubble filled with a protein fluid were formed. The stratum corneum, stratum granulosum and most of the stratum spinosum layer maintain integrity. The epidermis peels off at the level of the basement membrane - the image corresponds to damage to the desmosomes or the basement membrane itself with damage to only single cells. The preservation of the integrity of the basement membrane is also evidenced by the rapid regeneration at the site of damage. Directly below the damage zones, there are clearly fractional columns characterized by clearly increased collagen fiber density, reaching on average about 350 micrometers in the case of applying the energy of 28 mJ/point and about 426 micrometers in the case of applying the energy of 50 mJ/point. In the days following the treatment, fractional columns are gradually blurred, and signs of a weak and moderately intensified inflammatory process appear around them, indicating the occurrence of a skin regeneration process. In turn, the remains of the damaged area migrate towards the stratum corneum in the form of a small conglomerate, which is gradually exfoliated (which fully corresponds to the macroscopic picture). The regeneration of the damaged area is rapid - after three days the stratum spinosum is completely restored, and after 10 days the stratum granulosum and stratum corneum above the original damage is renewed. Importantly, the stratum granulosum and the stratum corneum are not directly damaged as a result of the procedure - their regeneration is delayed by about 10 days, but at no stage of observation was there any damage to the continuity of the skin.

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HISTOLOGIES

Based on the macroscopic and microscopic observations, the authors of the report came to the following conclusions:

1. The LaserMe medical device should be classified into the category of non-ablative fractional lasers, because as a result of the treatments performed, fractional columns are produced in the dermis, but there is no evaporation and no violation of the continuity of the epidermis;

2. The device presents a high security profile. No serious healing processes were noticed, and the observed mechanisms allow to define the postoperative course as predictable and controllable. Increasing the energy in the range from 28 mJ/point to 50 mJ/point (maximum parameters of the device) and increasing the density of laser operating points (in the range of 1,0 mm, which is the densest possible setting of the device) does not result in a clinically significant increase in healing time, and microscopically, it does not increase the dimensions of the damage zone, but only increases the depth of the impact of the fractional columns formed as a result of the treatment;

3. Considering the observed mechanisms at the cellular level (impact at the level of the dermal-epidermal junction with the formation of collagen density bands deep into the dermis - "fractional columns" with a simultaneous regenerative effect on all layers of the epidermis) after the procedure with the use of the LaserMe medical device in terms of skin, an improvement in skin texture, color and tone is to be expected, which makes this device useful in the treatment of scars, excessive porosity, discoloration, stretch marks and skin laxity.

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