Clinical Case Reports International

Research Article
Published: 29 Apr, 2024

Assessment of Safety and Mechanisms of Action of the 1470 nm LaserMe Device

Kubik P[1], Gruszczyński W[1] and Łukasik B[2]*

[1]K-LAB Badania i Rozwój, 81-312 Gdynia, Poland

[2]Medical Department, Matex Lab Switzerland SA, 1228 Geneve, Switzerland

Abstract

1470 nm laser is a medical device that emits radiation in the mode of multi millisecond pulses. The power of the emitted radiation beam is constant. The basic parameter set by the operator is the density of energy per single impulse, given in mJ/point (possible regulation of 5-50 mJ/ point), the length of the pulse time and the frequency of their repetition. The 1470 nm laser is a fractional, non-ablative, diode laser with a wavelength of 1470 nm and a maximum power of 2W, intended for fractional non-ablative skin resurfacing, with adjustable spacing from 1 mm to 4 mm. The aim of the case report was to evaluate the safety and mechanism of action of the LaserMe device, assessed by histological examinations.

Keywords: Fractional; Non-ablative; Laser; Safety; Mechanism of action; 1,470 nm

Introduction

The technological revolution that has taken place in the last two decades, and in particular in laser technology, has had significant impact on medicine in general and dermatology in particular, and aroused the interest of doctors and patients, opening up new methods of dealing with problems.

Advances in laser therapy have made huge strides improved clinicians' ability to treat cosmetic and non-cosmetic skin lesions safely and effectively. The number and variety of skin problems amenable to laser treatment is constantly increasing [1].

A significant advance in recent years has been the advent of non-ablative lasers.

Non ablative laser resurfacing represents one of the major advances in procedural dermatology over the past decade and has become the treatment of choice for a broad range of patients and aesthetic indications. Fractional lasers as a concept were introduced in 2004 and since then, it has revolutionized the field of laser resurfacing [2]. The mode of action of fractional lasers seems to be very easy, it creates microscopic heat columns causing areas of thermal damage known as microscopic thermal zones. These microscopic thermal zones range from 100 µm to 400 µm in width and approximately 300 µm to 700 µm in depth [3]. The microscopic thermal zones are separated by areas of unharmed, untreated skin, which acts as a reservoir for tissue regeneration and remodeling. In general, fractional lasers can be subdivided into two categories ablative and non-ablative which is depending on their impact on stratum corneum. Ablative fractional lasers are characterized by longer wavelengths - range of 2,940 nm to 10,600 nm and lead to full thickness destruction of skin. Non-ablative fractional lasers are mid infra-red lasers that target water instead of melanin and hence these lasers are safe for use in darker skin types [4].

The following case report was designed to perform safety assessment and determine the tissue mechanisms of action of the non-ablative medical device using an *in vivo* human model.

Laser device used in this case study

Medical device LaserMe 1470 nm (Berger&Kraft Medical Sp. z o.o., Poland) is designed for high energy light therapy, it is used to deliver monochromatic light to the skin surface in a contact manner in therapeutic procedures in the field of dermatology, aesthetic medicine, general and plastic surgery and cosmetology, which aim to skin rejuvenation, skin tightening, drug transdermal delivery, reduction of dilated pores and treatment of diseases or dysfunctions such as scarring (including acne scars and stretch marks). The Laser is further indicated for treatment of pigmented lesions, such as age spots, sun spots, melasma, dyschromia, and for treatment of wrinkles and fine lines. LaserMe 1,470 nm medical device for medical therapy emits radiation in the mode of

OPEN ACCESS

Correspondence:
Paweł Kubik, K-LAB Badania i Rozwój, 81-312 Gdynia, Poland,

Received Date: *26 Mar 2024*
Accepted Date: *24 Apr 2024*
Published Date: *29 Apr 2024*

Citation:
Kubik P, Gruszczyński W, Łukasik B. Assessment of Safety and Mechanisms of Action of the 1470 nm LaserMe Device. Clin Case Rep Int. 2024; 8: 1683.

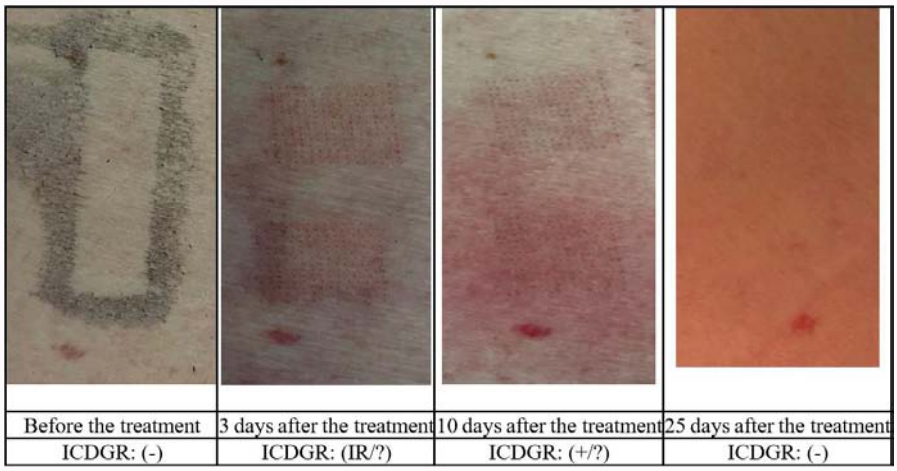

Figure 1: Patient - 40-year-old male. Laser treatment using the medium energy density (28 mJ per point) and the lowest spacing (1.0 mm). Observation area: Back skin.

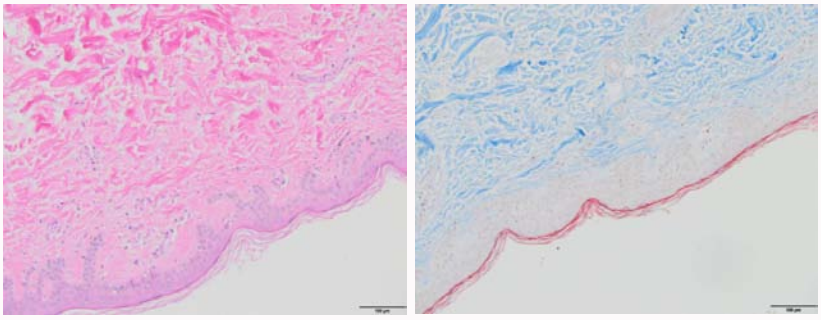

Figure 2: Before the treatment, from left to right: HE staining, 20x magnification, Trichrome-Masson staining, 20x magnification.

multi millisecond pulses. The power of the emitted radiation beam is constant. The basic parameter set by the operator is the density of energy per single impulse, given in mJ/point (possible regulation of 5-50 mJ/ point)and spacing between the points (possible regulation of 1.0 – 4.0 mm). 1470 nm laser is a fractional, non-ablative, diode laser (maximum power of 2W), intended for skin resurfacing. The device works by punctuating the skin (epidermis) with a focused laser beam in order to stimulate it to regenerate. The points are evenly spaced with adjustable spacing from 1 mm to 4 mm.

Medical device LaserMe can affect the skin and through selective photo-thermal effects leading to selective tissue targets (tissue water, collagen) warming.

Material and Methods

Patients

Three healthy volunteers (1 female and 2 male) aged 40 to 53 years (mean 45.3 years) were qualified for the study. Exclusion criteria included: Taking oral and/or local retinoids up to six months prior to the study, excessive tanning, active skin and connective tissue diseases characterized by photosensitivity (e.g., systemic lupus, collagenopathy, cutaneous porphyria), active herpes simplex infection, taking drugs and/or photoreactive cosmetics (including tetracycline antibiotics and immunosuppression, i.e., cortisone and its derivatives or anticoagulants, i.e., dipyridamole and coumarin derivatives, cosmetics containing thyme extract, or herbs containing St. John's wort) for up to six month prior to the study, diseases with immunodeficiency for reasons of caution (depending on the decision of the qualifying doctors), unregulated diabetes, state after other cosmetics and aesthetic procedures within the area undergoing surgery (depending on the particular procedure performed the decision each time was made by the qualifying doctor), acquired vitiligo or melanin production disorder (i.e., hypermelanosis), tattoos in the area undergoing treatment, or taking anti-inflammatory drugs. Each patient signed an informed consent document.

Each patient signed an informed consent. The leading standard adopted in this study was ISO 14155:2020 (clinical investigation of medical devices for human subjects — good clinical practice). The study was conducted in accordance with the Declaration of Helsinki, and approved by the Ethics Committee of Medical Chamber in Gdańsk, Poland (KB-5/93/2022; 25/10/2022).

Treatment protocol

Participants in the study underwent LaserMe treatment using the medium energy density (28 mJ per point) and the lowest spacing (1.0 mm), which represents the (yet relatively strong) common clinical application of the device. Participants of the study had the option of choosing the area to be treated, with the choice limited to the back, abdomen and limbs. Two participants decided to perform the procedure on the skin of the back, and 1 on the skin of the abdomen.

Methodology

Henna markers were applied to the areas to be assessed (skin on the back, and abdomen) to facilitate the complex assessment of the healing status and the collection of specimens before, immediately after, and on the third and tenth day after the procedure. The

areas intended for the collection of histopathological specimens were covered after the procedures with adhesive plaster, while the observation area was left free in order to eliminate additional factors affecting the course of the healing process.

After the preparation of the treatment area, a skin sample was collected for histopathological examination before the procedure. Then, in the areas intended for this, the laser therapy procedure was carried out using the LaserMe device. Immediately after the procedure, a sample was collected for histopathological examination from the area covered by the procedure. Subsequent samples from this area were collected on the third and tenth day after the procedure. At the same time, photographic documentation of the observation area was carried out. The pictures were taken on the third and tenth day after the procedure. If, on the tenth day after the procedure, any changes related to the procedure were observed (healing, remnants of traces after the procedure), the observation with the preparation of photographic documentation was continued until these changes disappeared.

Macroscopic evaluation

The assessment of healing time based on patients' self-observation included the assessment of two parameters: The time of redness and the time of swelling after the procedure.

Patients received standardized visual guidelines to assess the advancement of the observed changes. The guidelines provided are based on the ICDRG standardized consensus (International Contact Dermatitis Research Group).

Microscopic evaluation

For histological assessment, from all of study participants a full-depth skin samples were taken for microscopic evaluation at day 0, 3 and 10 after the treatment. The specimens taken using a biopsy punch with a diameter of 4 mm, were placed in a buffered solution of 10% formalin. The material prepared in this way was submitted for further evaluation to the Clinical Pathomorphological Department of the Nicolaus Copernicus University, Toruń, Poland.

Hematoxylin-Eosin (HE) staining was used to assess the overall structure of the tissue by counterstaining the cytoplasm and cell nuclei. Microscopic analysis of slides stained with Hematoxylin and Eosin (HE) and Trichrom Masson histochemical staining was performed using an ECLIPSE E400 (NIKON) light microscope with a 20x objective. Masson's trichrome stain (Special Stain Kit Masson's Trichrome, DiaPath, Martinengo, Italy) was used to assess collagen. Analysis of deep tissue impact was performed by evaluating samples at 4x magnification, which allows to highlight possible consequences that may occur as a result of potential damage accumulation due to close positioning of energy impact points (1.0 mm). The identifiable effects of the fractional impact of laser radiation were measured both in terms of the depth and the width of the impact.

Results

We reported histologic findings related to aesthetic procedure with the usage of 1,470 nm non-ablative fractional laser. As a result, after the procedure, the patient's skin showed substantial improvements in terms of skin topography. All patients qualified to this study represented the same features of healing. Below we present the collected results detailed on one of those patients (Figures 1-5).

Results of healing time observation

On the third day after the procedure a regular (every 1.0 mm) dark spots in the epidermis was noticed with accompanying skin irritation. On the tenth day some of those spots were still visible additionally with heterogeneously located redness, which is either a response to the performed procedure or an irritating reaction related to the proximity of the plaster placed after the collection of histopathological specimens for the purpose of the examination. On

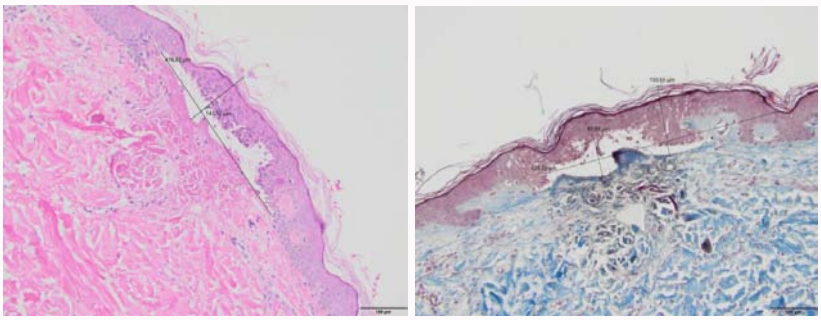

Figure 3: Directly after the treatment, from left to right: HE staining, 20x magnification, Trichrome-Masson staining, 20x magnification.

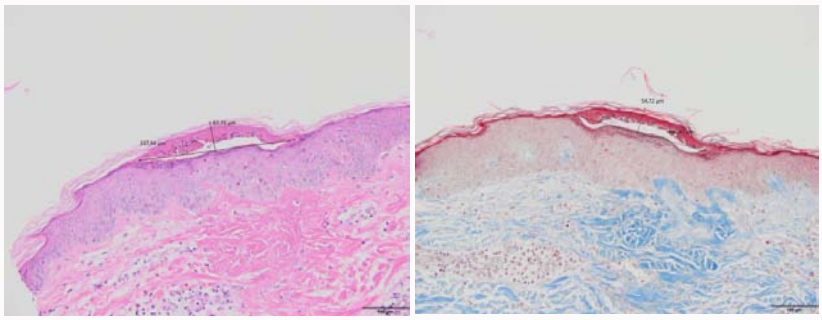

Figure 4: 3 days after the treatment, from left to right: HE staining, 20x magnification, Trichrome-Masson staining, 20x magnification.

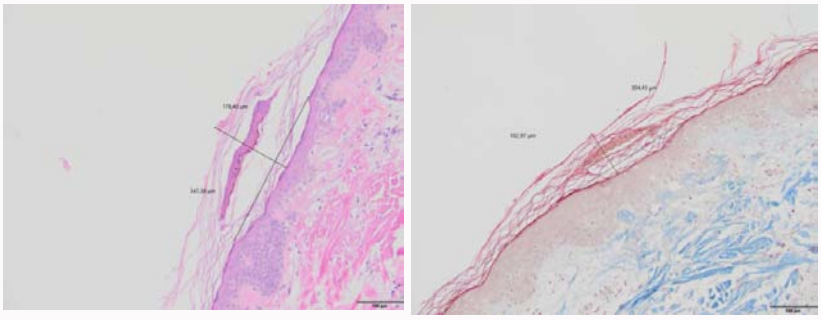

Figure 5: 10 days after the treatment, from left to right: HE staining, 20x magnification, Trichrome-Masson staining, 20x magnification.

the 25th day after the procedure all the spots, redness and irritation disappeared.

Results of histological assessment

Histopathological evaluation of the skin before the procedure showed no abnormalities.

The specimens taken directly after the procedure show a homogeneous area of fractional damage with depth in the tissue of between 143.10 and 150.65 micrometers, a width of between 416.83 and 525.50 micrometers, and a height of between 69.24 and 81.99 micrometers. The epidermis peels off at the level of the basement membrane. Thickening/dehydration/coagulation of the papillary dermis is noticeable. Damage in a very small extent affects the cells, primarily vascular damage. Discreetly visible protein-rich fluid in the bladder under the detached epidermis. A strong change in the coloration and shrinkage of collagen directly below the damage zone.

The specimens taken three days after the procedure show that the fractional damage area moves to the outer layer of the epidermis at a tissue depth of between 54.72 and 61.15 micrometers and a width of between 305.47 and 337.94 micrometers. Noticeable in relation to the condition immediately after the treatment is the regeneration of the stratum spinosum of the epidermis and gradual reconstruction of the stratum granulosum. Subepidermal stronger collagen staining in the dermis is clearly noticeable in the band running deep from the original damage.

The specimens taken ten days after the procedure show that the skin- epidermal junction and all layers of the epidermis were completely regenerated. Above the stratum granulosum, a fragment of the stratum corneum was raised, containing exfoliating remnants of damaged tissue, with dimensions between 102.97 and 178.40 micrometers in height and between 304.43 and 347.38 micrometers in width. Subepidermal stronger collagen staining in the dermis is noticeable in the band running deep from the original damage.

Discussion

Summary of observations of the direct damage site

Hematoxylin-Eosin staining and Trichrome-Masson staining allowed to determine the maximum depth ranges of impact on human skin using the tested LaserMe 1,470 nm device. The biological effect in the tissue took the form of columns of thermal impact with a small zone of damage and a greater depth of non-destructive impact, expressed primarily in collagen density revealed in Trichrome-Masson staining and the occurrence of an inflammatory infiltrate without damaging the cellular structure of the skin. The tissue below and to the side of the thermal impact column remained unchanged, which speaks for the safety profile of the tested device and fully reflects the idea of fractional laser therapy consisting in the creation of point tissue damage while leaving the surrounding zones of healthy tissue. Taking into account the pathomorphological picture of the areas of direct tissue damage, with the applied energy of 28 mJ/point it represents a fully reproducible pattern. When analyzing the nature of these changes, reference should be made to the biophysical aspects of the radiation used. Each time the final energy is set, the size of the treatment spot and the power of the source remain unchanged. The variable is the tissue exposure time to laser radiation, and in the case of 28 mJ/point - it is 16.8 ms.

Effects observed immediately after the procedure

In the case of an exposure time of 16.8 ms at 28 mJ/point, which is the most typical therapeutic setting of the LaserMe device, a blister filled with protein fluid was formed immediately after each treatment, located at the dermal-epidermal border. Its average dimensions are 113.24 micrometers in height and 373.83 micrometers in width, and its base extends an average of 184.06 micrometers from the outermost cells of the stratum corneum. The stratum corneum, granular layer, and most of the stratum spinosum retain 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 individual cells. Maintaining the integrity of the basement membrane is also evidenced by rapid regeneration at the site of damage.

Effects observed 3 days after the procedure

Three days after the procedure in the case of the exposure time of 16.8 ms (28 mJ/point), the basement membrane in the area of the primary damage is clearly regenerated with complete reconstruction of the spinous layer. The granular layer, above which the conglomerate of the remains of the damaged area, covered with the original stratum corneum, is located. The magnitude of this change is an average of 91.37 micrometers in height and 359.59 micrometers. The microscopic picture correlates the macroscopic picture with the clinical picture in the form of subepidermal, small, dark dots in the treated area.

Effects observed 10 days after the procedure

Ten days after the procedure, all layers of the epidermis, including the granular and stratum corneum, are completely regenerated. Within the stratum corneum is a gradually exfoliating conglomerate of lesion remnants with an average of 133.67 micrometers high and 390.03 micrometers wide. The microscopic picture correlates the macroscopic picture with the clinical picture in the form of gradually exfoliating small, dark dots in the treated area. In addition, in the area around the band of more strongly stained collagen extending in

the dermis below the area of primary damage ("fraction column"), Hematoxylin and Eosin staining shows a weak or moderate inflammatory infiltrate, indicating the ongoing skin repair process.

It is worth emphasizing that as a result of the procedure there was no direct damage to the stratum granulosum and the stratum corneum, and no damage to the continuity of the skin was detected at any stage of observation.

Conclusion

Macroscopic and microscopic observation of the consequences of treatments performed using the LaserMe medical device on a healthy volunteers revealed the occurrence of a normal skin healing process in a predictable and repeatable pattern. The LaserMe medical device is a non-ablative fractional laser, which as a result of the treatments performed, fractional columns are produced in the dermis, without violation of the continuity of the epidermis. The tested device has demonstrated high safety profile, no serious side effects, were noticed, and the observed mechanisms allow to define the postoperative course as predictable and controllable. The observed mechanisms at the cellular level may indicate this device useful in the treatment of scars, discoloration, stretch marks and skin laxity. Of course, it would be advisable to enlargement of the sample, and longer follow-up, which should be the subject of further observations.

References

1. Massey RA, Marrero G, Goel-Bansal M, Gmyrek R, Katz BE. Lasers in dermatology: A review. Cutis. 2001;67(6):477-84.
2. Manstein D, Herron GS, Sink RK, Tanner H, Anderson RR. Fractional photothermolysis: A new concept for cutaneous remodeling using microscopic patterns of thermal injury. Lasers Surg Med. 2004;34(5):426-38.
3. Fisher GH, Geronemus RG. Short-term side effects of fractional photothermolysis. Dermatol Surg. 2005;31(9 Pt 2):1245-9; discussion 1249.
4. Alexiades-Armenakas Mr, Dover JS, Arndt KA. The spectrum of laser skin resurfacing: Nonablative, fractional, and ablative laser resurfacing. J Am Acad Dermatol. 2008;58(5):719-37; quiz 738-40.