

CLINICAL EXPERIENCE IN THE USE OF ELECTRODE PHARMAPHORESIS IN TREATMENT AND PREVENTION OF SCAR LESIONS

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Prevention and treatment of pathological skin scarring is both a medical and a social problem. Rough, unsightly scars significantly reduce 'quality of life' and in some instances lead to disability and development of neurological and psychological disorders. Scarring can manifest itself as a wide range of morphological, biochemical and clinical types which makes it exceedingly hard to develop a suitable treatment regime. Regardless of the particular type of wound process, it always results in fibrose-related skin changes (Darzi M.A., Chowdri N.A., Kaul S.K., et al., 1992; Peled Z.M., Chin G.S., Lie W.L. et al., 2000; Dasegelb B., Phillips T., 2006). A feature common for both keloid and hypertrophic scars is excessive volume of extracellular matrix, raised above the skin level (Grossman K.L., 2000; Arndt K.A., Dover J.S., Alam M., 2006). The main type of protein in the scar tissue is collagen. Skin collagen renewal occurs as a result of fibroblast activity, which not only secrete collagen but also destroy it through phagocytosis and enzyme release (O S Ozerskaya, 2002; V A Kozlov, S S Mushkovskaya, S B Konovalskaya et al., 2005). So called resident fibroblasts at various stages of maturity, such as young ones, fibrocytes and fibroblasts, which are responsible for the extracellular matrix turnover, are found in the intact derma. As traumas, injuries and surgical interventions occur, so called 'wound' fibroblasts appear in wounds. These cells are also referred to as short-lived or myofibroblasts. 'Wound' fibroblasts express alpha actin and therefore have the properties of smooth muscle cells which in turn produce excessive extracellular lesion matrix. New methods of physiotherapeutic treatment have emerged which enable medicinal products with collagenolytic activity to penetrate the skin barrier and destroy excessive scar tissue collagen (A.G.Nemeth) (1993). One of such methods is Fermencol Electrode Pharmaphoresis using "Farmateb Trans Epidermal Barrier Physio" medical device for transdermal administration. "Farmateb Trans Epidermal Barrier Physio" generates complex electric signals with various characteristics depending on the depth or type of tissue or damaged organ and delivers them where maximum drug concentration is required (M Misefari, A D'Africa, F Mo-rabido, 2001). The method is based on "transdermal transfer" of the medicinal product through the skin, the natural human body barrier. Farma T.E.B. Trans Epidermal Barrier Physio device uses electric signals which allow even high molecular weight products to penetrate deep into the scar tissue, which is to say, into the core of the cells at the site of injury with a positive result for all types of injury or localised pathologies. Active substances activated by the Farma T.E.B device signals cause intermittent tissue changes, increase stratum corneum permeability and promote the opening of ionic channels in the tissue cells which require active substances from the outside to regenerate. Having reached their destination, the receptors are activated in less time, with higher concentration and outside of the systemic circulation (Pliquett U.F. et al , 2006). Increased permeability is achieved by using various forms of electrical current modulated in frequency and amplitude and/or combinations thereof. The use of evolutionary electronic components has created special complex wave forms, which make it possible to selectively manipulate the permeability of the cell membrane, analysing the reaction in order to automatically optimise the intensity of the electric signal and substance transfer. Electrode Pharmaphoresis uses not only accessory transfer paths but also a more effective means of extracellular and intracellular transfer, targeting the throughput of ionic channels, using the "pump effect" of cell membranes which expand and contract in the alternating electric field. This phenomenon is referred to as a kind of "reversible molecular lengthening or stretching which occurs both under the influence of modulated electric current and through controlled mechanical compression / relaxation of cell membranes". In this way, larger molecules (not only ions or ionic particles) could be transferred (U F Pliquett et al, 2006). Fermencol is a unique natural complex of collagenase isoenzymes with molecular weight between 23 and 36 kDa, capable of deconstructing a 3-helical collagen molecule. This complex demonstrates not only collagenolytic but also overall proteolytic activity. This means that the enzyme complex action is not limited by triple spiral of the native collagen hydrolysis, collagen fragments destruction occurs up to the level of individual amino acids. The reduction in scar tissue occurs as a result of collagen hydrolysis. The Electrode Pharmaphoresis method, using Fermencol medicinal product and "Farmateb Trans Epidermal Barrier Physio" transdermal administration medical device was used in 28 patients with keloid and hypertrophic scarring facial and body skin lesions in the cosmetology department of ZAO "Arbat Beauty Institute" Active Longevity Clinic for treatment and long-term pathological scarring prevention. The patients' age was between 6 and 64 years old, the age of skin lesions between 4 months and 7.5 years. Before treatment, ultrasound scanning of scar tissue at fixed points was carried out. Based on the clinical form, age, area and depth of scar tissue, Fermencol solutions of various strength were used. Solactin was used to prepare solutions. Recommended concentration for keloid tissue correction is 0.5-1 mg/ml, for hypertrophic tissue 0.1-0.2 mg/ml.

After cleaning the surface of the skin lesion with antiseptic solution, an active substance is applied to the site. The electrode handle is positioned at a 45 degree angle to the skin, and the medicinal product is introduced via a rotating roller using smooth movements, without applying unnecessary pressure and lifting the handle from the surface. A different treatment programme is selected for each patient according to the diagnosis. "Scarring" setting is used for

keloid and hypertrophic lesions treatment, "stretchmarks" setting for the atrophic ones. For each treatment regime, the device offers certain parameters for the depth and duration of the procedure, which could be altered, if necessary. The length of treatment was between 10 and 15 procedures every other day. The course of treatment was repeated if it was deemed necessary, with an interval of 7 to 10 days between them.

Evaluation of treatment outcomes

Compared to healthy skin, pathological scar tissue is dehydrated, water content in the extracellular matrix is reduced. Without correctional treatment, only after 30-40 days after scarring tissue is formed, hydration begins to gradually improve but never reaches the initial level. The scar tissue hydration process is relatively slow. As a result of Fermencol administration through electrophoresis, after 15-20 days the overall proportion of total and structured water content in the scar tissue begins to approach the parameters found in healthy skin, as evidenced by EHF dielectrometry. Good results were observed in 21 patients (75%), which were evidenced by suspension in the scar tissue active growth, its total or partial regression, disappearance of localised subjective unpleasant sensations, such as pruritus, burning or soreness, and colour difference between the scar and surrounding tissue. Satisfactory results of the treatment were achieved in 7 patients (25%). All patients reported subsidence and softening, a reduction in localised unpleasant subjective sensations, such as itching and burning, a reduction in the severity of the features of the scar tissue appearance (protrusion).

Clinical example

Pic 2 A.



The appearance of forming keloid deformation of the front and side of the upper thigh area and post-burn atrophy of the dermis and subcutaneous fat area on the back of the right buttock in a 7 year old patient before the treatment.

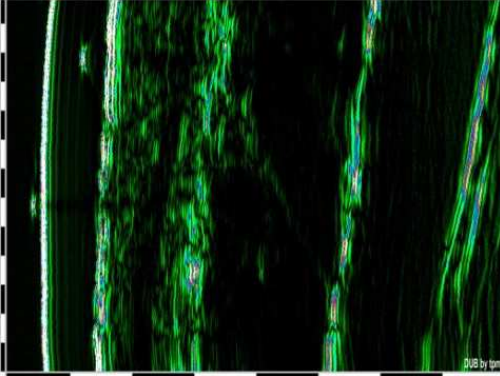
Pic 2 B.



The appearance of the scarring damage of the front and side area of the upper thigh and post-burn dermal and subcutaneous fat atrophy on the back of the right buttock in a 7 year old patient after 10 sessions of Fermencol pharmacophoresis, using "Farmateb Trans Epidermal Barrier Physio" transdermal administration device. Patient M V P-va, 7 years old, was referred to the cosmetology department with post-burn scar lesions in the pubic and groin area and both thighs. Disease history: boiling water burn 1.5 years ago on 30 September 2012, primary surgical treatment carried out locally, on 17 October 2012 a gluteal free flap transplant was carried out. Three months after the wound surface epithelisation, in some areas exposed to tension and locomotor activity severe hyperaemia, induration, pruritus, burning, scar tissue soreness, especially at palpation and contact with clothing, appeared. On the periphery of the scar deformation, along the border line with the intact tissues, marked hyperpigmentation was observed. Surgical correction was carried out using free flap transplantation. Use of compression underwear and external drug therapy appeared to be insufficient, as alongside with hypertrophy, scar tissue lesions appeared to be spreading beyond the original damaged area. Due to contracture and deficit of cover tissue in the pubic and groin area, contracture appeared to be forming accompanied by pronounced unpleasant sensations. Considering the area, localisation and age of the scar lesions, Grenz-ray therapy in the pubic area was carried out as the first stage treatment and physiotherapy using pharmaphoresis with Fermencol for the whole area of scarring deformation.

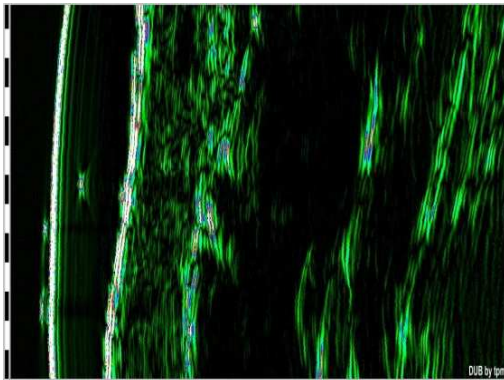
Research methods

An ultrasound scan was carried out using the Digital System of Ultrasound Visualisation Skinscanner DUB (Tabernapromedicum GmbH Германия). Scanning was carried out by a line sensor (applicators) at 22 MHz, with 10 mm deep scan. Axial resolution was 72 μm for 22 MHz. A and B mode imaging was used. Under A-mode imaging a spectrum of reflected signals amplitude was achieved in each scanned point, under B-mode imaging a two-dimensional, 10 mm deep and 12.8 mm long (the size of a sensor screen) scanned area image was achieved. Compound two-dimensional B-mode image was compiled using 384 scanned images with a 33 μm interval. Ultrasound gel was used as a contact medium to provide ultrasound conductivity. It was possible to visualise epidermis, dermis, subcutaneous fat, muscle fascia, hair follicles and skin blood vessels using 22 MHz frequency. Acoustic dermis density was measured on the scarred area and, as a control, acoustic dermis density of the healthy contralateral skin area was also measured as well as acoustic dermis density of the scar tissue immediately after pharmaphoresis treatment and after the course of treatment was completed.



Pic 3A

Ultrasound scan results of a forming keloid scar tissue of the upper thigh side surface in Patient P, 7 years old, before treatment. Epidermis contour surface is relatively smooth, occasionally intermittent. Dermal-epidermal delineation is clear. Echo distribution in dermis is uniform, layer differentiation is present. In deep dermal sections there is an increase in echogenicity in the form of fibrotic fold, possibly, connective tissue. Cutaneous-dermal delineation is clear. Echo signals distribution in subcutaneous fat is uniform, thickening is present.



Pic 3 B

Ultrasound scan results of a forming keloid scar tissue of the upper thigh side surface in Patient P, 7 years old, after treatment. Epidermal contour is relatively smooth. Dermal-epidermal delineation is clear. Echo distribution in dermis is uniform. Layer differentiation is absent. A reduction in the thickness of hyperechogenic fibrotic fold in deep dermal sections is detected, small sections of normal echogenicity are detected. Cutaneous-dermal delineation is clear. Echo signals distribution in subcutaneous fat is uniform, some thickening is present. Conclusion. As a result of the use of electrode pharmaphoresis with Fermencol medicinal product administered with "Farma T.E.B. Trans Epidermal Barrier Physio" transdermal administration medical device in patients with scar tissue lesions demonstrated high clinical efficacy. Good results were observed in 21 patients, or 75%, which included active growth suspension, total or partial scar tissue regression, disappearance of localised subjective negative sensations, such as pruritus, burning and soreness and scar tissue colour recovery to the colour of surrounding healthy tissue. An increase in mean acoustic density and mean dermal thickness during ultrasound is also associated with an increase in the fibrous components synthesis and increased volume of extracellular matrix. As a result of the therapeutic and preventative measures it was possible to improve the appearance of the scar tissue and reduce contracture. Electrode pharmaphoresis method using Fermencol with "Farmateb Trans Epidermal Barrier Physio" medical device for transdermal administration is pain-free, technologically simple, could be used in paediatric patients without seasonal restrictions and no side-effects or complications. One can conclude that this technology could be used as a new and effective alternative for the treatment of pathological scarring.