125047, Moscow

The Cosmetology Research and Science Center

independent non-profit organization

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PROTOCOL No. 2-05

Of

Clinical trials of the JET PEEL medical system for Dermatology and Cosmetology manufactured by Tav Tech ltd. Israel

Moscow
2005

1. The clinical trials of the JET PEEL medical system manufactured by TavTech Ltd. (Israel) for application in Dermatology and Beauty Therapy were undertaken by the independent non-profit organization The Cosmetology Research and Science Center in the period of September 14, 2995 through November 21, 2005. The trial and study were performed using the demonstration prototype referred to as DEMO.

2.The objective of the study was to evaluate possibilities of use of the said system in the medical dermatological and beauty practice in the Russian Federation.

3. To complete the study the following was provided:
a. the completely furnished working prototype of the JET PEEL system model JTP-222 (DEMO), manufactured by TavTech, one unit;
b. a set of sterile attachments;
c. saline solution for infusions supplied in sterile plastic bags;
d. operation manual.

4.Technical properties and general description of the principles of the system's operation:

Gas source:	compressed oxygen tank
Gas pressure:	100 PSI (6.8 atmospheres).

The device's operation is based on the use of the energy of the jet bi-phase flow (mixture of saline solution and oxygen) with the purpose of desquamation of epidermal and dermal skin layers.

The action mechanism is based on the exfoliating effect resulting from the treatment of skin with the jet of high energy spay that is formed by mixing sterile saline solution and gas (oxygen) in the special container (sterile attachment). The source for the compressed oxygen connected to the main control unit, supplies gas with the pressure of 6.8 atmospheres, which pulls out the saline solution out of its container. The liquid portion of the spray exits the nozzle attachment in the form of the 5-200 nm diameter drops, going at the speed of 200 m/sec, which is ensured by the 3-spray nozzle attachment system.

Report

Objectives of the study:
1. To study the safety of using the said system in the field of clinical beauty therapy – evaluation of the irritation and allergy-inducing effect from physical and chemical properties of the system during peeling procedures.
2. To evaluate a degree of efficiency in using the device on physical defects: hyperkeratosis, hyperpigmentation, wrinkles as indicated:
   2.1. skin profile (depth and width of wrinkles);
   2.2. degree of hyperkeratosis;

2.3. Degree of hyperpigmentation of skin before and after the series of treatment using the studied device.

The study also used the Skin Sys skin diagnostics system (USA).

Description of the group of volunteers

The study was performed on 25 (female) patients aged 29 through 60 who demonstrated signs of aging skin – hyperkeratosis, hyperpigmentation, mimic and age-related face and neck wrinkles with various degree of prominence. All volunteers were familiarized with the objective of the performed study and they all provided voluntary consent to receive the series of peeling treatment using the JET PEEL system. The basic profiling survey of the patients with the study of their medical history, corresponding diseases, and allergy status didn't establish any contra-indications with regard to the performed peeling and physical therapy procedures.

Method of application

The peeling session was performed on a weekly basis. The average duration of the session lasted from 15 to 20 minutes depending on individual properties of the patient's skin and its sensitivity. Following the makeup removal and treatment with the antiseptic solution (without preliminary local anesthesia), the skin of the patient's face and neck was subjected to the effect of the jet stream of the gas and liquid mix supplied through the sterile one-time use nozzle attachment under the 50-70C towards the skin surface. The distance between the area of treatment and the attachment varied from 0.5 to 1.5 cm. The treatment of the skin of face and neck was performed following traditional massage lines, in smooth slow movements with a longer and more forced action on the problem area (wrinkles, hyperpigmentation spots) resulting in punctate hemorrhage (so called "blood dew"). The skin in the periorbital area wasn't treated. Pantenol-spray was applied to the skin of face and neck after the treatment on the skin was completed.

Results of the study

1. The following parameters were considered as parameters of safety: absence of allergy-inducing effect and presence of a slight irritation effect from physical and chemical factors of the system (in accordance with the stated objectives of the system's action).

1.1. The clinical evaluation of the irritation effect based on degree of inflammatory erythema and its prominence following the procedure session.

Table 1

Degree of the erythema prominence in grades*, average meaning in the group of volunteers			
After the procedure	30 minutes later	1 hour later	3 hours later
1.8	1.2	0.6	0.26

- Grade evaluation of the erythema degree

Very prominent	4
Prominent	3
Moderate	2
Slight	1
None present	0

Conclusion: After the peeling session, an irritation effect was confirmed, which was demonstrated through a severely or a moderately expressed erythema that was maintained for no longer than three hours.

1.2. No patient demonstrated any allergy-induced response.

2. The following parameters were considered as parameters of the treatment effectiveness:
2.1. a. Clinical:
In the course of the treatment session – change of the skin color of the treated read towards a paler shade as a result of the reflector spasm of smaller capillaries, the focal areas of punctate hemorrhage ("blood dew") after the treatment – moderate degree hyperemia as well as slight swelling of skin;

b. Subjective: In the course of the treatment session – the sensation of "cold and skin being prickly", after the treatment – the sensation of "burning" that lasts no more than one or two hours.

2.2. The evaluation of the beauty correction with the help of the Skin Sys unit based on the following parameters:

a. Degree of exfoliation (hyperkeratosis)

Table 2

Degree of skin exfoliation, in grades		Average data on the degree of hyperkeratosis in the group of volunteers	
		Source level	After the series of treatment sessions (2 months later)
Very high High Average Low Very low	4 3 2 1 0	1.4	0.26
Assessment of the keratolytic (exfoliating) effect in %		**100**	**-81**

Conclusion: The course treatment with the use of the JET PEEL system in order to specify the keratolytic (exfoliating) effect demonstrated expressed exfoliation of the horny layer cells which was confirmed by the significant average decrease in the skin hyperkeratosis by 81% which proved positively high effectiveness of treatment sessions on the keratinization process as a whole.

b. Degree of hyperpigmentation.

In order to evaluate the de-pigmentation effect of the treatment with the use of the JET PEEL system, the areas of study included the parts of face with diffuse (generalized) hyperpigmentation as well as hyperpigmentation focal points with localized dyschromia (the current study didn't take into account causes of pigmentation).

Table 3

Degree of the pigmentation prominence, average statistical indicators in the group of volunteers	Source level	After the series of treatment sessions (2 months later)
Standard conv. units	3.93	1.26
%	100	**-67.9**

Conclusion: The application of the JET PEEL system (multiple – as a course or one or two episodes with the engagement of the skin's papillary level) demonstrated expressed effect of the de-pigmentation action which resulted in the average 68% decrease of the hyperpigmentation of the skin of face.

c. Skin profile (depth and width of wrinkles).

Table 4.

Dynamics of depth and width of wrinkles, average statistical indicators in the group of volunteers	Source level	After the series of treatment sessions (2 months later)
Standard conv. units	2.8	1.46
%	100	**-47.85**

Conclusion: After completing the series of peeling sessions using the JET PEEL system, the patients demonstrated expressed correction of mimic and age-related wrinkles, as well as an average 48% decrease in depth and width of wrinkles.

Conclusion:

The use of the JET PEEL medical system manufactured by TavTech Ltd (Israel) for application in Dermatology and Beauty Therapy according to its operator's manual proves its safety and efficiency.

The irritation effect in the form of a slight or a moderately expressed erythema, a slight swelling as well as of a burning sensation and "prickly" skin of various intensity

depending on the skin type, its condition, is adjusted automatically. Typically, it is corrected within 3 hours, and cannot be considered a negative impact of the use of the said system.

The application of the system didn't result in any allergy-induced response in any of the patients.

The results of the correction of beauty defects—hyperkeratosis, local and diffuse hyperpigmentation, wrinkles of various degrees of prominence—as established during the clinical trials and study, prove the high effectiveness of the said method.

During the course of treatment sessions, skin demonstrated adaptation towards active impact of physical and chemical factors of the system that were demonstrated in the less expressed irritation effect with every treatment session.

The active physiological regeneration of tissues was noted during the analysis of skin of the volunteers that were subjected to the peeling sessions that engaged skin's papillary layer.

Visual control and functional methods of diagnosis of skin demonstrated the need to combine the peeling procedures with the use of the JET PEEL system with intensive sessions that are directed at the restored aqua-lipid layer of epidermis.

The system is fairly physiologic, simple to use, and the saline solution that is ended for the treatment is economically affordable.

With certain skills, this system would allow the professional to control the intensity of the effect on skin, i.e. depth of peeling, in other words:

a. allowing for the individual regime of treatment courses for every patient with the obtained desired results;
b. using the JET PEEL system to solve a wide range of beauty therapy problems.

Exponents:

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