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**Original Article** 

## Evaluation of the clinical effectiveness of the method of Skin Rejuvenation

#### using Electrostimulation

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#### Abstract

**Objectives:** Purpose of the study evaluation of the cosmetic effect using the "Aganyan" plaster for facial rejuvenation.

Materials and Methods: The study was carried out in 106 participants with presence of perioral wrinkles of the skin. Participants applied four patches (2 copper and 2 zinc) on the face in the area of wrinkles crosswise according to the instructions. The patches were applied for eight hours every third day for three months.

The participants tactilely and visually assessed the effects of the patch for three months. Clinical assessment of treatment results (satisfaction by subject and investigator physician) was performed. The immediate results were assessed 1 month after the course and long-term results at the end of 3 months of observation. Perioral wrinkles were assessed by comparing photographs at the beginning and at the end of the study for each individual case. The efficacy was assessed according to the International Global Aesthetic Improvement Scale (GAIS Table 1-3) on the 1st (M01), 2nd (M02), 3rd (M03), 6th (M06) month of complex therapy. Visual confirmation of clinical improvement was also obtained by Life Viz 3D camera pictures.

**Results:** After analyzing the photographs taken before and after using the patch (Figure 1-3) and a personal conversation with each participant, the following data were obtained from participants:

a decrease in puffiness and dark circles under the eyes was noted: 6 out of 15 men, 34 out of 91 women:

- smoothing of small mimic wrinkles was noted: 24 women out of 106 people;
- lifting of the face oval was noted: 14 women out of 106 people.

Evaluation of the effectiveness of the GAIS procedure on M03 and M05, 2/3 of patients had significant improvement as assessed by physician and participants according to GAIS (Table 3). Most of the patients also showed significant improvement at visit M12, Table 3. After analyzing the photographs taken before and after the experiment, and a personal conversation with each patient of the cosmetology profile, the following results were obtained: in 38% of patients, puffiness and dark circles under the eyes decreased, in 23% of participants fine facial wrinkles were smoothed, in 12%



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of participants the oval of the face was tightened. Our results suggest that "Ajanyan" plaster can serve as a novel therapy for controlled skin rejuvenation, effective wrinkles and folds.

**Conclusion:** The results of the studies provide a basis for concluding that the method of skin rejuvenation using electrostimulation method is effective on the clinical manifestations skin.

The "Aganyan" plaster has proven its effectiveness through electrical stimulation with low intensity current in patients in different age groups, the study revealed a large number of positive cosmetic effects.

Keywords: Wrinkles; Skin rejuvenation; Novel method of electrostimulation

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#### Introduction

The aging process of the skin is complex and depends on many internal and external factors. Internal skin aging occurs over time and is influenced by genetic factors. The main clinical signs of skin aging include wrinkles and uneven pigmentation. The most common causes of wrinkles are age-related changes and ultraviolet radiation [1,2].

#### Wrinkles can be

**Static wrinkles:** These wrinkles are visible at all times and do not change in appearance with facial movements.

**Dynamic wrinkles:** These are expression lines that may appear as folds when the skin is not moving, and deepen with facial movements or expressions. Dynamic wrinkles appear when expressing emotions, such as fear, worry, joy, sadness, or surprise [3]. Cosmetologically manipulations can solve this problem. In modern aesthetic medicine, a variety of methods are used to rejuvenate the skin of the face [4-6]. Esthetic medicine differs from other medical care because it is not based on saving lives, but on improving the quality of life for the client. A person's autonomous decision is an indicator for esthetic treatments that will improve the client's self-image, self-esteem, and appearance to others. Medical estheticians

work in accordance with strong, ethical considerations in every meeting with the client. This includes reaching consensus in deciding which esthetic treatments to do. Over the past decade, there has been a growth in the popularity of both non-surgical and surgical cosmetic procedures. These include both medically indicated surgical techniques and more gentle procedures used to maintain skin tone. Even 10 years ago, plastic surgery methods were mainly used for skin rejuvenation and correction of age-related changes. Surgical methods were used mainly to change the shape and appearance of the face, and this is not a way to improve the internal condition of the skin, rather the opposite (since blood circulation in the affected areas is impaired) [7,8]. Fear of surgery, use of anesthesia, long rehabilitation period, failure to achieve the desired results testify in favor of non-surgical methods.

Non-surgical methods are used can solve the following problems of age-related skin changes:

• smooth out wrinkles caused by muscles of expression (age related);

• significantly tighten the skin and correct the oval of the face;

• narrow the enlarged pores;

• enhance the natural production of anti-aging substances.

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The methods of non-surgical facial rejuvenation are mainly aimed at renewing the surface layers of the skin, at improving the internal structure, i.e., to stimulate your own collagen [9,10]. Modern therapies use a variety non-surgical facial rejuvenation method, these procedures include laser rejuvenation, photorejuvenation, radio frequency, ultrasound, electro-optical synergy, thermae. ozone peels. rejuvenation, chemical microdermabrasion, iniectable fillers. neurotoxins, platelet-rich plasma mesotherapy, botulinum therapy, etc. to rejuvenate the skin [11-14]. Among the popular methods of facial rejuvenation, mesotherapy should be noted [15-17]. This technique consists in injecting special preparations into the skin of the face: bioactive substances, preparations based on hyaluronic acid and fibroblasts- the key elements of the cell involved in the formation of collagen. These beneficial micro-injections contribute to effective facial rejuvenation. One of the most effective methods of facial rejuvenation is laser rejuvenation. The laser effectively penetrates the inner layers of the skin without damaging its outer layer. The technique of laser rejuvenation allows you to renew the cellular structure of the skin, make the skin smooth and elastic [18-20]. Ozone rejuvenation is a common method of facial rejuvenation [21]. Ozone stimulates the microcirculation of blood in the skin tissues, promotes the renewal of subcutaneous tissue, which leads to an improvement in complexion and provides a rejuvenating effect. Ozone is used in the form of injections into problem areas of the face and neck. Thermae is also a widely used facial rejuvenation method [22,23]. Under the influence of special radio frequency radiation, the temperature of the skin tissue rises, which leads to an increased production of cola gen and elastane, which are responsible for the smoothness, firmness and elasticity of the skin. However, the physical and chemical methods of the listed methods of treatment have certain disadvantages. The main disadvantage of modern methods of physical rejuvenation is that they deliver external energy to the entire mass of tissue, affecting both cells and the extracellular matrix; this changes the function

and architecture of the tissue being treated. The main disadvantage of chemical rejuvenation methods is that, although they only target cells, they involve the delivery of external molecules that can trigger a tissue response outside the target. This uncontrolled subsequent reaction can lead to clinical complications such as burns, vascular deformity of the skin, tumors, keloids, hypertrophic scars, skin contraction, facial paralysis, necrosis, intravascular penetration, and infection. Among the non-invasive rejuvenation, methods of skin electrostimulation can be used to achieve numerous cosmetic effects, such as: regeneration, toning, skin rejuvenation, etc. [24,25]. One of the most important innovations when it comes to aesthetics is the new medical advancements. The search for optimal and safe combinations. scientifically substantiated protocols for the correction of involutional changes in the skin of the face is a current trend in dermatocosmetology. An example of a device with a similar effect is the plaster of the "Aganyan" company, which will be discussed in our article. The uniqueness of this invention is that electrical stimulation can be used for long-term stimulation with low voltage and current without the use of wires and batteries. Here we report on a novel, non-invasive method of skin rejuvenation using electrostimulation plasters of "Aganyan" company.

#### Purpose of the study is evaluation of the cosmetic effect using the "Aganyan" plaster for facial rejuvenation

#### **Materials and Methods**

This was an open, pilot study conducted on 106 volunteers under the control of dermatologists. All the volunteers signed a consent form containing the information relative to the nature and procedures of the study. This study was conducted according to the ethics of the "Helsinki declaration".

Patients had a presence of peri-oral wrinkles of the

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<b>Table 1:</b> Distribution of participants in the cosmetology profile.				
Age (range)	M	F	Total	
30-39	3 (20%)	45 (49.5%)	48 (45.3%)	
40-49	5	27	32	
	(33.3%)	(29.7%)	(30.2%)	
50-59	7	19	26	
	(46.7%)	(20.8%)	(24.5%)	
Total	15	91	106	
	(100%)	(100%)	(100%)	

Inclusion criteria: healthy women; the patient's desire and ability to take part in the study; the presence of scales on skin over nanolabial lines, lower and upper lips, marrionete lines that show wrinkles of mild and moderate degrees according to the Merz Aesthetics Scale (MAS in the validated 5-point, where 0=no 2=moderate wrinkles, 1=mild wrinkles, wrinkles, 3=severe wrinkles, and 4=very severe wrinkles) [26]. Exclusion criteria: The presence of somatic, endocrine, oncological, infectious and skin diseases, blood diseases, pregnancy, lactation, the presence of permanent filler in marionette lines, skin, peels, mesotherapy and surgery performed within 6 months prior to this study. Participants in front of a mirror independently assessed signs of aging on his face, comparing with the standard of the scale. The doctor, having his own subjective opinion of the clinical picture on a visual scale (during consultation and analysis of photographs) exhibited the degree of severity wrinkles and folds in points, depending on the study design: either their subjective assessment. Participants were informed of the purpose of the study and the use of any photographs obtained in which the patients could not be identified. All participants provided written consent to be included in this study and to use facial images for the purposes of the study. Each participant was given a set of "Aganyan" plasters and a special brochure, in which the method of application was indicated in detail. Participants applied four patches (2 copper and 2 zinc) on the face in the area of wrinkles crosswise according to the instructions. The patches were

applied for eight hours every third day for three months. The wearable patch includes a flexible substrate, a binder an adhesive layer, with an electrode foil attached to it. Skin moisture is full of minerals, and is accepted as an electrolyte medium. Zinc foil thickness 0.025mm and Copper foil thickness 0.025mm (Figure 1). The electrical stimulation is caused by applying at least two electrodes but preferably four, to the skin for better results to create interferential for electrotherapy. Participants were warned that if any discomfort (redness, itching of the skin, etc.) occurs, they should immediately stop using the patch and inform the investigators. The participants tactilely and visually assessed the effects of the patch for three months. They recorded their observations in special brochures, which were later analyzed by researchers. All participants in the experiment were photographed before and after using the patch for visual assessment (Figure 2,3). The electrostimulation therapy with patch like electrodes can be conveniently performed for long periods of time, ranging from about 1 hour to 10 hours or even more. Clinical assessment of treatment results (satisfaction by subject and investigator physician) was performed. The immediate results were assessed 1 month after the course, long-term results at the in 3 months of observation. Perioral wrinkles were assessed by comparing photographs at the beginning and at the end of the study for each case studied. The efficacy was assessed according to the International Global Aesthetic Improvement Scale (GAIS Table 3) on the 1st (M01), 2nd (M02). 3rd (M3). 6th (M06) month of complex therapy. Visual confirmation of clinical improvement was also obtained by Life Viz 3D camera pictures.

#### Results

After analyzing the photographs taken before and after using the patch (Figure 1-3) and a personal conversation with each patient, the following data were obtained in participants:

• A decrease in puffiness and dark circles under the eyes was noted on: 6 of 15 (men), and 34 of 91 (women);

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- Smoothing of small mimic wrinkles was noted on: 24 of 106 people (all women);
- Lifting of the face oval was noted: on 14 of 106 people (all women).

Evaluation of the effectiveness of the GAIS procedure on M03 and M05, 2/3 of participants had significant improvement as assessed by physician and patient according to GAIS (Table 3). Most of the patients also showed significant improvement at visit M12 (Table 3).



**Figure 1:** The wearable patch includes a flexible substrate, a binder an adhesive layer, with an electrode foil attached to it. Zinc foil thickness 0.025mm and Copper foil thickness 0.025mm.



Figure 2: Patient at baseline (a) and (b) 12 weeks after skin rejuvenation using electrostimulation method under the eye's region.



**Figure 3:** Patient at baseline (a) and 12 weeks after skin rejuvenation using electrostimulation method nasolabial and marionette region (b).

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Table 2	: Global Aesthetic Improvement			
Scale (GAIS) Degree Description.				
SCORE	TREATMENT RESULT			
1	Exceptional improvement -			
	excellent corrective result			
2	Very improved - marked			
	improvement of the appearance,			
	but not completely optimal			
3	Improved patient - improvement			
	of the appearance, better			
	compared with the initial			
	condition, but a touch-up is			
	advised			
4	Unaltered patient - the appearance			
	substantially remains the same			
	compared with the original			
	condition			
5	Worsened patient - the appearance			
	has worsened compared with the			
	original condition			

Table 3: GAIS indicators.				
Visit	Doctor	Participants		
M01	$2.6 \pm 0.5$	$2.5\pm0.51$		
M02	2.8 ± 0.46**	2.9±0.31*		
M03	$2.7 \pm 0.48^{**}$	$2.5\pm0.73$		
M06	$1.8 \pm 0.64*$	$1.7 \pm 0.66*$		

**Note:** The value is statistically significantly different (p <0.05): \* from that of the indicator at the M01 visit. After analyzing the photographs taken before and after the experiment, and a personal conversation with each patient of the cosmetology profile, the following results were obtained: in 38% of participants, puffiness and dark circles under the eyes decreased, in 23% of participants fine facial wrinkles were smoothed, in 12% of participants the oval of the face was tightened (figure 4). The "Aganyan" plaster has proven its effectiveness through electrical stimulation with low intensity current in participants in different age groups, the study revealed a large number of positive cosmetic effects.



**Figure 4:** Effectiveness of the method of skin rejuvenation using electrostimulation method.

#### Discussion

With age, the people have a deepening of the nasolabial fold, drooping of the corners of the mouth and loss of the border of the lips [27-29]. The appearance of perioral wrinkles often prompts patients to seek treatment [30,31]. The number of requests for cosmetic procedures with permanent or temporary fillers (as a method of reduction in the number and depth of wrinkles, and giving lips desired volume) is growing with varying results. However, the number of less serious complications is also increasing, even with the use of safe molecules such as hyaluronic acid [32,33]. According to statistics from the American Society for Aesthetic Plastic Surgery (ASAPS), dermal fillers (from English to fill; syn: dermal fillers) occupy a leading position among the most popular non-surgical aesthetic procedure es [34]. One of the treatment options for these patients is soft tissue augmentation with skin fillers [35]. Skin fillers can provide the patient aesthetic result as these materials have the ability to reduce the appearance of wrinkles and give the face a more youthful appearance. Among non-surgical procedures according to statistics, fillers based on stabilized hyaluronic acid for the correction of involutional skin changes occupy a leading position [36]. For patients with early static lines and folds ( $\leq 2$ ) degrees of contraction and  $\leq 1$  degrees at rest Evaluation of the clinical effectiveness of the method of Skin Rejuvenation using Electrostimulation

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according to rating scales) for rejuvenation, physicians have the right tools in their hands to prevent or slow down skin aging. Injection procedures will be required to correct problems, and other methods, such as energy therapy, (electro-optical synergy), can be combined for optimal results. The effect of the skin biorevitalization procedure is provided by an increase in the body's production of its own hyaluronic acid, which helps to normalize the water balance [37]. At the same time, all metabolic processes are improved, local blood flow is enhanced, which provides an increase in skin elasticity, a decrease in flabbiness, and an improvement in complexion. In the complex of non-invasive skin rejuvenation methods, the electrostimulation method is very popular [39]. Unlike contemporary physical methods that affect all tissue components, electrostimulation is an intervention at the cellular level, which precisely targets cell membranes through electroporation without affecting the extracellular matrix architecture. Unlike chemical interventions, electrostimulation is a n on-invasive procedure that does not involve the application of external molecules [40]. This study presents results of using "Aganyan" plaster to address facial wrinkles and folds. The electrodes are made of different metals such as zinc and copper, and not connected to any electrical device such a voltage or current source. The difference in potentials causes electrons to flow on the surface of the skin from one of the electrodes to another. In this sense, one of the electrodes can be considered as a cathode, while another electrode can be considered as an anode. The difference in potentials can be created only when the electrodes are of different metals. These ranges of voltages and electrical currents appear to be very safe for humans with no side effects whatsoever. At the cellular level, the electrostimulation with patches therapy stimulates an increase in adenosine triphosphate (ATP), the energy that fuels all biochemical functions in a human body. It also bumps up protein synthesis, which is necessary for tissue repair. When exposed to the "Aganyan" plaster, a low-intensity electric

is passed through skin. current the Microcurrents activate protein synthesis (collagen and elastin), promote the renewal of epidermal cells, blood flow, lymph outflow, which increases the activity of metabolic and regeneration processes and, as a result, disappears puffiness and dark circles under the eyes. By increasing the tone of the muscles or, conversely, relaxing, if they were in a state of tension, the effect of smoothing out fine mimic wrinkles is achieved. Muscles trained after stimulation tighten the oval of the face, remove flabbiness and swelling of the skin, give the face a well-groomed and rejuvenated look. Our results show that low-intensity electric can improve skin function. The indisputable advantages of this invention are the absence of side effects on the human body [38].

#### Conclusion

Our results suggest that "Aganyan" plaster can serve as a novel therapy for controlled skin rejuvenation, effecting wrinkles and folds.

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#### Conflict of interest and financial disclosure:

The author declares that he has no conflict of interest and there was no external source of funding for the present study. None of the authors have any relevant financial relationship(s) with a commercial interest.

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#### **Consent statement**

Written informed consent was obtained from the patient for publication of this case report and accompanying images.

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