The immediate result of facial skin laxity treated by Newa lift

Takahiro Fujimoto

Clinic F Director, Ph.D. (Medical Science), Ph.D. (Engineering)
Clinical Topics

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Abstract

The effect and safety of homecare device Newa lift have been evaluated by subjective and objective tests. Comparison between measurements performed by VectraFace before and after the treatment show significant elevation of 4.19 mm on average (P<0.001) of contour lines drawn on the cheek area. In addition, volume of the cheek increased by 6.3 cc on average, and third party evaluation by Photoy noticed improvement of 0.76 (VAS, p<0.01) on average. Serious side effects were not observed. It is believed that Newa lift is a safe and useful homecare device that has immediate lift-up effect after the treatment, and allows to expect a long-term mild improvement of shape and quality of skin.

1. Background

To date cosmetic surgery and dermatology have used various anti-aging treatments to ameliorate the outward symptoms associated with aging. One of the aging phenomena of facial parts is symptoms related to the change in shape of the skin such as wrinkles and sagging. Since curative effect of oral and topical skin care is limited, so far such surgical procedures as face lift, thread lift etc. were commonly performed for these purposes. In the recent years non-invasive and minimally invasive therapies such as medical treatments using energy of lasers, visible rays, infrared rays, electromagnetic waves (RF), ultrasonic waves, infusion therapy etc. tend to be popular among the patients.

The principal effect of these noninvasive and minimally invasive treatments for wrinkles and sagging using the above mentioned energy sources is that they cause thermal
damage to a part of connective tissue of collagen fiber of dermis, hypodermis and elastic fibers, and thus promote the immediate tissue contraction, and production and remodeling of collagen fibers in the subsequent wound healing process. These treatments thermally break hydrogen bonds, thus changing the triple helical molecular structure of the collagen molecule, while the micro thermal damage causes immediate contraction in the collagen that prolongs life span of fibroblast and improves and normalizes appearance of collagen (promotes generation of a new collagen and restructuring) \(^2,3\). Further, it is thought that the temporary improvement in skin shape just after the treatment is associated with a mild inflammatory reaction like swelling or edema, or effect of excretion of water into tissue as a result of hypermetabolism or massage.

Recently a new category of products called beauty appliances was born in the Japan consumer electronics industry. Mass retailers and major consumer electronics manufacturers sell various home care beauty equipment in the expanding consumer market. Advertisements of these home care devices give consumer the impression that they have some cosmetic effect. Of course, safety of their use is somewhat silenced, and, though there are homecare devices that are believed to give a good cosmetic effect in the future, many products with no medical justification or products of questionable safety are seen here and there. So far, in Japan, very few medical evaluations have been published on the effect and safety of such beauty home care devices.

Recently I got an opportunity to evaluate a home care device Newa lift (EndyMed Inc., Israel) intended for improvement of aged sagging symptoms by tightening the skin for a smoother firmer look, and, along with the comparative evaluation of the sagging before and after treatment, to also investigate safety of the consumer electronics product. At the present time there is no method for evaluation of sagging improvement that is approved by the scientific community, apart from a subjective evaluation like VAS (Visual Analogue Scale)
score. Therefore, in addition to the conventional third party evaluation of test subject by subjective evaluation and evaluation of photos, I performed measurements using 3D image analysis system Vectra Face (Canfield Scientific, USA) to test the objective evaluation of sagging improvement from the change in contour lines drawn on the face image and cheek volume.

2. Methods and Materials

2.1. Object

17 healthy adults (1 male and 16 females) of 28 to 64 years age, wishing to improve sagging of facial part, who did not visit a beauty clinic within the past 6 months, without skin diseases and anamnesis at the time of treatment. Objective of the study and possible side effects were explained, and approval of all the participants was got.

2.2. Equipment

The home care device used in the study was Newa lift, a device having 3 independent low power generators that produce submicrowaves (kind of RF) between respective 3 pairs of bipolar electrodes that touch the skin (see Photo 1). 3DEEP technology is characterized by generation of electric field that reaches a depth corresponding to each interelectrode distance while avoiding interference by slight shifting of phases of the submicrowaves. (Drawing 1).

![Drawing 1. Lines of electric force of submicrowaves (image)](image)

Newa lift is designed with such safety features as moving detector and built-in temperature sensor. The generation of submicrowaves automatically turns off when the skin overheats.

Since Newa lift is a home care device the test participants administered the treatment themselves on a clean face while looking at mirror. They applied the dedicated conductive gel containing a cosmetic ingredient to the electrode portion of the device, placed the electrodes in contact with the skin and then slowly moved the device in large circular motion from cheek to lower jaw, as described in the instruction manual. At the time of treatment the test participants reported a slight heat sensation in the area of skin contact with the electrodes.
After 4 minute treatment generation of submicron waves automatically stopped and some vibration is felt. Then the device is moved to the other side of face, the entire self-treatment is completed in ~8 minutes.

2.3. Evaluation method

Three-dimensional image analysis system Vectra Face and software (Canfield Scientific, USA) were used for the objective evaluation of immediate effect of Newa lift on sagging improvement. The faces of test participants were photographed at the same conditions before and after Newa lift treatment, using Vectra Face equipped with 2 CCD cameras (Photo 2). The dedicated software permits to draw contour lines on a photo (Photo 3) and analyze the image. The contour lines are plotted from the tip of nose to the back of head of test subject in 5mm intervals in the direction of straight line connecting the camera and apex of nose (Photo 4).
The two images taken before and after the treatment are superimposed over a reference line that connects nose and glabella (so called T-zone) and remains unchanged after the treatment. The shift in the position of contour lines can be regarded as amount of change in the shape of skin (Photo 5).

![Photo 5. Measurement of the fifth contour line](image1.png)

![Drawing 2. Measurement of volume by Vectra Face](image2.png)

The shift of contour line that crosses center of the cheek (usually the fifth line from the apex of nose) served as the indicator for quantifying sagging improvement. If the cheek skin rises after the treatment the contour line drawn after the treatment appears higher than the contour line drawn before it. Straight lines of maximal shifts of the contour lines from nose apex point (reference point that is not changed by the treatment) were drawn on the superimposed images taken before and after treatment, and linear distances from the nose apex were measured on each image. The sagging improvement effect was considered high if the difference between the two distances was large. Vectra Face software includes also a function for measuring volume of cheek. As shown in Drawing 2, If using the software the images taken before and after treatment with reference to images taken in the vicinity to the nose and cheekbones are automatically superimposed thus permitting measurement of difference in the cheek volume before and after treatment by cutting area selected by mouse from the plane.

Degree of satisfaction of test participants with the results after completion of the treatment was examined by self-evaluation of test participants according to NRS (1: very dissatisfied 2: dissatisfied, 3: satisfied, 4: very satisfied). Further, third party evaluation by three persons was performed using the photos taken before and after the treatment (VAS score: 0 - unchanged to 10 – marked effect). In addition, when interviewing test participants having complains on pain and discomfort after treatment with Newa lift they were visually inspected to confirm the presence of absence of the side effects.

*) before in the original text – translator’s note
3. Results

A significant reduction of the distance between the root of nose and the 5th contour line (a line crossing the cheek center) of 4.191 mm on average was detected after Newa lift treatment, while the immediate sagging improvement was evaluated objectively (after normality test, paired t-test, \( P<0.001 \)). In addition, the upward shift of the all contour lines crossing the cheek can be confirmed visually. Cheek volume increased by 6.3cc on average. Degree of satisfaction of test participants with the effect was 3.6 (NRS) on average. The third party evaluation by 3 persons show improvement by 0.76 on average (VAS) (paired t-test, \( P<0.01 \)).

![Photo 6. Before and after Newa lift treatment (women of 50 years age)](image)

Photos 6, 7 show a representative example of the marked effect. There were no complaints on pain or discomfort at the time of the self-treatment and after the treatment. A mild erythema just out of the bath was reported by 2 of 17 test participants that disappeared in several ten minutes. Burns, skin diseases and other serious side effects were not observed.

4. Discussion

Newa lift is distributed as a home care device. In comparison with tightening RF devices for medical use Newa lift consumes 10 times less energy in terms of Joule heat than the devices of essentially limited effectiveness. Nevertheless, Newa demonstrates objectively
obvious sagging improvement effect immediately after its use, and show a high score of degree of patient satisfaction and third party evaluation. At the beginning the submicron waves of Newa lift cause a mild inflammatory reaction resulting in slight edema and swelling, while the patient guesses whether he is feeling tightening and firmness in the treated areas. Volume of the skin temporarily increases due to edema or swelling, and I think that it might be the reason that positions of contour lines rise upward. In the above mentioned Newa lift 3DEEP technology the electric field produced by bipolar electrodes reaches a wide range of skin with a weak energy, and can efficiently generate the above reactions.

In the past many reports have been published on the mechanism of action of RF medical tightening equipment for treating acne scar 4), hypertrophic scar and keloid 5), inflammatory acne of all types of skin 6) improving skin sagging by non-ablative tightening of skin structure and wrinkle reduction 7) 8). In particular, regarding the change in skin shape it is reported that ① collagen fibers are partially contracted by RF ② wound healing process promotes long term remodeling of dermis and accelerated production of collagen fibers. Submicrowave energy of Newa lift is kept low, within the safe area used for home care. Newa lift is not a medical RF device of high output, its action is not apparent, but it is very likely that it exploits the above mentioned ① and ②. It is recommended to repeat 8 min one-time treatment by Newa lift every day. It is possible that during long time use the production and remodeling of collagen fibers is stimulated at a micro level that needs to be clarified by a long term follow up of the process.

It is known that a weak electrical current causes contraction of muscles resulting from sliding of actin and myosin, the major proteins which constitute the muscles, without motor neuron activity. In particular, electrical stimulation excites fine axonal fibers prior to large muscle fibers that have a thick axon and response with delay 10), 11). The principle is used in EMS (Electric muscle stimulator). It is reported about residual contraction of muscles for a certain period of time at sites where the electric stimulation was continuously repeated 12). Thus, the medical use RF of conventional high output can initiate the not observed transient muscle contraction and raise the skin. Regarding Newa lift safety, no serious side effects were observed, no test participants complained on pain during and after the treatment. A mild erythema just out of the bath was reported by 2 of 17 test participants; it disappeared in several ten minutes and did not cause contact dermatitis or other skin decease. Even if repeating the treatment for a long time, it is very unlikely that the treatment may develop into some kind of skin disorder.

In Japan the number of beauty medical examinees is very small as compared to Europe, United States and South Korea. The author thinks that it is attributed to the culture
where one does not want others to know one receives beauty medical care. In recent years a number of cosmetic surgical operations decreased, probably since customers prefer medical treatments that use such devices of micro-plastic surgery as infusion therapy, non-invasive or minimally invasive lasers etc. In the future the popularity of home care devices that have a slight facial effect and are safe in use, and familiarity of consumer with beauty care will broaden the base of cosmetic medicine market. It is thought that there is a need to maintain a medical watch over the one by one announced homecare devices, accompanied by marketing activities, since it is thought that the limited evidences of their effect, along with the widening possibility of side effects, may lead to a disappointment and to dispirit the cosmetic medicine market.

Conclusions

Objective and subjective evaluation tests were conducted to evaluate effect and safety of Newa lift homecare device. After the treatment, significant improvement of sagging was observed, with no serious side effects. This time, though a long term follow up was not performed, even if the immediate sagging improvement effect after the treatment is transient, it is believed that Newa lift can be safely used as home care device that allows expecting for a long term mild improvement of skin shape and quality.
References


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