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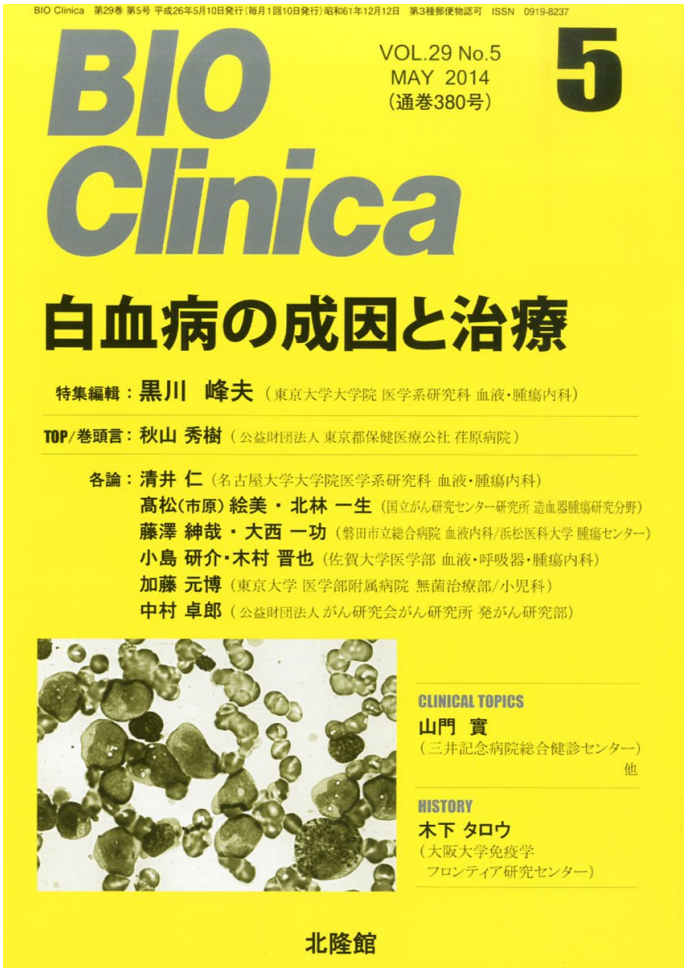
Clinic F Director, Ph.D. (Medical Science), Ph.D. (Engineering)



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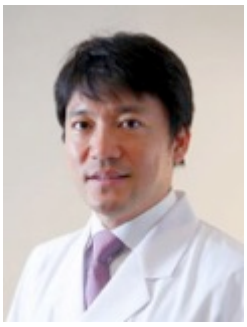

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The immediate result of facial skin laxity treated by Newa lift

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Key words: Skin Tightening, Skin Laxity, Three-Dimensional Imaging, Home Care Device

Abstract

The effect and safety of homecare device Newa lift have been evaluated by subjective and objective tests. Comparison between measurements performed by Vectra Face 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 photographic based evaluation noticed an improvement of 0.76 VAS (Visual Analogue Scale, $p<0.01$) 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 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 external aging symptoms. Wrinkles and sagging are viewed as two of the major facial aging phenomena. Since the effects of oral and topical skin care on wrinkles and

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skin laxity are limited, surgical procedures as face lift, thread lift etc. [1] were commonly performed for these purposes. In the recent years non-invasive and minimally invasive therapies such as medical treatments using energy of lasers, radiofrequency (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 the fibrous fibers in the dermal and hypo-dermal connective tissue promoting both immediate tissue contraction, and production and remodeling of new collagen fibers due to the subsequent wound healing process. The effect of heat on the triple helical molecular structure of the collagen molecule causes immediate contraction in the collagen. In parallel, heating the fibroblasts to 50-55 deg. Celsius promotes generation of new collagen restructuring and normalizing appearance of existing collagen [2,3]. The temporary improvement in skin and facial contour just after the treatment is allowed by fibrous tissue contraction accompanied by mild inflammation and edema caused by the massage and heat.

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. Safety of their use is somewhat silenced, as 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.

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Photo 1. Newa lift (EndyMed Inc., Israel)

Recently I got the opportunity to evaluate a home care device Newa lift (EndyMed Medical Ltd, Israel). In this study I investigated the improvement of aged sagging skin along with the safety of this new 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 using the change in contour lines drawn on the face image and variation in the cheek volume.

2. Methods and Materials:

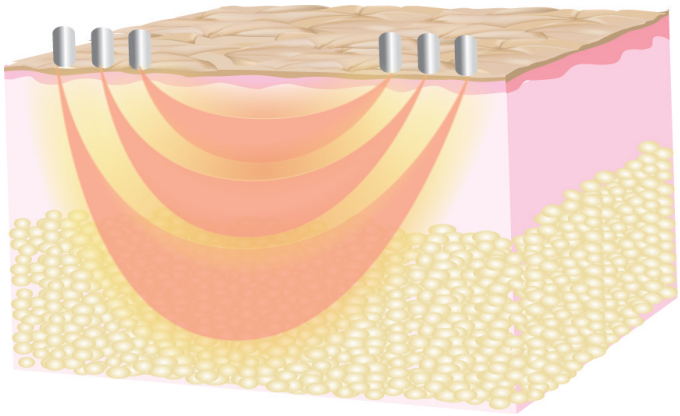
2.1. Object

17 healthy adults (1 male and 16 females) ages 28 to 64 years, wishing to improve sagging of facial part, who did not visit a beauty clinic within the past 6 months. The included patients did not have any skin diseases or notable lesions on the treatment area at baseline. Objective of the study and possible side effects were explained, and informed concept was achieved.

2.2. Equipment

The home care device used in the study was Newa lift, a device having 6 independent low power generators that produce medically safe RF energy (see Photo 1). The unique 3DEEP technology allows the safe heating of the dermis with significantly reduce heat the epidermis. . (Drawing 1). This patented technology assures for the first tine in a home

use device , the penetration of enough energy to the dermis without pain or risk to the epidermis (surface of the skin).



Drawing 1. Lines of 3DEEP RF energy (heat) distribution in the skin.

Newa lift is designed with such safety features as a real time motion detector and a built-in temperature sensor. The generation of energy 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 the 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 energy automatically stops and a mild vibration is felt. Then the device is moved to treat the other side of face. The entire self-treatment of two areas is completed in 8 minutes.

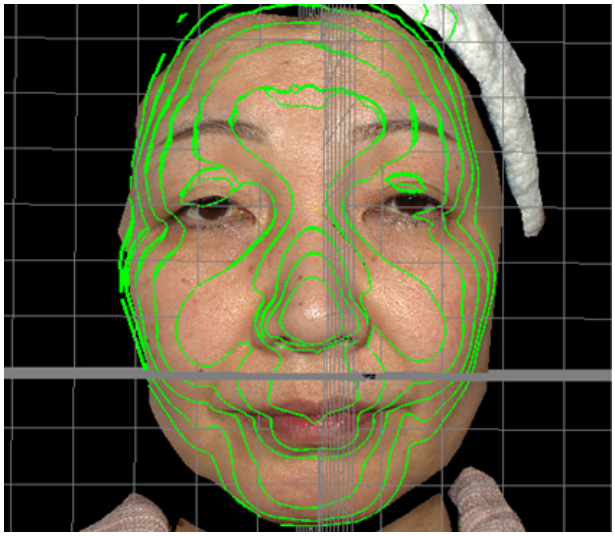


Photo 2. Vectra Face (Canfield Scientific, USA)

Photo 3. Facial contour lines (front view)

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).

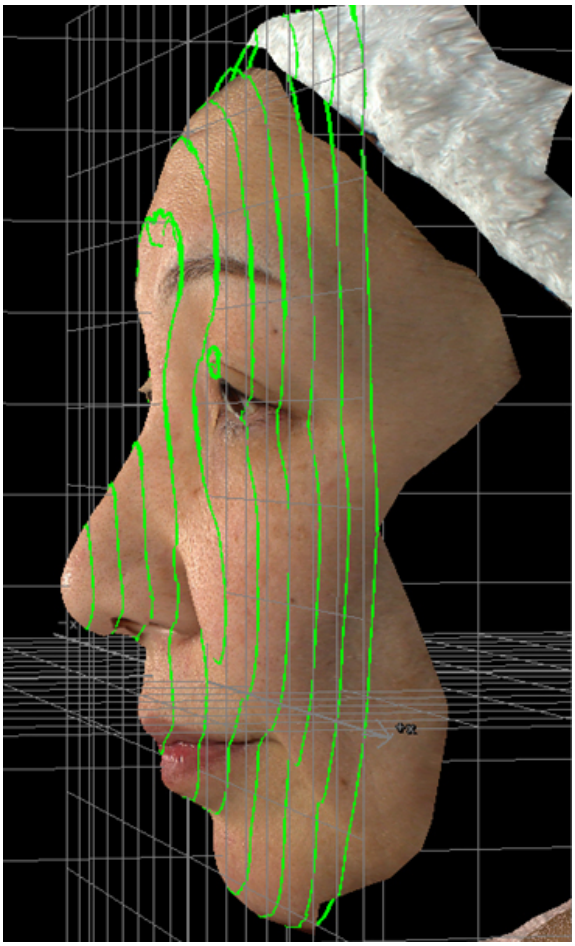


Photo 4. Facial contour lines (side view)

The two images taken before and after the treatment are superimposed over a reference line that connects nose and glabella (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).

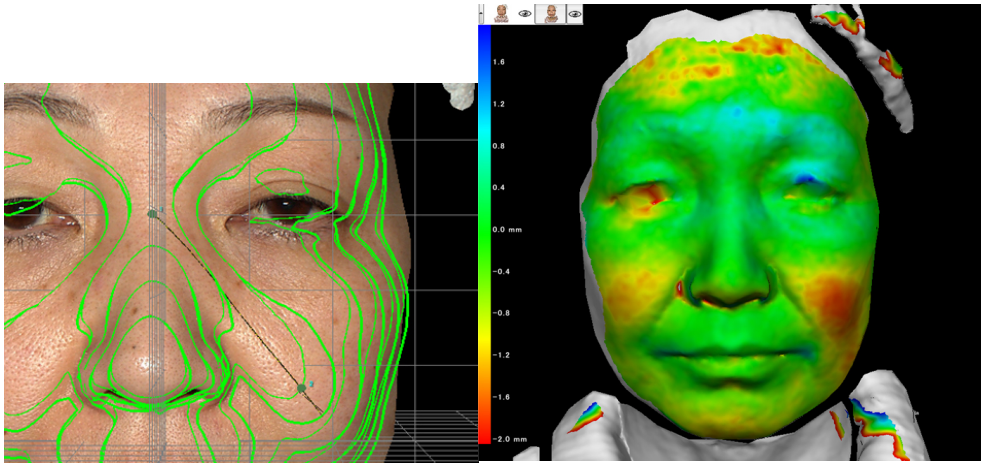


Photo 5. Measurement of the fifth contour line

Drawing 2. Measurement of volume by Vectra Face (distance from nose)

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 (Numeric Rating scale) (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.

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 matches an objectively assessed highly significant immediate reduction of sagging (after normality test, paired t-test, $P<0.001$). The upward shift of the all contour lines crossing the cheek was 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)

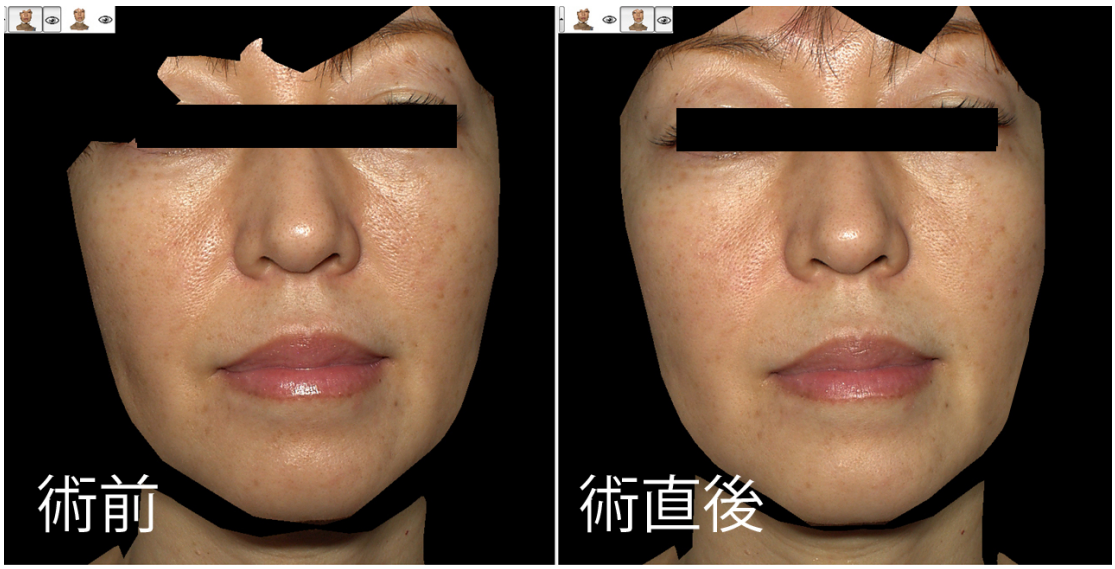


Photo 7. Before and after Newa lift treatment (women of 49 years age)

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 after the treatment 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. The Newa lift consumes 10 times less energy in terms of Joule heat than the tightening RF devices used in medical clinics. Nevertheless, Newa demonstrates objectively obvious reduction of sagging immediately after its use, and show a high score of degree of patient satisfaction and third party evaluation. At the beginning the RF waves of Newa lift cause a mild inflammatory reaction resulting in slight edema and swelling, generating a tightening and firmness feel in the treated areas. Volume of the skin temporarily increases due to edema or swelling clearly elevating the facial contour lines.

Many reports have been published in past looking into the on the mechanism of action of RF medical tightening equipment for treating acne scar [(4)], hypertrophic scar and keloid [(5)] , rosacea [(6)] inflammatory acne of all types of skin [(7)] improving skin sagging by non-ablative tightening of skin structure and wrinkle reduction [(8-9)] It is well accepted that the change in skin quality and shape is related to the process in which collagen fibers are partially contracted by RF and the wound healing process that promotes long term remodeling of dermis and accelerated production of collagen fibers. The RF energy produced by the Newa lift is low, within the safe range allowed for home use. Even though the Newa lift is not a medical RF device of high output it is very likely that it exploits the above mentioned collagen remodeling and skin lifting effects. It is recommended to repeat 8 min treatments by Newa lift every weekday. The long term production and remodeling of collagen fibers 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 ten minutes. There were no reports of contact dermatitis or other side effects. We believe that even if repeating the treatment for a long time, it is very unlikely that the treatment may cause any other side effect.

In Japan the number of beauty medical procedures 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 invasive cosmetic surgical operations decreased even further, probably since customers prefer non-invasive or minimally invasive lasers or RF treatments. In the future the popularity of home care devices that have a noticeable 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 the limited evidences of the effect of some home use devices, along with the widening possibility of side effects, may lead to a disappointment and to dispirit the cosmetic medicine market. In order to assure high user satisfaction, there is a need to maintain a scientific critical look assuring the the marketing claims of the different devices match their real efficacy and safety.

Conclusions:

Objective and subjective evaluation tests were conducted to evaluate effect and safety of Newa lift home care device. Immediately 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.

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