

Efficacy of beautytek Treatment (Female Breast and Upper Leg) Pre-Trial Results

Abstract The efficacy of the beautytek treatment was investigated by testing several skin-physiological parameters. Three female test persons (aged approx. 30, 40, and 50 years) received therapy of the breast and upper leg, whereby the left side was treated 12 times whereas the right side was treated only during the last 6 sessions. After treatment a moderate to substantial improvement of measured parameters was observed. beautytek therapy was particularly beneficial in reducing the undulation of the sub-skin layers in the upper leg, strongly indicating the reduction of and improvement in Cellulite. In general test results confirm that all test persons benefited from the beautytek therapy in the treated regions. The trial was conducted as a pre-trial for a planned main study documenting the effectiveness of beautytek therapy with statistical significance.

Aim of study For several years the beautytek method has been applied in cosmetic clinics, aesthetic institutes, and physicians' offices. Frequently a scientific prove of its effectiveness has been mandated by users, potential buyers and regulatory bodies. Currently only attempts of systematic scientific investigations of its efficacy exist [1]. Therefore a prospective scientific study was planned aimed to document the efficacy of beautytek related therapy

- according to a well defined treatment regiment
- applied to certain selected body areas
- tested by relevant parameters common in experimental dermatology
- comparing untreated and treated time intervals for control purposes.

In order to assess the suitability and relevance of parameters, the magnitude of treatment induced changes, and the structure and extend of the study (number of test persons, cost) a pre-trial of three test persons was conducted and is documented below.

Methods Three healthy female volunteers,

aged approx. 30, 40 and 50 years, were recruited, consulted about the intend of the study, and their consent obtained. The treatment was carried out by 'neosoma', an aesthetic institute located in Cologne, Germany (Heidelind Latz, Dr. Norbert Arndt) during March and April of 2003.

Test Person	Age	Weight (Kg)	Height (M)
SE	31	88	1.71
CG	43	61	1.72
BW	47	56	1.70

Table 1 contains the personal data of the test persons.

The test persons were treated during

Cycle 1

6 treatments on the left side of the body,

with an initial treatment of the upper leg and a subsequent treatment of the female breast in the same session, and during

Cycle 2

6 treatments on both sides of the body with an initial treatment of both upper legs and subsequent treatment of the breast in the same session.

During the treatments the usual electrolytes CEL 236 and CEL 231 were applied to the upper leg and breast respectively. ACT-treatments were carried out in all test persons starting with the 6th treatment during 4 sessions on both upper legs. All treatments followed the regular regiment of the beautytek-program using the regular probes.

Before the first, after the 6th and after the 12th session digital photographs were obtained by neosoma showing a frontal and lateral view of treated body areas.

Skin irritations- or other external symptoms were not observed throughout the duration of the study. Test persons did not report any abnormal physical or other noticeable conditions.

The measurement of skin-physiological parameters were carried out at the Institute for Experimental Dermatology at the University Witten-Herdecke in Witten, Germany (Director Prof. Dr. med. H. Tronnier) and were under guidance of Mrs. Priv. Doz. Dr. Ulricke Heinrich.

The tests itself were performed by laboratory technologist Mrs. Cornelia Wibusch. Tests were done

- before the 1st treatment
- after the 6th treatment (cycle 1) and
- after the 12th treatment (cycle 2).

During the tests the following parameters were recorded and evaluated:

Capillary Perfusion Determination of capillary perfusion using a the laser Doppler flow meter measuring the mean flow velocity of capillary blood in parts of the treated skin area.

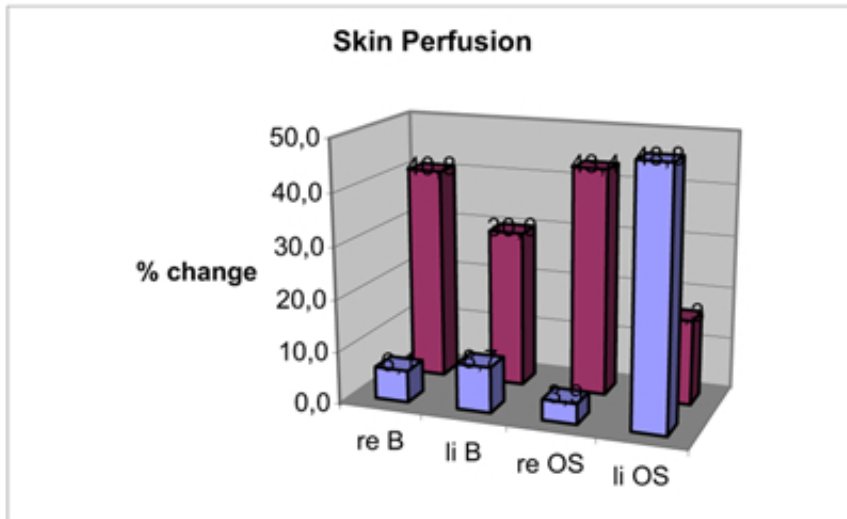
Elasticity of Skin (Cutometer) Determination of suction pressure required to draw a skin plexus into a cavity mold. By measuring the maximum pressure, time of pressure rise, and time of pressure drop the parameters elasticity R6, the viscoelastic properties of skin, and the elasticity R7, the biological elasticity were derived.

High Resolution Ultrasound Imaging (B-Scan) Using a 20 MHz ultrasound probe skin structures were displayed to a maximum depth of 7 mm at a resolution of 0.05 mm. Ultrasound images were evaluated by a special software algorithm determining the area of interest in sub-skin structures. This area is related to the occurrence of Cellulite and is supposed to show a decrease with progressing therapy (smoothing effect, reduction of "orange peel skin"). Infrared-Ther

Infrared-Thermography Measurement of superficial skin temperature by determining infra red radiation.

SELS-Test (Surface Evaluation of Living Skin) Profilometric investigation of skin surface by high resolution digital photography determining the parameters roughness, scaling, smoothness, and wrinkles using special automated software algorithms.

Results The graphs given below show changes of measured parameters after the 6th treatment (left side treated, right side untreated) and after the 12th treatment (left side had obtained 12 treatments, right side 6 treatments only)



Capillary skin perfusion

The left upper leg shows a marked and the left breast a moderate increase in skin perfusion after the 6th treatment. After the 12th treatments capillary perfusion is further enhanced in both breasts and the right, formerly untreated leg but is decreased in the left leg as compared to values after the 6th treatment.

Fig. 1: Skin perfusion measured by laser

Doppler flowmetry,

OS = upper leg, B = breast, re = right side, li = left side

Front row columns indicate relative changes after 6 treatments, back row columns indicate relative changes after 12 treatments, whereby left side was treated 12 times while right side received only 6 treatments. Right side therapy began together with 7th treatment of left side.

Elasticity, viscoelastic properties, R6 (Cutometer)

In both treated body areas (upper leg and breast) an improvement of viscoelastic properties can be observed in average. Negative values in R6 reflect improved skin condition.

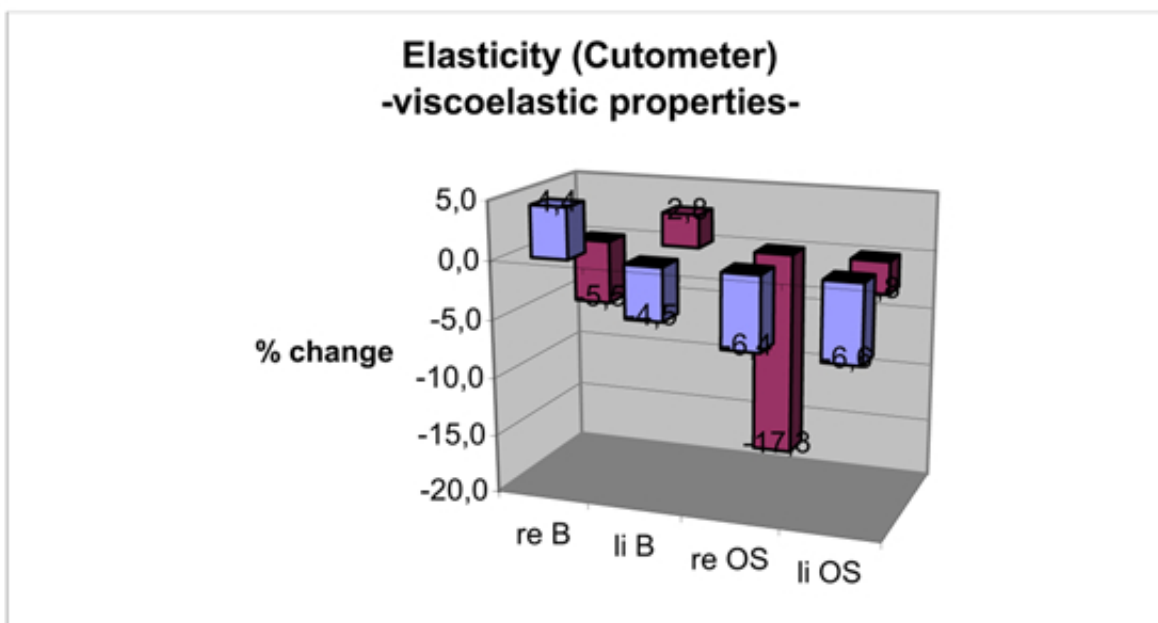


Fig. 2: Elasticity, viscoelastic properties R6 (Cutometer)

Elasticity, bioelastic properties, R7 (Cutometer)

In both treated body areas (upper leg and breast) an improvement of bioelastic properties can be observed in average. Positive values in R7 reflect improved skin condition.

In particular, marked differences between treated and untreated sides can be seen after 6 treatments, being equilibrated with the second therapy cycle.

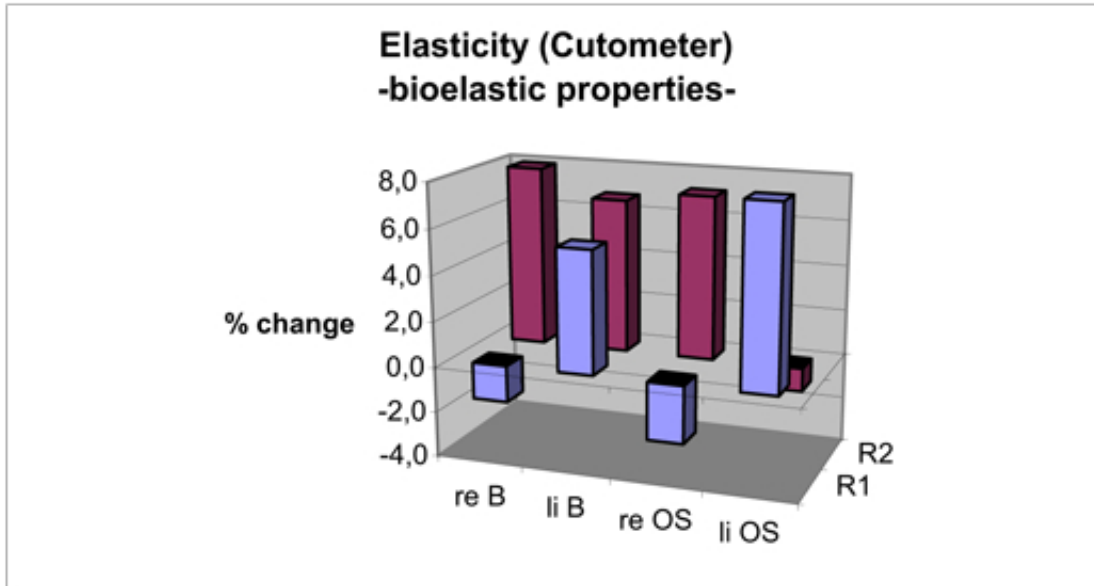


Fig. 3: Elasticity, bioelastic properties R7 (Cutometer)

Ultrasound imaging

As expected no noticeable differences of the parameter 'Area' were observed in the breast. In contrast a substantial improvement was reached during treatment of both upper legs. After the first treatment cycle of 6 treatments a marked difference between treated and untreated side was obtained (30% reduction in Area), equilibrated after the 2nd therapy cycle.

The reduction of Area, i.e. reduced undulation of sub-skin layers, is related to a decrease in Cellulite (also refer to Appendix, Fig. 8).

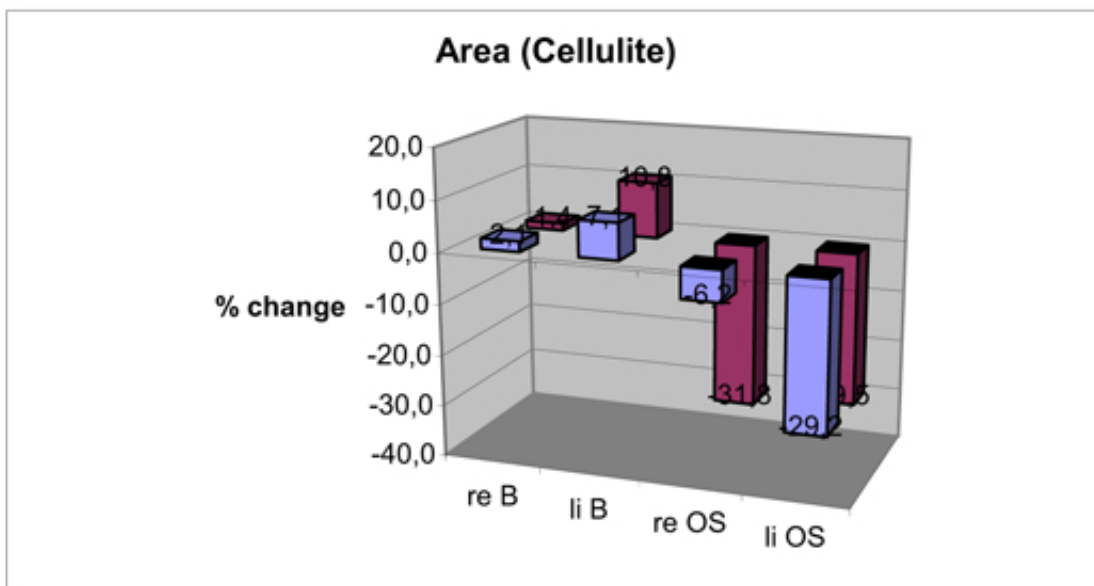


Fig. 4: 'Area' indicating area of sub-skin layers determined by high resolution ultrasound imaging

Thermography

No noticeable changes were observed in this parameter.

SELS-Test

In general a moderate to marked improvement was observed in the parameters roughness, scaling, smoothness, and wrinkling; only in the left breast no improvement in skin scaling occurred.

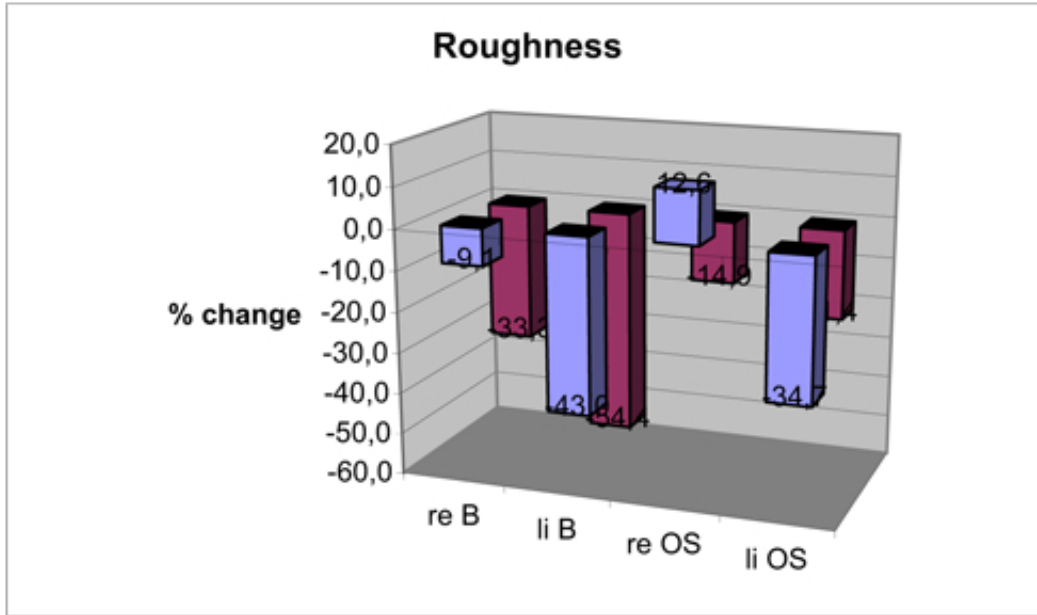


Fig. 5: Changes in skin roughness as determined by the SELS test method.

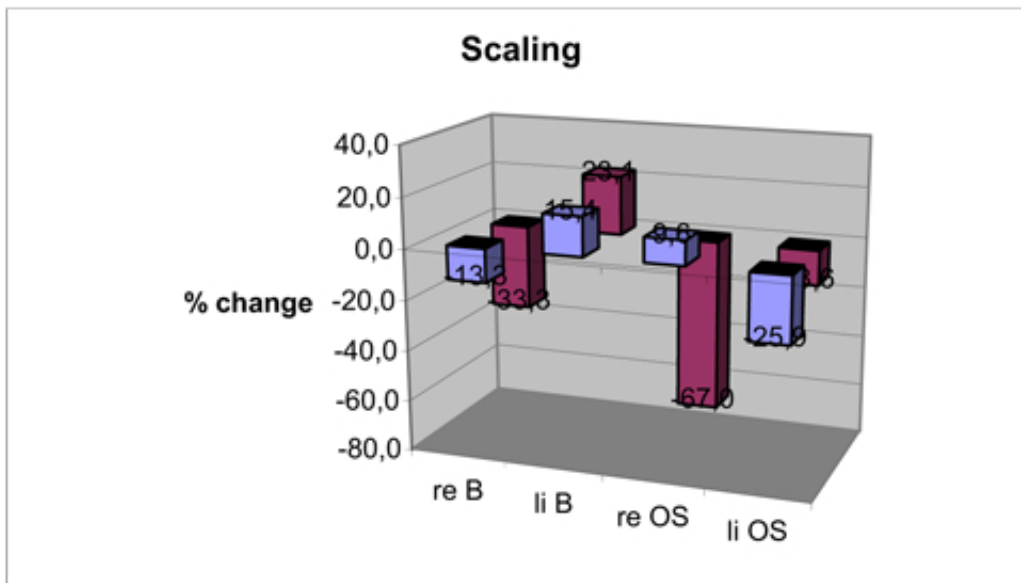


Fig. 6: Changes in skin scaling as determined by the SELS test method.

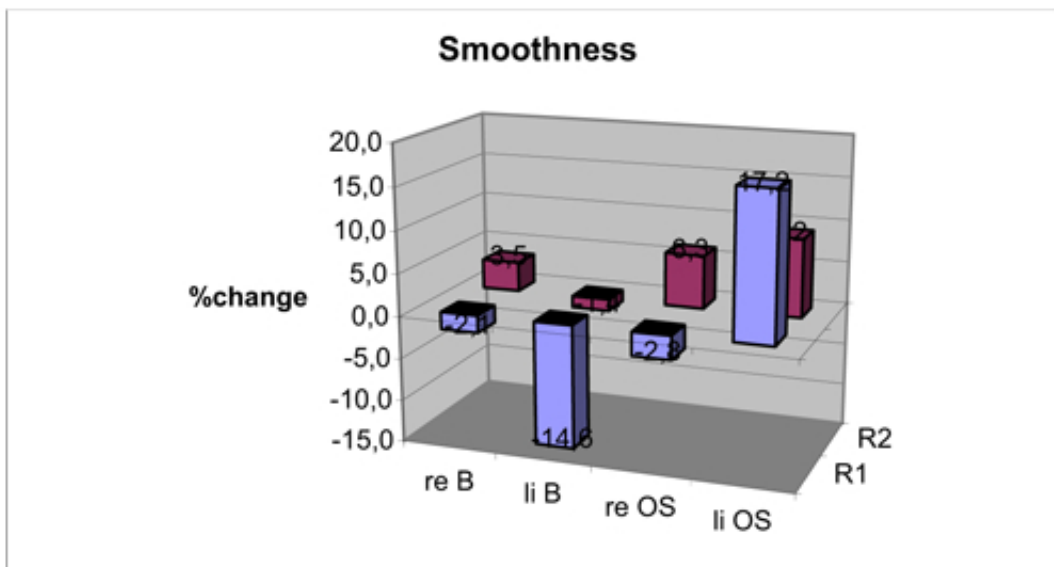
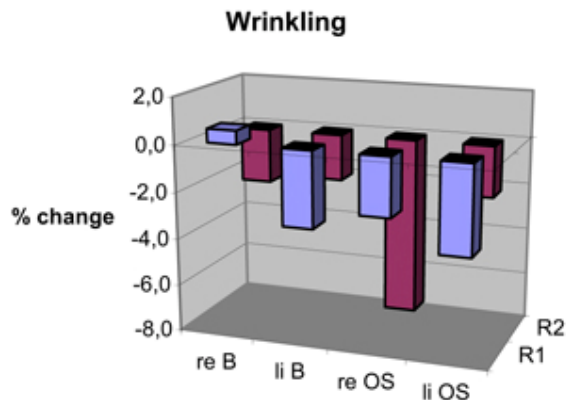


Fig. 7: Changes in skin smoothness as determined by the SELS test method.



Changes in wrinkling as determined by the SELS test method.

Subjective Results Test person SE: The breast looked floppy, pendulous, and worn out on both sides after seven months of breast feeding in twins. Post therapy the breast looked and felt firm, shaped and lifted. According to the test person the breast was comparable to pre-birth conditions.

Post therapy the circumference of thighs was reduced by 4 cm each; the total body weight was 4 kg lower.

Test person CG: After breast feeding of three children the breast was extremely pendulous and wrinkly. At the end of therapy the breast looked firmer and showed a natural curvature in supine position; wrinkles were markedly less visible. Although not treated, the abdomen showed an increased firmness.

On the upper legs a tightening and smoothing effect could be observed. Cellulite was visibly reduced.

Test person BW: Pre therapy the breast was tubular, floppy, and very pendulous, a pre-existing condition since the test person was 18. The breast also showed strong wrinkling. Post therapy a marked reduction in wrinkles on both breasts was seen.

The upper legs showed a tightening of skin and a complete reduction in Cellulite.

All three test persons reported a very noticeable increase in leg perfusion after therapy. (One of the treated women called this "a new livelihood in my legs").

Discussion The efficacy of the beautytek therapy was evaluated by measuring different skin-physiological parameters. Superficial skin temperature did practically not change after therapy. This result is not surprising as the test takes superficial temperature and does not reach deeper skin structures. Furthermore the test was not carried out immediately after the treatment but one to several days later. The result is also consistent with the intention of the beautytek therapy not to cause skin irritation or other complications of skin surface which could be enhanced by a rise in skin temperature over a longer period of time. The measurement of skin temperature immediately or a few hours after therapy could be more meaningful. Logistics required the test procedure to take place one or several days after the therapy. Empirical observations suggest that the beautytek therapy reaches an optimum between several hours and several

days after treatment. Therefore the time interval between end of treatment and tests was chosen, most likely picking peak or near-peak results.

The most impressive reaction was obtained in the parameter ‚Area‘. Its reduction correlates well with a decrease of Cellulite. After therapy of the upper leg a marked improvement was recorded in this parameter. During the treatment cycle though, no further decrease of Area was seen in the left upper leg. We view this result as a consequence of the initially unilateral therapy: Mainly the previously untreated right leg side benefited from the energy dissipated during the second treatment cycle.

Considering the skin structure of the breast, the Area remained practically unchanged in this part of body. SELS parameters did not substantially contribute to prove therapy effectiveness. Except for roughness, SELS data showed particularly little effect in the female breast.

By comparing treated and untreated sides, test results suggest that therapy extends well beyond the treated region effecting neighboring parts of the body. The treatment of two regions, breast and legs in one session, is not in agreement with standard beautytek therapy rules requiring only one region to be treated at one time. Logistic and cost considerations proposed the current study protocol but may have contributed to diminished test results in each of the regions.

The low number of test persons does not allow for statistical significance. Therefore an interpretation of results validating the beautytek therapy efficacy in general must be considered carefully. Tendencies and trends though can be derived. Taking the widely varying skin structure into account, transfer of the obtained results to other parts of the body should be expressed with caution.

Undoubtedly though the test results strongly suggest that all test persons benefited from the beautytek therapy in the treated regions.

Literature: [1] Doritke, Wahlen, Hönig d’Orville, Kardorff. Eine beachtenswerte Methode in der Lifestyle-Medizin: Beautytek. (A Remarkable Method in Life-Style Medicine: Beautytek.) Kosm Med. 2002,4: 213

Performance of beautytek treatment:

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Appendix

Example of high resolution ultrasound images in test person CG

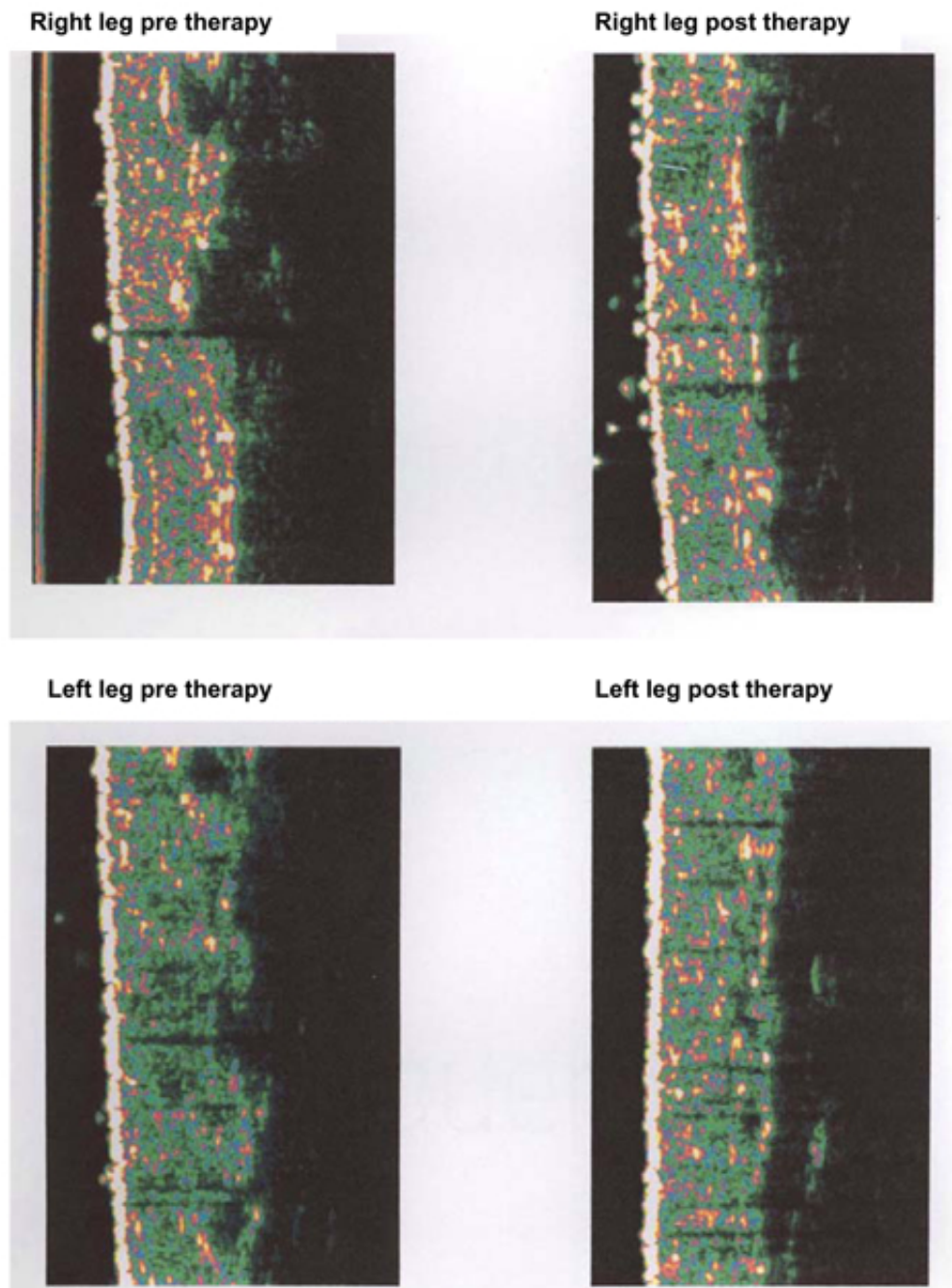


Fig.: 8: Ultrasound scans of upper leg with determination of „Area“. Images show skin surface on left side and undulation of lower skin layer on right side. Area determines the region between these border lines. beautytek therapy reduces undulation of lower structure as seen in right images.

Table of measured data

m0= Initial values before therapy

m1 = Values after 6 treatments

m2= Values after 12 treatments

Skin perfusion		m0	m1	m2
Right breast	re B	9,8	10,4	13,8
Left breast	li B	8,0	8,7	10,4
Right upper leg	re OS	7,6	7,9	10,9
Left upper leg	li OS	8,0	11,9	9,3
Elasticity (viscoelast.)		m0	m1	m2
Right breast	re B	0,183	0,191	0,173
Left breast	li B	0,176	0,168	0,181
Right upper leg	re OS	0,173	0,162	0,143
Left upper leg	li OS	0,181	0,169	0,176
Elasticity (biological)		m0	m1	m2
Right breast	re B	0,745	0,733	0,804
Left breast	li B	0,667	0,703	0,712
Right upper leg	re OS	0,711	0,693	0,762
Left upper leg	li OS	0,683	0,737	0,676
Ultrasound (Area)		m0	m1	m2
Right breast	re B	0,956	0,976	0,969
Left breast	li B	0,916	0,981	1,015
Right upper leg	re OS	1,592	1,494	1,086
Left upper leg	li OS	1,639	1,160	1,155
Thermography °C		m0	m1	m2
Right breast	re B	31,5	32,1	32,7
Left breast	li B	32,1	32,0	32,4
Right upper leg	re OS	29,9	29,4	30,0
Left upper leg	li OS	29,5	29,2	29,8
SELS (roughness)		m0	m1	m2
Right breast	re B	0,66	0,60	0,44
Left breast	li B	1,14	0,65	0,52
Right upper leg	re OS	0,87	0,98	0,74
Left upper leg	li OS	0,98	0,64	0,77
SELS (scaling)		m0	m1	m2
Right breast	re B	0,15	0,13	0,10
Left breast	li B	0,13	0,15	0,16
Right upper leg	re OS	0,94	1,03	0,31
Left upper leg	li OS	0,81	0,60	0,70

		m0	m1	m2
SELS (smoothness)				
Right breast	re B	23,41	22,93	24,23
Left breast	li B	28,04	23,94	27,65
Right upper leg	re OS	25,84	25,12	27,46
Left upper leg	li OS	23,01	26,96	25,13
SELS (wrinkling)				
Right breast	re B	43,96	44,22	42,94
Left breast	li B	45,78	44,28	44,88
Right upper leg	re OS	39,11	38,13	36,18
Left upper leg	li OS	46,00	44,25	45,00

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