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Date: 18.10.2016

Efficacy Test Conducted With "ByeByeCellulite"

(Cosmetic Study)

Summary

Study Sponsor .....: **Dr. Juchheim Cosmetics**
Eichleite 32
82031 Grünwald
Germany

Performance of Test .....: Derma Consult Concept GmbH
and Evaluation by Hermann-Wandersleb-Ring 4
53121 Bonn
Germany

Supervisors of Study .....: Dr. med. H. Prieur, Dermatologist – Allergist
B. Nissen, Manager Derma Consult Concept

Study Code .....: DCC16C007

Test Product .....: The test product, which was coded as follows, was provided by Dr. Juchheim Cosmetics in August 2016:

A. ByeByeCellulite (102076/1)

Subjects .....: Number of individuals.: 20 (+ 1 reserve subject)
Sex.....: female
Age range (completing) ..: 38-59 years (average: 47,5)

Test Areas.....: Thigh – half side trial against untreated

Application.....: Duration....: 28 days
Frequency.: twice daily

Test Period .....: September / October 2016

Test Parameters .....: 1. Determination of *skin firmness and elasticity (biomechanical properties of the skin)* by means of Cutometer MPA 580 (Courage & Khazaka GmbH, Cologne)

2. Determination of *skin roughness* by means of PRIMOS® 5.7 high-res (GFMeßtechnik GmbH, Teltow, Germany)

3. Determination of *thigh circumference*

4. Professional scoring of the level of *cellulite symptoms*

Design of Study.....: **Day 0**

- Professional scoring of cellulite symptoms
- Determination of the measured parameters in the test areas & creation of silicon imprints
- First test product application

Day 28

- Professional scoring of cellulite symptoms
- Determination of the measured parameters & creation of silicon imprints 8-12 hours following the final test product application

Evaluation .....: Descriptive statistics (average, median, minimum, maximum, variance, standard error, standard deviation); Wilcoxon Rank Test

Results .....: **Biomechanical Properties of the Skin**

The test product was found to statistically significantly enhance the biomechanical properties of the skin on the thigh towards the firm-elastic optimum. After 28 days of treatment, a mean increase by 9% (firmness) / 10% (elasticity) was observed and a positive effect of the test product was detected in 85% (firmness) / 90% (elasticity) of the volunteers.

Skin Roughness

The test product was found to statistically significantly increase smoothness on the thigh. After 28 days of treatment, a mean increase by 11% was observed and a positive effect of the test product was detected in 90% of the volunteers.

Thigh Circumference

No significant effect of the test product on thigh circumference could be observed over the course of the treatment.

Professional Scoring of Cellulite Symptoms

Use of the test product was found to significantly reduce the cellulite symptom score. After 28 days of treatment, a positive effect on the cellulite symptom score was observed in 65% of volunteers.

Methods

Measurement of Biomechanical Properties (Elasticity, Firmness)

The biomechanical properties of the skin are assessed using the Cutometer MPA580 (Courage + Khazaka Electronic GmbH, Cologne; S/N 31050887 tube: S/N 05325678).

The measurement is based on the vacuum-suction principle. By applying a constant negative pressure for a given time period, skin is drawn into a hollow tube with an orifice of 2 mm in diameter. Then, at normal air pressure, the skin is allowed to retract. The penetration depth of the skin into the tube is recorded optically without friction and without mechanical influence. A number of standardized parameters can be calculated from the resulting penetration depth curve. Most of the parameters are a function of skin thickness and thus cannot be simply compared between subjects and regions.
To increase accuracy and to capture information on the properties of skin under repeated external stress, the cycle is repeated several times and parameters selected for evaluation are based on areas rather than individual measurement points.

The delineation of the areas is based on the fitted logarithmic envelope curves of the minimum and maximum extensions according to the equation:

$$y = \frac{\ln x + b}{a}$$

(x = repetitions, y = max. amplitude or min. amplitude).

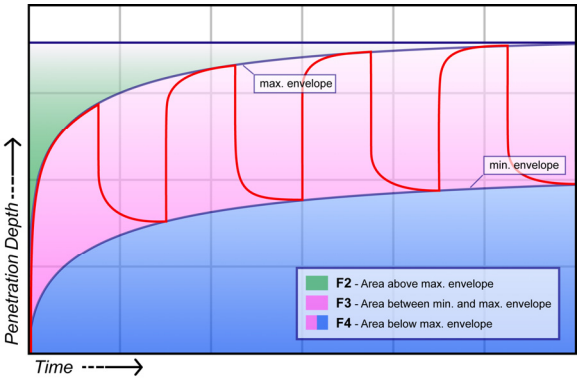


Fig. 1: Cutometer Parameters

The study was conducted with 20 successive measurement cycles, 1 second suction, 1 second retraction, with a 450 mbar vacuum. The following parameters were selected to assess changes in the biomechanical properties of the skin:

Skin firmness
Skin firmness is assessed by the parameter F4, the area below the approximated envelope function of the maximum extensions. → A decrease in F4 corresponds to an increase in skin firmness.

Skin elasticity
Skin elasticity is assessed by the ratio F3 / F4. The larger F3 in comparison to F4, the larger are the restoring forces and the smaller is the remaining residual deformation. → The closer the resulting value is to 1, the more elastic the skin.

The calculation of the parameters was conducted by WinCT (Courage & Khazaka GmbH, Cologne - Germany).

Measurement of Skin Roughness

PRIMOS (Phase-Shifting rapid in vivo measurement of skin) is a non-contact measurement device, which allows for real-time three-dimensional in vivo measurement of the micro topography of human skin based on the technology of active image triangulation. The measurement head consists of a digital micromirror device as projection unit and a CCD-camera as recording unit, mounted onto an adjustable rack. For active image triangulation an intensity encoded point M is projected onto the surface under investigation. Its image on the surface is recorded by the CCD-camera from a specific angle. The point M is a function of parameters like intensity, triangulation angle between projection system and camera and some other inner respectively outer coordinates of the camera and projection plane. The height information of the structured surface is coded in the distorted intensity pattern, which is recorded. The resolution and accuracy depends on the optical and topographical characteristics of the measured surface and on the noise characteristics of the measurement system. For accurate in vivo measurements of human skin, depending on the measured part of the human body (inner forearm, forehead, eye zone), different parameters of effective wavelength and amplification factor should be used.
The skin surface of the thigh is recorded from silicon imprints as a 3D topography using the PRIMOS system - the fast phase-shift technique was used for the measurement (phase width: 16 & 64 pixels). The silicon imprints (Detaseal Xlite, Detax GmbH & Co. KG, Germany) of the thigh were taken with a diameter of approximately 5 cm diameter (PRIMOS measurement centrally on the imprint).
The macro-structure of the area was digitally removed by a polynomial filter and, if necessary, areas with questionable reproductive character (air bubbles) excluded from the evaluation. Skin roughness was then assessed by means of the parameter R_Z (mean depth of roughness). To mitigate potential directional effects, the evaluation was conducted using the arithmetic average of R_Z from 32 radial cuts.
The mean depth of roughness is defined as:

$$R_Z = \frac{1}{n}\sum_{i=1}^{n} R_{Zi} \ ,$$

where n is the number of equal segments into which the scan length l has been divided into and R_{Zi} is the maximum peak to valley depth within each of the segments. In accordance with the German Standard Din 4768/1, R_Z was calculated using 5 segments of equal length. System used in this study: PRIMOS compact high-res S/N 108-00042, Software Version 5.7.

Professional Scoring of Cellulite Symptoms

Two trained evaluators graded the level of cellulite symptoms using a 5-point scale (0-4). Ambient conditions for the evaluation were standardized (artificial light source: LUMILUX 840 fluorescent tubes, 4000K cool white with excellent colour accuracy) and subjects asked to stand upright and to maintain a neutral expression during the evaluation. The evaluators made their rating independently inspecting the subjects from all angles. Analysed are their mean scores for each of the two treatment conditions. The scale used is based upon the 4 stages of cellulite:

0 = no signs
1 = slight dimpling of skin surface
2 = dimpling and skin depressions
3 = dimpling and depressed striations
4 = palpable nodules and striations

Thigh Circumference

The thigh circumference was measured under standardized conditions standing upright with a tape measure (tape measure was put around the thigh, pressed together and released, retracted until the measure could move without friction over the thickest point of the thigh) and recorded in 0.5cm intervals.

Performance of Test

The subjects were selected from the Derma Consult Concept GmbH database. They were informed about importance and meaning of the study; they could withdraw from the study at any time without giving any reason. Written informed consent was obtained from all the subjects prior to entry into the trial. The following criteria were used for selection of subjects:

for inclusion in study:
- female (≥ 18 years of age)
- ability to comply with the requirements of the study
- fundamentally clinically healthy
- cellulite grade: 3 – 4 (see scale above)

for exclusion from study:
- skin diseases or any other medical condition interfering with the objectives of the study
- planned medical treatment during study period
- pregnancy
- past surgery in the test areas
- weight-loss diet within past 3 month
- change or start of hormone replacement therapy within past 3 month
- change or start of oral contraception within past 3 month

A reserve subject in addition to the 20 original subjects, to replace potential drop-outs, started the study with a delay of 1 day (final readings only taken in case a drop-out needed to be replaced). The subjects were instructed not to use any topical preparations on the test areas starting from seven days prior to testing (preconditioning phase) and until the end of the test. For cleansing, water or a mild syndet (Eubos® flüssig – blau; manufacturer: Dr. Hobein, D-53340 Meckenheim-Merl, Germany) was allowed only (whole study inclusive the preconditioning phase). The subjects were asked to maintain their current sporting habits and nutrition throughout the study, not to use tanning beds and to report any medical treatment / medication to the study supervisor. For visits to the test institute, the subjects were instructed not to wear stretching clothes or underwear (to avoid leaving marks on the skin), not to visit saunas or swimming pools and not to consume alcohol within 24 hours before measurement / scoring.

Prior to the first application of the test product on the initial study visit to the test institute after the preconditioning phase, the cellulite grade of each thigh was assessed by two trained evaluators independently (scores averaged) and subsequently biomechanical properties measurements and silicon imprints were taken at clearly defined sites on each thigh and thigh circumference was measured. The exact measurement sites (defined and assessed in upright, standing position), selected as areas with the most defined symptoms, were recorded for each subject for later relocation. The silicon imprints (Detaseal Xlite, Detax GmbH & Co. KG, Germany) were taken

with a diameter of approximately 5 cm (PRIMOS measurement centrally on the imprint). One thigh (randomized selection) remained untreated and served as control. Further scoring, measuring and imprinting was performed after 28 days of regular treatment 8-12 hours following the final application before the concluding visit.

After a detailed explanation of the correct product application procedure by a Derma Consult staff member on the first study visit to the test institute after the preconditioning phase, the subjects used the test product twice daily (in the morning and evening) after cleansing at home according to the on-pack instructions (supplied by the study sponsor) – massaging the product into the skin of the designated treatment thigh with light pressure, starting with only a small amount of product, increasing it over time. The subjects were expressly advised about the specific characteristics of the product with possible minor discomfort in the form of reddening, feeling of warmth or stinging at the beginning of the treatment and to reduce the application amount, if required, to minimize these symptoms. Additionally as precaution, they were instructed not to use the product immediately after bathing. The first application was performed at the test institute after cleansing with wet towels under supervision of a Derma Consult staff member to ensure proper use.

All measurements and scoring were conducted after adaptation to the controlled environmental conditions of the test institute (room temperature: 21±1°C, relative humidity: 45±5%).

Biometry

Measurement data is automatically computerised and after validity check and quality assurance stored centrally in a database. Evaluation is conducted using the software NAG® Statistical Add-Ins for Excel – NAG Ltd., United Kingdom. The data were analyzed by Wilcoxon Rank Test. The 0.05 level was selected as the point of minimal acceptance of statistical significance.

Results

During the first week of treatment, original subject 16 chose to drop out of the study due to experienced discomfort (see incompatibility section below) and was replaced by the reserve subject. The data collected on the initial visit from the drop-out was discarded and hence the entire evaluation is based on the results from 20 completing volunteers, aged between 38 -59 years (average: 47,5).

Biomechanical Properties (Skin Firmness / Skin Elasticity)

In assessing skin firmness, evaluated are changes in the parameter F4 in the treated condition (thigh) in comparison to the changes in the untreated condition. The absolute values by condition and time point are shown below in figure two; the changes from the initial condition in figure three. A decrease in F4 corresponds to an increase in skin firmness.

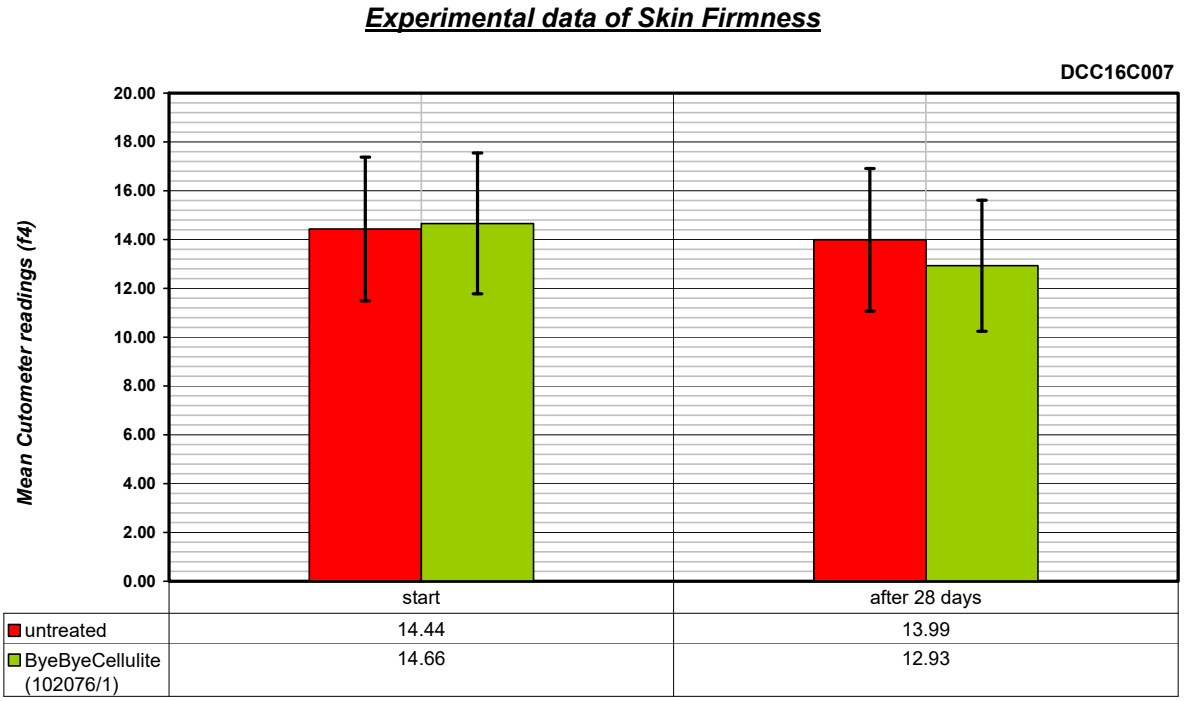


Fig. 2: F4 Values

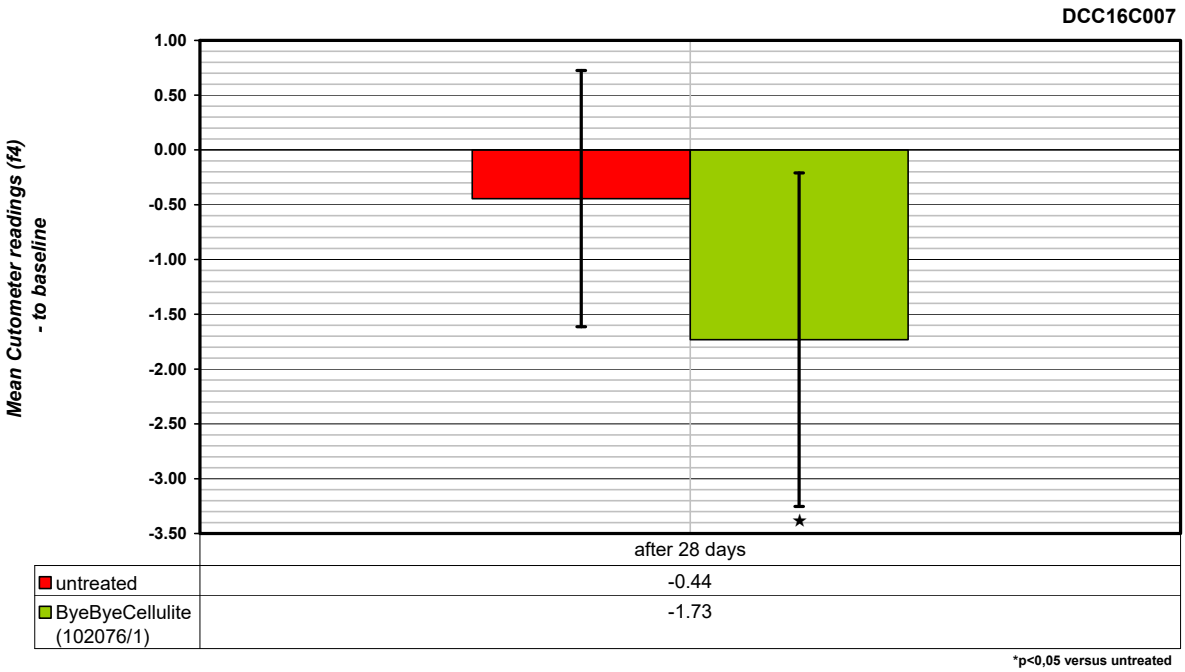


Fig. 3: Δ F4 Values

After 28 days of treatment, a statistically significant ($p<0.05$) decrease in F4 was observed in the product treated condition as compared to the changes in the untreated condition.
The test product was found to statistically significantly increase skin firmness; after 28 days of treatment a positive effect could be detected in 85% of the study participants. The respective percentage changes as compared to the initial condition and with regard of the changes in the untreated condition are shown in figure four below.

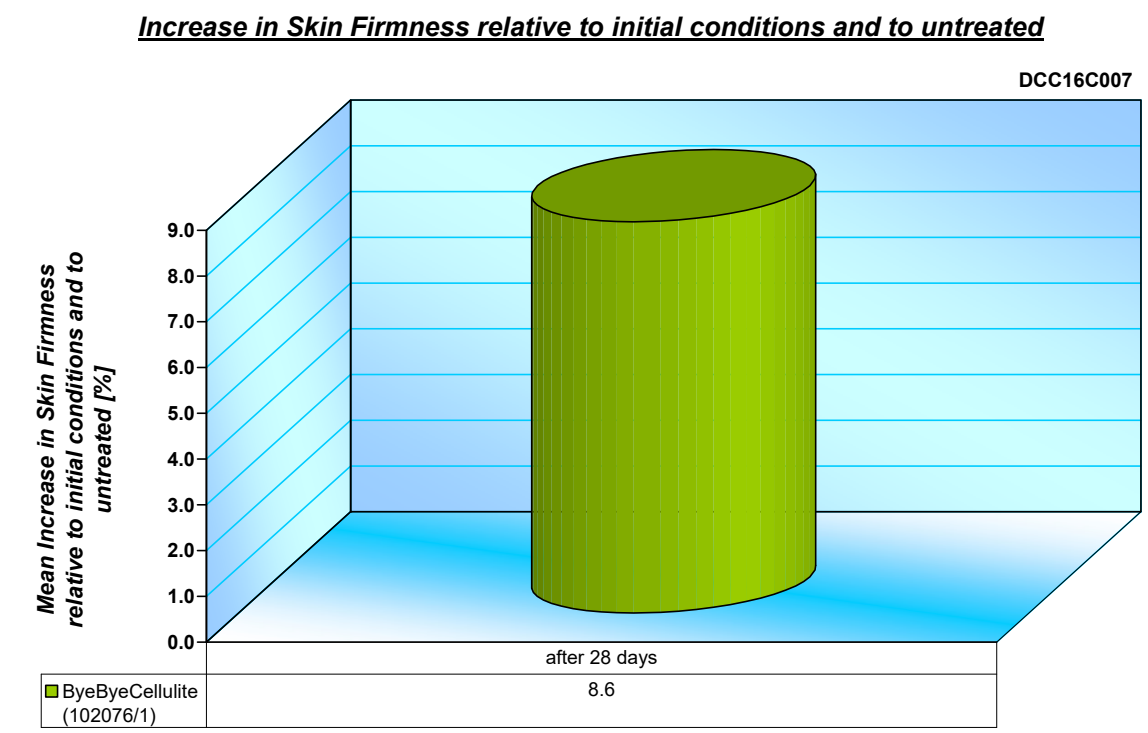


Fig. 4: Increase in Skin Firmness in %

In assessing skin elasticity, evaluated are the changes in the fraction F3 divided by F4 in the treated condition in comparison to the changes in the untreated condition. The absolute values by condition and time point are shown below in figure five; the changes from the initial condition in figure six. An increase in F3/F4 corresponds to an increase in skin elasticity.

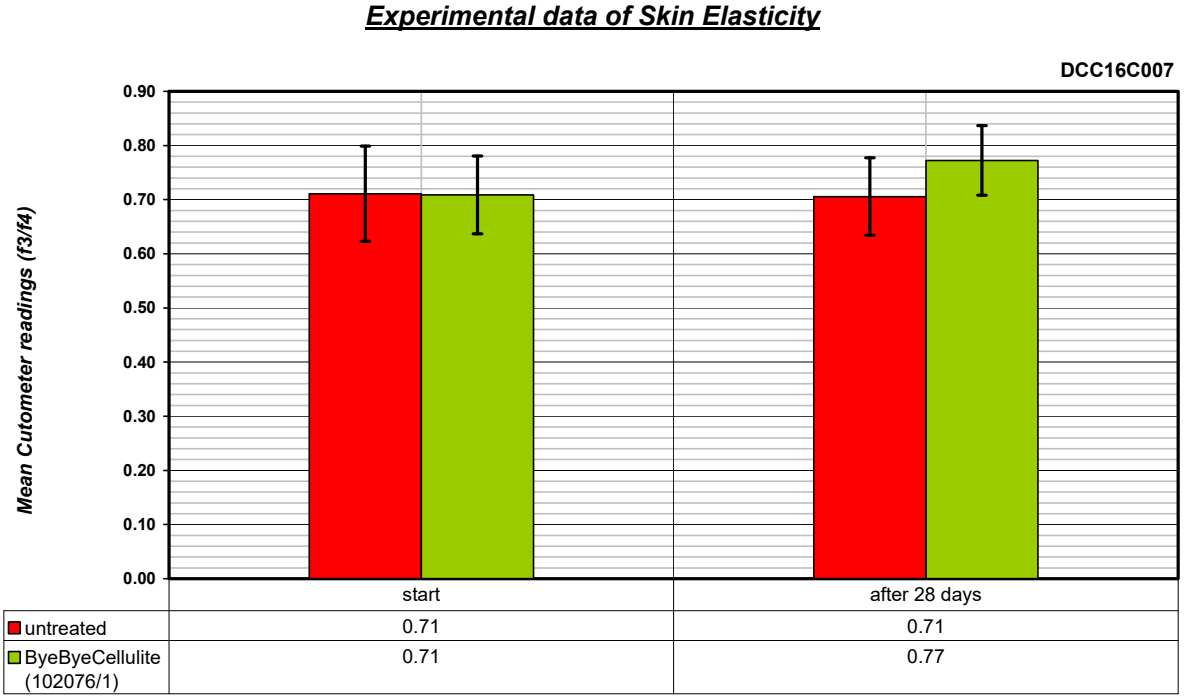


Fig. 5: F3/F4 Values

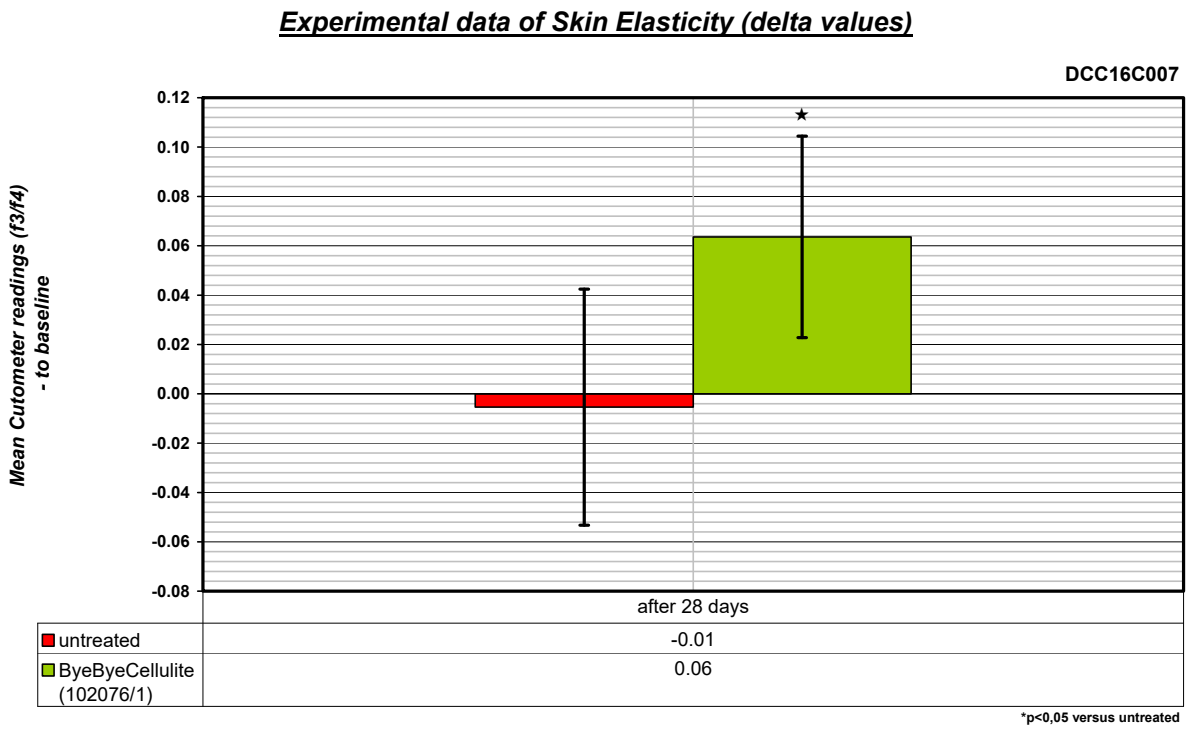


Fig. 6: Δ F3/F4 Values

After 28 days of treatment, a statistically significant ($p<0.05$) increase in F3/F4 was observed in the product treated test condition as compared to the changes in the untreated condition.
The test product was found to statistically significantly increase skin elasticity; after 28 days of treatment a positive effect could be detected in 90% of the study participants. The respective percentage changes as compared to the initial condition and with regard of the changes in the untreated condition are shown in figure seven below.

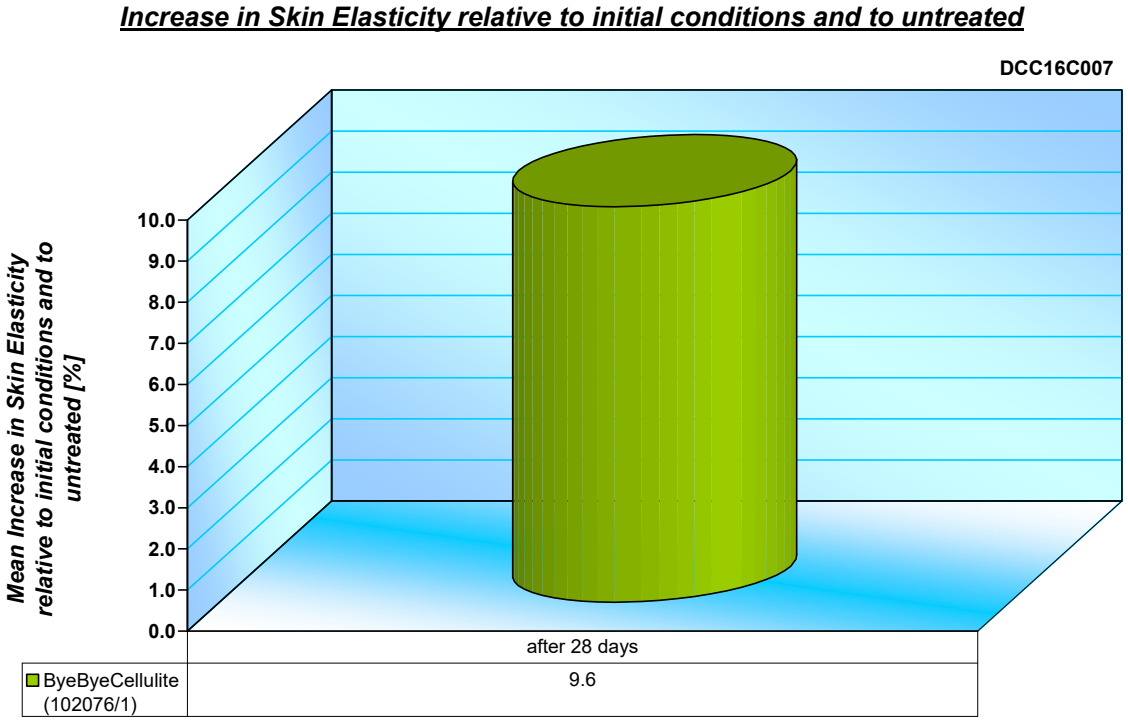


Fig. 7: Increase in Skin Elasticity in %

The test product was found not only to increase skin firmness, but at the same time to also increase skin elasticity. Overall, the test product induced a change in the biomechanical properties of the skin on the thigh towards the firm-elastic optimum.

Skin Roughness (Rz)

Evaluated are the changes in the parameter R_Z in the treated condition in comparison to the changes in the untreated condition. The absolute values by condition and time point are shown below in figure eight; the changes form the initial condition in figure nine. A decrease in R_Z corresponds to an increase in skin smoothness.

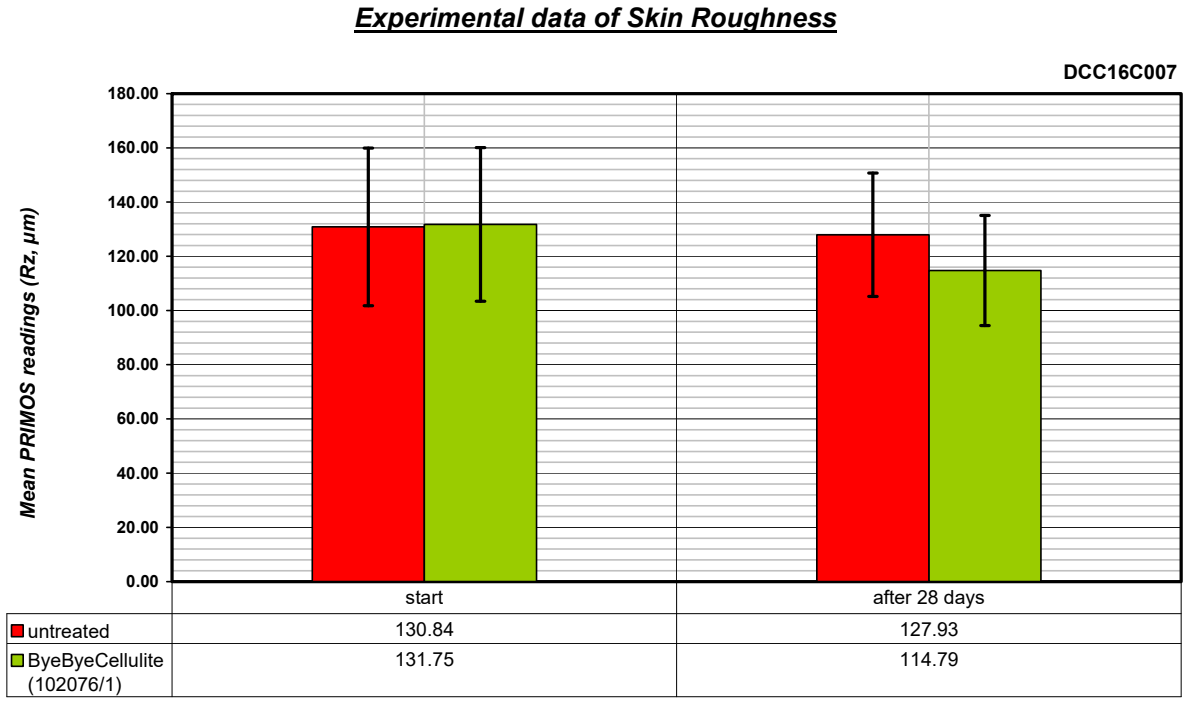


Fig. 8: R_Z Values

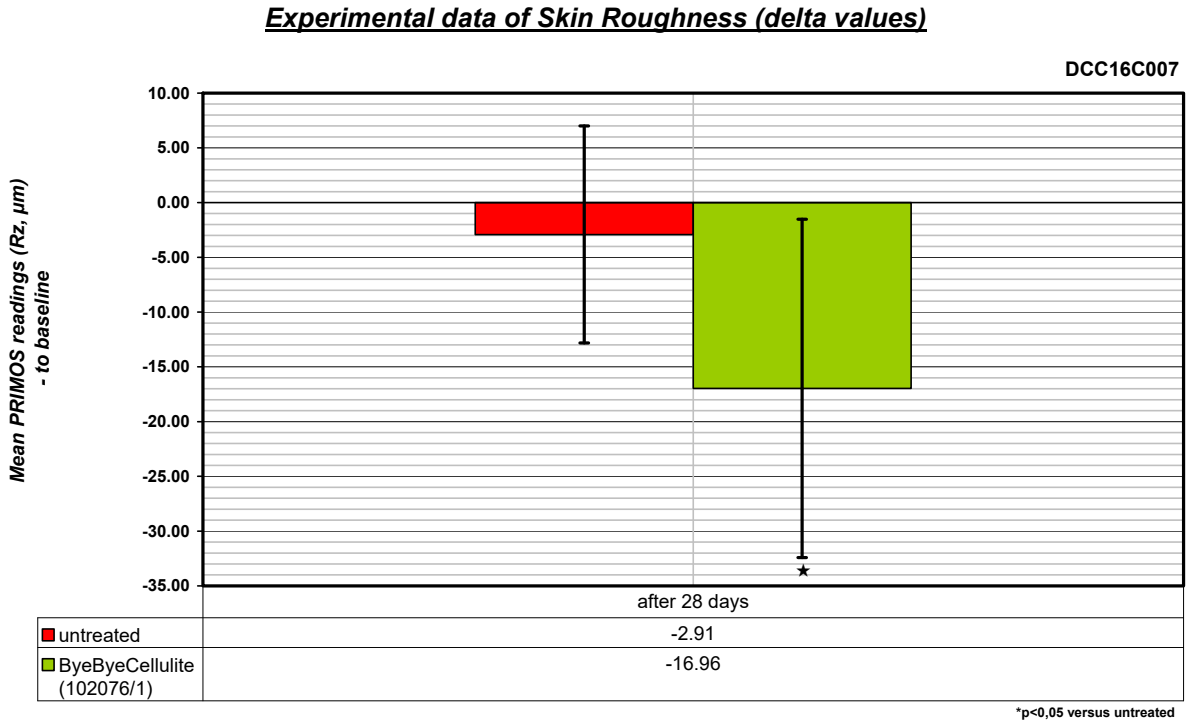


Fig. 9: ΔR_Z Values

After 28 days of treatment, a statistically significant ($p<0.05$) decrease in R_z was observed in the product treated test condition as compared to the changes in the untreated condition.
The test product was found to statistically significantly increase skin smoothness; after 28 days of treatment a positive effect could be detected in 90% of the study participants. The respective percentage changes as compared to the initial condition and with regard of the changes in the untreated area are shown in figure ten below.

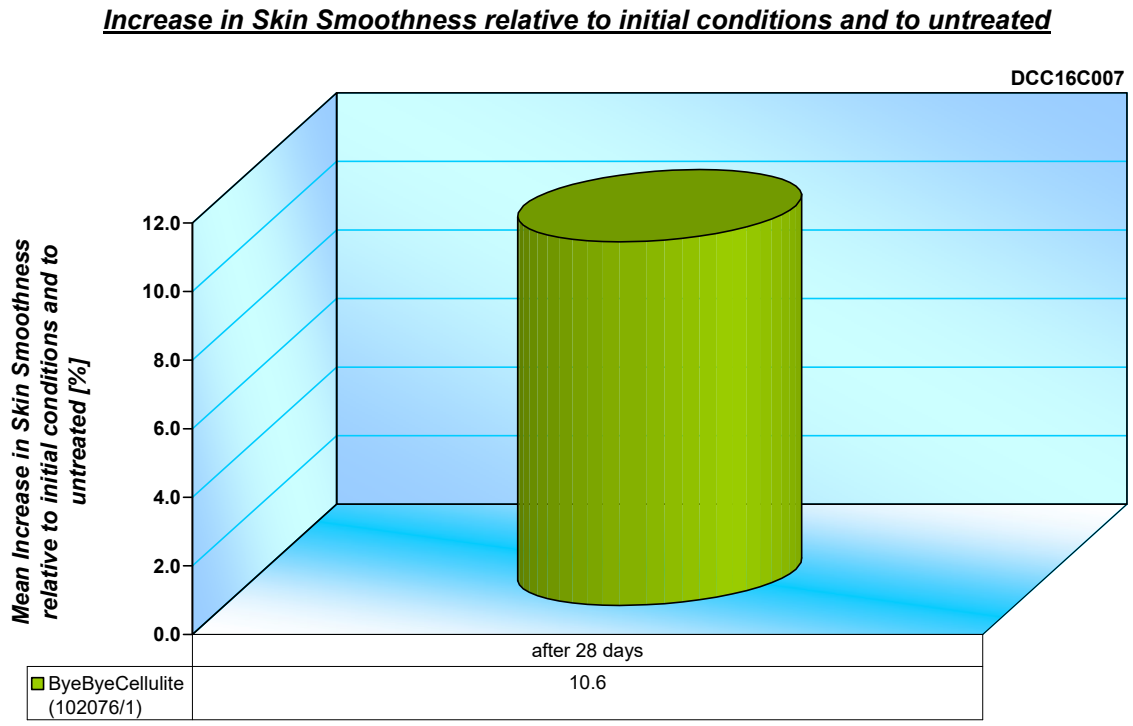


Fig. 10: Increase in Skin smoothness in %

Thigh Circumference

Evaluated are the changes in thigh circumference of the treated side as compared to the changes of the untreated side. The absolute values by condition and time point are shown below in figure eleven; the changes from the initial condition in figure twelve.
Use of the test product had no statistically significant effect on thigh circumference as compared to the changes in the untreated condition.

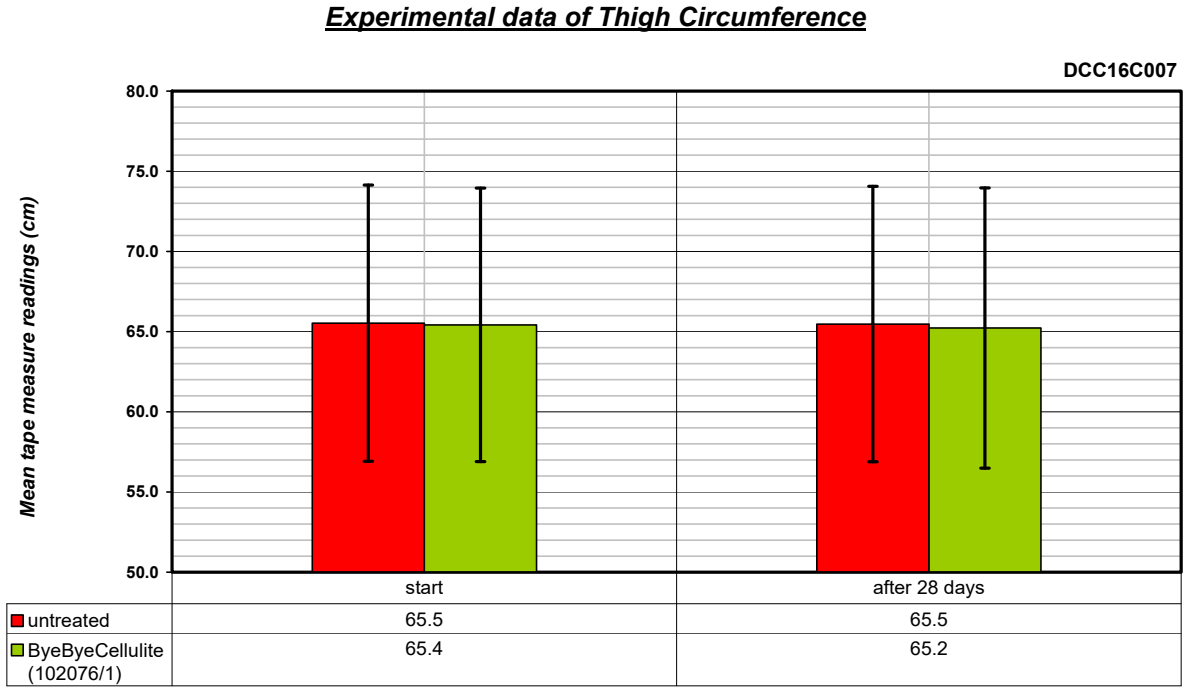


Fig. 11: Thigh Circumference

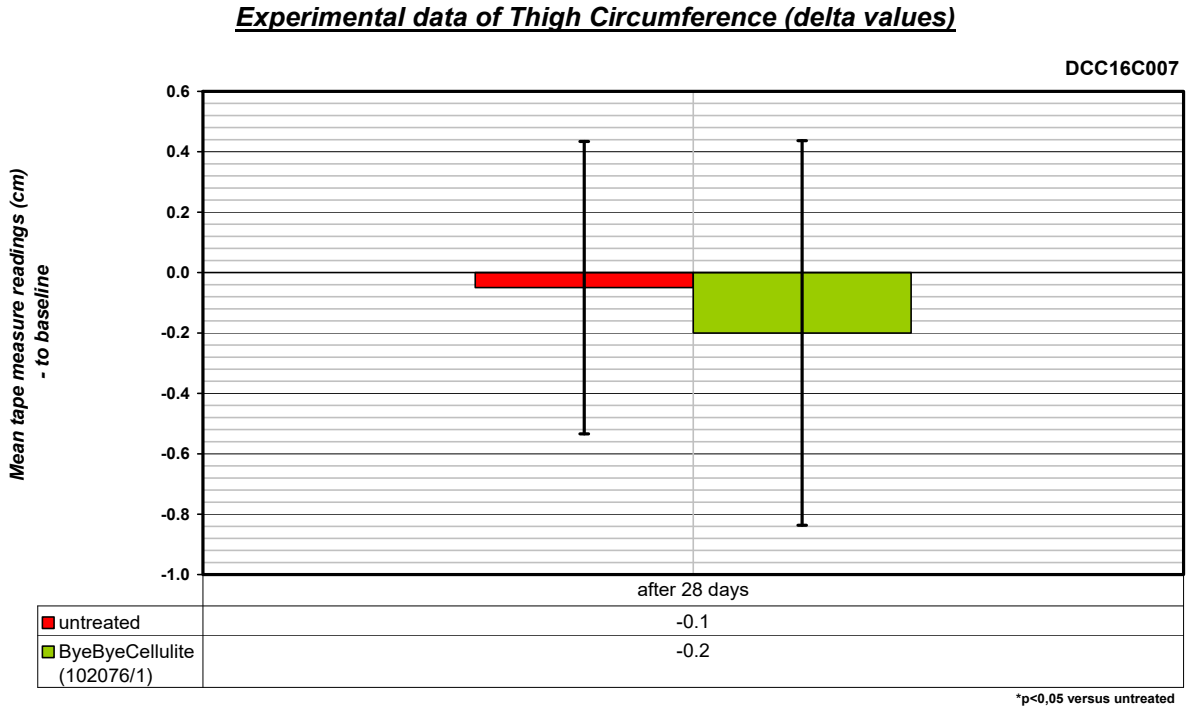


Fig. 12: Δ Thigh Circumference

Professional Scoring of Cellulite Symptoms

The level of cellulite symptoms (mean of both evaluators) was statistically significantly ($p<0,05$) reduced after 28 days of treatment in the test product treated side as compared to the untreated side. The average scores (5-point scale: 0-4) are shown below in figure thirteen; the changes from the initial condition in figure fourteen. After 28 days of treatment, a positive effect could be detected in 65% of the participants.

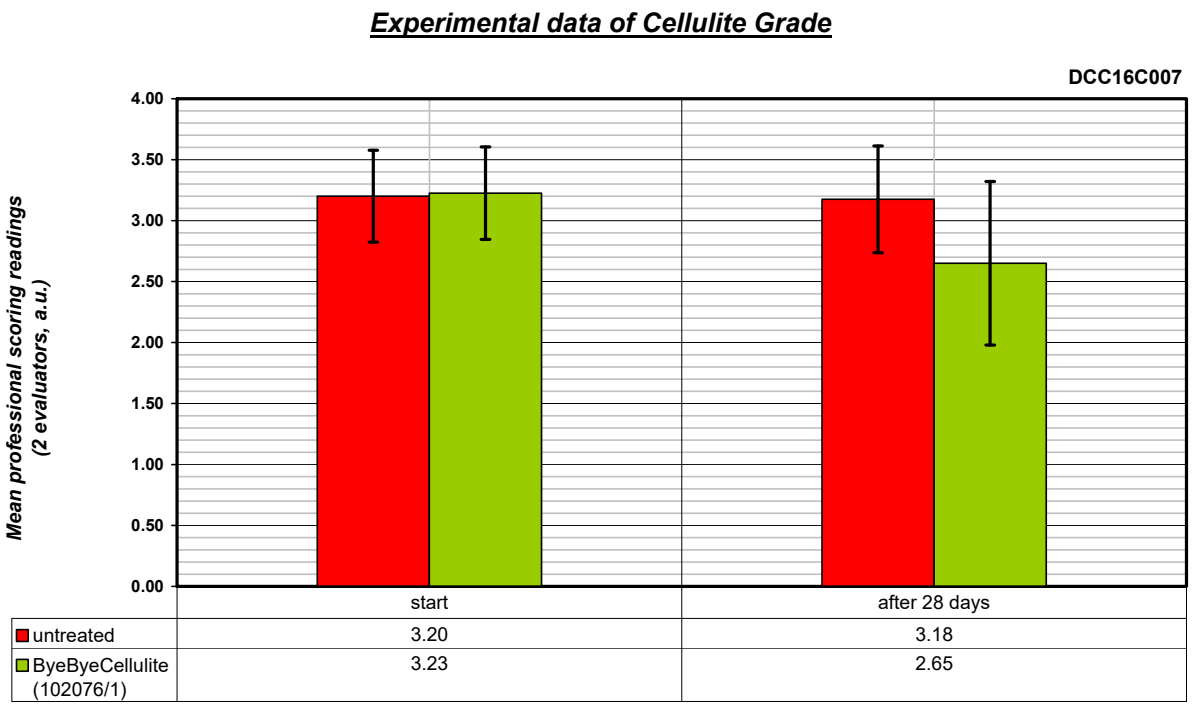


Fig. 13: Cellulite-Grade

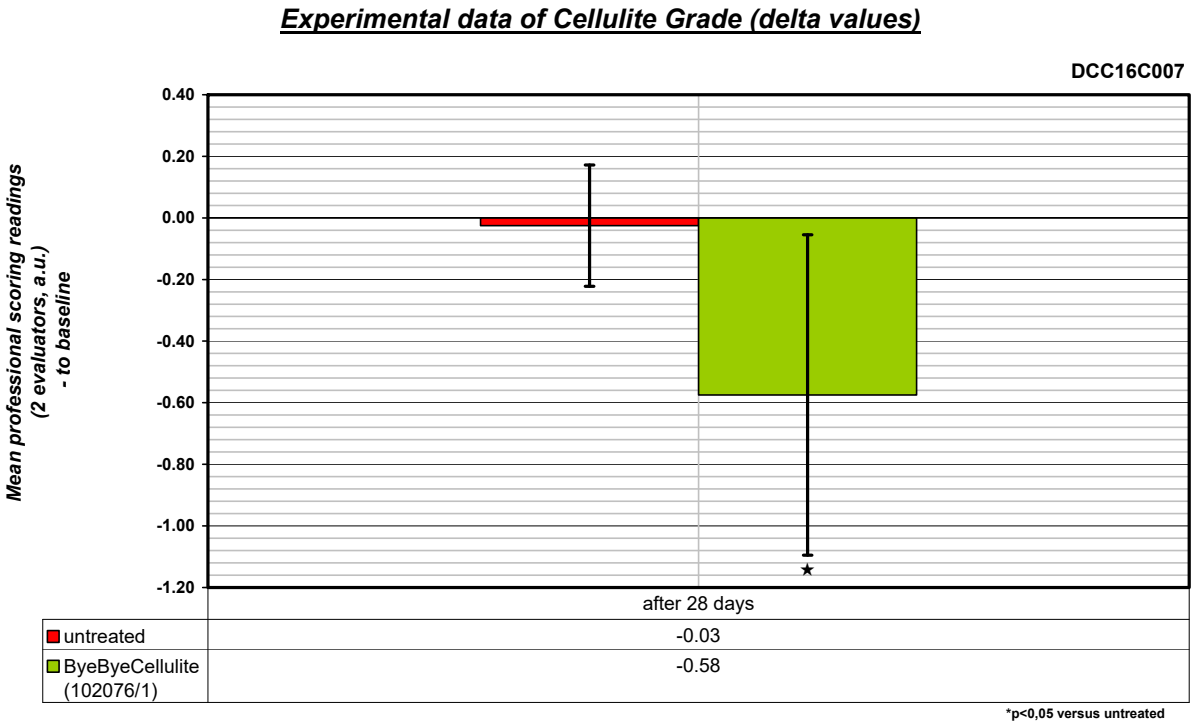


Fig. 14: Δ Cellulite-Grade

Incompatibility

Total three subjects reported discomfort exceeding the advised minor symptoms. Subject 2 reported about strong stinging sensations after the first three uses of test product, but agreed to continue application with a significantly reduced amount and was able to complete the study. Subject 11 reported about strong, but tolerable discomfort in the form of stinging, reddening and warmth after each application not affected by a reduction in the application amount, but decided to complete the full study. Original subject 16 (replaced by reserve subject) reported, after the second use of the test product, about strong reddening, stinging and feeling of warmth lasting for several hours; she first agreed to continue application with a significantly reduced amount, but decided to quit the study at the end of the first week of treatment.

Signature:

B. Nissen
Manager Derma Consult Concept

Signature:

Dr. med. H. Prieur
Dermatologist - Allergist

Enclosures:

Appendix I: Biomechanical properties – measurement values & statistical evaluation
Appendix II: Skin roughness – measurement values & statistical evaluation
Appendix III: Thigh circumference – measurement values & statistical evaluation
Appendix IV: Cellulite grade – scores & statistical evaluation
Appendix V: Subject Data

Appendix I

Biomechanical properties – measurement values & statistical evaluation

Experimental data of Skin Firmness, DCC16C007

Cutometer readings (f4)

	start		after 28 days	
	untr.	A	untr.	A
1	12.58	13.03	12.45	12.17
2	15.88	16.77	16.98	15.51
3	14.01	14.47	13.80	11.81
4	16.30	14.71	16.45	11.76
5	16.36	16.04	15.81	15.04
6	17.62	17.96	15.08	12.17
7	15.30	14.25	15.02	11.11
8	21.23	22.16	21.26	20.83
9	15.34	15.84	13.67	13.61
10	12.93	14.39	11.08	11.77
11	14.64	16.02	15.74	15.02
12	11.54	12.59	10.76	11.30
13	16.48	15.71	14.85	14.77
14	15.90	15.18	13.87	13.06
15	10.95	9.56	9.28	8.32
16	10.72	12.77	10.78	9.51
17	9.04	10.48	9.56	10.57
18	17.69	17.64	17.06	15.08
19	12.42	11.20	12.67	12.01
20	11.78	12.44	13.63	13.13
Average	14.44	14.66	13.99	12.93
S.D.	2.94	2.89	2.92	2.68
Median	14.97	14.59	13.84	12.17

Experimental data of Skin Firmness, DCC16C007

delta Cutometer readings (f4)

after 28 days

t1-t0

	untr.	A
1	-0.13	-0.86
2	1.10	-1.25
3	-0.20	-2.67
4	0.15	-2.95
5	-0.55	-0.99
6	-2.54	-5.79
7	-0.28	-3.14
8	0.03	-1.33
9	-1.67	-2.23
10	-1.85	-2.62
11	1.10	-1.00
12	-0.78	-1.29
13	-1.63	-0.93
14	-2.03	-2.12
15	-1.67	-1.23
16	0.05	-3.26
17	0.52	0.09
18	-0.63	-2.56
19	0.25	0.81
20	1.85	0.68
Average	-0.44	-1.73
S.D.	1.17	1.52
Median	-0.24	-1.31

Increase in Skin Firmness relative to initial conditions and to untreated, DCC16C007

corrected Cutometer readings (f4) [%]

after 28 days

	untr.	A
1	-1.0	-5.6
2	6.9	-14.4
3	-1.4	-17.0
4	0.9	-21.0
5	-3.3	-2.8
6	-14.4	-17.8
7	-1.8	-20.2
8	0.1	-6.1
9	-10.9	-3.1
10	-14.3	-3.9
11	7.5	-13.8
12	-6.8	-3.5
13	-9.9	4.0
14	-12.8	-1.2
15	-15.3	2.4
16	0.5	-26.0
17	5.8	-4.9
18	-3.6	-11.0
19	2.0	5.2
20	15.7	-10.2
Average	-2.8	-8.6
S.D.	8.4	8.8
Median	-1.6	-5.9
Impr.*	-	85

* % of subjects with relative improvement in test area as compared to initial condition and corrected by changes in untreated area

Descriptive Statistics of Skin Firmness, DCC16C007

start

	untr.	A
Valid cases	20.0	20.0
Mean	14.4	14.7
Std. error of mean	0.7	0.6
Variance	8.7	8.3
Std. Deviation	2.9	2.9
Variation Coefficient	0.2	0.2
Minimum	9.0	9.6
Maximum	21.2	22.2
Median	15.0	14.6

after 28 days

	untr.	A
Valid cases	20.0	20.0
Mean	14.0	12.9
Std. error of mean	0.7	0.6
Variance	8.5	7.2
Std. Deviation	2.9	2.7
Variation Coefficient	0.2	0.2
Minimum	9.3	8.3
Maximum	21.3	20.8
Median	13.8	12.2

Wilcoxon Rank Test of Skin Firmness, DCC16C007

start - comparison of absolute values

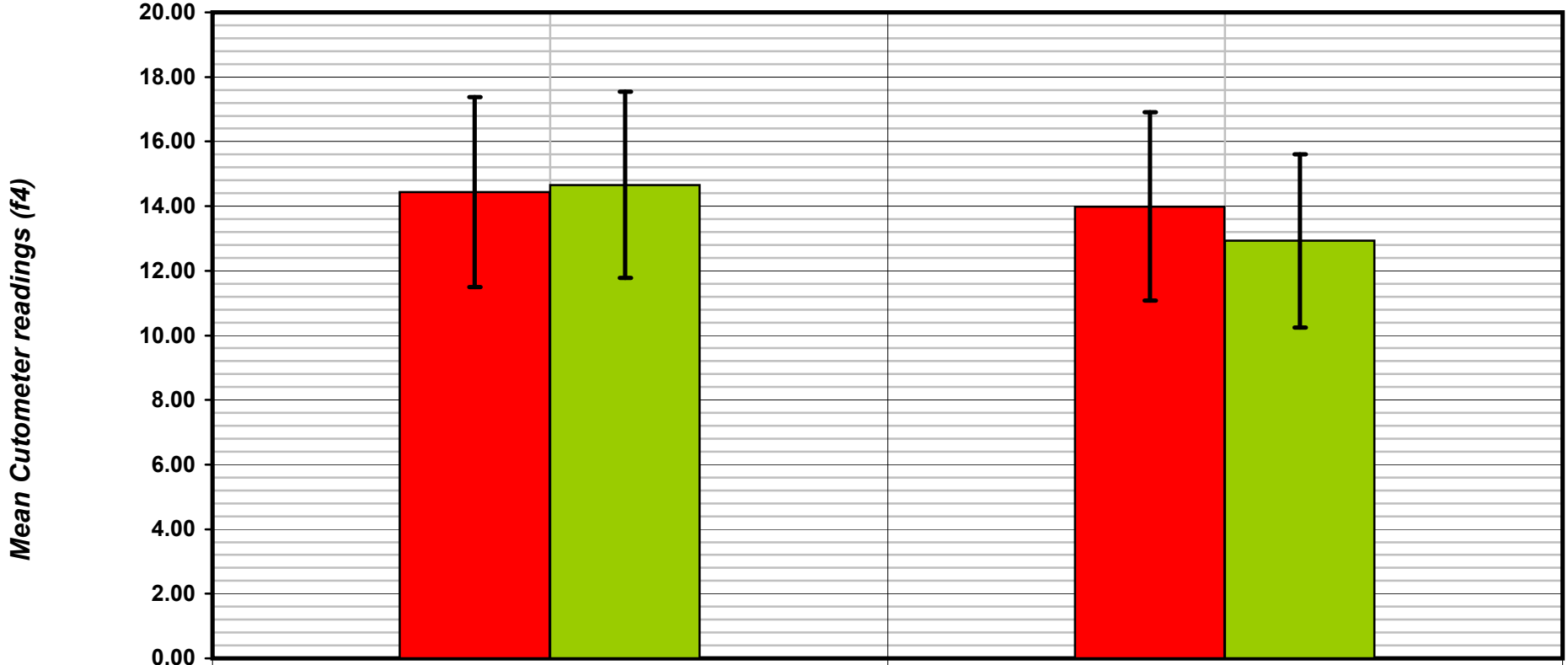
	untr. - A
Rank sum (positive)	82
Z-value	-0.8400
Significance	0.4091
non-zero observations	20

after 28 days - comparison of changes from initial condition

	untr. - A
Rank sum (positive)	192
Z-value	3.2293
Significance	0.0005
non-zero observations	20

Experimental data of Skin Firmness

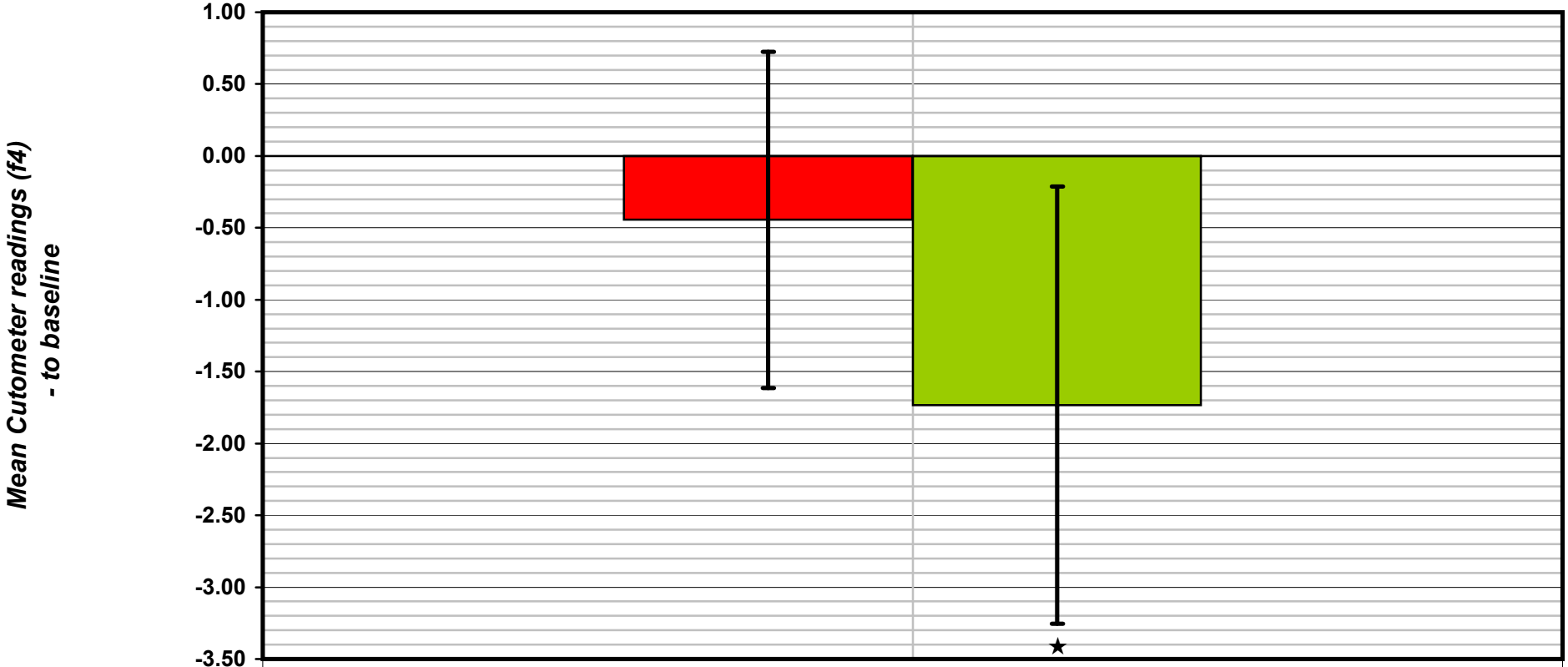
DCC16C007



	start	after 28 days
untreated	14.44	13.99
ByeByeCellulite (102076/1)	14.66	12.93

Experimental data of Skin Firmness (delta values)

DCC16C007

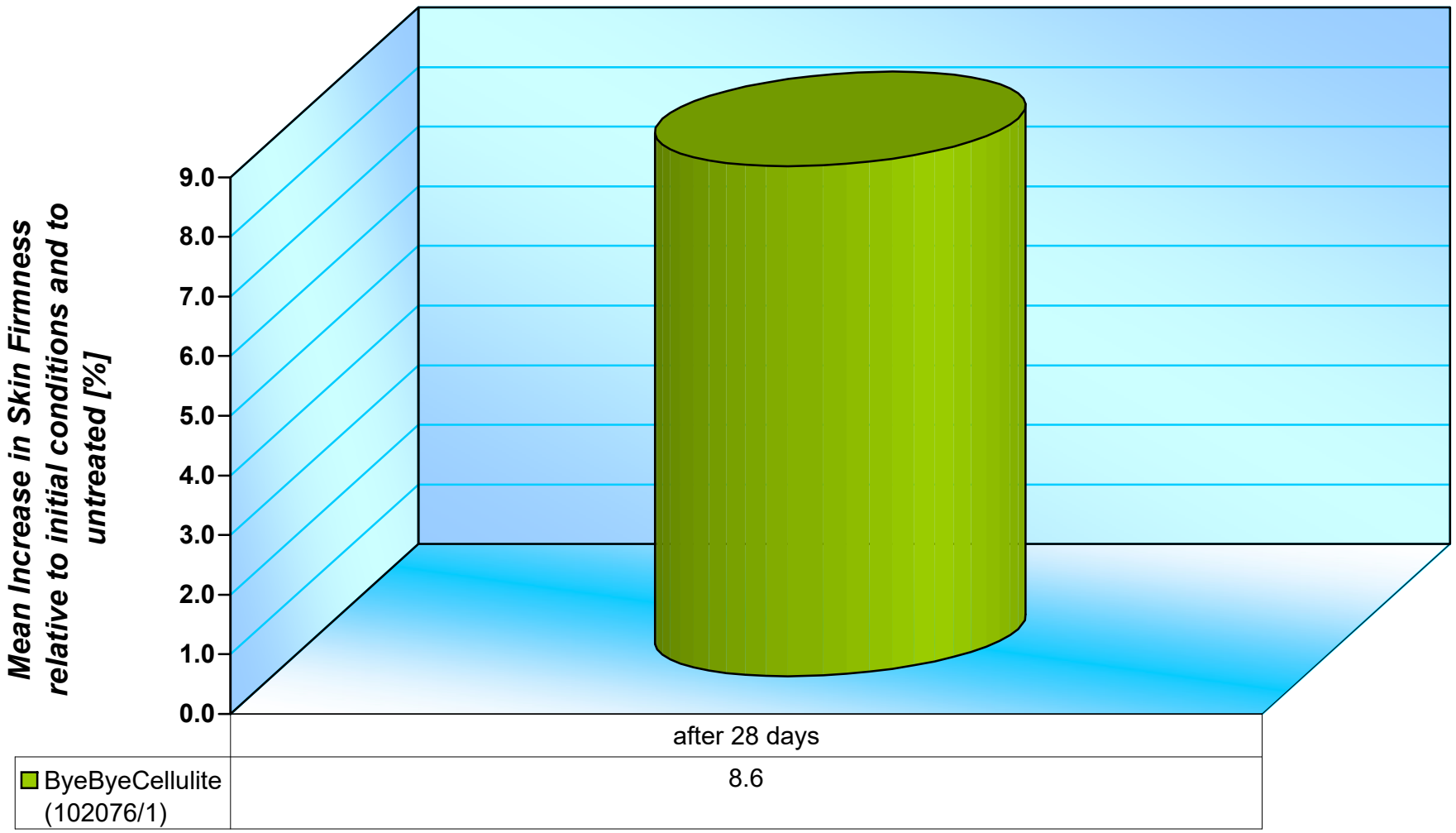


	after 28 days
untreated	-0.44
ByeByeCellulite (102076/1)	-1.73

***p<0,05 versus untreated**

Increase in Skin Firmness relative to initial conditions and to untreated

DCC16C007



Experimental data of Skin Elasticity, DCC16C007

Cutometer readings (f3/f4)

	start		after 28 days	
	untr.	A	untr.	A
1	0.67	0.71	0.74	0.75
2	0.70	0.74	0.62	0.80
3	0.71	0.65	0.74	0.80
4	0.69	0.62	0.68	0.71
5	0.66	0.74	0.75	0.84
6	0.49	0.51	0.54	0.62
7	0.77	0.70	0.74	0.76
8	0.70	0.74	0.68	0.78
9	0.78	0.76	0.76	0.75
10	0.56	0.69	0.61	0.81
11	0.63	0.69	0.69	0.77
12	0.85	0.79	0.82	0.86
13	0.80	0.76	0.76	0.81
14	0.69	0.71	0.72	0.72
15	0.66	0.60	0.59	0.72
16	0.77	0.76	0.75	0.80
17	0.72	0.68	0.66	0.70
18	0.75	0.76	0.71	0.80
19	0.83	0.72	0.79	0.74
20	0.80	0.83	0.78	0.91
Average	0.71	0.71	0.71	0.77
S.D.	0.09	0.07	0.07	0.06
Median	0.71	0.72	0.73	0.78

Experimental data of Skin Elasticity, DCC16C007

delta Cutometer readings (f3/f4)

after 28 days

t1-t0

	untr.	A
1	**0.07**	**0.03**
2	**-0.08**	**0.06**
3	**0.02**	**0.15**
4	**-0.01**	**0.09**
5	**0.09**	**0.10**
6	**0.05**	**0.11**
7	**-0.03**	**0.06**
8	**-0.03**	**0.04**
9	**-0.03**	**-0.01**
10	**0.06**	**0.11**
11	**0.06**	**0.08**
12	**-0.03**	**0.07**
13	**-0.04**	**0.05**
14	**0.03**	**0.01**
15	**-0.06**	**0.12**
16	**-0.03**	**0.05**
17	**-0.05**	**0.01**
18	**-0.04**	**0.04**
19	**-0.03**	**0.02**
20	**-0.01**	**0.08**
Average	**-0.01**	**0.06**
S.D.	**0.05**	**0.04**
Median	**-0.03**	**0.06**

Increase in Skin Elasticity relative to initial conditions and to untreated, DCC16C007

corrected Cutometer readings (f3/f4) [%]

after 28 days

	untr.	A
1	9.9	-5.4
2	-11.2	19.7
3	3.1	19.7
4	-2.1	16.3
5	12.9	0.7
6	10.5	10.0
7	-4.4	12.5
8	-4.0	9.7
9	-3.2	2.0
10	10.2	6.3
11	9.1	2.6
12	-3.4	11.9
13	-4.7	11.6
14	4.3	-2.3
15	-9.8	29.8
16	-3.4	9.5
17	-7.4	9.5
18	-5.3	10.1
19	-4.1	7.1
20	-1.6	11.1
Average	-0.2	9.6
S.D.	7.3	8.1
Median	-3.3	9.9
Impr.*	-	90

* % of subjects with relative improvement in test area as compared to initial condition and corrected by changes in untreated area

Descriptive Statistics of Skin Elasticity, DCC16C007

start

	untr.	A
Valid cases	20.0	20.0
Mean	0.7	0.7
Std. error of mean	0.0	0.0
Variance	0.0	0.0
Std. Deviation	0.1	0.1
Variation Coefficient	0.1	0.1
Minimum	0.5	0.5
Maximum	0.8	0.8
Median	0.7	0.7

after 28 days

	untr.	A
Valid cases	20.0	20.0
Mean	0.7	0.8
Std. error of mean	0.0	0.0
Variance	0.0	0.0
Std. Deviation	0.1	0.1
Variation Coefficient	0.1	0.1
Minimum	0.5	0.6
Maximum	0.8	0.9
Median	0.7	0.8

Wilcoxon Rank Test of Skin Elasticity, DCC16C007

start - comparison of absolute values

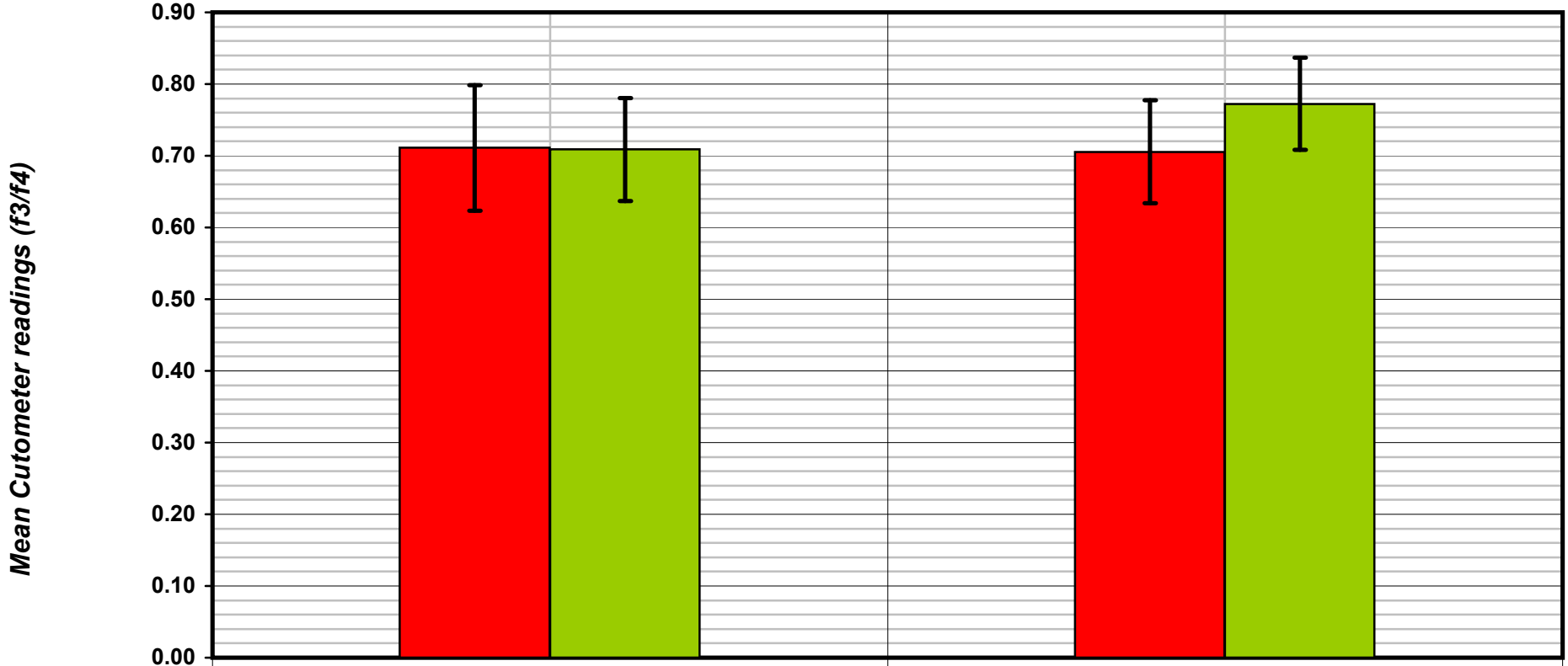
	untr. - A
Rank sum (positive)	113
Z-value	0.2800
Significance	0.7841
non-zero observations	20

after 28 days - comparison of changes from initial condition

	untr. - A
Rank sum (positive)	7
Z-value	-3.6399
Significance	0.0000
non-zero observations	20

Experimental data of Skin Elasticity

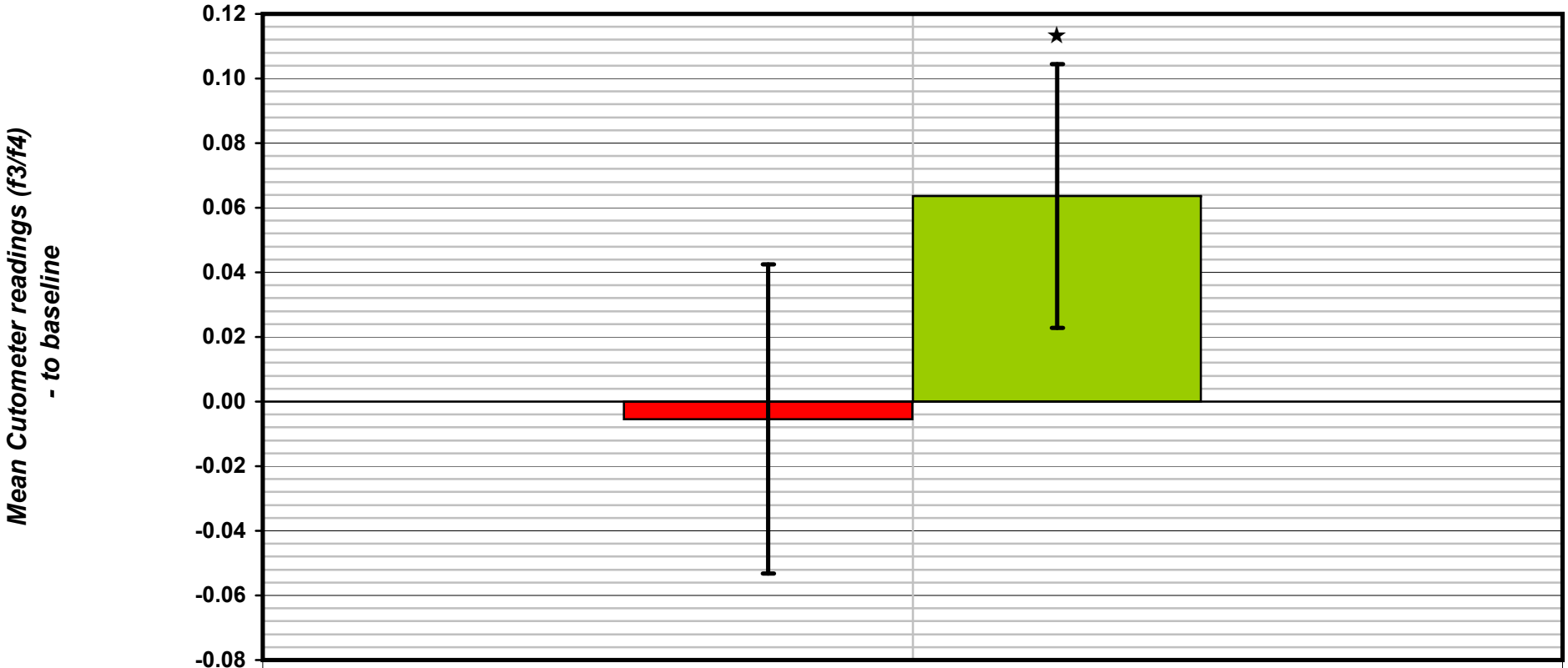
DCC16C007



	start	after 28 days
untreated	0.71	0.71
ByeByeCellulite (102076/1)	0.71	0.77

Experimental data of Skin Elasticity (delta values)

DCC16C007

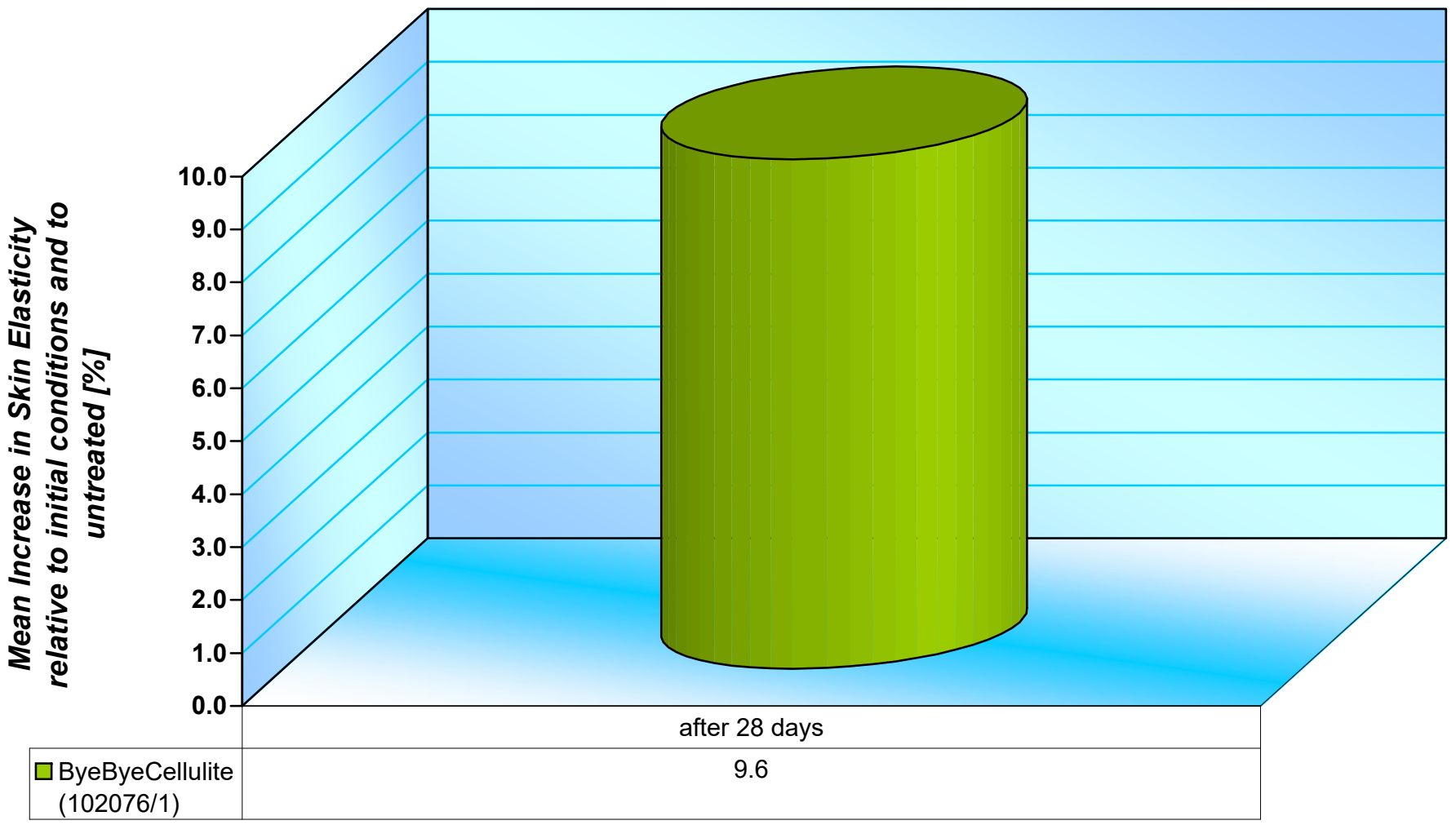


	after 28 days
untreated	-0.01
ByeByeCellulite (102076/1)	0.06

***p<0,05 versus untreated**

Increase in Skin Elasticity relative to initial conditions and to untreated

DCC16C007



Appendix II

Skin roughness – measurement values & statistical evaluation

Experimental data of Skin Roughness, DCC16C007

PRIMOS readings (Rz, µm)

	start		after 28 days	
	untr.	A	untr.	A
1	137.48	137.15	143.41	124.36
2	90.68	91.94	101.53	80.61
3	172.98	162.64	162.09	127.76
4	102.56	115.00	107.34	101.25
5	96.89	92.23	93.85	88.15
6	170.73	180.94	161.59	147.60
7	160.23	155.99	153.44	161.46
8	119.06	119.76	122.42	112.45
9	111.72	129.61	107.16	115.11
10	160.57	176.21	145.34	137.12
11	148.02	157.20	129.36	108.54
12	90.41	91.15	94.53	96.18
13	110.82	117.95	113.86	106.19
14	103.84	103.46	110.30	84.54
15	140.79	124.80	137.99	116.26
16	135.44	133.39	123.30	120.81
17	99.88	105.25	104.99	108.69
18	129.67	121.54	143.82	107.19
19	169.62	164.39	151.63	126.33
20	165.49	154.42	150.72	125.13
Average	130.84	131.75	127.93	114.79
S.D.	29.08	28.35	22.76	20.30
Median	132.56	127.21	126.33	113.78

Experimental data of Skin Roughness, DCC16C007

delta PRIMOS readings (Rz, µm)

after 28 days

t1-t0

	untr.	A
1	**5.93**	**-12.79**
2	**10.85**	**-11.33**
3	**-10.89**	**-34.88**
4	**4.78**	**-13.75**
5	**-3.04**	**-4.08**
6	**-9.14**	**-33.34**
7	**-6.79**	**5.47**
8	**3.36**	**-7.31**
9	**-4.56**	**-14.50**
10	**-15.23**	**-39.09**
11	**-18.66**	**-48.66**
12	**4.12**	**5.03**
13	**3.04**	**-11.76**
14	**6.46**	**-18.92**
15	**-2.80**	**-8.54**
16	**-12.14**	**-12.58**
17	**5.11**	**3.44**
18	**14.15**	**-14.35**
19	**-17.99**	**-38.06**
20	**-14.77**	**-29.29**
Average	**-2.91**	**-16.96**
S.D.	**9.91**	**15.45**
Median	**-2.92**	**-13.27**

Increase in Skin Smoothness relative to initial conditions and to untreated, DCC16C007

corrected PRIMOS readings (Rz, µm) [%]

after 28 days

	untr.	A
1	**4.3**	**-13.6**
2	**12.0**	**-24.3**
3	**-6.3**	**-15.2**
4	**4.7**	**-16.6**
5	**-3.1**	**-1.3**
6	**-5.4**	**-13.1**
7	**-4.2**	**7.7**
8	**2.8**	**-8.9**
9	**-4.1**	**-7.1**
10	**-9.5**	**-12.7**
11	**-12.6**	**-18.3**
12	**4.6**	**1.0**
13	**2.7**	**-12.7**
14	**6.2**	**-24.5**
15	**-2.0**	**-4.9**
16	**-9.0**	**-0.5**
17	**5.1**	**-1.8**
18	**10.9**	**-22.7**
19	**-10.6**	**-12.5**
20	**-8.9**	**-10.0**
Average	**-1.1**	**-10.6**
S.D.	**7.3**	**8.8**
Median	**-2.6**	**-12.6**
Impr.*	**-**	**90**

* % of subjects with relative improvement in test area as compared to initial condition and corrected by changes in untreated area

Descriptive Statistics of Skin Roughness, DCC16C007

start

	untr.	A
Valid cases	20.0	20.0
Mean	130.8	131.8
Std. error of mean	6.5	6.3
Variance	845.9	803.5
Std. Deviation	29.1	28.3
Variation Coefficient	0.2	0.2
Minimum	90.4	91.2
Maximum	173.0	180.9
Median	132.6	127.2

after 28 days

	untr.	A
Valid cases	20.0	20.0
Mean	127.9	114.8
Std. error of mean	5.1	4.5
Variance	518.2	412.0
Std. Deviation	22.8	20.3
Variation Coefficient	0.2	0.2
Minimum	93.9	80.6
Maximum	162.1	161.5
Median	126.3	113.8

Wilcoxon Rank Test of Skin Roughness, DCC16C007

start - comparison of absolute values

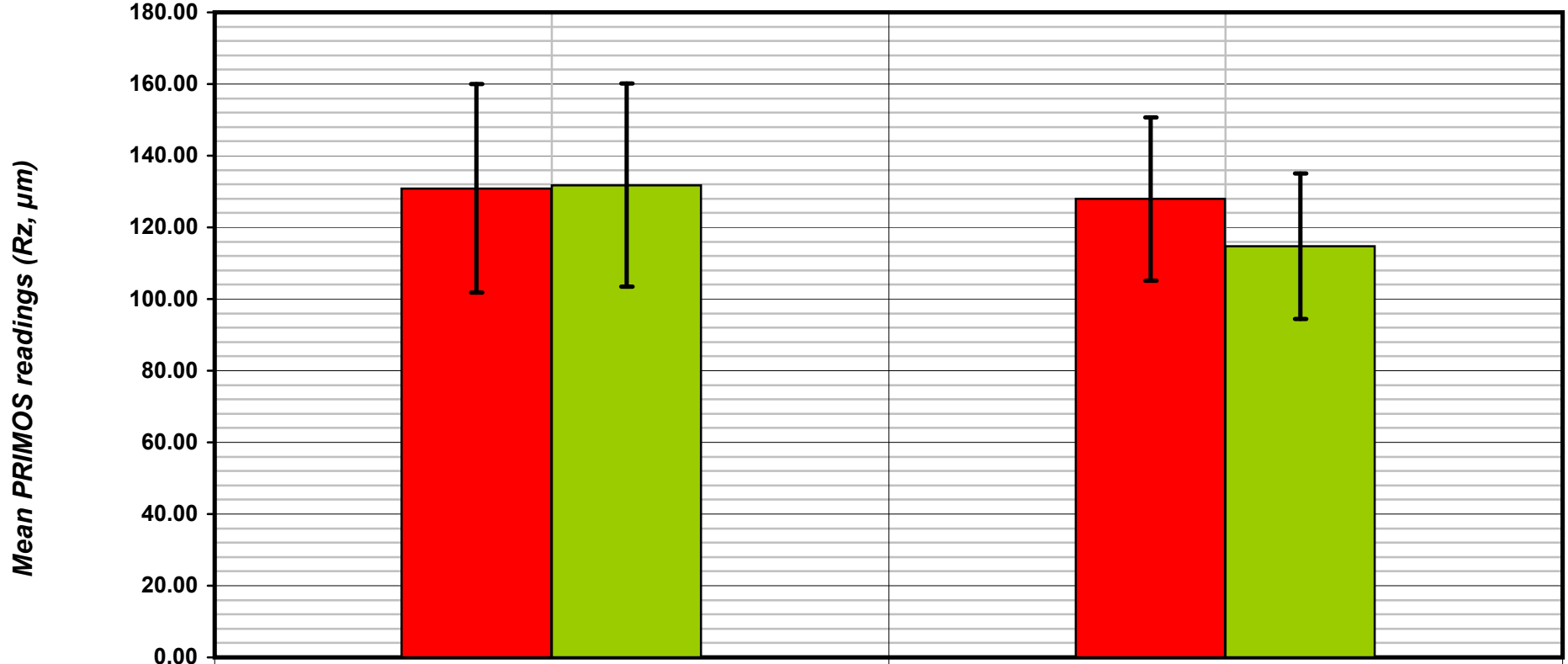
	untr. - A
Rank sum (positive)	95
Z-value	-0.3547
Significance	0.7285
non-zero observations	20

after 28 days - comparison of changes from initial condition

	untr. - A
Rank sum (positive)	200
Z-value	3.5279
Significance	0.0001
non-zero observations	20

Experimental data of Skin Roughness

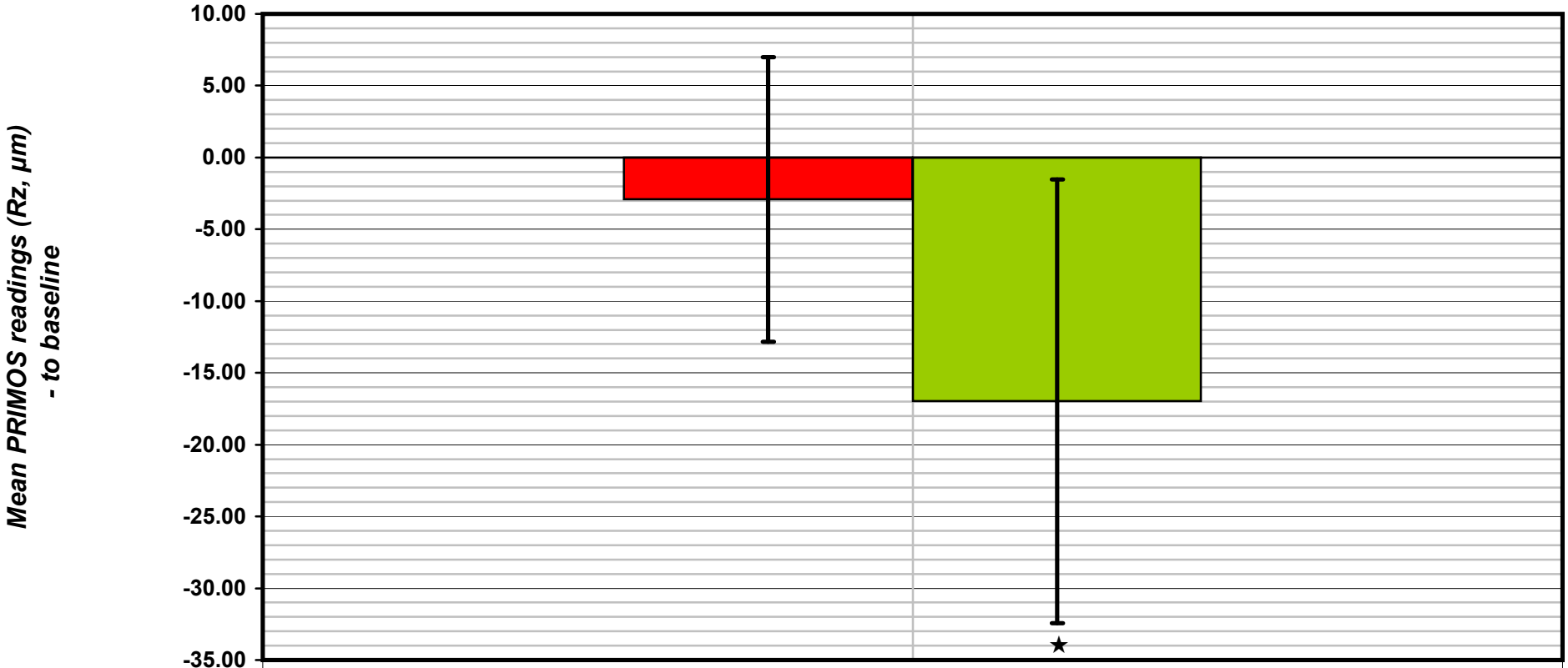
DCC16C007



	start	after 28 days
untreated	130.84	127.93
ByeByeCellulite (102076/1)	131.75	114.79

Experimental data of Skin Roughness (delta values)

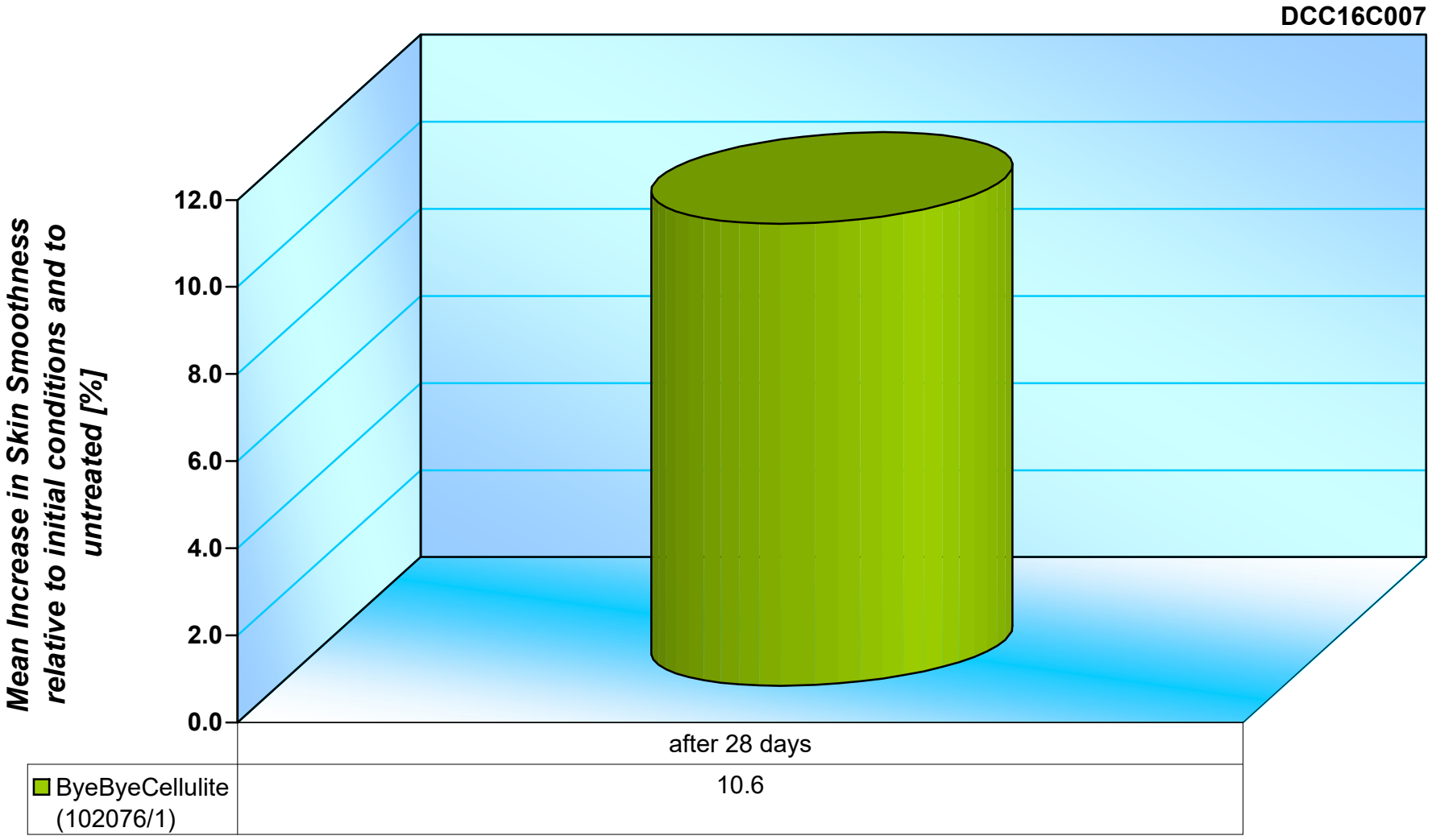
DCC16C007



	after 28 days
untreated	-2.91
ByeByeCellulite (102076/1)	-16.96

***p<0,05 versus untreated**

Increase in Skin Smoothness relative to initial conditions and to untreated



Appendix III

Thigh circumference – measurement values & statistical evaluation

Experimental data of Thigh Circumference, DCC16C007

tape measure readings (cm)

	start		after 28 days	
	untr.	A	untr.	A
1	55.5	54.5	55.0	53.5
2	56.5	56.5	56.5	56.5
3	61.0	61.0	60.0	60.0
4	63.0	63.0	63.0	63.0
5	77.5	77.0	77.0	77.0
6	50.0	50.0	50.0	50.0
7	56.0	56.0	56.0	55.5
8	63.0	63.0	63.0	62.5
9	66.5	67.0	67.5	67.0
10	64.5	64.5	64.5	65.0
11	72.0	72.0	71.5	71.0
12	67.5	67.0	67.0	65.5
13	79.0	79.0	79.0	79.0
14	61.0	61.5	61.0	61.5
15	58.0	58.5	59.0	58.5
16	80.0	79.0	80.0	80.5
17	70.0	70.0	70.0	70.0
18	64.5	64.0	64.0	64.0
19	66.0	66.0	66.5	65.5
20	79.0	79.0	79.0	79.0
Average	65.5	65.4	65.5	65.2
S.D.	8.6	8.5	8.6	8.7
Median	64.5	64.3	64.3	64.5

Experimental data of Thigh Circumference, DCC16C007

delta tape measure readings (cm)

after 28 days

t1-t0

	untr.	A
1	**-0.5**	**-1.0**
2	**0.0**	**0.0**
3	**-1.0**	**-1.0**
4	**0.0**	**0.0**
5	**-0.5**	**0.0**
6	**0.0**	**0.0**
7	**0.0**	**-0.5**
8	**0.0**	**-0.5**
9	**1.0**	**0.0**
10	**0.0**	**0.5**
11	**-0.5**	**-1.0**
12	**-0.5**	**-1.5**
13	**0.0**	**0.0**
14	**0.0**	**0.0**
15	**1.0**	**0.0**
16	**0.0**	**1.5**
17	**0.0**	**0.0**
18	**-0.5**	**0.0**
19	**0.5**	**-0.5**
20	**0.0**	**0.0**
Average	**-0.1**	**-0.2**
S.D.	**0.5**	**0.6**
Median	**0.0**	**0.0**
Impr.*	**-**	**40**

* % of subjects with relative improvement in test area as compared to initial condition and corrected by changes in untreated area

Descriptive Statistics of Thigh Circumference, DCC16C007

start

	untr.	A
Valid cases	20.0	20.0
Mean	65.5	65.4
Std. error of mean	1.9	1.9
Variance	74.2	72.6
Std. Deviation	8.6	8.5
Variation Coefficient	0.1	0.1
Minimum	50.0	50.0
Maximum	80.0	79.0
Median	64.5	64.3

after 28 days

	untr.	A
Valid cases	20.0	20.0
Mean	65.5	65.2
Std. error of mean	1.9	2.0
Variance	73.7	76.4
Std. Deviation	8.6	8.7
Variation Coefficient	0.1	0.1
Minimum	50.0	50.0
Maximum	80.0	80.5
Median	64.3	64.5

Wilcoxon Rank Test of Thigh Circumference, DCC16C007

start - comparison of absolute values

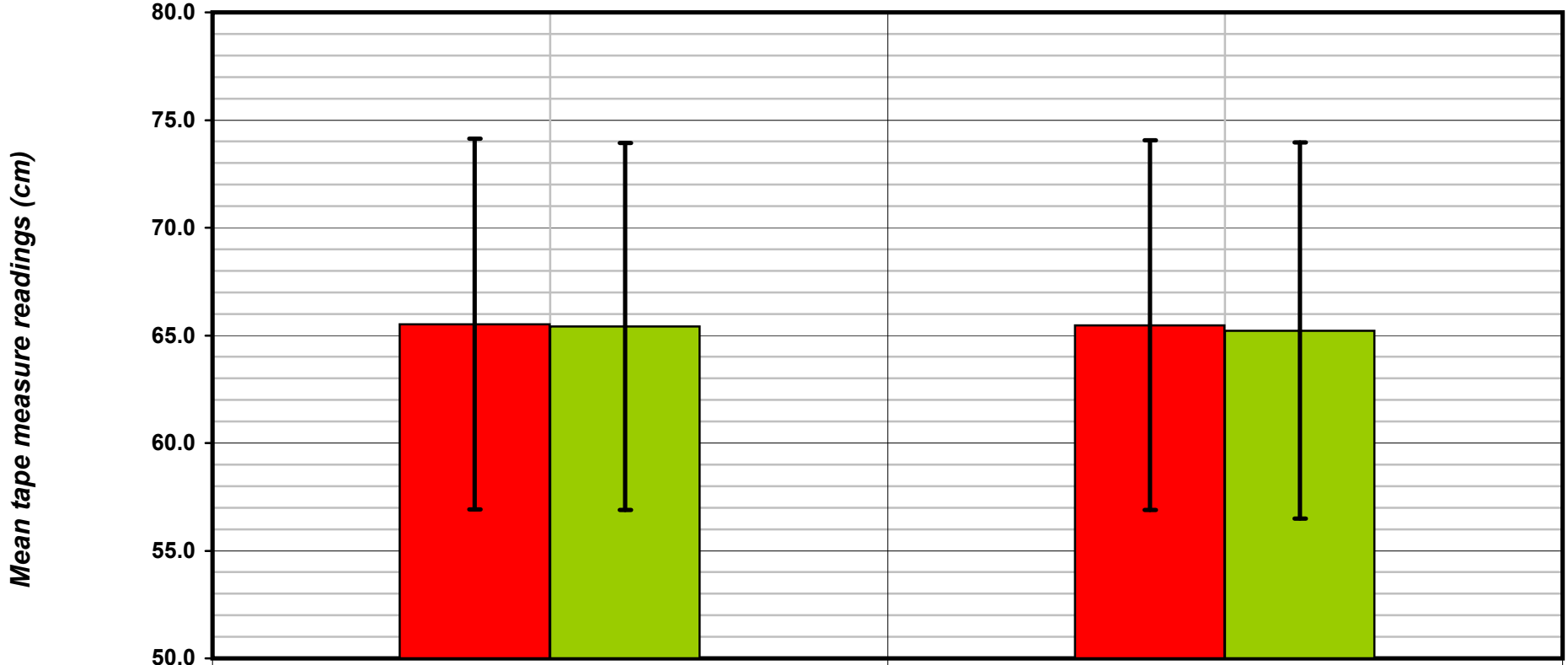
	untr. - A
Rank sum (positive)	25.5
Z-value	1.0265
Significance	0.3438
non-zero observations	8

after 28 days - comparison of changes from initial condition

	untr. - A
Rank sum (positive)	54
Z-value	1.1675
Significance	0.2437
non-zero observations	12

Experimental data of Thigh Circumference

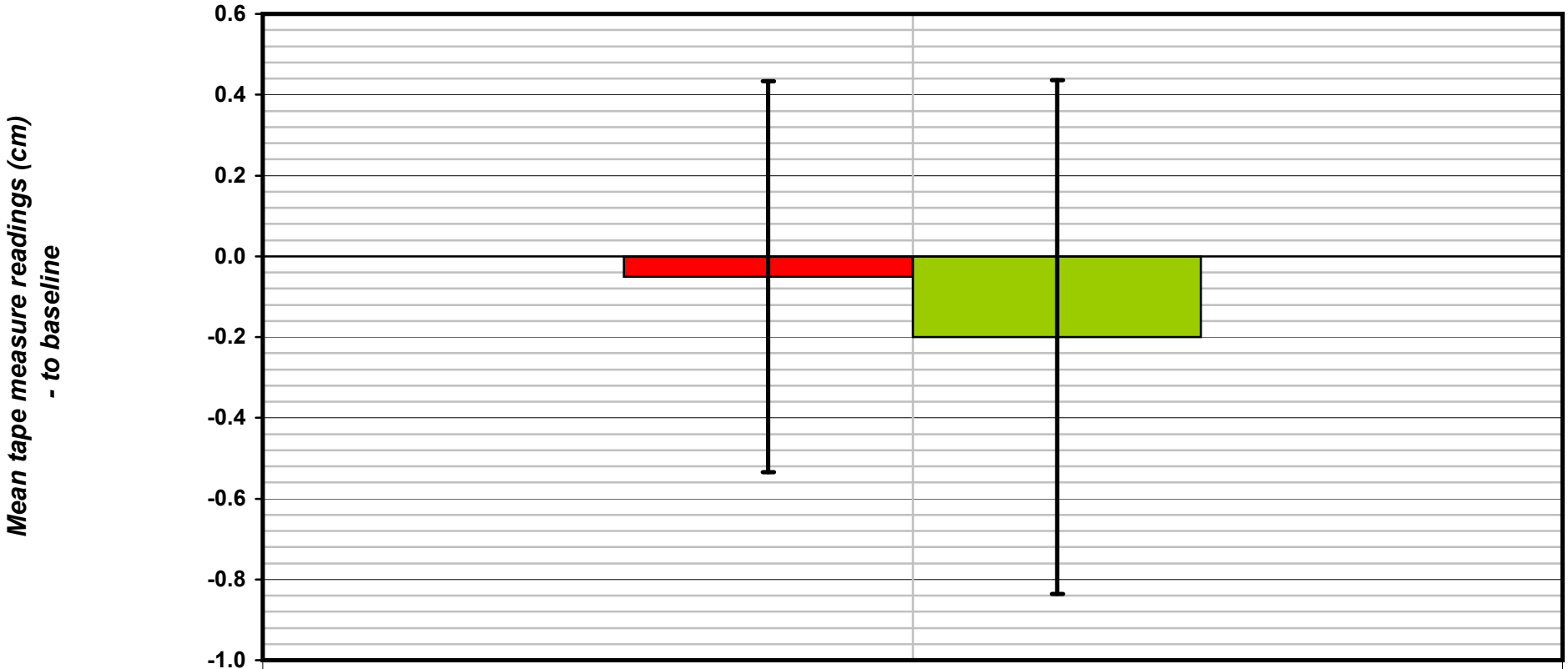
DCC16C007



	start	after 28 days
untreated	65.5	65.5
ByeByeCellulite (102076/1)	65.4	65.2

Experimental data of Thigh Circumference (delta values)

DCC16C007



	after 28 days
untreated	-0.1
ByeByeCellulite (102076/1)	-0.2

***p<0,05 versus untreated**

Appendix IV

Cellulite grade – scores & statistical evaluation

Experimental data of Cellulite Grade, DCC16C007

professional scoring readings (2 evaluators, a.u.)

	start		after 28 days	
	untr.	A	untr.	A
1	3.0	3.0	3.0	2.0
2	3.0	3.0	3.0	1.5
3	3.0	3.0	3.0	3.0
4	3.0	3.0	3.0	2.0
5	3.0	3.0	3.0	2.5
6	3.0	3.0	3.0	2.0
7	4.0	4.0	4.0	3.0
8	4.0	4.0	4.0	4.0
9	3.0	3.0	3.0	3.0
10	3.0	3.0	3.0	2.0
11	3.0	3.0	2.5	2.0
12	3.5	3.5	3.0	3.0
13	3.0	3.0	3.0	3.0
14	3.0	3.5	3.0	3.0
15	3.0	3.0	3.0	3.0
16	3.0	3.0	3.0	2.5
17	3.5	3.5	4.0	4.0
18	3.0	3.0	3.0	2.0
19	4.0	4.0	4.0	3.0
20	3.0	3.0	3.0	2.5
Average	3.20	3.23	3.18	2.65
S.D.	0.38	0.38	0.44	0.67
Median	3.00	3.00	3.00	2.75

Grading Scale

0 = no signs

1 = slight dimpling of skin surface

2 = dimpling and skin depressions

3 = dimpling and depressed striations

4 = palpable nodules and striations

Experimental data of Cellulite Grade, DCC16C007

delta professional scoring readings (2 evaluators, a.u.)

after 28 days

t1-t0

	untr.	A
1	0.0	-1.0
2	0.0	-1.5
3	0.0	0.0
4	0.0	-1.0
5	0.0	-0.5
6	0.0	-1.0
7	0.0	-1.0
8	0.0	0.0
9	0.0	0.0
10	0.0	-1.0
11	-0.5	-1.0
12	-0.5	-0.5
13	0.0	0.0
14	0.0	-0.5
15	0.0	0.0
16	0.0	-0.5
17	0.5	0.5
18	0.0	-1.0
19	0.0	-1.0
20	0.0	-0.5
Average	**-0.03**	**-0.58**
S.D.	**0.20**	**0.52**
Median	**0.00**	**-0.50**
Impr.*	**-**	**65**

* % of subjects with relative improvement in test area as compared to initial condition and corrected by changes in untreated area

Descriptive Statistics of Cellulite Grade, DCC16C007

start

	untr.	A
Valid cases	20.0	20.0
Mean	3.2	3.2
Std. error of mean	0.1	0.1
Variance	0.1	0.1
Std. Deviation	0.4	0.4
Variation Coefficient	0.1	0.1
Minimum	3.0	3.0
Maximum	4.0	4.0
Median	3.0	3.0

after 28 days

	untr.	A
Valid cases	20.0	20.0
Mean	3.2	2.7
Std. error of mean	0.1	0.2
Variance	0.2	0.5
Std. Deviation	0.4	0.7
Variation Coefficient	0.1	0.3
Minimum	2.5	1.5
Maximum	4.0	4.0
Median	3.0	2.8

Wilcoxon Rank Test of Cellulite Grade, DCC16C007

start - comparison of absolute values

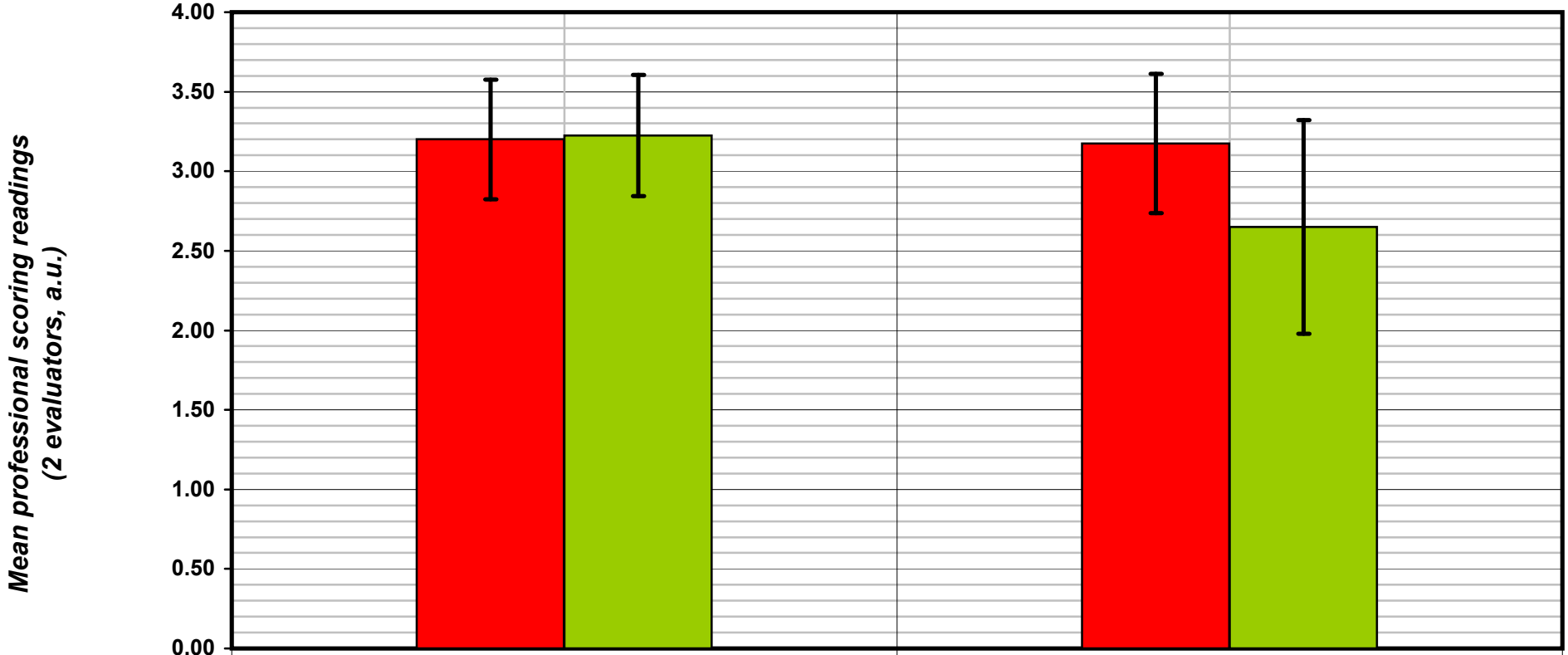
	untr. - A
Rank sum (positive)	0
Z-value	0.0000
Significance	1.0000
non-zero observations	1

after 28 days - comparison of changes from initial condition

	untr. - A
Rank sum (positive)	91
Z-value	3.2205
Significance	0.0002
non-zero observations	13

Experimental data of Cellulite Grade

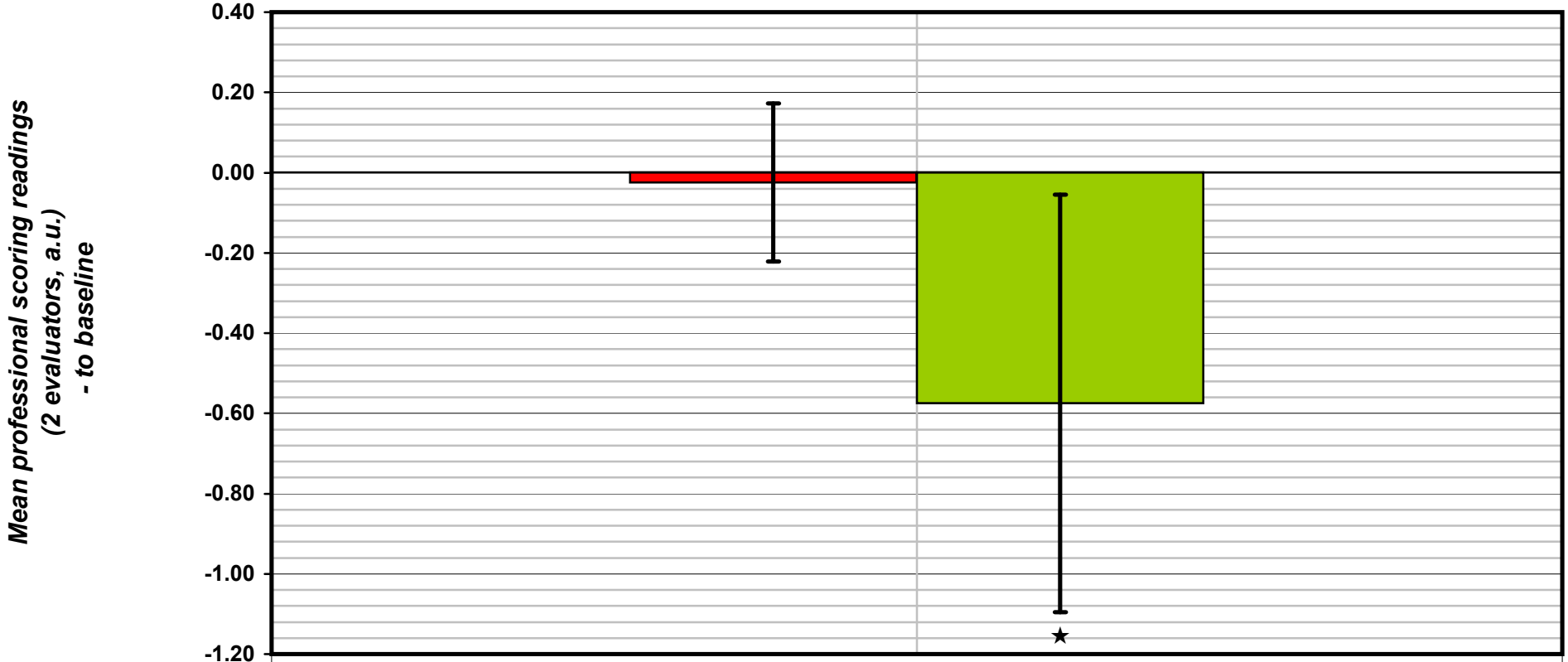
DCC16C007



	start	after 28 days
untreated	3.20	3.18
ByeByeCellulite (102076/1)	3.23	2.65

Experimental data of Cellulite Grade (delta values)

DCC16C007



	after 28 days
untreated	-0.03
ByeByeCellulite (102076/1)	-0.58

***p<0,05 versus untreated**

Appendix V

Subject Data

Subject Data, DCC16C007

	Gender	Age	Left	Right	Comments / Problems
1	F	41	untr.	A	
2	F	54	untr.	A	Reported about very strong stinging after first three treatments lasting each time for over an hour by phone; agreed to try further applicaitons with significantly reduced samples amount; reported to have been able to increase application amount again during the second week; completed study regularly
3	F	43	untr.	A	
4	F	47	untr.	A	
5	F	57	untr.	A	
6	F	38	untr.	A	
7	F	46	untr.	A	
8	F	38	untr.	A	
9	F	59	untr.	A	
10	F	45	untr.	A	
11	F	57	A	untr	Reported about strong, but tolerable discomfort (stringing, reddening, warmth) upon every treatment by phone during 2nd week of treatment; reduction of application amount had no noticable effect; completed study regularly, but symptoms persisted throughout the study
12	F	51	A	untr.	
13	F	43	A	untr.	
14	F	51	A	untr.	
15	F	53	A	untr.	
16*	F	41	untr	A	
17	F	42	A	untr.	
18	F	50	A	untr.	
19	F	52	A	untr.	
20	F	42	A	untr.	
Average	-	47.5	-	-	-
S.D.	-	6.5	-	-	-
Median	-	46.5	-	-	-

Drop-out	F	51	A	untr.	Reported about strong redening, extreme feeling of warmth and stinging sensations lasting for several hours by phone (after 2nd treatment); agreed to try further applications with significantly reduced sample amount; quit study because of discomfort at the end of the first week of treatment. Replaced by reserve subject

* replaced by reserve subject