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CONTOURWRAP

CO_2 Body Sculpting

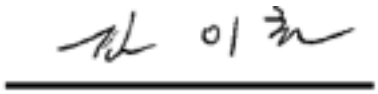
TEST REPORT

I. Test Report and Quality Assurance

The Clinical Trial Center for Bio-Industry at Semyung University was requested to carry out a human trial by C&Tech Corp. to evaluate the effects of “Miracle Body Shaping Treatment” in temporarily reducing cellulite. The test was carried out according to the Clinical Trial Center for Bio-Industry at Semyung University’s test methods and the results are reported below.

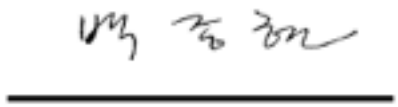
In carrying out the test, the head of the Clinical Trial Center for Bio-Industry at Semyung University and principal investigator reviewed the integrity of the study and compliance with the Center’s SOP, and we verify that the raw data associated with the final report were properly managed and supervised.

January 17, 2013
Clinical trial institution: Clinical Trial Center for Bio-Industry at Semyung University
Head of institution Director of Clinical Trial Center for Bio-Industry at Semyung University



Kim, Ewha, Ph.D., Oriental Medicine

Principle investigator Affiliated Professor of Clinical Trial Center for Bio-Industry at Semyung University



Baek, Jonghyeon, M.D., Dermatologist

III. Introduction

1. Purpose of study
Human trial to evaluate the test sample's effects in temporarily reducing cellulite

2. Study No.
IL-6004-A

3. Report No.
SMC-140117-4015

4. Sponsor
C&Tech Corp.

5. Clinical trial institution
Clinical Trial Center for Bio-Industry at Semyung University
65 Semyeong-ro, Sinwol-dong, Jecheon-si, Chungcheongbuk-do, Korea
Tel: 043-653-6303, Fax: 043-653-6302
Homepage: http://www.smctc.co.kr

6. Name of sample
"Miracle Body Shaping Treatment"
C&Tech Corp. was obligated and responsible to ensure the safety of the sample and test subjects returned the samples to the investigator when the study was concluded.

7. Sample No.
"Miracle Body Shaping Treatment", 13-CX0256

8. Timeline
Sample received: December 3, 2013
Started on: December 11, 2013
Ended on: January 10, 2014
Report written on: January 17, 2014

IV. Test method

1. Summary of study

This study was carried out on women between the ages of 30 and 60 after receiving the sample from the sponsor. The test subjects were required to use the sample according to instructions (refer to Summary) and the effects of the sample were evaluated through ultrasonography, photographic images and a questionnaire. The evaluation was in compliance with the Center's SOP and tests not included in the MFDS Public Notification were carried out based on other references.

2. Test subjects

2.1. Selection of test subjects

Women between the ages of 30 and 60 who satisfied the selection criteria and did not fall under the exclusion criteria were selected for this study. In order to measure the evaluation items of the sample, information in the form of a document was provided to the test subjects and the investigator offered a detailed oral and documentary description of the study and all test subjects voluntarily participated in the study after signing the written consent.

2.2. Selection criteria

a. Persons who received a thorough description of the study from the investigator after which the subject wrote and signed a written consent of their own free will.
b. Healthy persons currently without any acute or chronic diseases including skin diseases.
c. Persons who can be followed up during the period of the study.

2.3. Exclusion criteria

Persons who fell under one or more of the following were excluded from the study.
a. A person who was pregnant, breastfeeding or had the possibility of being pregnant.
b. A person who had used a skin preparation that contains steroid for one or more months to treat a skin disease.
c. A person who participated in the same study and hadn't exceeded six months since leaving the study.
d. A person with sensitive or hypersensitive skin.
e. A person who had a skin abnormality on the body part of interest such as a mole, acne, erythema or capillary dilatation.
f. A person who used a cosmetic or pharmaceutical product identical or similar to the sample on the body part of interest within three months of joining the study.
g. A person who went through medical procedures involving the skin such as exfoliation or rhytidoplasty within six months of joining the study.
h. A person who was considered to be unqualified for the study by the investigator.

2.4. Instructions provided to test subjects

a. Test subjects were instructed to be punctual and comply with the study schedule.
b. Test subjects were instructed to avoid applying friction to the body part where the sample was applied during the period of the study.
c. Test subjects were instructed to avoid excessive drinking of alcoholic beverages and smoking.
d. Test subjects were instructed not to expose the body part applied with the sample to direct sunlight.
e. Test subjects were instructed to avoid deviating significantly from their everyday activities including excessive stress.

2.5. Elimination criteria

A test subject who satisfied the selection criteria without satisfying any exclusion criteria was excluded from the study by the principal investigator or investigator when one or more of the following occurred, and the subject was excluded from the results of the study which were described in the report.

a. When a serious adverse event occurred in the test subject or when the test subject requested to be removed from the study due to serious adverse events such as itching or erythema.
b. A subject who was discovered to have a systemic disease that was not identified before the human trial.
c. A subject who was exposed to excessive amount of UV rays on the body part where the test sample was intended to be applied during the study.
d. When difficulties occurred in obtaining proper results and evaluation due to excessive smoking or drinking of alcoholic beverages during the study.
e. When a test subject or legal representative requested the subject to be removed from the study during the study.
f. When an investigator or subject violated the study protocol.
g. When a test subject faced difficulties in applying the sample.
h. When a subject took medicine that could affect the outcomes of the study without the consent or instruction of a doctor during the follow-up period.
i. When a subject was considered to be unqualified to continue in the study by an investigator.

2.6. Voluntary withdrawal during the period of the study

Throughout the period of the study, all test subjects had the right to voluntarily withdraw his or her consent to participate in the study at any point in time.

2.7. Measures for adverse events

The institution made all efforts to ensure the safety of the test subjects throughout the period of the study and minimized the risk of adverse events to take swift and appropriate measures for predictable adverse events. The head of the institution and the principal investigator were given responsibility to investigate and manage this issue. In the occurrence of an adverse event related to the study (sample applied to subjects), testing was suspended for the subject and the subject was seen by a dermatologist when symptoms did not improve or in cases of abnormal skin reactions. The principal investigator and other investigators kept a detailed record of the symptoms and situations along with dermatologic evaluation and measures taken.

2.8. General instructions

Investigators described the purpose and method of the study to all test subjects and notified that adverse events such as itching, erythema or irritation could occur during the study, and that all test subjects would not receive any penalties for immediately leaving the study after the conclusion of the study or for refusing or withdrawing consent to participate in the study, and that adverse events could occur by the sample and that other measures including treatment and elimination from the study could be considered when an adverse event occurs.

2.9. Confidentiality and good faith

The confidentiality of test subjects who participated in this study is guaranteed and information obtained from the subjects was used for medical evaluation purposes only within the limit of maintaining confidentiality for the identity of test subjects.

Information of the subjects obtained from this study was kept confidential until the conclusion of the study and all data were compiled based on the principle of good faith.

2.10. Number of subjects

Twenty subjects who satisfy the selection criteria and not the exclusion criteria were selected for the study.

3. Body part of interest

The right lower extremity was used for this study.

4. Test method

4.1. Preparation

The right lower extremity was kept clean and dry in order to make the measurement conditions identical across test subjects during ultrasonography, and measurements were made after keeping the leg at a constant temperature and humidity (22±2 , R.H. 40~60%) for at least 30 minutes.

4.2. Measurement:

4.2.1. Ultrasonography

DERMA SCAN® C Ver 3. COMPACT (CORTEX TECHNOLOGY, Denmark) was used for the ultrasonography and distilled water was injected inside the water chamber of the scanner head to ensure proper scanning which was recorded as a video. The distilled water acted as a medium for the ultrasonic waves.

4.2.2. Photography

A high-resolution digital camera (CANON 50D, JAPAN) was used under an identical lighting environment. For standardization, images were taken by the same investigator and conditions (direction and location of measurement) were fixed using specially prepared equipment.

5. Schedule and procedure

5.1. Visit 1 (Week 0, study start)

Test subjects were selected based on the selection criteria and exclusion criteria, and their skin conditions were checked and evaluated and recorded using Derma scan C.
C.

5.2. Visit 2 (Week 2)

Skin irritation evaluation, equipment evaluation using Derma scan C and photographic images were obtained from subjects who used the sample for two weeks according to instructions.

5.3. Visit 3 (Week 4)

Skin irritation evaluation, equipment evaluation using Derma scan C and photographic images were obtained from subjects who used the sample for four weeks according to instructions.

6. Questionnaire

General evaluation (user experience), efficacy (temporary reduction of cellulite, etc.), preference and skin irritation were evaluated using a questionnaire at week 4.

7. Skin irritation evaluation

The onset of adverse events including erythema, edema, scaling, itching, stinging, burning, tightness or prickling caused by the sample were observed carefully, and in the case of an adverse event, the severity was graded and recorded and an inspection record was written for the adverse event. When a subject was unable to continue to participate in the study, the subject was instructed to write and sign a consent form to withdraw from the study.
The grades for adverse events are shown below.

Skin irritation evaluation (adverse event)
* Adverse grade
0: none, 1: mild, 2: severe, 3: very severe

Erythema	Edema	Scaling	Itching	Stinging	Burning	Tightness	Prickling

8. Result analysis

8.1. Temporary reduction of cellulite

Equipment evaluation used Image-pro plus to process images obtained from Derma scan C to select the AOI (area of interest) and count the area, and a small number was considered as a reduction in cellulite. The measured variable is a calculated value of the program and has an arbitrary unit A.U.

8.2. Reduction rate analysis

The reduction rate was analyzed by comparing the measurements taken before and after the use of the sample.
The formula for calculating the reduction rate is shown below:

$$\text{Reduction Rate (\%)} = \left(\frac{\text{Measurement taken after use of sample - Measurement taken before use of sample}}{\text{Measurement taken before use of sample}} \right) \text{x100}$$

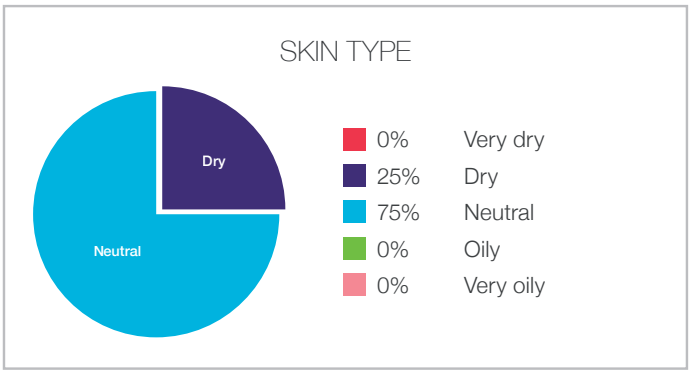
8.3. Statistical analysis

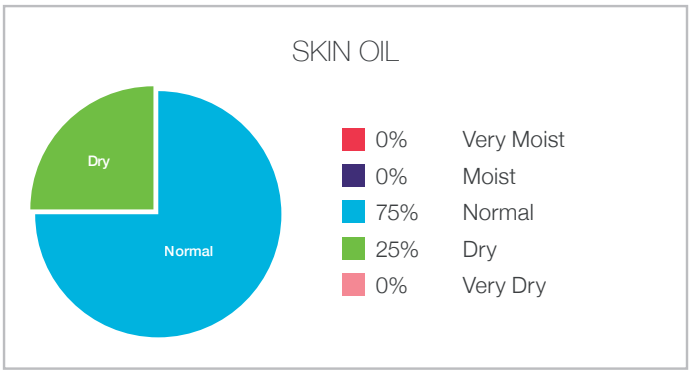
The paired t-test was used for statistical analysis to compare the difference between before and after use of the sample. SPSS 10.0 was used for statistical analysis and all statistical results were considered significant when the level of significance was 5% ($p<0.05$)

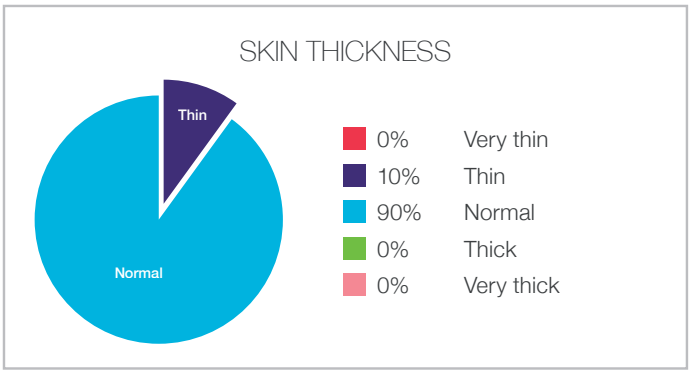
1.2. Type and condition of skin

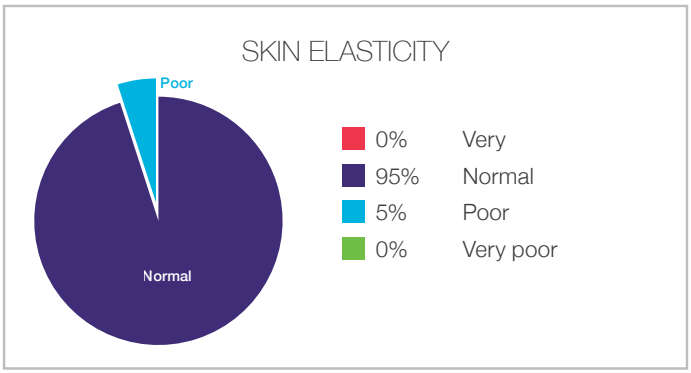
Test subjects were required to fill in a questionnaire on the type and condition of their skin before the use of the sample and the results are shown in Fig. 2.

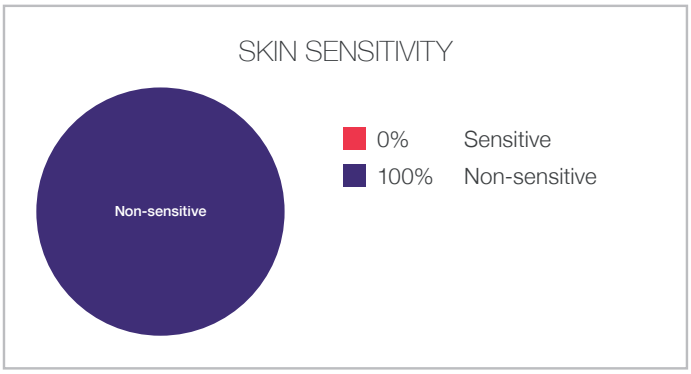
Fig. 2 Questionnaire on skin condition (unit: %)

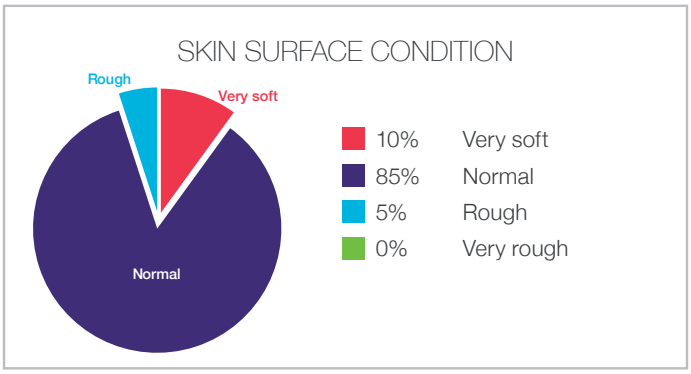


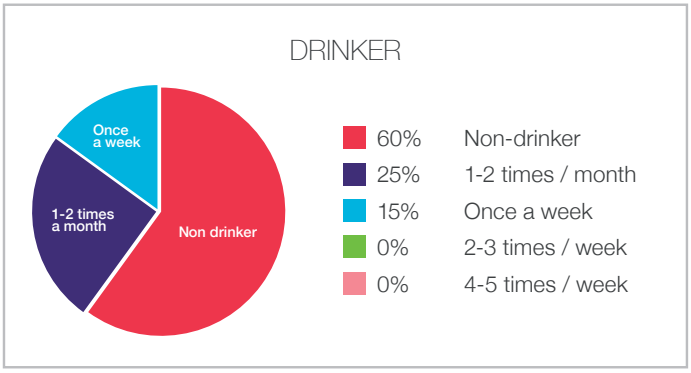


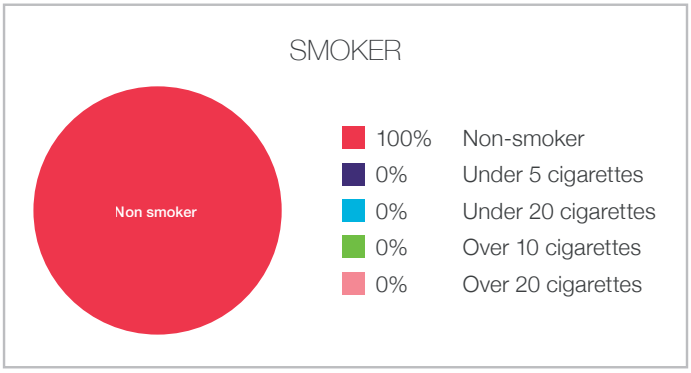












2. Measurement results

2.1. Measurement of temporary cellulite reduction (Derma scan C)

The measurements for temporary reduction of cellulite after the use of “Miracle Body Shaping Treatment” are shown in Tables 3 and 4.

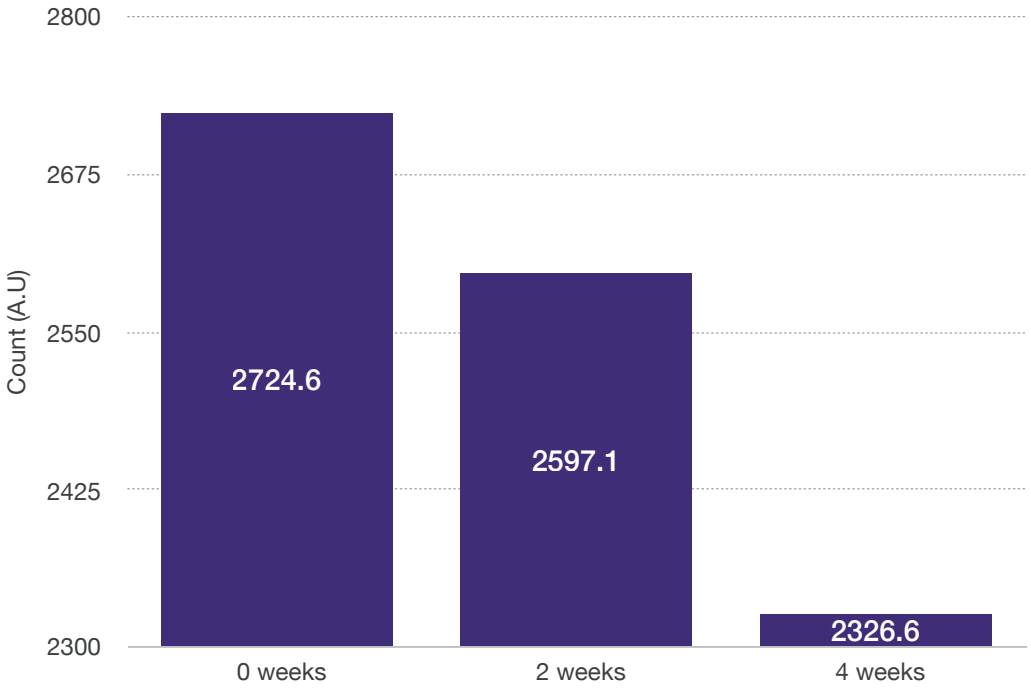
Table 3. Results of Derma scan C (unit: A.U.)

No.	Initial	0w	2w	4w
1	1KHJ-1	1565	1576	1012
2	KDY	3048	2900	2698
3	MGS	1627	1319	1046
4	KDH	2428	2685	2572
5	KEY	2156	2073	1730
6	KJS	2393	2384	1730
7	LEK	3539	3436	3110
8	CEK	3530	3124	3148
9	CMN	3131	3038	2925
10	GHJ	2108	1669	1382
11	PMJ	3706	2252	2580
12	KSE	5161	5856	5903
13	KHJ-2	1613	1584	1575
14	CSY	2920	2907	2823
15	LJY	1963	1868	1355
16	SAK	2487	2789	2775
17	KYH	2062	1979	1262
18	MMH	1863	1739	1335
19	GMS	4553	4527	3752
20	LDS	2638	2236	1484
Average		2724.6	2597.1	2326.6
Standard deviation		983.4	1089.1	1174.3

Table 4. Statistical analysis of outcomes of Derma scan C

	2w	4w
p-value	0.176(p>0.05)	0.001(p<0.05)

Fig. 3 Temporary reduction of cellulite



The measurements of temporary cellulite reduction after the use of “Miracle Body Shaping Treatment” are shown in Fig. 3. * *Statistical level of significance comparing before and after the use of the sample was p<0.05*

The measurement taken before the use of “Miracle Body Shaping Treatment” (0w) was 2724.6A.U. and 2597.1A.U. at 2w and 2326.6A.U. at 4w. The outcome at 4w was statistically significant compared to that of 0w showing that the sample temporarily reduces cellulite (p<0.05).

2.2 Variation in temporary cellulite

The variation in temporary cellulite measured with Derma scan C is shown below.

Variation in temporary cellulite = measurement of temporary cellulite after use of sample – measurement of temporary cellulite before use of sample

Table 5. Temporary variation in cellulite after use of “Miracle Body Shaping Treatment” (unit: A.U.)

No.	Initial	Temporary variation in cellulite	
		2w–0w	4w–0w
1	KHJ-1	11	-553
2	KDY	-148	-350
3	MGS	-308	-581
4	KDH	257	144
5	KEY	-83	-426
6	KJS	-9	-329
7	LEK	-103	-429
8	CEK	-406	-382
9	CMN	-93	-206
10	GHJ	-439	-726
11	PMJ	-1454	-1126
12	KSE	695	742
13	KHJ-2	-29	-38
14	CSY	-13	-97
15	LJY	-95	-608
16	SAK	302	288
17	KYH	-83	-800
18	MMH	-124	-528
19	GMS	-26	-801
20	LDS	-402	-1154
Average		-127.5	-398.0
Standard deviation		405.5	457.8

2.3. Temporary variation in cellulite

The temporary reduction of cellulite after use of the sample was calculated by obtaining the temporary variation in cellulite and the results are shown below:

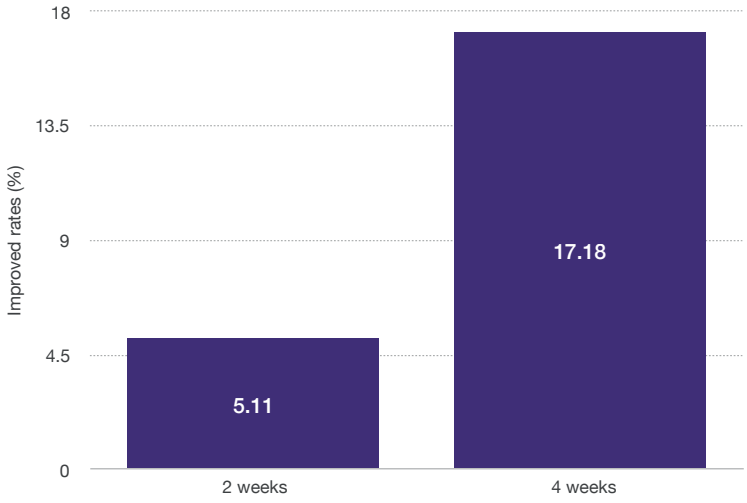
$$\text{Reduction Rate (\%)} = \left(\frac{\text{Measurement taken after use of sample - Measurement taken before use of sample}}{\text{Measurement taken before use of sample}} \right) \text{x100}$$

Table 6. Temporary reduction of cellulite after use of “Miracle Body Shaping Treatment” (unit: %)

No.	Initial	Temporary variation in cellulite	
		2w	4w
1	KDY	-0.7	35.3
2	MGS	4.9	11.5
3	KDH	18.9	35.7
4	KEY	-10.6	-5.9
5	KJS	3.8	19.8
6	LEK	0.4	13.7
7	CEK	2.9	12.1
8	CMN	11.5	10.8
9	GHJ	3.0	6.6
10	PMJ	20.8	34.4
11	KSE	39.2	30.4
12	KHJ-2	-13.5	-14.4
13	CSY	1.8	2.4
14	LJY	0.4	3.3
15	SAK	4.8	31.0
16	KYH	-12.1	-11.6
17	MMH	4.0	38.8
18	GMS	6.7	28.3
19	LDS	0.6	17.6
20		15.2	43.7
Average Standard deviation		5.11 12.05	17.18 17.22

The temporary reduction of cellulite after use of “Miracle Body Shaping Treatment” is summarized in Fig. 4.

Fig. 4 Temporary reduction of cellulite after use of “Miracle Body Shaping Treatment” (unit: %)

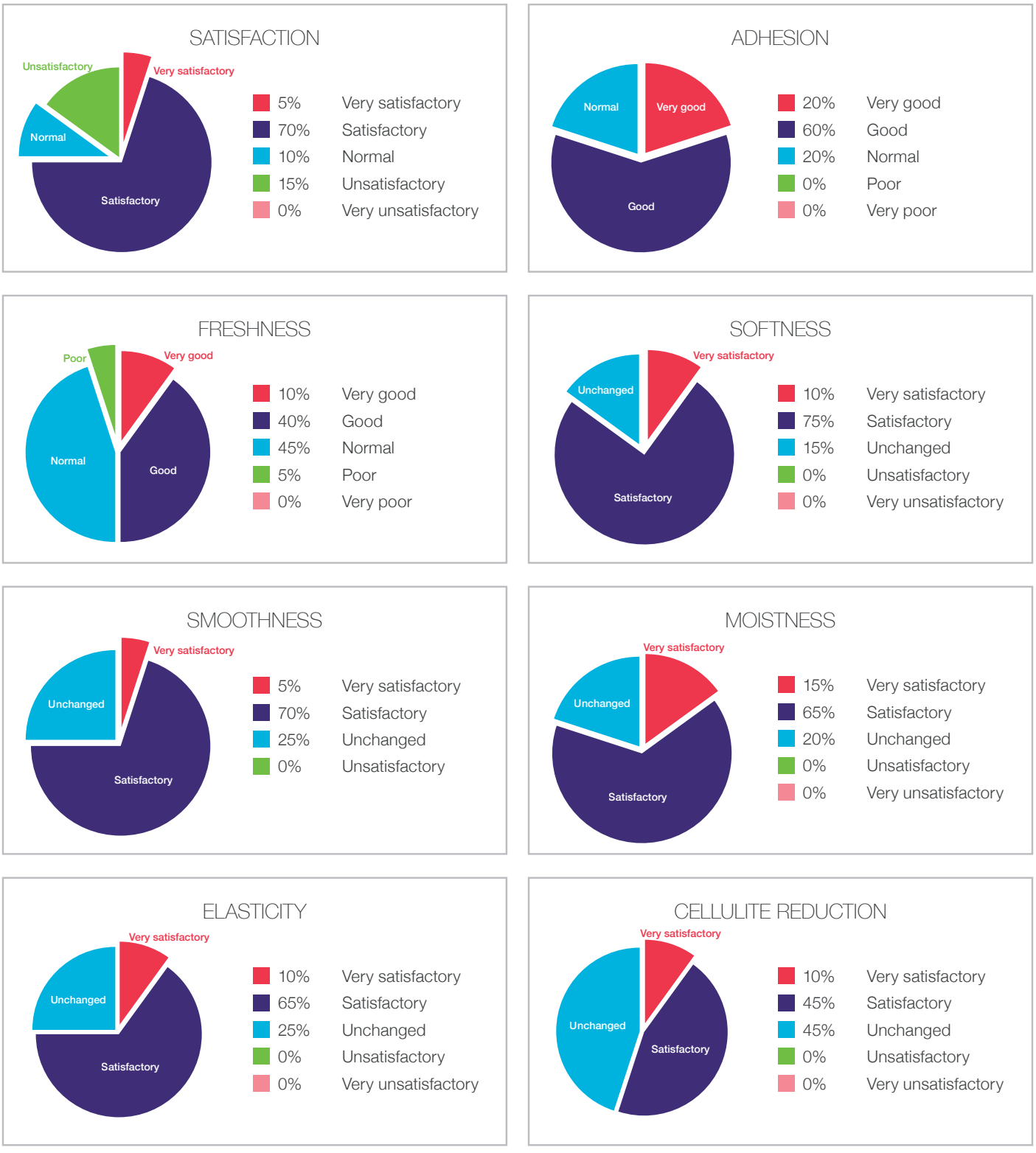


Analysis of the temporary reduction of cellulite after use of “Miracle Body Shaping Treatment” showed that temporary cellulite reduction of 5.11% and 17.18% occurred at 2w and 4w, respectively, after use of the sample compared to that of before use of the sample.

4. Questionnaire

The results of the questionnaire on the effects of the sample are shown in Fig. 5.

Fig. 5 Questionnaire results on effects of sample (unit: %)



VI. Discussion and Conclusion

This human trial was carried out based on a request from C&Tech Corp. to evaluate the effects of “Miracle Body Shaping Treatment” in temporarily reducing cellulite.

The study was carried out on 20 adult women between the ages of 30 and 60, and no subjects were eliminated during the study.

To evaluate the sample, subjects were required to use “Miracle Body Shaping Treatment” three times a week and subjects were instructed to spread the sample on the middle of the CO2 patch built in the sample product and apply the patch to the lower extremity after removing the protective film, and remove the patch after 30~40 minutes and wipe off the remaining sample. Instrumental evaluation was carried out before the use of the sample (0w), 2 weeks and 4 weeks after the use of the sample using Derma scan C and photography.

Temporary reduction of cellulite was 2724.6A.U. at 0w, 2597.1A.U. at 2w and 2326.6A.U. at 4w.
Temporary reduction of cellulite was significant at 4w when compared to before the use of the sample (0w) ($p<0.05$).
Also, temporary reduction of cellulite by 5.11% and 17.18% was observed at 2w and 4w compared to that of 0w.

The skin irritation evaluation was carried out by a questionnaire and visual observation by the investigator, and no adverse events were observed from the use of the sample.

Based on the above results, we conclude that “Miracle Body Shaping Treatment” provided by C&Tech Corp. is effective in temporarily reducing cellulite ($p<0.05$).