

CONCLUSION

A third party professional assessment performed by a leading contract research organization revealed that Galvanic Spa™ II Body Shaping Gel used with the Nu Skin® Galvanic Spa™ System II instrument was able to deliver significant improvements in the skin condition known as cellulite.

Overall, 35% of study participants experienced a one-inch or more reduction in the thigh circumference with either treatment.

Clinical professionals determined that Galvanic Spa™ II Body Shaping Gel used with the Galvanic Spa™ System II instrument performed as follows:

73% of study subjects demonstrated a reduction in thigh diameter.

50% showed an improvement in appearance of the test area.

35% exhibited a smoother skin surface.

46% had an improvement in the overall condition.

Self-assessment by study subjects revealed:

50 % of subjects noticed ≥ 1 grade level improvement for the overall cellulite condition. Further, 15% noticed ≥ 2 grade levels of improvement. (0=None, 1=Minimum, 2=Mild, 3=Moderate, 4=Severe)

Further clinical evaluations have revealed that when the Galvanic Spa™ System II Instrument and Body Shaping Gel are used in conjunction with Dermatic Effects® Body Contouring Lotion, the benefits are even greater. Professional graders noted almost double the reduction in the extent of the cellulite condition.

- 1 Dahl Pr, Salla MJ, Winkelmann RK. Localized involutinal lipotrophy: a clinicopathologic study of 16 patients. *J Am Acad Dermatol* 1996;35:523-8.
- 2 Scherwitz C, Braun-Falco O. So-called cellulite. *J Dermatol Surg Oncol* 1978;4:230-4.
- 3 Nurnberger F, Muller G. So-called cellulite: an invented disease. *J Dermatol Surg Oncol* 1978;4:221-9.
- 4 Marbaix E, Kokorine I, Henriet P, Donnez J, Courtoy PJ, Eeckhout Y. The expression of interstitial collagenase in human endometrium is controlled by progesterone and by oestradiol and is related to menstruation. *Biochem J* 1995;305:1027-30.
- 5 Singer CF, Marbaix E, Lemoine P, Courtoy PJ, Eeckhout Y. Local cytokines induce differential expression of matrix metalloproteinases but not their tissue inhibitors in human endometrial fibroblasts. *Eur J Biochem* 1999;259(1-2):40-5.
- 6 Jeziorska M, Nagasae H, Salamonsen LA, Woolley DE. Immunolocalization of the matrix metalloproteinases gelatinase B and stromelysin 1 in human endometrium throughout the menstrual cycle. *J Reprod Fertil* 1996;107(1):43-51.
- 7 Smith WF. Cellulite treatments: snake oil or skin science. *Cosmet Toilet* 1995;110:61-70.
- 8 Curri SB. Cellulite and fatty tissue microcirculation. *Cosmet Toilet* 1993;108:51-8.
- 9 Curri SB, Bombardelli E. Local lipodystrophy and districtual microcirculation. *Cosmet Toilet* 1994;109:51-65.



©2001 Nu Skin International, Inc.
75 West Center Street
Provo, UT 84601
www.nuskin.com

1-800-487-1500

GALVANIC SPA™ II BODY SHAPING GEL AND NU SKIN® GALVANIC SPA™ SYSTEM II CLINICAL BULLETIN

Summarized from a third party professional assessment performed according to Good Clinical Practices and the Standard Operating Procedures of the organization.

2004 Nu Skin International, Inc., Provo, UT

INTRODUCTION

Excess adipose tissue, more commonly known as cellulite, is a condition about which relatively little is known. In medical literature, cellulite is known as adispis edematosa, dermopanniculosis deformans, status protrusus cutis, and by several other medical terms! Cellulite can be located anywhere on the body that contains excess subcutaneous fat and appears as uneven, bumpy skin texture often seen with side lighting of the affected area. Skin influenced by cellulite has been described as having an “orange peel” or “cottage cheese” appearance. Obesity is not necessary for the presence of cellulite since the pattern of adipose deposits that lead to cellulite may be genetically determined? It is not commonly seen in men and certain areas are more likely than others. It is most commonly seen on the upper outer thighs, the posterior thighs (banana roll), and buttocks, but can also be seen on the breasts and upper arms.

The cause of cellulite deposits is unknown. Although the word cellulite means “cell inflammation,” cellulite cannot be considered a disease. It is considered a normal body change associated with puberty and it is estimated that 85% of females are afflicted with the condition? It may be seen most often in women because the female subcutaneous fat is sequestered into discrete pockets by the presence of septa or separating membranes. The current theory holds that cellulite is an inflammatory process that results in breakdown of the collagen in the dermis leading to subcutaneous fat ruptures. The onset of cellulite with puberty has led some researchers to evaluate the effect of the elevated levels of collagenases and gelatinases that occur during menstruation? Elevation of collagenases can cause the breakdown of the fibrillar collagens present in the dermis, and gelatinase elevation can lead to an influx of immune system cells that contribute to inflammation? With repeated cyclical collagenase production, more and more dermal collagen is destroyed, resulting in the worsening of cellulite seen with age. When enough collagen is destroyed to weaken the dermis, it can rupture and allow fat to move between the structural fibrous septa found in female fat. If more fat is present, the rupture is larger. Because the dermal capillary network is damaged in the process, excess fluid is retained with the dermal and subcutaneous tissue further accentuating the appearance of cellulite? This loss of the capillary network is thought to be due to engorged fat cells clumping together and inhibiting venous blood return??

Xanthine derivatives from plants can be effective against cellulite because they are able to stimulate the fat breakdown in adipocytes. *Theobroma cacao* (cocoa) extract containing theobromine from cocoa is very effective. Another plant extract from *Chrysanthellum indicum* can assist with increased fat breakdown (lipolysis) by linking the α_2 adrenergic receptors together to prevent the generation of cellular signals that turn off lipolysis (fat breakdown).

Capillary and lymphatic circulation improvement can also assist with the treatment of cellulite. An extract of *Chrysanthellum indicum* can reduce edema and inflammation and promote tissue drainage and the elimination of toxins.



Before treatment, cellulite visible After treatment, cellulite reduced

CLINICAL STUDY

Twenty-seven women between the ages of 25 and 50, with body weight within 30% of their body mass index, were enrolled in an 8-week clinical study to demonstrate product efficacy. Clinical investigator assessments (investigators were blinded to the treatment), subject assessments, and thigh measurements were conducted. The treatment regimen consisted of the use of Galvanic Spa™ II Body Shaping Gel applied to the test area twice per day, two times per week, and massaged into the skin using the Nu Skin® Galvanic Spa™ System II instrument. The instrument was configured to deliver a negative charge and set for 5 minutes.

Body Shaping Gel with Galvanic Current Investigator Measurement	
0 weeks	Baseline
8 weeks	73%

Figure 1. Percentage of subjects that exhibited a reduction in thigh diameter after 8 weeks of product usage.

A regimen consisting of the Nu Skin® Galvanic Spa™ System II used with Galvanic Spa™ II Body Shaping Gel twice each of the two days per week was evaluated for efficacy. The circumference of the thigh was measured at 0 (baseline), 4, and 8 weeks by a professional grader and the number of study subjects demonstrating a reduction in thigh diameter was counted. Compared to baseline, 73% of subjects exhibited a reduction in thigh diameter at 8 weeks ($p=0.005$).

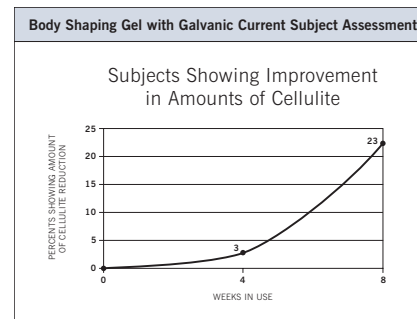


Figure 2. Represents the percent of reduced visible cellulite amounts by study participants.

A regimen consisting of the Nu Skin® Galvanic Spa™ System II used with Galvanic Spa™ II Body Shaping Gel twice per each of the two days per week was evaluated for efficacy.

Study subjects evaluated the amount of cellulite visible at 0 (baseline) and 8 weeks using a grading scale where 0=none, 1=minimum, 2=mild, 3=moderate, and 4=severe. Compared to baseline, at 8 weeks 50% of participants noticed more than 1 grade level improvement and 15% of participants noticed an improvement of more than 2 grade levels ($p=0.001$).

Percentage Showing Skin Regimen Study Results Improvements After 8 Weeks of Use	
Appearance	50%
Smoothness	34%
Overall Cellulite Condition	47%

Figure 4. Study investigator, blinded to the regimen used, evaluated appearance, smoothness, and overall cellulite condition.

A regimen consisting of the Nu Skin® Galvanic Spa™ System II used with Galvanic Spa™ II Body Shaping Gel twice each of the two days per week was evaluated for efficacy. Study subjects evaluated the amount of cellulite visible at 0 (baseline), 4, and 8 weeks. The results at 8 weeks (compared to baseline) showed Galvanic Spa™ II Body Shaping Gel, when used with the Galvanic Spa™ System II instrument providing a controlled galvanic current, significantly reduced cellulite ($p=0.001$). Subjects documented a 23% improvement in the amount of cellulite.

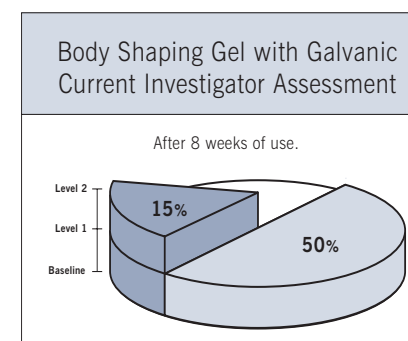


Figure 3. Percentage of subjects that exhibited one grade level or more improvement in the amount of visible cellulite.

A regimen consisting of the Nu Skin® Galvanic Spa™ System II used with Galvanic Spa™ II Body Shaping Gel twice each of the two days per week was evaluated for efficacy.

The study investigator, blinded to the regimen used, evaluated the appearance, smoothness, and overall cellulite condition of the test areas at 0 (baseline) and 8 weeks. At 8 weeks, improvements were seen in all parameters.