

Using High Frequency Ultrasound to Assess the Efficacy of Anti-Cellulite Treatments

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Introduction: The number of anti-cellulite therapies has been increasing steadily, as cellulite is an undesirable cosmetic defect affecting approximately 90% women worldwide. Despite this plethora of treatments, an objective method to enable their efficacy assessment is yet to be established.

Purpose: The aim of the study was to assess the usefulness of high frequency ultrasonography for evaluating the effectiveness of anti-cellulite therapy.

Patients and Methods: Eighty-four women aged 21–66 years with cellulite were randomised to one of 3 groups to receive one of three anti-cellulite treatments - ALIDYA™ mesotherapy treatment [Group 1, G1], cellulite-reducing body wrap treatment [Group 2, G2] or Endermologie® [Group 3, G3]. All measurements and ultrasound assessments were carried out at baseline and on day 14–18 following treatment completion at the same body location and using identical ultrasound scanner settings.

Results: A significant reduction in subcutaneous tissue thickness, skin echogenicity and surface area of fat protrusions at the dermal–subcutaneous junction was demonstrated. There was a significant reduction of dermal thickness G2 and G3, but not in G1. Reduction in thigh circumference and BMI was also statistically significant in each group. Correlations were demonstrated between cellulite severity and the surface area of fat protrusions at the dermal subcutaneous junction and subcutaneous tissue thickness. The participants in G3 reported highest satisfaction with treatment outcomes.

Conclusion: The present study demonstrated that high frequency ultrasound enables efficacy assessment of anti-cellulite treatments and, as a reliable, available and easy to use assessment method, it has a potential to become a common aspect of daily clinical practice. Further research is warranted to develop a uniform assessment protocol and standards.

Keywords: cellulite, ultrasound, high frequency ultrasound, anti-cellulite therapies

Introduction

In the 2023 American Society for Dermatologic Surgery (ASDS) Consumer Survey on Cosmetic Dermatologic Procedures, cellulite was recognised as a new leading concern from previous years with 72% of responders listing it as the most bothersome.¹ The Future Market Insights report shows a consistent growth of anti-cellulite treatment market, with a projected increase by 7.2% (which translates into USD 7.37 billion) by 2034, as compared to 2024. It forecasts that the vast majority of that growth will take place in Western countries.² Cellulite is a cosmetic defect of multifactorial etiology. It is defined as a non-inflammatory degenerative process of the subcutaneous tissue, leading to edematous, fibrotic, and sclerotic alterations. These changes in the subcutaneous tissue are most commonly observed on the thighs and buttocks, where they manifest as surface irregularities, nodules, and dimples. Cellulite has negative effect on the perception of one's body, attractiveness, and is thus unacceptable to those affected.^{3,4} In many cases, seeking to improve one's cosmetic appearance is a way to meet one's emotional needs. Thus, such treatment for instance becomes a confidence booster, which translates into a higher satisfaction with one's social life and improved quality of life.^{3,4} In response to a steadily growing demand for cellulite-reducing treatments, a number of cosmetic products, devices and techniques have been developed. Patients can now choose between cosmetic products, devices based on new technologies and medical procedures.^{5–7} Unfortunately, for

the majority of those treatments, there is no reliable information on their efficacy. This is associated with the difficulty in assessing and grading the severity of cellulite,^{8–10} on one hand, and the paucity of a standardised and reliable assessment protocol to determine the efficacy of anti-cellulite treatments^{10,11} on the other. The methods used to assess the severity of cellulite and the effectiveness of treatment, based mainly on visual and palpation assessment, are subjective and have limited repeatability. Recent reports suggest that high frequency ultrasound, researched and valued in dermatology and aesthetic medicine, may be a solution to both challenges.^{12–15} Considering that cellulite affects approximately 90% women worldwide, research focusing on cellulite-reducing treatments, and their monitoring, seems relevant.^{4,6}

This study focused on providing an answer to the question whether high frequency ultrasound is a useful diagnostic modality for the efficacy assessment of three different anti-cellulite treatments.

Materials and Methods

This prospective comparative effectiveness research was carried out in 2016–2022 and approved by the Ethics Committee of the Medical University of Warsaw (approval number: KB/67/2014). The study protocol was compliant with the Declaration of Helsinki.

A total of 93 women expressed their informed consent and were initially enrolled in the study. As 9 women failed to complete all the required study procedures, they were excluded from analyses. Thus, our study sample consisted of 84 women aged 21–66 years (mean age 39.7 y.o.; SD = 9.88) (Figure 1 and Table 1). The inclusion criteria were cellulite presence on the posterior aspect of the thighs and informed consent to participate. Cellulite severity was assessed using the Nürnberger-Müller scale.¹⁰ The Nürnberger-Müller scale categorizes cellulite into 4 grades based on skin appearance:

- grade 0—no cellulite, skin is smooth on pinching,
- grade I—skin is smooth at rest, but shows a mattress-like appearance upon pinching,
- grade II—skin is smooth at rest, but shows a mattress-like appearance upon standing,
- grade III—the skin has a mattress-like appearance in both the lying and standing positions. A pinch test and an assessment of cellulite severity were performed in each patient.

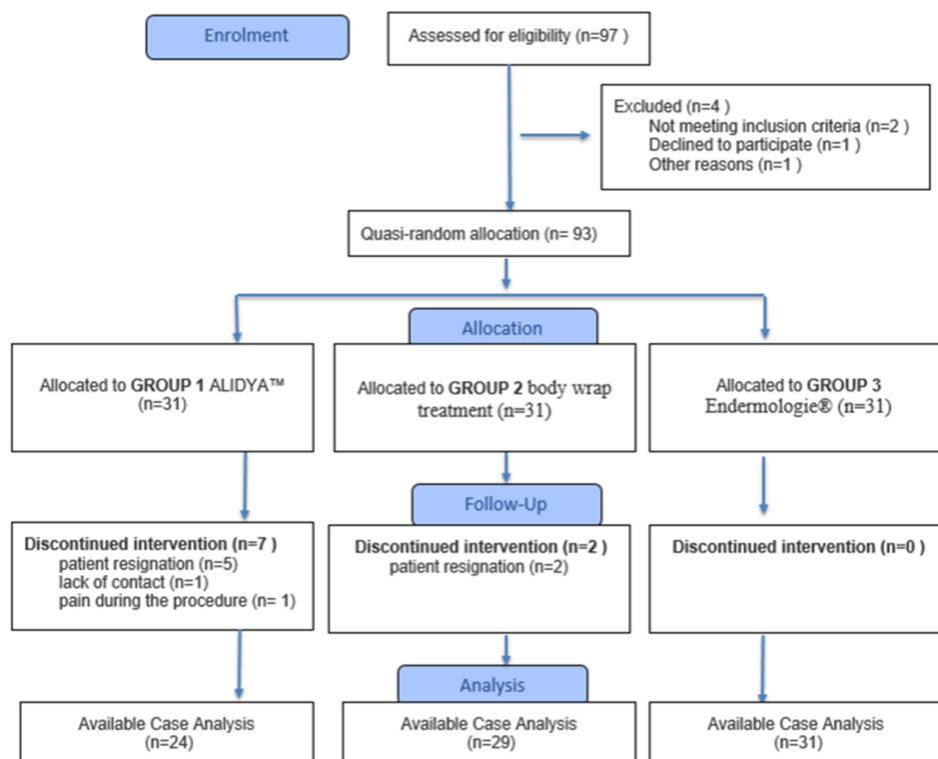


Figure 1 Patient flow diagram.

Table 1 Baseline Characteristics of the Study Population

Parameter	Group 1 ALIDYA™ n = 24	Group 2 Body Wrap n = 29	Group 3 Endermologie® n = 31
Aged (M ± SD)	38.00 ± 9.69	37.97 ± 8.75	42.65 ± 10.31
Cellulite severity assessed using Nürnberger- Müller scale (M ± SD)	2.04 ± 0.62	2.17 ± 0.66	2.23 ± 0.72
Grade I (n)	4	4	5
Grade II (n)	15	16	14
Grade III (n)	5	9	12
BMI (M ± SD)	23.47 ± 2.81	24.32 ± 3.81	23.54 ± 2.74
Thigh circumference [cm] (M ± SD)	56.58 ± 4.78	57.29 ± 4.52	57.47 ± 4.52

Abbreviations: BMI, body mass index; M, mean; n, number; SD, standard deviation.

The exclusion criteria included pregnancy, breastfeeding, diabetes, malignancies, severe varicose veins, and anti-cellulite treatment used within 6 weeks prior to enrolment. Participants were quasi-randomised allocations to one of 3 groups to receive one of three anti-cellulite treatments. Contraindications to the treatment were excluded in each of the women, based on the collected history. All women provided written informed consent before the study commenced. All participants were instructed not to use any cosmetics/care products on their thighs during therapy.

Group 1 consisted of 24 women aged 21–66 years (mean age 38 y.o.; SD = 9.69). They were administered 6 sessions of ALIDYA™ (Ghimas S.p.A, Italy) mesotherapy treatment for cellulite delivered at 6–7-day intervals. The product was administered using the 4 mm long 30G needle via the papule injection technique (approx. 0.2–0.3 mL) into the superior portion of the subcutaneous tissue. The total volume of 10 mL of the product, obtained by the reconstitution of lyophilized powder within the solvent, was injected during a single treatment, without topical anaesthesia. All procedures were carried out by a trained physician. Therapy lasted between 32 and 35 days, and its efficacy was assessed at 14–18 days from the last treatment.

Group 2 consisted of 29 women aged 25–58 years (mean age 37.97 y.o., SD = 8.75), who were administered 8 body wrap treatments delivered at 3–5-day intervals. Body wrap treatments included the application of professional care products (Afrodita Cosmetics, Rogaška Slatina, Slovenia): Grapefruit & Caffeine Body Wrapping Cream [INCI: Aqua, Glyceryl Stearate, Caprylic/Capric Triglyceride, Decyl Oleate, Glycerin, Paraffinum Liquidum, Propylene Glycol, Citrus Paradisi Peel Oil, Ceteareth-12, Ceteareth 20, Stearyl Alcohol, Cetyl Alcohol, Hydrolyzed Glycosaminoglycans, Caffeine, Theophylline, Theobromine, Pelargonium Graveolens Flower Oil, Cupressus Sempervirens Oil, Juniperus Communis Fruit Oil, Hedera Helix Leaf Extract, Ruscus Aculeatus Root Extract, Sambucus Nigra Flower Extract, Sodium Polyacrylate, Tocopherol, Hydrogenated Vegetable Glycerides Citrate, Maltodextrin, Silica, Polysorbate 60, Dimethicone, Butylene Glycol, Rosmarinus Officinalis Leaf Extract, Brassica Campestris Seed Oil, Methylparaben, Propylparaben, Diazolidinyl Urea, Limonene, Citronellol, Geraniol, Linalool, Citral], and Lipolytic Concentrate with Cecropia [INCI: Aqua, Alcohol Denat., Propylene Glycol, Pentyleneglycol, Cecropia Obtusa Bark Extract, Mentha Arvensis Leaf Oil, Rosmarinus Officinalis Leaf Oil, Juniperus Communis Fruit Oil, Lavandula Angustifolia Oil, Cupressus Sempervirens Oil, Foeniculum Vulgare Oil, Camphor, Menthol, Betula Alba Leaf Extract, Hedera Helix Leaf/Stem Extract, Panax Ginseng Root Extract, Panthenol, Lactic Acid, Sodium Benzoate, Potassium Sorbate, Triethanolamine, Carbomer, Citric Acid, Methylparaben, Diazolidinyl Urea, Limonene, Linalool, Geraniol]. After the products were rubbed into the skin of the thighs, the treated areas were wrapped in cosmetic foil to improve the absorption of the active ingredients and left for 45 minutes. Therapy lasted between 25 and 35 days, and its efficacy was assessed at 14–18 days from the last treatment.

Group 3 consisted of 31 women aged 22–65 years (mean age 42.65 y.o., SD = 10.31). They were administered a series of 12 treatments including negative pressure vacuum-based tissue mobilisation using a mechanical device

Endermologie® (LPG Systems, Valence, France), delivered at 3–5-day intervals. Women were required to wear a special body suit Endermowear™ (LPG Systems, Valence, France) during each treatment. The posterior thigh treatment duration was 25–30 minutes. The device power settings were adjusted individually, based on the patient's pain tolerance, starting from the pain-free level, and gradually increased. Therapy lasted between 34 and 48 days, and its efficacy was assessed at 14–18 days from the last treatment.

The biometrics, including body height and weight, BMI, and thigh circumference, were ascertained in each participant before and after treatment. Additionally, at the end of treatment all participants were requested to express their satisfaction with treatment outcomes using an 11-point Likert scale, where 0 was “I am very dissatisfied, I do not see any change” and 10 was “I am very satisfied, I can see a very big change”.

Ultrasound Assessments

Each ultrasound assessment was carried out using two scanners. Subcutaneous tissue thickness was measured using the Philips Epiq 5 scanner (Philips, USA) with the 18MHz linear transducer (L18-5 model). The epidermis and dermis thickness, as well as the surface area of fat protrusions at the dermal subcutaneous junction (called papillae adipo-sae) were assessed using the DermaMed, skin-dedicated ultrasound device (Draminski, Poland) with the 48 MHz mechanical single-element transducer. Dermis echogenicity was determined by carrying out grayscale histogram analysis of acquired ultrasound images using the coefficient developed by Gniadecka et al.¹⁶ This was done using the high frequency ultrasound scanner-dedicated software. Pixels within the range of 0–30 in the standard grayscale range of 0–255 were counted within the region of interest (ROI) located in the dermis. Their number was divided by the total of pixels within that ROI and expressed as a percentage. An increased count of pixels within the range of 0–30 within the ROI provided the evidence of reduced dermal echogenicity.

In each participant, prior to the ultrasound examination of the thigh, the transducer application site was determined. The site was identified in proximity to characteristic anatomical features, such as skin marks or nevi. In the absence of such features, the measurement site was localized by measuring the distance from the popliteal crease using a ruler. The point of transducer application was then marked on the skin with a marker, photographed, and thoroughly documented in the patient's record. This procedure ensured that subsequent examinations could be performed at exactly the same location. All measurements and ultrasound assessments were carried out twice throughout the study: at baseline (prior to treatment) and on day 14–18 following treatment completion. The ultrasound scanner settings were identical for all ultrasound assessments carried out as a part of the study. To minimize measurement errors, two consecutive measurements of each parameter were performed on the ultrasound image, and the mean value was used for statistical analysis.

Statistical Analysis

The data was analysed using the Statistica 13.3 software bundle. Distribution normality was ascertained using the Shapiro–Wilk test. The within-group differences were ascertained using two-sample *t*-test (for parametric variables) and Mann–Whitney *U*-Test (for non-parametric variables). To ascertain the between-group differences, one-way ANOVA on ranks was used. Pearson's correlation coefficient and Spearman's rank correlation coefficient were also used. The $\alpha = 0.05$ was considered statistically significant for all comparisons.

Results

The data was analysed both within-groups to ascertain change from baseline and between-groups to ascertain differences in baseline status as well as change in individual parameters between groups receiving different anti-cellulite treatments. All data is presented as Table 2.

Epidermis Thickness

At baseline, there were significant differences in epidermis thickness between Group 2, where the mean epidermis thickness was 0.14 mm vs Group 1 and Group 3, where the values were comparable. We have demonstrated a significant ($Z = 3.14$, $p = 0.002$ and $t = 2.33$, $p = 0.027$, respectively) epidermis thickness reduction from baseline in Groups 2 (by 14.29%) and 3 (by

Table 2 Changes in Skin Assessment Parameters in Groups 1–3 by Anti-Cellulite Treatment Type

Parameter	Timepoint		Group 1 ALIDYA™ Mesotherapy n = 24			Group 2 Afrodita Cosmetics Body Wrap n = 29	Group 3 Endermologie® Tissue Mobilisation n = 31	Between-Group Differences: One-Way ANOVA (F)/Kruskal-Wallis test (H)							
			M	min	max			SD	M	min	max	SD	M	min	max
High frequency US	Epidermis thickness [mm]	Baseline	0.11	0.08	0.19	0.03	0.14	0.08	0.2	0.04	0.12	0.08	0.19	0.03	H = 10.56
		After treatment	0.11	0.08	0.16	0.02	0.12	0.08	0.19	0.02	0.11	0.07	0.16	0.02	H = 3.08
	Student's T-test (t)/Wilcoxon signed-rank test (T/Z)		T = 73		Z = 3.14					t = 2.33					
	p		0.868		0.002					0.027					
	% of change		0%		−14.29%					−8.33%					
	Dermis thickness [mm]	Baseline	1.52	1.08	1.93	0.2	1.67	1.30	2.18	0.22	1.62	1.26	2.04	0.2	F = 3.55
		After treatment	1.5	1.04	1.96	0.23	1.51	0.92	1.87	0.24	1.54	1.21	2.09	0.22	F = 0.27
	Student's T-test (t)/Wilcoxon signed-rank test (T/Z)		t = 0.68		t = 3.89					t = 2.30					
	p		0.5		≤0.001					0.03					
	% of change		−1.31%		−9.58%					−4.35%					
	Dermal echogenicity (pixel range of 0–30) [%]	Baseline	2.61	0.73	4.2	1.01	2.5	0.18	6.19	1.44	2.22	0.85	3.85	0.8	H = 1.84
		After treatment	3.02	0.79	5.2	1.12	2.95	0.95	6.39	1.49	3.36	0.82	4.93	1.28	H = 1.95
	Student's T-test (t)/Wilcoxon signed-rank test (T/Z)		t = −2.99		t = −4.84					Z = 4.82					
	p		0.006		≤0.001					≤0.001					
	% of change		+15.71%		+18%					+51.35%					
Surface area of fat protrusions at the dermal subcutaneous junction [mm²]	Baseline	1.14	0.45	2.0	0.43	0.88	0.39	1.96	0.44	1.05	0.2	2.58	0.67	H = 4.65	
	After treatment	0.73	0.17	1.19	0.31	0.55	0.14	1.53	0.42	0.84	0.13	2.59	0.72	H = 5.6	
Student's T-test (t)/Wilcoxon signed-rank test (T/Z)		t = 7.42		Z = 4.38					Z = 2.59						
p		≤0.001		≤0.001					0.009						
% of change		−35.96%		−37.5%					−20%						
Conventional US	Subcutaneous tissue thickness [mm]	Baseline	20.34	10.7	33.2	6.47	20.03	11	34.6	6.96	20.87	6.8	36.8	8.08	H = 2.09
		After treatment	16.53	9.2	28.9	5.44	14.19	9.1	20.5	2.92	13.48	6.5	30.5	4.16	H = 1.1
	Student's T-test (t)/Wilcoxon signed-rank test (T/Z)		T = 0		Z = 4.57					Z = 4.86					
	p		≤0.001		≤0.001					≤0.001					
	% of change		−18.73%		−29.16%					−35.40%					

(Continued)

Table 2 (Continued).

Parameter	Timepoint		Group 1 ALIDYA™ Mesotherapy n = 24			Group 2 Afrodita Cosmetics Body Wrap n = 29	Group 3 Endermologie® Tissue Mobilisation n = 31	Between-Group Differences: One-Way ANOVA (F)/Kruskal–Wallis test (H)							
			M	min	max	SD	M	min	max	SD	M	min	max	SD	F/H
Parameters ascertained clinically	Thigh circumference [cm]	Baseline	56.58	49	65	4.78	57.29	50	67	4.52	57.47	51	69	4.52	H = 0.61
		After treatment	55.02	47	64	4.64	55.93	50	65	4.52	55.34	49	66	4.52	H = 0.67
	Student's T-test (t)/Wilcoxon signed-rank test (T/Z)		t = 9.76		Z = 4.39						Z = 4.30				
	p		≤0.001		≤0.001						≤0.001				
	% of change		−2.76%		−2.37%						−3.71%				
	Body weight [kg]	Baseline	66.64	55	92	8.51	68.01	55	94	10.27	67.1	51	92	8.15	H = 0.15
		After treatment	66.04	54	89	8.31	66.90	53	93	10.46	66.13	52	89	7.83	H = 0.05
	Student's T-test (t)/Wilcoxon signed-rank test (T/Z)		t = 2.68		Z = 3.9						t = 5.48				
	p		0.01		≤0.001						≤0.001				
	% of change		−0.9%		−1.63%						−1.45%				
	BMI	Baseline	23.47	19.71	31.1	2.81	24.32	19.16	35.65	3.89	23.54	17.65	31.1	2.74	H = 0.55
		After treatment	23.25	19.41	30.07	2.76	23.92	17.92	34.85	3.95	23.20	17.99	30.08	2.62	H = 0.33
	Student's T-test (t)/Wilcoxon signed-rank test (T/Z)		t = 2.69		Z = 3.84						t = 5.56				
	p		0.013		≤0.001						≤0.001				
	% of change		−0.94%		−1.64%						−1.44%				
	Cellulite severity assessed using Nürnberg- Müller scale	Baseline	2.04	1	3	0.62	2.17	1	3	0.66	2.23	1	3	0.72	H = 1.71
		After treatment	1.21	0	2	0.59	1.24	0	2	0.51	1.29	0	3	0.74	H = 0.492
	Student's T-test (t)/Wilcoxon signed-rank test (T/Z)		T = 0		Z = 4.29						Z = 3.99				
	p		≤0.001		≤0.001						≤0.001				
	% of change		−40.67%		−42.86%						−41.15%				

Note: F, the ANOVA F-test statistic; H, Kruskal–Wallis test statistic; M, mean; max, maximum; min, minimum; n, number; p, statistical significance level; SD, standard deviation; t, Student's T-test statistic; T, Wilcoxon signed-rank sum for $n \leq 25$; Z, Wilcoxon signed-rank sum for $n > 25$. All statistically significant results were marked in bold.

Abbreviation: BMI, body mass index.

8.33%) (Figure 2). The mean epidermis thickness (0.11 mm at baseline) in Group 1 did not change after treatment. Following treatment completion, there were no significant between-group differences in epidermis thickness.

Dermis Thickness

At baseline, there were significant differences in dermis thickness between Group 1 vs Group 2 and Group 1 vs Group 3. Group 1 had the lowest dermis thickness, with higher measurements (comparable between the groups) seen in Groups 2

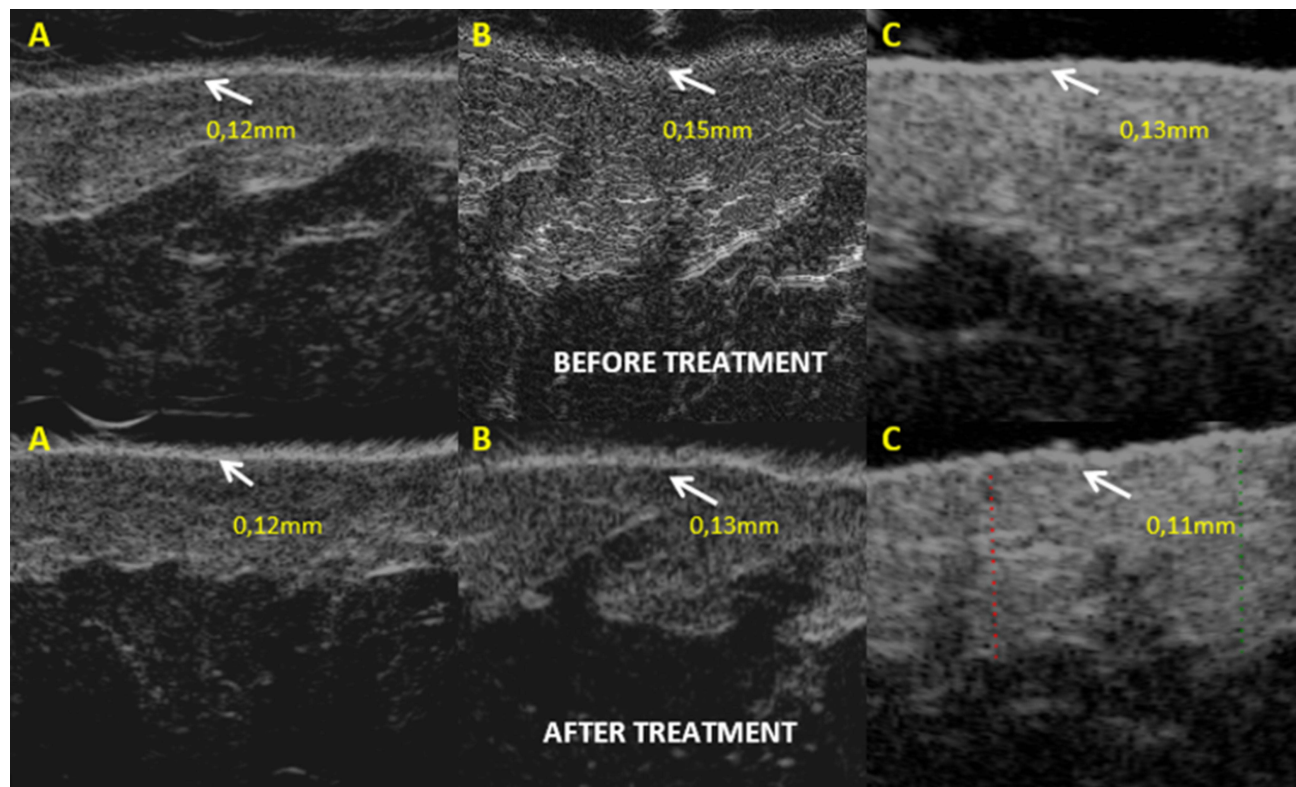


Figure 2 Change from baseline in epidermis thickness after anti-cellulite treatment. (A) -Group 1 (ALIDYA™ mesotherapy), (B) - Group 2 (Afrodita Cosmetics body wrap), (C) - Group 3 (Endermologie® tissue mobilisation).

and 3. We have demonstrated dermis thickness reduction within all three groups following each study treatment (Figure 3). The largest change from baseline (of 9.58%) was shown in Group 2 ($t = 3.89$; $p \leq 0.001$), followed by a smaller yet significant change shown in Group 3 ($t = 2.3$; $p = 0.03$). Dermis thickness in Group 1 was only reduced by 1.31% which was non-significant. Following treatment completion, there were no significant between-group differences in dermis thickness.

Dermal Echogenicity

At baseline, there were no significant between-group differences in dermal echogenicity. After treatment, we have demonstrated a significant increase in the percentage of pixels within the range of 0–30 from baseline, which provides evidence of significantly reduced dermal echogenicity within all three groups (Figure 4). This reduction ranged from 15.71% (Group 1), through 18% (Group 2), to 51.35% (Group 3). Following treatment completion, there were no significant between-group differences in dermal echogenicity.

The Surface Area of Fat Protrusions at the Dermal Subcutaneous Junction (Papillae Adiposae)

At baseline, there were no significant between-group differences in the surface area of fat protrusions at the dermal subcutaneous junction. We have demonstrated a significant reduction of surface area of papillae adiposae within all three groups – by 35.96% (from 1.14 mm² to 0.73 mm²), 37.5% (from 0.88 mm² to 0.55 mm²), and 20% (from 1.05 mm² to 0.84 mm²) in Group 1, 2 and 3, respectively (Figure 5). Following treatment completion, there were no significant between-group differences in the surface area of fat protrusions at the dermal subcutaneous junction.

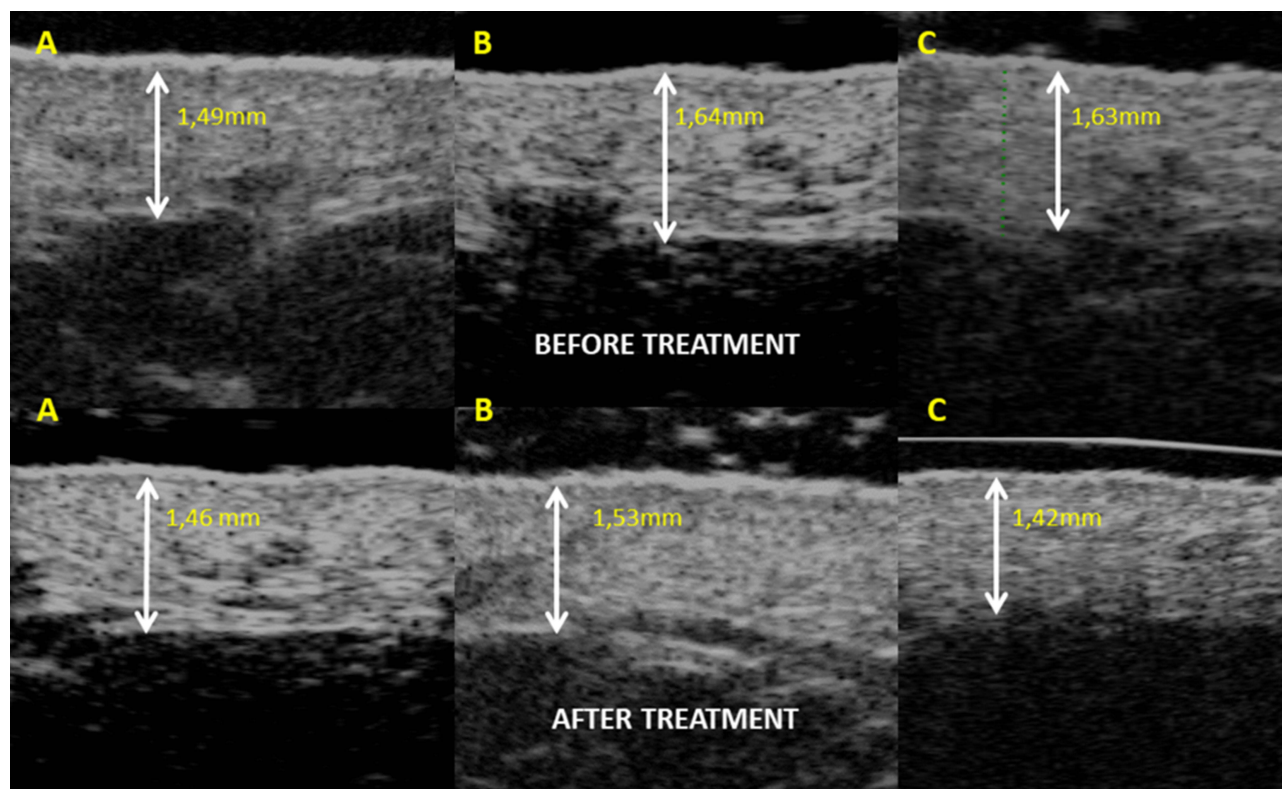


Figure 3 Change from baseline in dermis thickness after anti-cellulite treatment. (A) -Group 1 (ALIDYA™ mesotherapy), (B) - Group 2 (Afrodita Cosmetics body wrap), (C) - Group 3 (Endermologie® tissue mobilisation).

Subcutaneous Tissue Thickness

At baseline, there were no significant between-group differences in the subcutaneous tissue thickness. We have demonstrated a significant reduction in the subcutaneous tissue thickness within all three groups – by 18.73% (from 20.34 mm to 16.53 mm), 29.16% (from 20.03 mm to 14.9 mm), and 35.40% (from 20.87 mm to 13.48 mm) in Groups 1, 2 and 3, respectively (Figure 6). Following treatment completion, there were no significant between-group differences in the subcutaneous tissue thickness.

Parameters Ascertained Clinically: Thigh Circumference, Body Weight, BMI, and Cellulite Severity Assessment

At baseline, there were no significant between-group differences in any of the parameters ascertained clinically. Following treatment completion, we have demonstrated a reduction in thigh circumference, body weight and BMI within all three groups. The largest reduction in thigh circumference (by 3.71%) was seen in Group 3, whereas the largest reduction in body weight and BMI was seen in Group 2. All differences, except for body weight in Group 1, were significant. Cellulite severity assessment using the Nürnberger-Müller scale demonstrated a significant reduction (above 40%) within all three groups after treatment. Following treatment completion, there were no significant between-group differences in any of the parameters ascertained clinically.

Participant-Reported Satisfaction with Treatment Outcomes

All participants provided high ratings of their satisfaction with treatment outcomes, the mean score among all women who took part in the study ($n = 84$) was 7.54 points. The highest level of satisfaction (8.48 points) was expressed by participants from Group 3, followed by those in Group 2 (7.34 points) and Group 1 (6.58 points). Statistically significant differences between groups are confirmed by the result of the Kruskal–Wallis test ($H = 17.62$, $p = 0.024$).

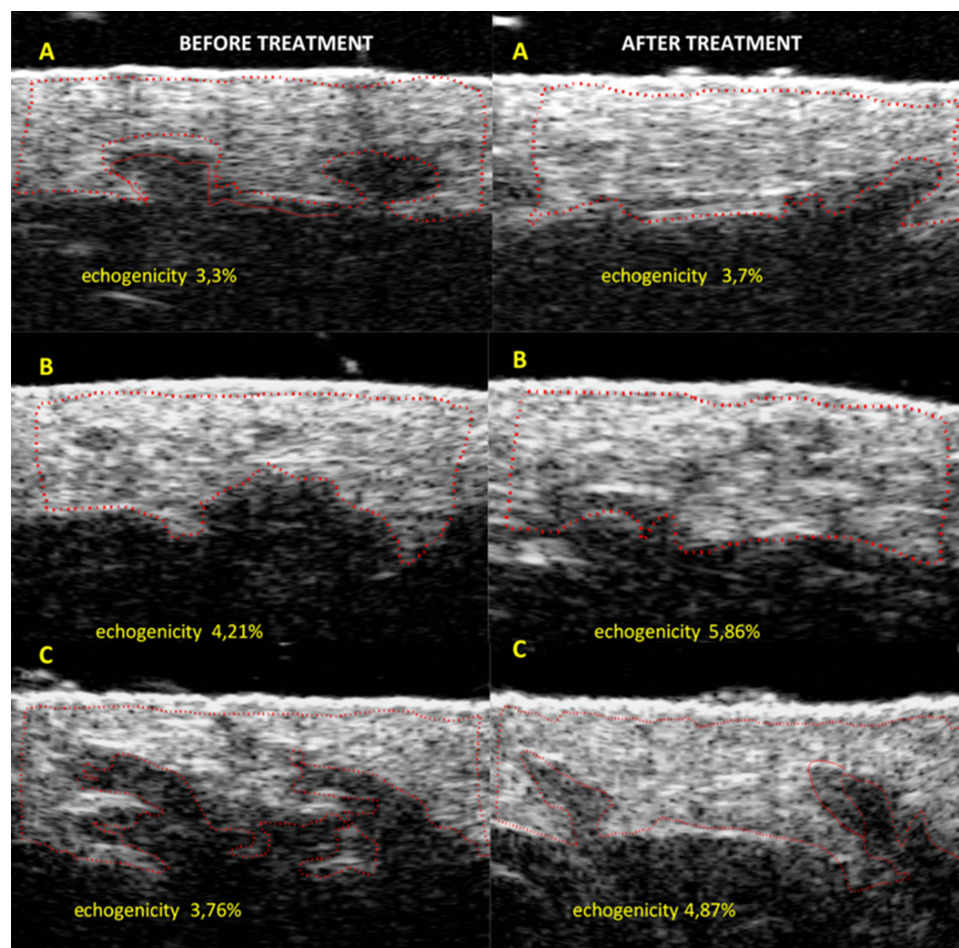


Figure 4 Change from baseline in dermal echogenicity after anti-cellulite treatment. (A) -Group 1 (ALIDYA™ mesotherapy), (B) - Group 2 (Afrodita Cosmetics body wrap), (C) - Group 3 (Endermologie® tissue mobilisation). The area of interest (ROI) is marked with a red dotted line.

Evaluation of Relationships Between Variables

The relationships between the variables assessed during the ultrasound scan and the variables assessed by palpation, ie thigh circumference, body weight, BMI and cellulite severity as assessed using the Nürnberger-Müller scale, were also evaluated. The relationships between variables were evaluated separately for results obtained before and after anti-cellulite therapies (Table 3).

Statistically significant results indicative of a correlation were seen between cellulite severity as assessed using the Nürnberger-Müller scale and the surface area of papillae adiposae in all study groups before therapy and in Group 3 after therapy. The highest pre-therapy correlation ($r = 0.8$, $p \leq 0.001$) was found in Group 3, and the lowest ($r = 0.58$, $p \leq 0.001$) was found in Group 2, which was treated with cosmetic products. After the completion of anti-cellulite therapies, statistically significant results were obtained only for Group 3 ($r = 0.55$, $p = 0.001$).

The obtained results also enabled establishing a significant relationship between subcutaneous tissue thickness and cellulite severity as assessed using the Nürnberger-Müller scale. The results collected before therapy in Groups 1–3 are indicative of high correlations. The highest correlation was reported in Group 3 ($r = 0.82$, $p \leq 0.001$) and the lowest in Group 2 ($r = 0.59$, $p \leq 0.001$). After the completion of anti-cellulite therapies, lower correlations were found than before the start of therapy; however, the results are statistically significant with the exception of Group 2.

Statistically significant results were also obtained for the relationship between dermal echogenicity and thigh circumference, body weight and BMI, both before and after therapy, but only in Group 2.

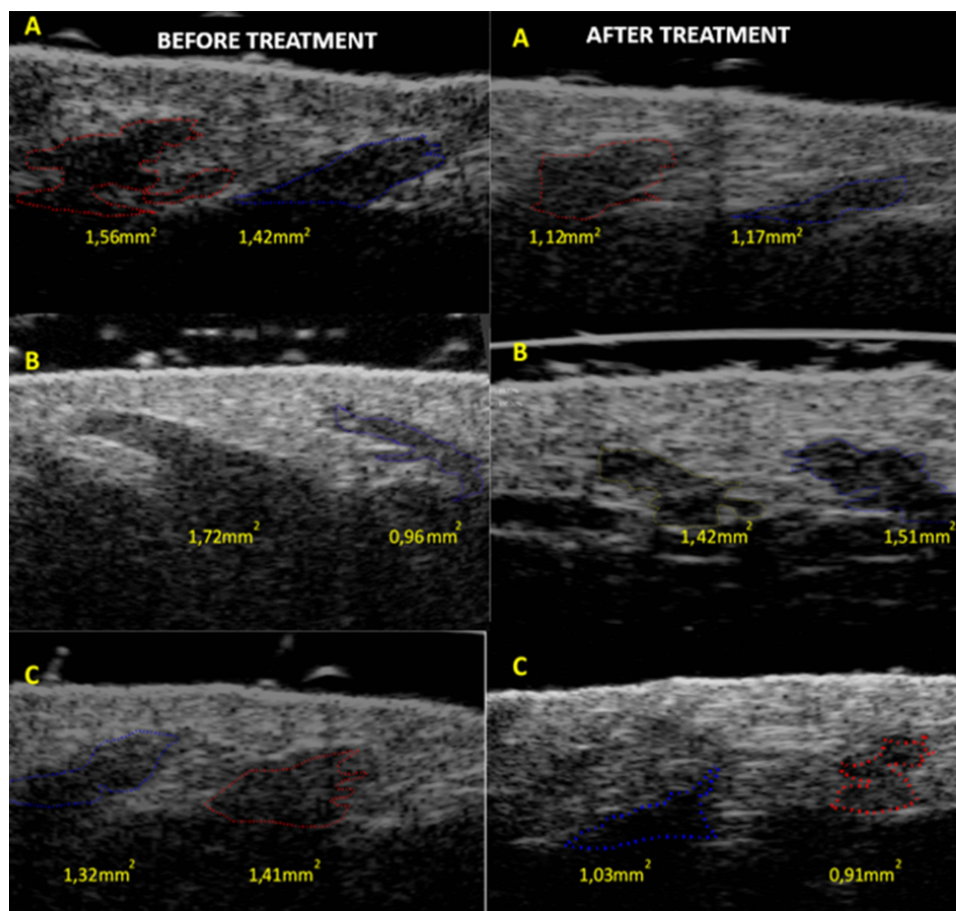


Figure 5 Change from baseline in surface area of fat protrusions at the dermal subcutaneous junction after anti-cellulite treatment. (A) -Group 1 (ALIDYA™ mesotherapy), (B) - Group 2 (Afrodita Cosmetics body wrap), (C) - Group 3 (Endermologie® tissue mobilisation). The red and blue dotted lines indicate examples of fat protrusions at the dermal subcutaneous junction.

Statistically significant results were not reported or were only incidental with respect to other compared variables (Table 3).

Discussion

This study provides relevant information on how high frequency ultrasound imaging can be utilised in assessing cellulite severity, and monitoring changes within the skin and subcutaneous tissue to determine the efficacy of individual anti-cellulite treatments.

Cellulite was assessed using two types of ultrasound devices: a conventional scanner with a linear probe and a specialized skin-dedicated device with a mechanical probe, both of which are commercially available. The decision to use both types of scanners was linked to the fact that an increasing transducer frequency corresponds to lower tissue penetration. The tissue penetration capacity of a 50 MHz mechanical probe is only 3–4 mm.¹⁵ Thus, to visualise slightly deeper located structures, such as subcutaneous tissue, a lower frequency transducer is required. As a result of using both types of ultrasound devices, imaging of subcutaneous tissue, as well as dermis and epidermis was possible and reliable measurements could be obtained. Based on own clinical experience as well as experiences reported by other authors,^{17–24} cellulite was assessed by means of 5 ultrasound markers. Four of them (epidermis thickness, dermis thickness, dermal echogenicity and surface area of the papillae adiposae) were assessed using a scanner with a mechanical probe, while the subcutaneous tissue thickness was measured using a conventional ultrasound scanner.

Among the parameters assessed using high frequency ultrasound, the surface area of fat protrusions at the dermal subcutaneous junction was considered the most useful one. Those protrusions, referred to as papillae adiposae, are an

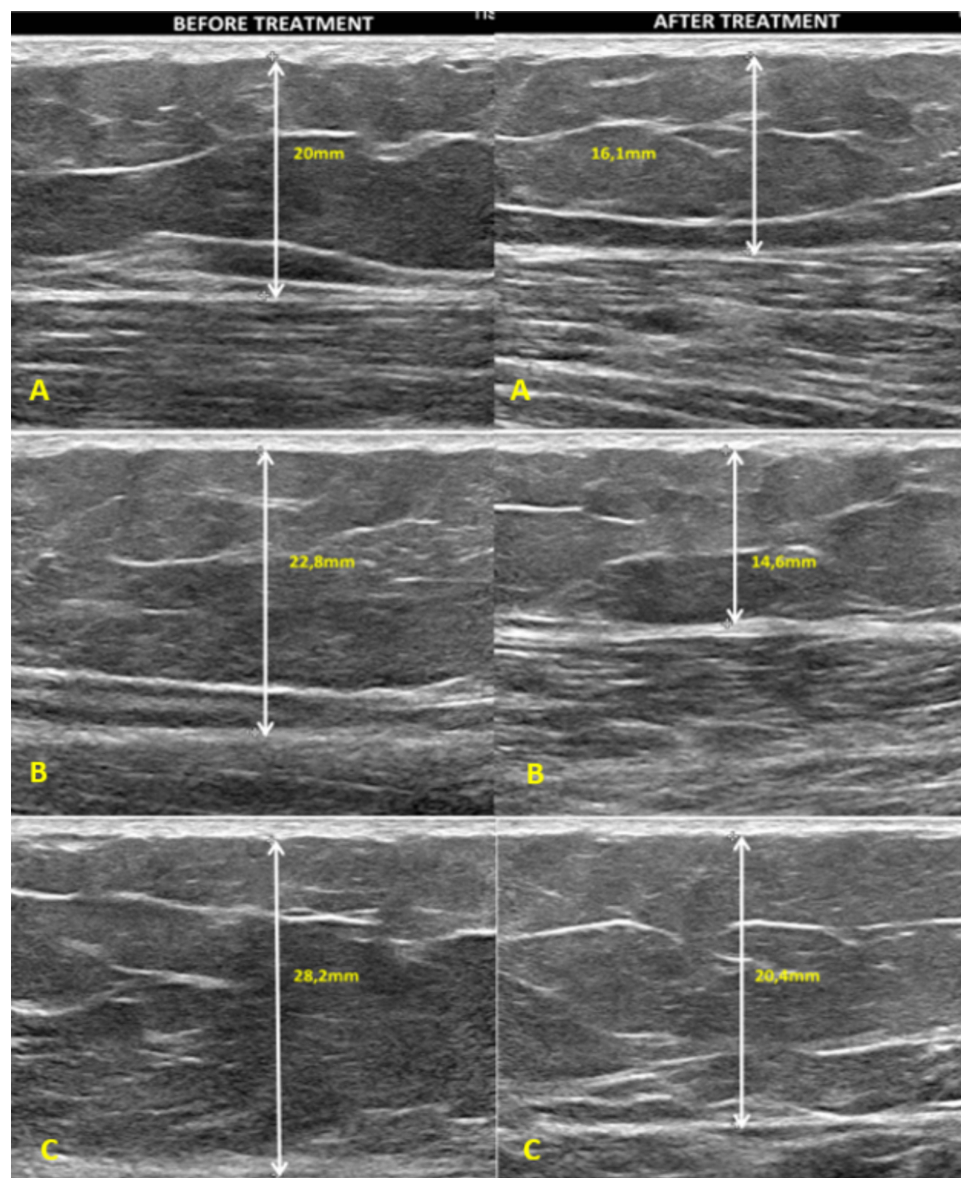


Figure 6 Change from baseline in subcutaneous tissue thickness after anti-cellulite treatment. (A) -Group 1 (ALIDYA™ mesotherapy), (B) - Group 2 (Afrodita Cosmetics body wrap), (C) - Group 3 (Endermologie® tissue mobilisation).

ultrasound finding pathognomonic of cellulite.^{17,18,21,22,25,26} While the surface area of the papillae adiposae was assessed, other ascertainable parameters include the length of the dermis-hypodermis interface²⁶ or the length of the papillae adiposae.^{17,21} The authors' experience indicates that the measurement of the area of fat protrusion is considered to be the most objective and easy to perform, as the ultrasound machine used includes this function in its software.^{17,18,21,22} The authors believe that the selected parameter may be considered as a measure of treatment efficacy: the reduced surface area of fat protrusions at the dermal subcutaneous junction in each subgroup was demonstrated. The recognition of this parameter as important for cellulite assessment is also supported by the fact that it correlates with the cellulite severity scale, as demonstrated by the study. Furthermore, other authors also support the notion of cellulite severity reduction with the reduction of the papillae adiposae, by demonstrating the correlation between the surface area of those fat protrusions at the dermal subcutaneous junction and Nürnberger-Müller scale-based cellulite severity assessment.^{10,22,27} What follows is a conclusion that an effective anti-cellulite treatment leads to a reduction of the papillae adiposae and of cellulite severity.

Table 3 Correlations Between Variables Before and After the Completion of Anti-Cellulite Therapy in Each Group

Parameter		Thigh Circumference [cm]	Body Weight [kg]	BMI	Cellulite -the Nürnberger-Müller Scale	Thigh Circumference [cm]	Body Weight [kg]	BMI
		BASELINE				AFTER TREATMENT		
Epidermis thickness [mm]	Group 1 ALIDYA ™ n = 24	−0.02	−0.16	−0.14	−0.15	−0.3	−0.21	−0.25
		p = 0.92	p = 0.512	p = 0.51	p = 0.48	p = 0.154	p = 0.324	p = 0.231
	Group 2 body wrap n = 29	−0.13	−0.09	−0.17	−0.06	0.19	0.32	0.33
		p = 0.513	p = 0.66	p = 0.379	p = 0.748	p = 0.33	p = 0.092	p = 0.085
	Group 3 Endermologie ® n = 31	−0.17	−0.01	−0.11	0.23	0.42	0.39	0.43
		p = 0.37	p = 0.956	p = 0.594	p = 0.215	p = 0.02	p = 0.029	p = 0.016
Dermis thickness [mm]	Group 1 ALIDYA ™ n = 24	0.006	−0.17	−0.01	−0.1	0.19	−0.04	−0.02
		p = 0.978	p = 0.428	p = 0.645	p = 0.649	p = 0.378	p = 0.858	p = 0.923
	Group 2 body wrap n = 29	−0.09	−0.21	−0.13	−0.23	−0.03	−0.27	−0.27
		p = 0.632	p = 0.256	p = 0.518	p = 0.231	p = 0.89	p = 0.161	p = 0.157
	Group 3 Endermologie ® n = 31	0.08	0.02	0.01	−0.01	0.13	0.2	0.15
		p = 0.662	p = 0.898	p = 0.948	p = 0.943	p = 0.475	p = 0.289	p = 0.409
Dermal echogenicity (pixel range of 0–30) [%]	Group 1 ALIDYA ™ n = 24	0.54	0.30	0.20	−0.05	0.2	0.11	0.05
		p = 0.007	p = 0.161	p = 0.351	p = 0.831	p = 0.345	p = 0.608	p = 0.828
	Group 2 body wrap n = 29	−0.47	−0.39	−0.42	−0.13	−0.6	−0.48	−0.52
		p = 0.012	p = 0.035	p = 0.023	p = 0.512	p = 0.001	p = 0.008	p = 0.004
	Group 3 Endermologie ® n = 31	0.15	0.09	0.07	−0.08	0.1	−0.12	−0.11
		p = 0.407	p = 0.647	p = 0.709	p = 0.654	p = 0.609	p = 0.523	p = 0.543

Surface area of fat protrusions at the dermal subcutaneous junction [mm ²]	Group 1 ALIDYA [™] n = 24	−0.16	0.07	0.11	0.77	−0.09	−0.07	0.13
		p = 0.453	p = 0.798	p = 0.605	p ≤ 0.001	p = 0.676	p = 0.742	p = 0.54
	Group 2 body wrap n = 29	−0.15	−0.18	−0.19	0.58	−0.32	−0.36	−0.35
		p = 0.449	p = 0.34	p = 0.336	p ≤ 0.001	p = 0.096	p = 0.058	p = 0.059
	Group 3 Endermologie [®] n = 31	0.1	0.1	0.09	0.8	−0.28	−0.11	−0.11
		p = 0.598	p = 0.611	p = 0.628	p ≤ 0.001	p = 0.133	p = 0.572	p = 0.568
Subcutaneous tissue thickness [mm]	Group 1 ALIDYA [™] n = 24	−0.01	0.12	0.13	0.73	0.06	0.17	0.27
		p = 0.953	p = 0.585	p = 0.546	p ≤ 0.001	p = 0.784	p = 0.437	p = 0.22
	Group 2 body wrap n = 29	0.24	0.04	0.11	0.59	0.15	0.03	0.15
		p = 0.207	p = 0.819	p = 0.556	p ≤ 0.001	p = 0.435	p = 0.864	p = 0.439
	Group 3 Endermologie [®] n = 31	0.07	0.03	0.02	0.82	−0.13	−0.09	−0.08
		p = 0.699	p = 0.877	p = 0.929	p ≤ 0.001	p = 0.491	p = 0.629	p = 0.679

Notes: n – number; p – statistical significance level; grey fields – results obtained using Pearson's correlation coefficient; remaining fields – results obtained using Spearman's rank correlation coefficient. All statistically significant results were marked in bold.

Measurements of dermis thickness demonstrated its significant reduction after cellulite-reducing body wrap and Endermologie® tissue mobilisation treatment with non-significant reduction after ALIDYA™ mesotherapy. This may suggest that tissue mobilisation through massage that constituted a part of treatment in Groups 2 and 3, is required to induce dermis thickness reduction.²⁸ However, in the light of other published data on the lack of correlation between dermis thickness and other ultrasound-ascertained parameters^{22,27,29} dermis thickness might be considered irrelevant as an efficacy marker of anti-cellulite treatments.

Similarly to dermis thickness, a reduction in epidermis thickness after anti-cellulite treatment was observed, but it was only significant in Groups 2 and 3. This may suggest the key role of mechanical exfoliation, which occurs during rubbing products into the skin before wrapping or tissue mobilisation as a part of Endermologie® treatment. Administration of anti-cellulite products by mesotherapy is not associated with the exfoliation of stratum corneum, hence no significant changes in dermis thickness in our Group 1. The high variability of results reported by other authors can be explained by the fact that the epidermis is a particularly thin structure and the measurements taken based on images acquired using conventional scanners with linear transducers are associated with a high risk of measurement error.^{21,27,30}

Dermal echogenicity analysis demonstrated the effect of all treatments on its reduction. The biggest change seen in Group 3 could be explained by improved microcirculation in the treated area.^{31,32} Unfortunately, our results are not sufficient for concluding, due to the paucity of comparable studies other than our own.^{17,18} Several authors assessed dermal echogenicity based on bright pixels, likely in keeping with collagen fibres which are expected to reappear after anti-cellulite treatment.^{23,25,33} What seems lacking, though, is a clear methodology for dermal echogenicity assessment. Based on our experience, we believe that while echogenicity assessment appears useful, further research is needed to identify appropriate pixel range it should be based upon.

Results suggest that an effective anti-cellulite treatment leads to a reduction of subcutaneous tissue thickness. All our studied treatments met this efficacy endpoint. Subcutaneous tissue thickness is most common parameter assessed during skin ultrasound, and all authors support the notion of reduction in subcutaneous tissue thickness as a result of anti-cellulite treatments.^{18,21,24,25,30} Therefore, two types of ultrasound equipment are necessary in the assessment of cellulite. Considering an established correlation between subcutaneous tissue thickness and cellulite severity, as confirmed by this study, a change in subcutaneous tissue thickness seems one of the key efficacy markers of anti-cellulite treatments.

Our comparative efficacy research on three different cellulite-reducing treatments demonstrated the efficacy of all three approaches. Our data is obviously insufficient to determine which of the three treatments proved most effective. Each treatment was associated with comparable changes within the studied parameters, with no significant between-group differences following treatment completion. However, based on the number values and participant-reported satisfaction with treatment outcomes, we would be inclined to consider ALIDYA™ mesotherapy to be slightly less effective than the two other study treatments.

Despite its promising results, the study has its limitations, namely a small sample and subgroup size, and a short follow-up following treatments. When interpreting the results, it should be taken into account that they may be partially affected by measurement error due to the very small thickness of the examined structures and the difficulty in precisely defining the transducer application site. Another limitation that needs to be considered is the manual performance of measurements on ultrasound images. In the present study, to minimize potential errors, each parameter was measured twice and the mean value was used for analysis. However, the development of software enabling automatic measurements would be of particular importance in the future, as it would reduce errors associated with imprecise marking of the analyzed structures by the investigator. Another significant limitation is the lack of full study randomisation, which may affect group comparability and increase the risk of bias. In addition, this study did not take into account variables such as hormonal contraceptive use, the menstrual cycle phase in which ultrasound scans was performed, as well as menopause and the use of hormone replacement therapy, all of which may affect the presentation of skin affected by cellulite.^{34,35} Technically, the need to use both conventional and high frequency ultrasound may be seen as a limitation which prevents such assessment from becoming more common in clinical practice. Considering the above limitations, the results of this research should be analysed taking into account the possibility of uncontrolled confounding variables.

The study demonstrated new possibilities emerging in aesthetic medicine and cosmetology associated with the use of high frequency ultrasound to monitor the efficacy of anti-cellulite treatments. With high frequency ultrasound, it is

possible to assess the condition of the skin and subcutaneous tissue at baseline, and after different treatments. It is particularly important, as a new tool is thus available in aesthetic medicine, cosmetology and dermatology, which enables safe and non-invasive monitoring of changes within the skin and subcutaneous tissue.

High frequency ultrasound has a potential to become a routine skin assessment method, thus meeting the essential need for a reliable diagnostic assessment tool to be used in aesthetic medicine and cosmetology. Furthermore, with objective monitoring of treatment outcomes, it is now possible to offer patients bespoke treatment options which accurately meet their needs. This can translate into improved treatment efficacy and contribute to eliminating ineffective treatment modalities. Finally, ultrasound assessment before and after treatment, which captures and documents changes occurring within the skin in response to treatment, may make our clinical practice more evidence-based and robust, as well as provide objective evidence of treatment efficacy with the absence of complications for the purposes of potential litigation.

The availability of mobile US scanners can contribute to an improved uptake of skin ultrasound. It seems promising that those are increasingly more advanced, offering superior imaging quality, at a relatively low price, which addresses both technological and financial barriers and makes us hopeful about a wide application of high frequency ultrasound in routine practice.¹⁵

Conclusion

The results of the study confirm that high frequency ultrasound is useful in cellulite imaging and in assessing the efficacy of anti-cellulite treatments. Subcutaneous tissue thickness and the surface area of fat protrusions at the dermal–subcutaneous junction were found to be the most useful parameters in the assessment of cellulite.

From a practical perspective, high frequency ultrasound – due to its numerous advantages, such as non-invasiveness, safety, accessibility, reliability – has a chance to become common in the daily practice of cosmetology clinics, where it will be used to assess cellulite and the efficacy of therapies.

Despite the positive results, further research is required in this regard. Research should focus on developing a uniform protocol for the assessment of cellulite and standards for the ultrasound imaging of cellulite. A randomized trial on a large patient cohort, including several months of post-treatment follow-up, is therefore needed. It is also essential to consider additional variables, such as the phase of the menstrual cycle. An important direction in the development of high frequency ultrasonography is the creation of dedicated software that would enable multiple measurements within the same image, thereby minimizing potential measurement errors. Research on an ultrasound-based cellulite severity scale also appears to be important.

Data Sharing Statement

The data presented in this study are available on request from the corresponding author.

Ethics Approval

The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of the Medical University of Warsaw (approval number: KB/67/2014). The study protocol was compliant with the Declaration of Helsinki.

Patient Consent

Written informed consent was obtained from all patients.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors have no conflicts of interest to declare for this work.

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