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Efficacy and Safety of EqualsTwo® Body Firming Cream in Lactating Postpartum Women with Cellulite: An Open-Label Single-Arm Study

Dhruv Zaveri[1], Trupti Patel[2], Kinjal Barot[3], Parth Joshi[4], Sunil S. Iyer[5], M. E. Kannan[5]

[1]Senior Executive, Zydus Lifesciences Limited, Pharmaceutical Technology Centre (PTC), Sarkhej Bavla N.H. No.8A, Moraiya, Tal: Sanand, Dist.: Ahmedabad 382 210, Gujarat, India.
[2]Deputy General Manager, Zydus Wellness Centre, Ahmedabad 382481, Gujarat, India
[3]Deputy General Manager, Zydus Lifesciences Limited, Pharmaceutical Technology Centre (PTC), Sarkhej Bavla N.H. No.8A, Moraiya, Tal: Sanand, Dist.: Ahmedabad 382 210, Gujarat, India.
[4]Principal Investigator, Cliantha Research Limited, TP 86, FP 28/1, Off S.P. Ring Road, Sarkhej, Ahmedabad – 382210, Gujarat, India.
[5]Head, Zydus Lifesciences Limited, Pharmaceutical Technology Centre (PTC), Sarkhej Bavla N.H. No.8A, Moraiya, Tal: Sanand, Dist.: Ahmedabad 382 210, Gujarat, India.

Corresponding Author: Dhruv Zaveri

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ABSTRACT

Context: Cellulite causes skin dimpling and psychosocial distress. Invasive procedures and pharmacological agents offer limited, short-lived benefit. Botanical extracts improve dermal structure, circulation, and hydration.
Aims: To evaluate the efficacy and safety of EqualsTwo® body firming cream (Investigation product) containing Centella asiatica, Sacred Lotus, and Longan fruit extracts in reducing cellulite and improving skin biophysical properties in lactating mothers.
Settings and Design: Open-label, single-arm prospective trial in lactating postpartum women (infants aged 0–36 months) with stage I–III cellulite.
Methods and materials: Investigation product (4-5g) was applied to hips, buttocks, thighs, and abdomen twice daily for 12 weeks. Primary outcomes were cellulite stage/severity, skin tonicity and circumference reduction. Secondary outcomes included change in elasticity, hydration, trans epidermal water loss (TEWL), participant-reported satisfaction, and product response index.
Statistical Analysis Used: Descriptive statistics with paired comparisons; significance at $P<0.0001$.
Results: Fifty-four out of 60 participants completed the study. At baseline, one-third each were classified as stage I, II, or III. By day 84, 40.7% exhibited no detectable cellulite and 57.4% showed mild involvement; none remained in advanced stages. Mean reductions in circumference were 1.8 cm (thighs), 2.1 cm (buttocks), and 2.0 cm (hips) ($P<0.0001$). Elasticity improved 5–6%, hydration increased by 20 units, and TEWL decreased 12–13%. All participants reported improved skin clarity, and moisturization; no adverse events observed.
Conclusions: EqualsTwo® body firming cream (Investigation product) significantly reduced cellulite severity and circumference while enhancing elasticity, hydration, and barrier function in lactating mothers, demonstrating excellent safety over 12 weeks.

Keywords: Botanical cream; Cellulite; Centella asiatica; Dimocarpus longan; Nelumbo nucifera; Lactating mother.

INTRODUCTION

Cellulite is a common dermatologic condition, affecting an estimated 80–90% of post-pubertal women irrespective of body mass index or ethnicity.[1–3] Cellulite reflects structural changes in dermis, fat, microcirculation, and fibrous septae, not just "extra weight" specifically in lactating women. Among female hormones that can affect this condition estrogen is central to cellulite development. Pregnancy is a high estrogen state and nursing during the post-partum phase is repeatedly noted to worsen or accelerate cellulite progression.[4]

In most cases cellulite arises from structural alterations at the dermal–subcutaneous junction, producing a dimpled appearance most evident on the thighs, buttocks, and abdomen. Although clinically benign, its high prevalence and visibility exert a significant psychosocial burden, often reducing body image satisfaction and quality of life.[5]

The pathophysiology of cellulite is multifactorial, involving fibrous septae tension, protrusion of subcutaneous fat into the dermis, microvascular and lymphatic dysfunction, and extracellular matrix remodeling.[6,7] Increasing demand for non-invasive aesthetic dermatology procedures has been reported globally.[8,6]

Management strategies include procedural interventions such as subcision, laser-assisted lipolysis, acoustic wave therapy, and radiofrequency devices, which may yield improvements but are invasive, costly, and associated with variable long-term efficacy.[9,10] Topical and pharmacological agents, including caffeine, retinoids, and aminophylline, have shown modest benefit through mechanisms of lipolysis, dermal thickening, and improved circulation. However, their prolonged use is often limited by irritant dermatitis, systemic absorption, or inconsistent tolerability.[11]

Lactating postpartum women constitute a distinct population where cellulite has been described as a normal adaptation that maximizes lower body fat stores for pregnancy and lactation for adequate calorie availability.[12] Although aesthetic concerns such as cellulite must be addressed alongside heightened safety considerations, including local tolerability and the potential for systemic absorption. Active ingredients in topical treatments struggle to penetrate beyond the dermis into subcutaneous fat layers, restricting benefits to superficial hydration or transient oedema reduction. Poor delivery systems usually cause methylxanthines, retinoids, and circulation agents (Ginkgo biloba, papain) to show only minimally effective results.[13] These limitations have prompted growing interest in herbal and plant-derived compounds, which are perceived as safer alternatives for long-term use. Centella asiatica has been shown to stimulate fibroblast activity and collagen synthesis, enhancing dermal tensile strength.[14,15] Nelumbo nucifera (Sacred Lotus) exhibits antioxidant and lipolytic effects that may mitigate adipocyte hypertrophy[16], while Dimocarpus longan (Longan fruit), rich in polyphenols, contributes to hydration and barrier restoration.[17] Together, these bioactive agents offer a mechanistically plausible approach to addressing adipose protrusion, vascular impairment, and hydration deficits central components of cellulite pathology.

As clinical evidence on topical anti-cellulite therapies in lactating women remains limited, this study was undertaken to evaluate the efficacy and safety of the investigational body firming cream in lactating postpartum women with cellulite.

We hypothesized that twice-daily application of EqualsTwo® Body Firming Cream (investigation product) over 84 days would reduce cellulite severity and improve skin biophysical properties, including elasticity, hydration, transepidermal water loss (TEWL), and body circumference, while maintaining an excellent safety profile.

MATERIALS & METHODS

Study Design and Setting: This is a prospective open-label, single-arm, interventional clinical trial designed to evaluate the safety and efficacy of the investigation product in lactating women conducted at a single dermatology centre (Ahmedabad, India) from August 2022 to February 2023.

Study Population: The study population comprised lactating postpartum mothers aged between 22-40 years with infants aged 0 to 36 months. Eligible participants were required to have visible cellulite of grade I–III as per the Cellulite Severity Grading Scale and grade 1–2 according to the Nürnberger–Müller classification, with involvement of the thighs, buttocks, hips, and/or abdomen. Participants were excluded if they had any active dermatological condition or lesion in the treatment areas (including psoriasis, eczema, erythema, edema, scars, wounds, or other visible lesions), varicose veins, or a history of phlebitis. Additional exclusion criteria included receipt of any cellulite treatment within 30 days prior to screening, any surgical procedure in the treatment areas within the preceding 3 months, or participation in another clinical study within the previous 90 days. A total of 60 participants were enrolled, out of which 54 completed the study while 6 were lost to follow-up.

Study Objective: The primary objective of the study was to evaluate the efficacy of the investigation product in improving cellulite severity, skin tonicity, and circumferential reduction of the thighs, buttocks, and hips. Secondary objectives included assessment of changes in skin elasticity, hydration, barrier function, and overall subject satisfaction and the product response index. The safety profile of the product was also monitored throughout the study period.

Investigation product Application Protocol: Approximately 4–5 g of the investigational product was applied topically on the hips, buttocks, thighs, and abdomen twice daily for a total duration of 84 days. Participants were instructed on proper application techniques and compliance was monitored throughout the study through a subject diary.

Study Procedures and Visits: All participants underwent a screening visit within 30 days prior to baseline, during which eligibility was confirmed and written informed consent was obtained. Following enrolment (Day 1 or baseline), participants attended follow-up visits on Days, 28, 56, and 84. At each visit, dermatological assessments and instrumental evaluations were performed. Safety was assessed at every visit by monitoring adverse events and evaluating tolerability. Compliance was assessed by return of used product containers and subject diary documentation.

Outcomes Measured: The primary outcomes were the dermatological assessment of cellulite severity using the Nurnberger-Muller Scale and the Cellulite Severity Grading Scale. Measurement of circumferential reduction at thigh, buttock, and hip at the baseline and consequent follow-up visits using circumference measurement.

Secondary outcomes included evaluation of skin elasticity by Cutometer, skin hydration by Moisturemeter SC, and skin barrier function (reduction in TEWL) by Vapometer. Subject satisfaction was recorded through the Satisfaction Questionnaire in addition to the product response index.

Safety outcomes included the assessment of any adverse events and hypersensitivity reactions such as redness, swelling, dryness, burning rash or any reported irritation throughout the study period.

Ethical Considerations

The study was conducted in accordance with the principles of the Declaration of Helsinki and

Good Clinical Practice (GCP) guidelines. The protocol was approved by the Om Independent
Ethics Committee on 26 July 2022 (ECR/1168/Inst/GJ/2018/RR-22). This clinical study was
registered at CTRI (Clinical Trial Registry of India) under the trial registration number CTRI/2022/08/044565.

Statistical Analysis

Data analysis was conducted using SPSS version 25.0. Efficacy analyses were performed on the per-protocol population (n=54). Continuous variables were summarized as mean ± standard deviation, and categorical variables as frequencies and percentages. Changes in continuous outcomes (circumference, elasticity, hydration, and TEWL) across visits (baseline, Day 28, Day 56, and Day 84) were assessed using repeated measures ANOVA, Changes in categorical (cellulite severity grade distributions) across visits were assessed using the Cochran's Q test. A p-value <0.0001 was considered statistically significant. Safety data were summarized descriptively.

RESULT

Baseline characteristics: A total of 60 healthy lactating females were enrolled in the study; of these 54 completed the study while six were lost to follow-up. The mean age of the study population was 29.2 ± 3.75 years. The mean height and weight were 159.39 ± 6.91 cm and 62.42 ± 8.49 kg, respectively. The mean BMI was 24.41 ± 2.72 kg/m², indicating that most participants fell within the normal to overweight range. At baseline, all participants presented with visible cellulite, classified as mild, moderate, or severe.[18] (Table 1)

Table 1. Baseline demographic characteristics of participants (n=54)

Characteristic				Value
Parameter	**Age (years)**	**Height (cm)**	**Weight (kg)**	**BMI (kg/m²)**
Mean	29.18	159.39	62.42	24.41
Min	22	136.06	34.6	18.6
Max	36	174.2	88.7	29.3

Primary outcomes:

Improvement in cellulite grading

Improvement assessed by Cellulite Severity Grading Scale (N = 54)

By day 56, stage 3 cellulite had completely resolved, and 16.7% of participants had reached the “no cellulite” category. The shift toward lower severity grades from baseline to day 84 was statistically significant (p<0.0001); by day 84, complete resolution was observed in 40.7% of participants, 57.4% were classified as stage 1, and only one participant (1.85%) remained at stage 2. (Table 2) (Figure 1)

Table 2. Reduction in Cellulite-by-Cellulite Severity Grading Scale (N = 54)

Visit	No Cellulite n (%)	Stage 1 (Mild)n (%)	Stage 2 (Moderate) n (%)	Stage 3 (Severe) n (%)
Baseline	0 (0.0)	17 (31.48)	18 (33.33)	19 (35.19)
Day 28	0 (0.0)	19 (35.19)	19 (35.19)	16 (29.63)
Day 56	9 (16.67)	25 (46.30)	20 (37.04)	0 (0.0)
Day 84	22 (40.74)	31 (57.41)	1 (1.85)	0 (0.0)

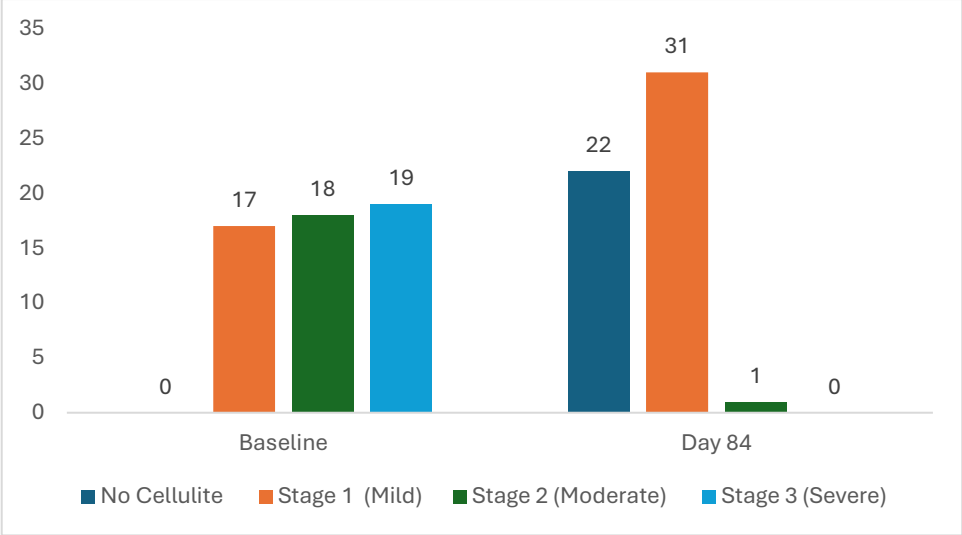

Figure 1. Change in number of patients in cellulite severity according to the Cellulite Severity Grading Scale over 84 days (N = 54)

Improvement assessed by Nürnberger–Müller Scale (N = 54)

At baseline, the majority of participants (68.5%) had grade 2 or 3 cellulite severity, while the remainder (31.5%) were classified as grade 1. None of the participants were free of cellulite. A gradual improvement was observed across visits, with reductions in grade 2 severity and parallel increases in the proportion of participants achieving grade 0 or 1. By day 56, nearly half of the cohort had shifted to grade 1 and 16.7% demonstrated complete resolution. At the end of treatment (day 84), 40.7% of participants achieved grade 0, 57.4% were at grade 1, and only one participant (1.9%) remained at grade 2. No participants had persistent severe involvement. (Table 3) (Figure 2)

Table 3. Improvement in Skin Tonicity by Nürnberger–Müller Scale (N = 54)

Visit	No Cellulite n (%)	Grade 1 n (%)	Grade 2 n (%)
Baseline	0 (0.0)	17 (31.48)	37 (68.52)
Day 28	0 (0.0)	18 (33.33)	36 (66.67)
Day 56	9 (16.67)	26 (48.15)	19 (35.19)
Day 84	22 (40.74)	31 (57.41)	1 (1.85)

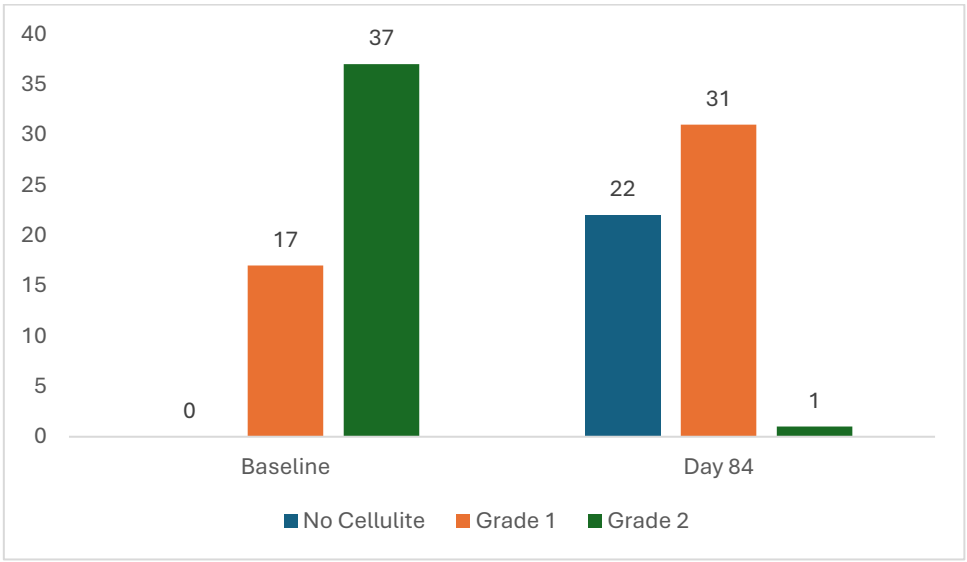

Figure 2. Changes in number of patients in cellulite severity grades from baseline to Day 84 according to the Nürnberger–Müller Scale (N = 54)

Secondary Outcomes

Circumference reduction:

Instrumental assessments for circumference measurements showed statistically significant reductions in circumference measurements across buttocks, hips, and thighs (all p<0.0001). Buttocks circumference decreased progressively from a baseline of 114.4 ± 6.50 cm by 0.9 ± 0.40%, 1.5 ± 0.69%, and 2.1 ± 0.78% at sequential follow-ups, achieving a reduction of -1.9 ± 0.69%. Hips reduced from 124.2 ± 6.54 cm by 0.5 ± 0.54%, 1.3 ± 0.55%, and 2.0 ± 0.70%, for a cumulative 1.6 ± 0.56% decrease. Thigh measurements dropped from 61.7 ± 5.37 cm by 0.5 ± 0.57%, 1.2 ± 0.50%, and 1.8 ± 0.64%, yielding a reduction of 3.0 ± 1.05%, representing the largest reduction among measured sites, while buttocks and hips showed smaller but consistent decreases. (Table 4)

Table 4. Changes in instrumental parameters

Parameter	Baseline (Mean ± SD)	Day 28 (Mean ± SD)	Day 56 (Mean ± SD)	Day 84 (Mean ± SD)	CFB (Mean ± SD)	p-value
Circumference						
Buttocks (cm)	114.4 ± 6.50	113.5 ± 6.56	112.9 ± 6.53	112.3 ± 6.50	−2.1 ± 0.78	<0.0001
Hips (cm)	124.2 ± 6.54	123.7 ± 6.39	122.9 ± 6.39	122.2 ± 6.43	−2.0 ± 0.70	<0.0001
Thighs (cm)	61.7 ± 5.37	61.2 ± 5.34	60.5 ± 5.41	59.9 ± 5.37	−1.8± 0.64	<0.0001
Elasticity (Cutometer® dual MPA 580)						
Thighs	0.49 ± 0.031	0.50 ± 0.031	0.51 ± 0.031	0.52 ± 0.028	+0.03 ± 0.009	<0.0001
Buttocks	0.49 ± 0.031	0.50 ± 0.031	0.51 ± 0.032	0.52 ± 0.030	+0.03 ± 0.010	<0.0001
Hips	0.50 ± 0.031	0.51 ± 0.031	0.52 ± 0.030	0.53 ± 0.029	+0.03 ± 0.011	<0.0001
Hydration (MoistureMeterSC)						
Thighs	34.72 ± 1.35	44.54 ± 1.63	49.45 ± 1.37	53.77 ± 1.20	+19.05 ± 1.66	<0.0001
Buttocks	34.36 ± 1.27	44.78 ± 1.58	50.00 ± 1.37	54.20 ± 1.86	+19.84 ± 1.76	<0.0001
Hips	34.85 ± 0.89	45.11 ± 1.17	50.30 ± 1.19	54.84 ± 1.84	+19.99 ± 1.79	<0.0001
Skin Barrier Function (TEWL (g/m²h)						
Thighs	9.79 ± 0.31	9.40 ± 0.33	9.01 ± 0.29	8.54 ± 0.30	−1.25 ± 0.14	<0.0001
Buttocks	9.70 ± 0.36	9.30 ± 0.36	8.89 ± 0.35	8.44 ± 0.32	−1.26 ± 0.17	<0.0001
Hips	9.68 ± 0.39	9.29 ± 0.40	8.84 ± 0.35	8.38 ± 0.31	−1.30 ± 0.23	<0.0001

***N = 54 completed participants**

Improvement in skin elasticity:

The skin elasticity assessments showed statistically significant improvements in skin elasticity from baseline to study end across thighs, buttocks, and hips (all p<0.0001). Thigh elasticity increased by 0.03 ± 0.01 (5.64 ± 2.08%), buttocks elasticity by 0.03 ± 0.01 (5.80 ± 2.26%), and hips elasticity by 0.03 ± 0.01(5.99 ± 2.35%) from baseline to the end of the study (84 days). (Table 4)

Improvement in skin hydration:

MoistureMeterSC for skin hydration assessments revealed statistically significant improvements in skin hydration from baseline to study end across thighs, buttocks, and hips (all p<0.0001). Thigh hydration increased from 34.72 ± 1.349 to 53.77 ± 1.195. Buttocks hydration rose from 34.36 ± 1.267 to 54.20 ± 1.856 (improvement of 19.84 ± 1.757 or 57.86 ± 6.121%). Hip hydration improved from 34.85 ± 0.885 to 54.84 ± 1.836 (improvement of 19.99 ± 1.786 or 57.44 ± 5.672%) at the end of study from baseline. (Table 4)

Improvement in skin barrier function (TEWL):

VapoMeter assessment for improvement in TEWL showed statistically significant reductions in TEWL from baseline to study end across thighs, buttocks, and hips (all $p<0.0001$), indicating improved skin barrier function. Thigh TEWL decreased from 9.79 ± 0.306 to 8.54 ± 0.296 (reduction of 1.25 ± 0.144; 12.80 ± 1.393%). Buttocks TEWL reduced from 9.70 ± 0.362 to 8.44 ± 0.324 (reduction of 1.26 ± 0.171; 12.97 ± 1.605%) and hip TEWL dropped from 9.68 ± 0.388 to 8.38 ± 0.311 (reduction of 1.30 ± 0.234; 13.40 ± 2.196%). (Table 4)

Subjective Self-Assessment and Product Response Index (Product Perception)

Subjective evaluation on day 84 revealed unanimous perception of benefit across all domains. All 54 participants reported visible improvement in orange-peel appearance, skin clarity, and body contour, consistent with the objective reductions in cellulite and circumference. Perceived gains in elasticity, moisturization, and overall smoothness were also universally endorsed, with every subject describing their skin as soft, supple, and nourished. Product perception ratings were predominantly in the "strongly agree" category across parameters. The investigation product was consistently rated as easy to apply, rapidly absorbed, pleasant in fragrance, and non-greasy, with good spreadability and suitability for individual skin types. Overall liking was universal, suggesting excellent cosmetic acceptability and user satisfaction. (Table 5)

Table 5. Subjective Self-Assessment and Product Perception at Day 84 (N = 54)

Parameter	n (%) Agreeing	n (%) Strongly agreeing
Subjective Self-Assessment		
Reduction in orange-peel appearance	9 (16.67%)	45 (83.33%)
Improved skin clarity (no dimpling)	9 (16.67%)	45 (83.33%)
Reduction in thigh/buttock/hip circumference	9 (16.67%)	45 (83.33%)
Improvement in elasticity	8 (14.81%)	46 (85.19%)
Improvement in skin tightness	6 (11.11%)	48 (88.89%)
Improved moisturization	5 (9.26%)	49 (90.74%)
Reduction in dryness	4 (7.41%)	50 (92.59%)
Skin felt soft, smooth, supple	4 (7.41%)	50 (92.59%)
Skin felt nourished	5 (9.26%)	49 (90.74%)
User Experience characteristics		
Ease of application	4 (7.41%)	50 (92.59%)
Pleasant fragrance	3 (5.56%)	51 (94.44%)
Rapid absorption	3 (5.56%)	51 (94.44%)
Good spreadability	2 (3.70%)	52 (96.30%)
Non-greasy texture	1 (1.85%)	53 (98.15%)
Product suitability	1 (1.85%)	53 (98.15%)

Safety Outcomes

The investigation product was generally well tolerated, with no adverse reactions or withdrawals reported. Throughout the study period, no participants reported any hypersensitivity reaction, burning rash, redness, swelling or irritation, showing good tolerability.

DISCUSSION

This study investigated the efficacy and tolerability of the investigation product in reducing cellulite severity and improving skin biophysical parameters over 12 weeks. The intervention produced clinically relevant improvements in cellulite grading, body circumference, elasticity, hydration, and barrier function, with no adverse events reported. These findings suggest that a topical, non-invasive approach may offer measurable benefits in the management of cellulite, a condition that remains a major aesthetic concern for women globally, specifically in postpartum phase.

Cellulite, affecting up to 90% of post-pubertal women, remains an aesthetic concern with limited long-term, non-invasive solutions.[3,19] Randomized studies on topical agents (e.g., caffeine, retinol) have demonstrated moderate efficacy in reducing cellulite severity and circumference.[1] Similarly, botanical creams like UP1307 improved skin hydration, elasticity, and cellulite appearance over eight weeks.[20] Results showing 40% of participants achieving Stage 0 cellulite and notable circumference reduction, comparable to previously published studies evaluating botanical and topical formulations and outcomes are likely due to synergistic formulation enhancing dermal collagen synthesis and microcirculation.

The present study data confirms that consistent twice-daily application can shift skin morphology and grading substantially over 12 weeks. This effect may be attributed to enhanced dermal remodeling, improved hydration, and extracellular matrix restructuring. Ingredients such as caffeine, retinoids, peptides, and botanical extracts have been shown to improve microcirculation, increase dermal thickness, and stimulate fibroblast activity.[1,21] Moreover, our findings support the concept that topical agents, when used persistently, can achieve durable changes in skin quality without procedural interventions and ingredients like retinol that are used in caution in lactation period.

We observed 5–6% improvements in elasticity and 20% in hydration, alongside 12–13% reductions in TEWL in the current study. These instrumental results parallel literature on topical treatments. For example, UP1307 botanical cream induced significant improvements in skin hydration and elasticity, alongside cellulite appearance.[20] The improvements in elasticity and barrier function also echo findings from hyaluronic acid–based creams like Profhilo® Figura, which improved moisturizing and elasticity by over 40% and 6%, respectively.[21] Collectively, these outcomes highlight that cosmetic creams can improve both superficial and deeper skin characteristics that contribute to cellulite.

Taken together, this study supports the role of topical therapy as a feasible, safe, and effective strategy for managing cellulite in everyday practice. Unlike invasive options such as subcision or energy-based devices, creams offer high acceptability and potential for long-term use. The absence of adverse events and high compliance further reinforce its translational value. Nonetheless, limitations must be acknowledged. The relatively short duration (12 weeks) limits the ability to assess durability of effects. In addition, cellulite grading involves a degree of subjectivity despite standardized scoring systems. Future randomized, placebo-controlled trials with longer follow-up and objective imaging-based assessments will be important to validate these results. Integration with lifestyle interventions, such as diet and physical activity, may further enhance and sustain benefits.

CONCLUSION

This study shows that twice-daily use of a botanical Equals Two® Body Firming Cream (Investigation product) for 12 weeks significantly reduces cellulite severity and body circumference while improving skin elasticity, hydration, and barrier function in lactating mother. These results support the potential of plant-derived topical therapies to address the complex pathophysiology of cellulite non-invasively. This topical treatment has the potential to address the complex pathophysiology of cellulite non-invasively, is accessible, and hence a justifiable option for long-term cellulite management in clinical practice.

Declaration by Authors

Ethical Approval: Approved

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