



A Clinical Trial to Evaluate the Effect of a Topical Oil to Enhance Breast Size and Appearance

Clinical Trial

Author: Citruslabs Research Team

Citruslabs, 5725 S. Valley View Blvd Suite 7, Las Vegas, NV 89118 USA

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Abstract

This single-group clinical trial evaluated the effects of the Genetix Organics Activated Enhancement Oil on enhancing breast size and appearance over 12 months. Thirty female at-birth participants aged 18+ applied two pumps of the test product twice daily; once earlier in the day, and once in the evening. Participants completed questionnaires at Baseline, Month 1, Month 2, Month 3, Month 6, Month 9, and Month 12, and provided self-taken photographs of their breasts/chest at Baseline, Month 2, Month 6, and Month 12. By Month 12, seven of the ten evaluated breast size and appearance parameters showed significant improvement, including satisfaction with breast size, and breast skin firmness, moisture, and smoothness. Participant perception data revealed strong satisfaction, with 12 of 22 product-related statements receiving $\geq 50\%$ agreement by Month 12, including improvements in breast skin moisture, plumpness, softness, and smoothness. These results suggest that the Genetix Organics Activated Enhancement Oil is effective in improving satisfaction with breast size and breast skin appearance, including smoothness, moisture, and plumpness. Further large-scale, controlled studies are recommended to validate and expand on these outcomes.

1. Introduction

Breast augmentation and enhancement have been subjects of significant interest across various cultures and eras, reflecting a deep-seated quest for beauty, confidence, and feminine identity. In modern society, the pursuit of non-invasive, natural alternatives to surgical procedures has led to increased interest in topical solutions such as breast enhancement oils. These products promise a safer, less intrusive, and more accessible means of achieving desired aesthetic outcomes. Investigating the efficacy and safety of

breast growth or enhancement oils is crucial, as it provides a foundation for evidence-based use and supports the development of products that are both effective and safe.

The application of topical oils containing phytoestrogens represents a fascinating area of research within the field of natural cosmetic enhancements, particularly for breast growth. Phytoestrogens are plant-derived compounds that mimic the action of estrogen, the primary female sex hormone responsible for the development and



maintenance of female characteristics, including breast tissue growth. When applied topically, these oils are thought to penetrate the skin, allowing phytoestrogens to interact with estrogen receptors in the breast tissue. This interaction could potentially stimulate the growth of breast tissue, akin to the natural growth seen during puberty or pregnancy.

The formulation of the test product was based on the above hypothesis and contains a range of ingredients that are thought to support both breast growth and the health of the breast skin.

Olive oil is recognized for its antioxidant properties, attributed to its squalene content, which contributes to hydration and chemoprevention due to its ability to bind with water molecules¹. This characteristic underscores its potential in skin care applications, particularly in enhancing skin hydration and combating oxidative stress. Almond oil is lauded for its high Vitamin E content, which plays a crucial role in maintaining skin cell health, offering protection against UV radiation damage, and aiding in the reduction of fine lines. Its emollient properties contribute to smoother and softer skin². Zhi Mu (*Anemarrhena asphodeloides*) is purported to influence adipogenesis, leading to the proliferation and enlargement of fat cells in the areas it is applied, suggesting a potential mechanism for localized fat retention³. Fenugreek is believed to stimulate the mammary glands and promote the growth of breast tissue, potentially through the elevation of prolactin levels, which plays a significant role in breast enlargement^{4,5}. Pueraria Mirifica is a herb noted for its high phytoestrogenic activity, which may naturally augment breast growth without adversely affecting hormonal balance^{6,7}. Pau D'Arco has been investigated for its anti-cancer properties, including its capacity to inhibit the proliferation of cancer cells, highlighting its potential therapeutic benefits⁸. Black Cohosh contains compounds that mimic estrogenic

effects, which may be beneficial in naturally enhancing breast size through natural hormonal modulation⁹. Stinging Nettle is recognized for its ability to stimulate blood flow to applied areas, supporting overall feminine health and potentially enhancing breast tissue through improved circulation^{10,11}. Wild Yam is widely regarded for its breast enlargement benefits. Wild Yam promotes healthy breast tissue. It is believed to do so without increasing estrogen levels, while also offering relief from premenstrual dysphoric disorder (PMDD) and menopausal symptoms^{12,13}. Milk Thistle Seed is associated with cellular and skin regeneration, highlighting its potential in rejuvenating skin and promoting overall cellular health¹⁴. Jasmine Essential Oil is characterized by its antidepressant, antiseptic, aphrodisiac, antispasmodic, and calming sedative properties, contributing to its multifaceted applications in aromatherapy and therapeutic practices¹⁵.

This study aimed to evaluate the effects of the Genetix Organics Activated Enhancement Oil on improving breast growth and overall breast skin health over 12 months.

2. Methods

2.1. Participants

A total of 30 female at-birth participants aged 18+ were recruited for this study. All participants reported wanting to increase breast size and had concerns with breast firmness, scarring on the breasts, wrinkles/wrinkling on the breast, or overall breast skin health, and satisfied the inclusion and exclusion criteria outlined in the study protocol.

2.2. Study Design and Intervention Procedure

This was a virtual single-group clinical trial that lasted for 12 months. Consent forms describing the study process, instructions, evaluation methods, and bill of



rights were provided to participants before study onboarding. Following the consent process, participants completed the Baseline questionnaire and took a Baseline photo of the breast/chest. Participants were asked to apply two pumps of the product twice daily; once earlier in the day, and once in the evening. Participants applied the product after showering or ten minutes before putting on clothes. Participants massaged the oil into the breast, gently towards the center of the chest, and pulled gently on the breast. Further questionnaires were completed at the end of Month 1, Month 2, Month 3, Month 6, Month 9, and Month 12. Further photos were provided by participants at Month 2, Month 6, and Month 12.

2.3. Data Analysis and Statistics

Data from the questionnaires were collected using a textual 5-point Likert scale for each question. The textual Likert data was transformed into numerical values of 1-5. For eight questions, 1 represented the worst outcome, and 5 represented the best outcome. For two questions, 1 represented the best outcome, and 5 represented the worst outcome.

Data were checked for normality using the Pearson test, depending on the number of values being analyzed. Data were analyzed using a two-way ANOVA test with Dunnett's multiple comparisons test. Statistical analyses were performed in GraphPad Prism 10.6, and the significance level was set at 0.05.

For product-specific questions not evaluated at Baseline, results were presented as the percentage of subjects reporting each answer.

3. Results

3.1. Impact of the Test Product on Breast Growth and Appearance

The effect of the Genetix Organics Activated Enhancement Oil on ten breast growth and appearance parameters was evaluated at Baseline, Month 1, Month 2, Month 3, Month 6, Month 9, and Month 12.

By Month 1, five of the ten parameters were significantly improved from the Baseline, including satisfaction with breast size, breast skin moisture, smoothness, youthfulness, and elasticity (Table 1, Table 2, Figure 1, Figure 2). The most notable improvement was a 50.25% increase in the satisfaction with breast size score (Table 1, Figure 1).

By Month 2, three of the ten parameters were significantly improved from the Baseline, including satisfaction with breast size, breast skin moisture, and smoothness (Table 1, Table 2, Figure 1, Figure 2). The most notable improvement continued to be the satisfaction with breast size score, with a 58.38% increase (Table 1, Figure 1).

By Month 3, five of the ten parameters were significantly improved from the Baseline, including satisfaction with breast size, breast skin firmness, moisture, smoothness, and elasticity (Table 1, Table 2, Figure 1, Figure 2). Notable improvements included a 42.60% increase in the breast skin elasticity score and a 64.47% increase in the satisfaction with breast size score (Table 1, Figure 1).

By Month 6, six of the ten parameters were significantly improved from the Baseline, including satisfaction with breast size, breast skin firmness, plumpness, moisture, smoothness, and elasticity (Table 1, Table 2, Figure 1, Figure 2). Notable



improvements included a 51.36% increase in the breast skin firmness score and a 52.96% increase in the breast skin smoothness score (Table 1, Figure 1).

By Month 9, seven of the ten parameters were significantly improved from the Baseline, including satisfaction with breast size, breast skin firmness, plumpness, moisture, smoothness, youthfulness, and elasticity (Table 1, Table 2, Figure 1, Figure 2). The most notable improvement was a 82.74% increase in the satisfaction with breast size score (Table 1, Figure 1).

By Month 12, seven of the ten parameters were significantly improved from the Baseline, including satisfaction with breast size, breast skin firmness, plumpness, moisture, smoothness, youthfulness, and elasticity (Table 1, Table 2, Figure 1, Figure 2). Notable improvements included a 51.36% increase in the breast skin firmness score and a 69.04% increase in the satisfaction with breast size score (Table 1, Figure 1).

At all time points, there were no significant improvements in the appearance of scarring or wrinkles on the breasts compared to Baseline (Table 2, Figure 2).

3.2. Participants' Perception of the Test Product and the Impact on Breast Growth and Appearance

Participants were asked to respond to questions at the end of Month 1, Month 2, Month 3, Month 6, Month 9, and Month 12, which provided insight into their perceptions of the test product. They responded to product evaluation questions with a "strongly agree" to "strongly disagree" scale. The "strongly agree" and "agree" responses were combined into a single "combined agree" result to evaluate the overall participant perception.

In Month 1, 3 of the 15 parameters showed $\geq 50\%$ participant agreement (Table 3). These included 'over the past month, the skin on my breasts has been more moisturized' (79.17%), 'over the past month, the skin on my breasts has felt softer and smoother' (79.17%), and 'I enjoy using this product' (75.00%) (Table 3). These results were maintained through Month 2.

In Month 3, 4 of the 15 parameters showed $\geq 50\%$ participant agreement, including 'over the past month, the skin on my breasts has appeared plumper' (52.94%) (Table 3). All other parameters from previous months were maintained.

In Month 6, 3 of the 15 parameters showed $\geq 50\%$ participant agreement (Table 3). These included 'over the past month, the skin on my breasts has been more moisturized' (80.00%), 'over the past month, the skin on my breasts has felt softer and smoother' (73.33%), and 'I enjoy using this product' (60.00%) (Table 3).

In Month 9, 6 of the 15 parameters showed $\geq 50\%$ participant agreement (Table 3). These included 'over the past month, the skin on my breasts has appeared plumper' (80.00%), 'over the past month, the skin on my breasts has felt more elastic' (53.33%), and 'over the past month, my bras have felt tighter' (53.33%) (Table 3). All other parameters from Month 6 were maintained.

In Month 12, 13 of the 22 parameters showed $\geq 50\%$ participant agreement (Table 3, Table 4). These included 'over the past month, my breasts have become more perky' (50.00%), 'over the past month, the skin on my breasts has appeared plumper' (50.00%), 'over the past month, the skin on my breasts has been more moisturized' (83.33%), 'over the past month, the appearance of any wrinkles on my breasts has reduced' (50.00%), 'over the past month, the skin on my breasts has felt softer and smoother'



(91.67%), 'over the past month, my breasts look more lifted' (50.00%), 'I enjoy using this product' (50.00%), 'I am satisfied with the results of the product' (58.33%), 'the oil had a pleasant scent' (66.67%), 'the oil was enjoyable to apply' (58.33%), 'the oil was easy to incorporate into my daily routine' (66.67%), 'I would like to continue using the oil' (66.67%), and 'I would recommend the product to my friends and family' (50.00%) (Table 3, Table 4).

Additionally, three participants reported inconsistencies in the product's color or scent across bottles.

4. Discussion

This study evaluated the efficacy of the Genetix Organics Activated Enhancement Oil in enhancing breast size and appearance over 12 months, using a combination of participant-reported outcomes and standardized breast size and appearance parameter assessments.

Findings from the breast size and appearance parameter evaluations demonstrated steady and significant improvements across a broad range of measures. Improvements were observed as early as Month 1, with the most notable early effect being improved satisfaction with breast size. By Month 12, seven of the ten parameters had significantly improved, including satisfaction with breast size, and breast skin firmness, moisture, and smoothness. These outcomes suggest that the Genetix Organics Activated Enhancement Oil offers a progressive, cumulative benefit for satisfaction with breast size and appearance.

Participant perception data aligned closely with these findings, with early improvements in breast skin moisture, softness, and smoothness reported by Month 1. By Month 12, $\geq 50\%$ of participants reported

that their breasts were more perky and lifted, and that their breast skin appeared plumper, more moisturized, softer, and smoother. These self-reported outcomes highlight the visible changes and the experiential benefits users perceived throughout the trial.

Overall, the results support the potential of the Genetix Organics Activated Enhancement Oil as an effective solution for improving satisfaction with breast size and appearance. The product was well-tolerated and showed both subjective and objective benefits.

5. Conclusion

The findings of this study highlight the efficacy of the Genetix Organics Activated Enhancement Oil in improving satisfaction with breast size and appearance over 12 months. Significant improvements were observed in key areas, including breast skin firmness, moisture, and smoothness, with the most notable enhancement being satisfaction with breast size. Participant feedback reflected strong satisfaction with the product, including perceived improvements in breast skin moisture, plumpness, softness, and smoothness. These results suggest that the Genetix Organics Activated Enhancement Oil is an effective, well-tolerated solution for individuals seeking to improve satisfaction with breast size and appearance. Further research with a larger population could help validate and expand upon these promising findings.

6. References

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Table 1. Changes in Breast Size and Appearance Parameters. % Change indicates a change in mean values from the Baseline. An increase in score indicates an improvement in the breast size and appearance parameters. This table provides the numerical data presented in Figure 1. Green cells highlight statistically significant outcomes (P<0.05).

Question	Baseline (N=30)		Month 1 (N=24)				Month 2 (N=17)				Month 3 (N=17)				Month 6 (N=15)				Month 9 (N=15)				Month 12 (N=12)			
	Mean	STD	Mean	STD	P-Value	% Change	Mean	STD	P-Value	% Change	Mean	STD	P-Value	% Change	Mean	STD	P-Value	% Change	Mean	STD	P-Value	% Change	Mean	STD	P-Value	% Change
How satisfied are you with the size of your breasts currently?	1.97	0.89	2.96	0.95	0.0006	50.25	3.12	1.05	0.0003	58.38	3.24	0.83	<0.0001	64.47	3.13	0.92	0.0004	58.88	3.60	0.83	<0.0001	82.74	3.33	0.65	0.0001	69.04
How firm is the skin on your breasts?	2.20	0.89	2.83	0.64	0.0682	28.64	2.76	0.75	0.2143	25.45	3.00	0.79	0.0257	36.36	3.33	0.90	0.0007	51.36	3.40	0.83	0.0003	54.55	3.33	0.78	0.0022	51.36
How would you rate the plumpness of the skin on your breasts?	2.37	0.93	2.75	0.85	0.5123	16.03	3.00	0.71	0.1250	26.58	3.00	0.87	0.1250	26.58	3.33	0.98	0.0059	40.51	3.47	0.64	0.0011	46.41	3.42	0.90	0.0056	44.30
How moisturized is the skin on your breasts?	2.83	0.79	3.63	0.77	0.0108	28.27	3.59	0.80	0.0409	26.86	3.65	0.79	0.0222	28.98	3.87	0.83	0.0026	36.75	3.67	0.98	0.0257	29.68	4.00	0.85	0.0014	41.34
How smooth is the skin on your breasts?	2.53	0.90	3.50	0.93	0.0009	38.34	3.35	0.93	0.0208	32.41	3.35	0.70	0.0208	32.41	3.87	0.64	<0.0001	52.96	3.67	0.82	0.0007	45.06	3.58	0.51	0.0056	41.50
How soft is the skin on the back of your hands?	3.37	1.10	3.54	1.06	0.9732	5.04	3.24	1.09	0.9964	-3.86	3.18	1.13	0.9756	-5.64	3.07	1.53	0.8502	-8.90	3.13	1.25	0.9474	-7.12	3.08	1.24	0.9123	-8.61
How youthful does the skin on your breasts appear?	2.33	1.06	3.00	1.02	0.0479	28.76	2.76	1.09	0.4957	18.45	3.06	0.90	0.0546	31.33	3.07	0.88	0.0669	31.76	3.20	0.86	0.0182	37.34	3.25	0.75	0.0219	39.48
How would you rate the elasticity of the skin on your breasts?	2.23	0.94	3.17	0.92	0.0015	42.15	2.59	1.00	0.6959	16.14	3.18	1.07	0.0049	42.60	3.13	1.06	0.0127	40.36	3.47	0.83	0.0002	55.61	3.33	0.89	0.0032	49.33



Table 2. Changes in Appearance of Breast Scarring and Wrinkles Parameters. % Change indicates a change in mean values from the Baseline. A decrease in score indicates an improvement in the appearance of breast scarring and wrinkles parameters. This table provides the numerical data presented in Figure 2. There were no statistically significant outcomes among any of the parameters ($P < 0.05$).

Question	Baseline (N=30)		Month 1 (N=24)				Month 2 (N=17)				Month 3 (N=17)				Month 6 (N=15)				Month 9 (N=15)				Month 12 (N=12)			
	Mean	STD	Mean	STD	P-Value	% Change	Mean	STD	P-Value	% Change	Mean	STD	P-Value	% Change	Mean	STD	P-Value	% Change	Mean	STD	P-Value	% Change	Mean	STD	P-Value	% Change
How would you describe the appearance of any scarring on your breasts?	2.17	1.05	2.17	1.13	>0.9999	0.00	2.00	0.94	0.9874	-7.83	1.94	0.90	0.9458	-10.60	1.87	0.83	0.8502	-13.82	2.00	0.76	0.9898	-7.83	2.08	0.67	0.9999	-4.15
How would you describe the appearance of any wrinkles on your breasts?	2.63	1.13	2.54	1.06	0.9991	-3.42	2.41	0.87	0.9499	-8.37	2.24	1.09	0.5827	-14.83	2.13	0.74	0.3777	-19.01	2.27	0.7	0.7033	-13.69	2.25	0.75	0.7317	-14.45

Table 3. Participant Perceptions of the Impact of the Product on Breast Growth and Appearance. Blue cells highlight a combined positive response of $\geq 50\%$.

How much do you agree or disagree with the following:	Combined Agree %					
	Month 1 (n=24)	Month 2 (n=17)	Month 3 (n=17)	Month 6 (n=15)	Month 9 (n=15)	Month 12 (n=12)
Over the past month, my breasts have grown.	25.00%	29.41%	29.41%	13.33%	40.00%	25.00%
Over the past month, my breasts have looked bigger.	25.00%	35.29%	29.41%	40.00%	40.00%	41.67%
Over the past month, my breasts have become more firm.	29.17%	29.41%	41.18%	26.67%	40.00%	33.33%
Over the past month, my breasts have become more perky.	25.00%	29.41%	29.41%	26.67%	40.00%	50.00%
Over the past month, the skin on my breasts has appeared plumper.	45.83%	35.29%	52.94%	40.00%	80.00%	50.00%
Over the past month, the skin on my breasts has been more moisturized.	79.17%	88.24%	82.35%	80.00%	73.33%	83.33%
Over the past month, my breasts have appeared more youthful.	29.17%	23.53%	47.06%	33.33%	46.67%	25.00%



Over the past month, the appearance of any scarring on my breasts has reduced.	16.67%	23.53%	35.29%	33.33%	26.67%	41.67%
Over the past month, the appearance of any wrinkles on my breasts has reduced.	29.17%	35.29%	35.29%	33.33%	40.00%	50.00%
Over the past month, the skin on my breasts has felt softer and smoother.	79.17%	76.47%	64.71%	73.33%	86.67%	91.67%
Over the past month, the skin on my breasts has felt more elastic.	41.67%	29.41%	41.18%	13.33%	53.33%	41.67%
Over the past month, my breasts look more lifted.	25.00%	23.53%	29.41%	26.67%	33.33%	50.00%
Over the past month, my bras have felt tighter.	29.17%	23.53%	41.18%	33.33%	53.33%	33.33%
Over the past month, my breasts have looked bigger in clothes.	29.17%	23.53%	29.41%	26.67%	46.67%	33.33%
I enjoy using this product.	75.00%	64.71%	70.59%	60.00%	66.67%	50.00%

Table 4. Participant Perceptions and Satisfaction of the Product at Month 12. Blue cells highlight a combined positive response of $\geq 50\%$.

How much do you agree or disagree with the following:	Combined Agree %
	Month 12 (n=12)
The oil is an effective replacement for surgical breast augmentation.	25.00%
I am satisfied with the results of the product.	58.33%
The oil had a pleasant scent.	66.67%
The oil was enjoyable to apply.	58.33%
The oil was easy to incorporate into my daily routine.	66.67%
I would like to continue using the oil.	66.67%
I would recommend the product to my friends and family.	50.00%

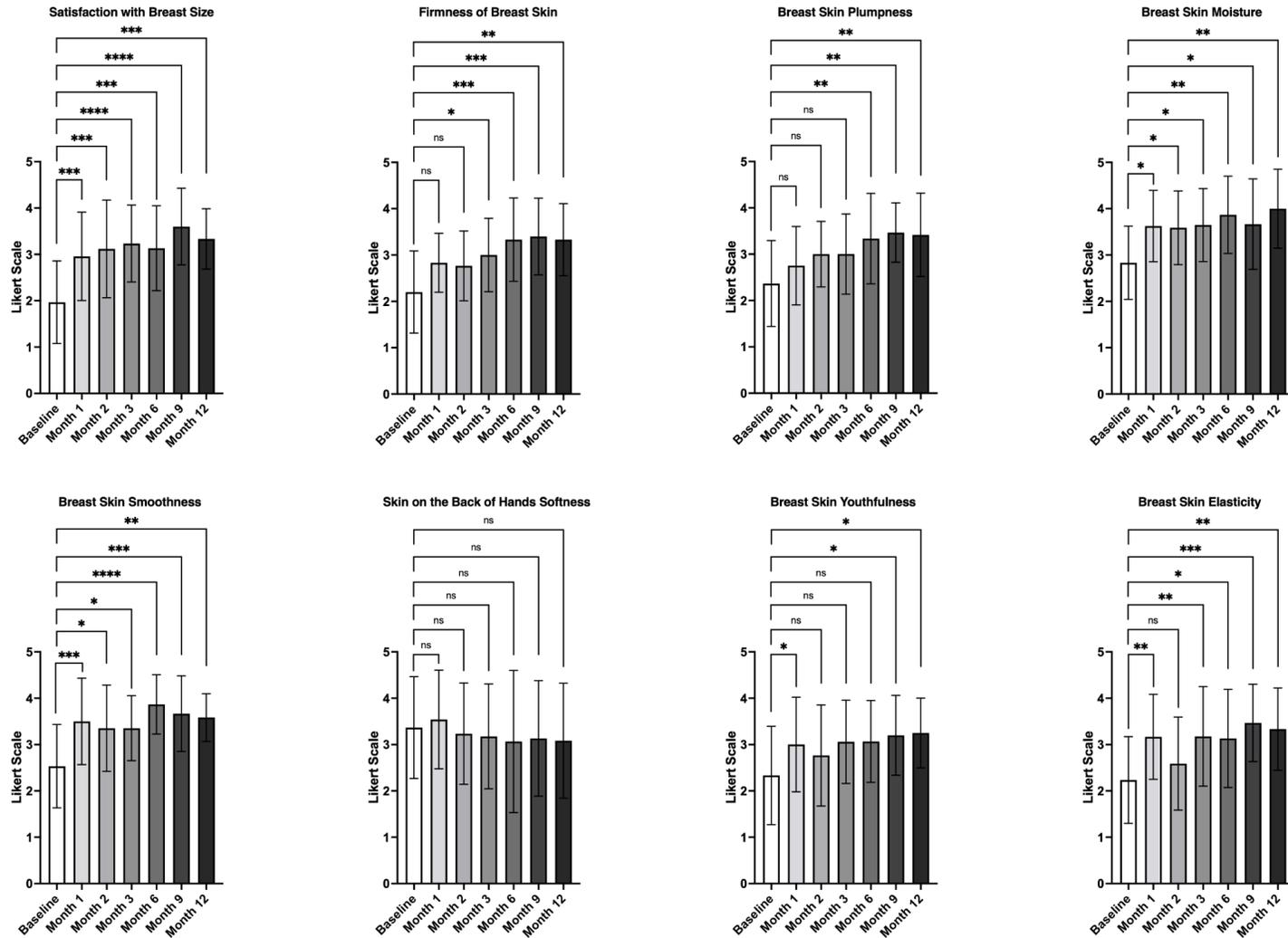


Figure 1. Visual Representation of Breast Size and Appearance Data. Data is graphed as group means, and standard deviations are shown. An increase in score indicates an improvement. ns = $P > 0.05$, * = $P < 0.05$, ** = $P < 0.01$, *** = $P < 0.001$, **** = $P < 0.0001$.

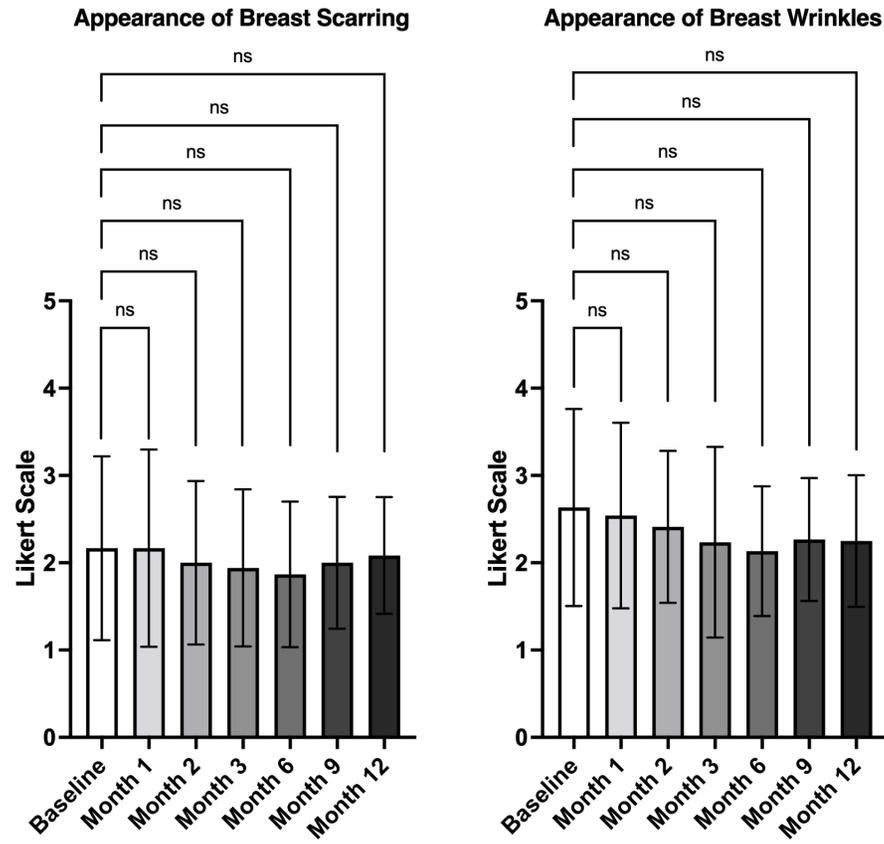


Figure 2. Visual Representation of Appearance of Breast Scarring and Wrinkles Data. Data is graphed as group means, and standard deviations are shown. A decrease in score indicates an improvement. ns = P>0.05.



Appendix A: Data Interpretation

(Please consult an attorney before using any claims – these are just example claims from the data that could be used)

*The following information is provided for educational and informational purposes only. Claim examples by Citruslabs are not intended as legal advice or guidance. Citruslabs does not endorse any specific claims made by its clients and cannot guarantee the accuracy, reliability, or completeness of the information provided. The information contained herein is not a substitute for professional legal advice. Anyone seeking to make marketing claims based on the results of a clinical study should consult a qualified attorney to discuss the legal and regulatory requirements governing such claims. Citruslabs shall not be liable for any damages or losses arising from using this information or any reliance on the accuracy or completeness thereof.

At Month 1, there was a statistically significant improvement in:

- Satisfaction with breast size.
- Breast skin moisture.
- Breast skin smoothness.
- Breast skin youthfulness.
- Breast skin elasticity.

At Month 1

- 79.17% of participants agreed that the skin on their breasts had been more moisturized over the past month.
- 79.17% of participants agreed that the skin on their breasts had felt softer and smoother over the past month.
- 75.00% of participants agreed they enjoyed using the product.

At Month 2, there was a statistically significant improvement in:

- Satisfaction with breast size.
- Breast skin moisture.
- Breast skin smoothness.

At Month 2:

- 88.24% of participants agreed that the skin on their breasts had been more moisturized over the past month.
- 76.47% of participants agreed that the skin on their breasts had felt softer and smoother over the past month.
- 64.71% of participants agreed they enjoyed using the product.

At Month 3, there was a statistically significant improvement in:

- Satisfaction with breast size.
- Breast skin firmness.
- Breast skin moisture.



- Breast skin smoothness.
- Breast skin elasticity.

At Month 3:

- 52.94% of participants agreed that the skin on their breasts appeared plumper over the past month.
- 82.35% of participants agreed that the skin on their breasts had been more moisturized over the past month.
- 64.71% of participants agreed that the skin on their breasts had felt softer and smoother over the past month.
- 70.59% of participants agreed they enjoyed using the product.

At Month 6, there was a statistically significant improvement in:

- Satisfaction with breast size.
- Breast skin firmness.
- Breast skin plumpness.
- Breast skin moisture.
- Breast skin smoothness.
- Breast skin elasticity.

At Month 6:

- 80.00% of participants agreed that the skin on their breasts had been more moisturized over the past month.
- 73.33% of participants agreed that the skin on their breasts had felt softer and smoother over the past month.
- 60.00% of participants agreed they enjoyed using the product.

At Month 9, there was a statistically significant improvement in:

- Satisfaction with breast size.
- Breast skin firmness.
- Breast skin plumpness.
- Breast skin moisture.
- Breast skin smoothness.
- Breast skin youthfulness.

At Month 9:

- 80.00% of participants agreed that the skin on their breasts appeared plumper over the past month.
- 73.33% of participants agreed that the skin on their breasts had been more moisturized over the past month.
- 86.67% of participants agreed that the skin on their breasts had felt softer and smoother over the past month.
- 53.33% of participants agreed that the skin on their breasts felt more elastic over the past month.

At Month 12, there was a statistically significant improvement in:

- Satisfaction with breast size.



- Breast skin firmness.
- Breast skin plumpness.
- Breast skin smoothness.
- Breast skin youthfulness.
- Breast skin elasticity.

At Month 12:

- 50.00% of participants agreed their breasts had become more perky over the past month.
- 50.00% of participants agreed that the skin on their breasts appeared plumper over the past month.
- 50.00% of participants agreed that the appearance of any wrinkles on their breasts had reduced over the past month.
- 50.00% of participants agreed their breasts looked more lifted over the past month.

Appendix B: Regulatory Guidance for Claim Usage

Overview

This appendix provides general guidance on the appropriate use of claims derived from clinical or consumer perception studies conducted by Citruslabs. It is intended to support regulatory compliance in the development of marketing, labeling, and promotional materials based on study findings.

Regulatory Framework

In the United States, claims regarding dietary supplements, cosmetics, and similar products are governed by:

- The Food and Drug Administration (FDA) under relevant regulations, including the Dietary Supplement Health and Education Act (DSHEA) for supplements.
- The Federal Trade Commission (FTC) under truth-in-advertising standards.

Key requirements include:

- **Structure/Function Claims Only:** Permissible claims must describe how a product supports normal body structures or functions (e.g., “supports digestive health,” “promotes skin hydration”).
- **No Disease Claims:** Claims suggesting diagnosis, treatment, cure, or prevention of disease (e.g., “treats eczema” or “cures digestive issues”) are not permitted unless the product is approved as a drug.
- **Truthfulness and Substantiation:** All claims must be truthful, not misleading, and supported by competent and reliable scientific evidence.

Claim Usage Requirements



Requirement	Description
Structure/Function Only	Claims should describe support, maintenance, or promotion of health, not treatment or cure of conditions.
Substantiation	Claims must directly reflect the study findings and should not overstate results.
Consumer Context	Where participant perception data is cited, it should be made clear that results are based on self-reported outcomes, not clinical diagnosis.
Mandatory Disclaimer	The following FDA disclaimer must accompany all structure/function claims:
<i>“These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”</i>	
Alignment with Study Design	Claims should be consistent with the study design. For example, if a study was a single-arm open-label trial without a placebo control, marketing materials should not state or imply “clinically proven” outcomes.

Recommended Language Practices

Acceptable Examples	Unacceptable Examples
“Supports digestive health”	“Cures digestive disorders”
“Promotes skin hydration”	“Eliminates eczema”



“Helps maintain healthy energy levels”	“Treats chronic fatigue syndrome”
“Shown in a study to support gut and skin health”	“Clinically proven to heal gut lining”
“Participants reported improvements in energy and vitality”	“Cures energy depletion”

Specific Claim Wording Best Practices

- **Statistical Outcomes:** Use language such as “statistically significant improvements were observed in [parameter]” where applicable.
- **Perception Outcomes:** Participant-reported outcomes should be phrased as “participants reported improvements in [area]” or “X% of participants agreed that [outcome]” rather than implying clinical diagnosis.
- **Timepoint Specificity:** When referencing results observed at particular timepoints (e.g., Week 2, Week 8), ensure claims accurately reflect the measured or reported improvement compared to baseline.
- **Context of Support:** Where appropriate, use phrasing like “in a consumer study” or “as reported by participants” to frame the context of subjective results.

Additional Considerations

- All marketing communications (labels, websites, Amazon listings, advertisements, etc.) must include the FDA-required disclaimer where structure/function claims are made.
- A substantiation file, including the complete clinical study report and claim tables, should be maintained internally to support regulatory inquiries.
- Clients planning large-scale advertising campaigns (e.g., television, influencer partnerships) are encouraged to obtain legal review from regulatory counsel specializing in the dietary supplement, cosmetic, or wellness industries.

Example of Compliant Product Language

“In an 8-week study, participants reported improvements in digestive comfort, skin hydration, and energy levels with daily use of the product. †

†These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”



Disclaimer

This appendix is intended for informational purposes only and does not constitute legal advice. Companies are encouraged to consult qualified legal counsel when developing marketing claims or advertising materials based on clinical or consumer perception studies.