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ORIGINAL ARTICLE

Effects of repeated use of a commercial topical lotion on subcutaneous fat thickness in resistance-trained male athletes

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Abstract

This study tested whether subcutaneous fat loss is enhanced via application of a popular topical fat loss lotion. Twenty resistance-trained men (mean ± SD age of 26.3 ± 6.3 years and weight of 86.8 ± 11.1 kg) had a topical fat-loss lotion containing *Coleus forskholii*, Silybin, *Eucommia ulmoides* leaf, *Paullinia cupana* seed, caffeine, and black pepper essential oil applied twice daily for 8 weeks to the front and lateral thigh of one of the participant's leg, and a placebo control lotion was applied to the same sites on the other leg. After 8 weeks, there were no significant differences between the placebo and treatment legs for the change in subcutaneous fat thickness of the front thigh ($p = 0.73$) or for leg fat percentage ($p = 0.52$). However, there was a slight, yet significant difference in the change in subcutaneous fat thickness of the lateral thigh favoring the treatment leg (−0.42 vs +0.75 mm, $p = 0.029$), but with this difference disappearing depending on the statistical tests being used. Only 2/19 participants perceived a difference in fat loss in response to each condition. Although the topical lotion tested here resulted in statistically significantly greater subcutaneous fat loss at the lateral but not front thigh, this effect was very small, contingent upon the statistical test being used, and unperceivable by the participants themselves.

KEYWORDS
coleus forskholii, fat loss, resistance training, supplements

1 | INTRODUCTION

Fat reduction is commonly undertaken by athletes to improve locomotion performance, power-to-weight ratio, aesthetic appearance, or to reach a target weight class.[1-3] While energy restriction—or "dieting"—is typically implemented to achieve the desired fat loss, this practice is accompanied by compensatory metabolic and hormonal responses that cause attenuation of weight loss, undesirable changes in appetite and mood, performance impairment, and an increase in the likelihood of weight rebound.[2-5] Thus, alternative strategies to further facilitate fat loss in combination with energy restriction would be of great interest to athletes, by potentially enhancing fat loss results, or allowing the adoption of a less aggressive energy deficit.

While energy restriction is the fundamental requirement of fat loss.

One such a strategy with the potential to improve localized fat loss is the use of topical fat loss lotions. These products have been developed and sold worldwide, marketed as facilitators of fat loss without the need for energy restriction. Topical lotions have received some attention from the public given the non-invasive nature of their administration,[6-8] delivering the active ingredients directly to the site of action. Although there is a body of literature that questions the benefits of these products,[9-11] some studies have provided evidence that some of the compounds included in some topical fat loss lotions, such as aminophylline and caffeine, can cause a reduction in subcutaneous fat (shown via ultrasound and

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caliper measurement) and improve the appearance of cellulite.[6,12-15] For instance, twice-daily application of a mixed ingredient topical lotion for 28 days on the thighs of female participants was reported to result in a greater reduction in thigh skinfold thickness (−3.7 mm vs. −2.0 mm) and thigh fat mass (−100 g vs. −53 g) compared with a placebo lotion.[14] Similarly, the twice-daily application of a mixed ingredient topical fat-loss gel for 3 months on the thighs of female participants[13] improved the cellulite appearance in 81% of the participants compared with 32% in the placebo group. However, it is worthwhile to note that the aforementioned studies[6,13-15] were sponsored by the manufacturers of the products being examined, and one study was conflicted by the concomitant prescription of a hypocaloric diet and exercise intervention.[14]

One very popular fat loss lotion for athletes is advertised to athletes as a "body shaping serum" and "fat mobiliser" that can achieve regional stubborn body fat reduction by mobilizing fat from the subcutaneous fat layer. The product contains several active ingredients including *Coleus forskholii*, Silybin, *Eucommia ulmoides* leaf, *Paullinia cupana* seed, caffeine, and black pepper essential oil, with some evidence that some of these ingredients may be effective at improving body composition following their ingestion in humans[16,17] or topical application in rats.[18] In particular, the ingestion of forskolin (the active compound in *Coleus forskholii*) for 12 weeks was reported to reduce body fat percentage compared with a placebo in overweight men,[16] but not in overweight women.[19] Also, the peroral administration of a Japanese thistle *Cirsium oligophyllum* (from which Silybin is derived) extract to rats for 32 days significantly reduced subcutaneous and visceral fat weight compared with control.[18] Additionally, the topical application of the extract to rats for 7 days reduced subcutaneous fat by 23.2%.[18]

While the aforementioned studies do support the efficacy of some of the ingredients found in the fat loss lotion,[16-18] these studies involved testing in rats, or the ingredients were administered orally rather than being applied topically. Thus, the question remains of whether these ingredients are effective as a topical fat loss lotion for promoting localized fat loss in humans. To date, no trial has investigated the effect of this fat loss lotion (or any other topical fat loss lotions) on localized fat loss in athletes.

In light of the above considerations, the aim of this study was to test the hypothesis that twice-daily application of the aforementioned popular fat loss lotion for 8 weeks to the thigh of male athletes results in greater reduction in thigh subcutaneous fat compared with the application of a placebo lotion. We chose to investigate this lotion (over other topical fat loss lotions) because of the popularity of this product among athletes, thus making this study highly relevant for the athletic community.

2 | MATERIALS AND METHODS

2.1 | Eligibility criteria of participants

In order to test our hypothesis, 20 participants were recruited to this study. Eligible participants were men aged between 18 and 54 years, who were engaged in competitive sports (i.e., bodybuilding, powerlifting, boxing, and MMA) and had completed resistance training at least twice per week for at least the previous 12 months. Participants were deemed eligible only if they were not involved in any sports involving asymmetric limb use (e.g., football, soccer). As a measure to prevent participants from potentially identifying the treatment lotion, they were accepted into the study only if they had not used any topical fat loss lotions in the past.

2.2 | Experimental design

In order to examine the response of subcutaneous fat to the topical application of the fat loss lotion, an 8-week double-blind, randomized placebo-controlled, within-group investigation was performed. The participant's thigh served as their own control, with the treatment lotion being applied to marked sites on the front and lateral thigh of one leg, and a placebo lotion being applied to the same sites on the other leg. All participants received two sets of lotions of equal quantity in small containers labeled with the two codes, Gamma and Omega, representing placebo or the treatment lotion, respectively. The key to these codes was held by a member of the Human Sciences research team who was not involved in the data collection or data analysis of the study. The key was not revealed to any of the researchers involved with the data collection or data analysis during the study. The treatment lotion contained a proprietary blend of several ingredients including *Coleus forskholii*, Silybin, *Eucommia ulmoides* leaf, *Paullinia cupana* seed, caffeine, and black pepper essential oil. Due to litigation concerns and potential for reputational damage, our research institution requested that we did not disclose the name of the product and manufacturer being investigated. The placebo lotion was an inert moisturizing cream (Cetaphil, Galderma, Texas, USA), which does not impact subcutaneous fat loss, and has been previously used as a placebo in a study investigating the efficacy of another fat loss lotion.[14] The participants were deceived about the true purpose of the study, being informed that the aim of the study was to compare the efficacy of two different fat loss lotions.

In accordance with the manufacturer's guidelines, participants were instructed to apply 5 g (weighed using a food scale) of each lotion to the assigned thigh once every morning, and once every night after showering. Participants were also instructed to wash their hands before and after applying the lotion to the second thigh to prevent contamination and to avoid application of any other lotions to the thighs during the study. A member of the research team (JP), blinded to the treatment, had weekly interactions with the participants via email to monitor compliance with the lotion application.

Measures of weight, height, total body fat percentage, regional leg fat percentage, and thigh subcutaneous fat tissue (of the front and lateral thigh) were completed at Weeks 0 and 8. In addition, a food and training diary were completed at Weeks 0, 4, and 8 to monitor any potential changes in daily energy or macronutrient intake or weekly training minutes or training intensity across the study. All participants were instructed to follow their habitual diet and not to engage in any weight loss program for the duration of the study.

TABLE 1 Energy and macronutrient intake, and training completed during the 8-week intervention

	Week 0	Week 4	Week 8
Energy (kJ/day)	12,510 ± 2385	12,130 ± 2590	11,920 ± 2550
Protein (g/day)	199 ± 48	187 ± 48	193 ± 48
Carbohydrate (g/day)	341 ± 88	325 ± 87	316 ± 82
Fat (g/day)	86 ± 28	85 ± 33	81 ± 28
Training minutes (min/w)	395 ± 164	380 ± 194	358 ± 212
Training intensity (out of 10)	7.8 ± 0.7	7.7 ± 1.0	7.4 ± 1.4

*Statistically significant differences compared to week 0 at the significance level of $p < 0.05$. Data are presented as mean ± SD.

Participants were also told to continue their regular training regimen consistently. Upon completion of the study, the participants were asked which of the lotions they deemed to be more effective for fat loss, and their responses were recorded.

2.3 | Outcome measures

2.3.1 | Body weight and height

Body weight was measured on a platform digital weighing scales (August Sauter GmbH, Ebingen, Germany) to the nearest 0.01 kg, and height was measured using a wall mounted stadiometer (Novel Products Inc., Illinois, USA) to the nearest 0.1 cm.

2.3.2 | Total body fat percentage and leg fat percentage

Total and leg body fat percentage were assessed via whole-body dual-energy X-ray absorptiometry (GE Lunar iDXA, GE Medical Systems Ultrasound & Primary Care Diagnostics LLC, Wisconsin, USA) in standard thickness mode, with analyses performed using GE enCORE v 16.0. Calibration checks were conducted as per the manufacturer's guidelines prior to assessment sessions. Participants were instructed to adhere to standardized presentation protocols[20] prior to their assessment session. A recommended positioning protocol[21] was adopted to align the participants on the scanning bed and regions of interest for the analysis. The first scan for each participant was performed in triplicate to establish a value for precision error and least significant change.[22]

2.3.3 | Subcutaneous fat thickness of the thigh

Participants had their lateral thigh and front thigh sites on both the right and left legs marked by an accredited ultrasound technician, in accordance with the International Association of Sciences in Medicine and Sports (IASMS) standardized protocol.[23] Ultrasound images of these sites were captured via a B-mode ultrasound system (Telemed Echo Blaster 128 EXT-1Z, Telemed UAB, Vilnius, Lithuania) with linear transducer and requisite software (Telemed Echo Wave II v 3.2.0). Detailed instructions and protocols for site marking of the lateral thigh and front thigh and image capturing are further described elsewhere.[24,25] Ultrasound images were captured on each site in duplicate to calculate the average for analysis, and semi-automatic measurements of subcutaneous adipose thickness were evaluated to the nearest 0.01 mm using a software (Fat Analysis Tool v3.3, Rotosport, Austria; rotosport.at).

2.4 | Statistical analysis

A previous study investigating the effect of 4 weeks of daily topical lotion application on subcutaneous thigh fat loss (via ultrasound) was significantly powered with $n = 18$ to detect a 2.1 mm difference in fat loss between treated and untreated thighs at $p < 0.005$.[12] Since we expected our study to produce an effect of similar magnitude, we recruited 20 participants. Comparisons in outcome measures between the treatment lotion and placebo legs, and for outcome measures taken before and after the 8-week intervention, were made using paired Student's t-tests, with the assumption of normality of the data being verified using a Shapiro–Wilk test. In the case of a violation of the assumption of normality of the data, a Wilcoxon test was used instead of a paired Student's *t*-test. Changes in energy and macronutrient intake as well as in training minutes and intensity during the intervention were analyzed with repeated measures ANOVAs. Upon any findings of a significant *F*-ratio, pairwise comparisons were performed with Bonferroni's correction. All effects were considered significant when $p < 0.05$. Data are reported as means (standard deviations) unless otherwise specified.

3 | RESULTS

Participants were recruited between July 2020 and August 2020. Of the twenty men who began the intervention, one withdrew due to work commitments. The remaining 19 participants, with a mean (SD) age of 26.3 ± 6.3 years and height of 172.8 ± 9.5 cm, were all compliant with the lotion application protocol. In our study, 10/19 of the participants engaged in bodybuilding, 4/19 in powerlifting, 2/19 in boxing, 2/19 in mixed martial arts, and 1/19 in cricket. Average daily energy and macronutrient intake, and weekly training minutes and intensity are presented in Table 1, with no significant changes during the intervention.

There was no significant change in either body weight ($p = 0.158$) or body fat percentage ($p = 0.198$) during the intervention (Table 2).

The 8-week intervention did not result in any significant difference between the treatment lotion and placebo legs for the change in subcutaneous fat thickness of the front thigh ($p = 0.73$) or for leg fat percentage ($p = 0.52$). However, there was a slight, yet significant, 1.17 mm difference in the change in subcutaneous fat thickness of the lateral thigh ($p = 0.029$) favoring the treatment lotion (Table 3).

Upon completion of the final testing session, the participants were asked whether they could discern a fat loss superiority for either of the lotions. In this study, 15 of 19 participants (79%) reported that they could not detect a difference in fat loss effects between the lotions, 2 of 19 (10.5%) reported that the treatment lotion was superior, and 2 of 19 (10.5%) reported that the placebo lotion was superior.

4 | DISCUSSION

It is unclear whether the daily application of the treatment fat loss lotion for 8 weeks to the thigh of male athletes results in greater reduction in thigh subcutaneous fat compared with the application of a placebo lotion. This study shows that, in resistance-trained adult men, the twice-daily application of the treatment lotion for 8 weeks results in a slight, yet statistically significant, reduction in subcutaneous fat of the lateral thigh (−0.42 mm, $p = 0.029$) compared with a placebo treatment, but not for the front thigh, and no effect on overall leg fat percentage.

Of note, although the greater reduction in subcutaneous fat thickness at the lateral thigh level following application of the treatment lotion did reach statistical significance, this effect likely lacks practical significance given that 17 of 19 participants (89.5%) could not perceive a superior fat loss effect with the use of the treatment lotion, as was also the case with the comparator placebo treatment. This absence of detectable visual differences is not surprising considering that, under ideal conditions, the human eye has a visual acuity of only one line pair per arcminute (0.02 degrees or 0.0003 radians).[26] In practical terms, this means that the human eye cannot distinguish objects that are less than 0.56 mm apart, when viewed from 2 m away.[26] Thus, since the 0.42 mm non-significant difference in thickness reported here is not within the resolution boundaries of a naked eye acuity at 2 m distance, the participants would not be expected to detect such a small difference, particularly

TABLE 2 Body weight and body fat percentage before and after the 8-week intervention

	Week 0	Week 8	*p* value
Body weight (kg)	86.8 ± 11.1	87.5 ± 11.0	0.158
Body fat (%)	19.8 ± 5.6	20.2 ± 5.7	0.198

Note: *Statistically significant differences compared to week 0 at the significance level of $p < 0.05$. Data are presented as mean (SD).

TABLE 3 Thigh subcutaneous fat thickness and leg fat percentage measured before and after the 8-week intervention

	Lateral thigh subcutaneous fat thickness (mm)				Front thigh subcutaneous fat thickness (mm)				Leg fat (%)			
Week	0	8	Change	*p* value	0	8	Change	*p* value	0	8	Change	*p* value
Active leg (R)	12.93 ±7.29	12.51 ± 6.93	−0.42 ± 2.42		4.19 ± 2.76	4.37 ± 2.70	+0.18 ± 0.52		19.12 ± 5.47	19.57 ± 4.97	+0.45 ± 1.90	
Placebo leg (L)	14.09 ± 7.77	14.84 ± 7.35	+0.75 ± 2.11	0.029*	4.36 ± 2.69	4.50 ± 2.62	+0.14 ± 0.49	0.728	18.79 ± 5.25	19.12 (4.98)	+0.33 ± 1.91	0.522

Note: *Statistically significant differences between the change on the treatment lotion and Placebo legs between weeks 0 and 8, at the significance level of $p < 0.05$. Data are presented as mean (SD).

considering that the changes in fat thickness arose from measurements taken 8 weeks apart.

It is also important to mention that the slight violation in the assumption of normality of the lateral thigh subcutaneous fat thickness data (determined using a Shapiro–Wilk test) had a major effect on the statistical significance of the difference between the treatment lotion and placebo legs reported here. The assumption of normality of the data was deemed violated at $p < 0.05$, resulting in the use of a Wilcoxon test instead of a paired Student's t-test for the lateral thigh data. The p value for the assumption of normality of the lateral thigh subcutaneous fat data was 0.049, missing the cutoff threshold by 0.001. Despite this trivial difference, a Wilcoxon test had to be used instead of a paired Student's t-test, causing the p value for the statistical difference between the treatment lotion and placebo legs to change considerably from $p = 0.082$ (Student's t-test) to $p = 0.029$ (Wilcoxon test), a non-significant statistical difference to a significant one. Thus, it is worthwhile considering that while there was a slight statistically significant difference in subcutaneous fat loss between the treatment lotion and placebo legs at the lateral thigh, this "difference" was ultimately due to statistical analysis nuance, and an extremely slight improvement in the normality of the data would have negated this identified difference completely. Additionally, when we completed an alternative analysis of the data using an analysis of covariance (ANCOVA), with baseline values as a covariate, there were no significant differences observed between the treatment lotion and placebo legs for any outcome measures. While ANCOVA is the recommended statistical method for detecting differences between groups, with the advantages of this method including better power, better ability to detect interactions, and availability of extensions to deal with measurement error in the covariates,[27] we chose to publish our findings using the more conservative paired t-test analyses to prevent any accusation of statistical bias if one was to re-analyze our raw data. As such, for full transparency, we made the raw data available in Data S1.

The findings in this differ from those of previous works reporting that the topical application of multi-ingredient fat loss lotions improve the visual appearance of leg fat and/or cellulite.[6,12-15] However, it is important to note that the ingredient compositions of the fat loss lotions used in these studies were different to the treatment lotion used in this study, and the multi-ingredient composition of the treatment lotion makes it difficult to isolate the specific influence of each ingredient to the effects—or lack thereof—of the treatment lotion. Finally, as stated above, many of these studies were sponsored by the manufacturers of the products being tested, whereas our study was not supported by any commercial sponsor.

The lack of notable localized differences in fat loss between legs following the application of the treatment lotion is not surprising considering previous inconclusive research on "spot reduction"; the ability to reduce body fat from a specific region of the body.[28] For example, lower body unilateral resistance training protocol in men and women does not result in preferential fat loss in the trained leg.[28] Similarly, unilateral arm training does not result in any difference in subcutaneous fat changes between the trained and untrained arms.[29] Thus, upon consideration of past research on unilateral training and the findings provided here, the absence of a practically significant difference in localized loss of subcutaneous fat between legs due to the use of the treatment lotion is to be expected. Additional research on fat metabolism also suggests that for non-surgical fat reduction technologies that access a non-invasive closed route to the fat tissue face a challenge regarding the repackaging of lipid droplets for digestion by macrophages.[30] In other non-surgical fat loss procedures such as cryolipolysis and injectable lipolytic agents, the adipose cell is damaged to different degrees, with the contents of the adipocyte subsequently released to be absorbed by the macrophages over ensuing weeks.[30] It is therefore possible that the treatment lotion used in our study was not able to damage the adipose cell without an additional method of fat cell manipulation, and thus, was ineffective for causing the release of adipocyte contents into the extracellular space for absorption.

Despite the notable strengths of this study, being a double-blind, placebo-controlled trial, with one of each participant's legs acting as their own control, this study also has several limitations. Firstly, while this study recruited more participants than typically recruited in other studies of this nature,[8,12,14] it is possible that a larger sample size might have revealed more conclusive findings about the potential fat loss effects of the treatment lotion, but its effect would still be expected to be undetectable to the naked eye. Secondly, all participants were instructed to follow their habitual diet and training regimen during the 8-week study period. It is possible, but unlikely, that our results may have been different had a strictly controlled energy and macronutrient intake and training regimen study design been adopted for all participants. Furthermore, it is conceivable that results may have differed if the treatment lotion was applied in combination with a strategy already known to cause liberation of body fat, such as the implementation of an energy deficit via a reduction in energy intake, an increase in exercise activity, or both. In this sense, it is possible that the treatment lotion could be *complementary* to an existing fat loss regime, as opposed to being an effective facilitator of fat loss in isolation; however, this is yet to be confirmed. It is also worth noting that the measurement of the leg body fat percentage included all components of the leg, not just the thigh where the treatment lotion was applied, possibly explaining why the lotion had no detectable effect on this outcome variable. Finally, our findings are limited by the fact that we recruited trained men only, and we acknowledge that results may differ with inclusion of additional populations such as women and sedentary people.

5 | CONCLUSION

In conclusion, although the twice-daily application of the treatment lotion for 8 weeks resulted in a statistical test-dependent significant higher subcutaneous fat loss at the lateral thigh compared with the

control thigh, but not at the upper thigh level, the effect was marginal, largely due to a slight violation of data normality, and unperceivable to the naked eye.

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CONFLICT OF INTEREST

We declare that no financial interest or benefit has arisen from the direct application of this research.

AUTHOR CONTRIBUTIONS

JJP led the drafting of the manuscript. JJP and JO conceived of the study. JJP and JO coordinated the study and conducted the statistical analyses. All authors participated in the design of the study protocols, helped to draft the manuscript, read, and approved the final manuscript.

ETHICAL APPROVAL

This study was approved by the Human Research Ethics Committee at the University of Western Australia (RA/4/20/5772) on January 6, 2020.

DATA AVAILABILITY STATEMENT

Data generated during this study have been provided in Data S1.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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