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DRUGS • DEVICES • METHODS

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EMERGING TOPICAL APPROACHES  
IN THE MANAGEMENT OF FEMALE  
PATTERN HAIR LOSS

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## Efficacy of a Dual-Serum Cosmetic System in Women With Female Pattern Hair Loss

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### ABSTRACT

Hair loss is a widespread condition with a potentially severe psychological burden, especially among women. The chance of suffering from female alopecia increases with menopause, and topical treatments beyond minoxidil are scarce. Over the past several years, new combinations of natural ingredients and patented mixtures have shown promising results to improve hair shedding, thus helping recover self-esteem and confidence. In this work, results of a prospective, open-label clinical trial conducted in women of predominantly menopausal age provides evidence that the dual cosmetic serum system developed by KilgourMD displays statistically significant and clinically meaningful effects on female hair loss, measured through an objective combing test, modified hair wash test, and clinical expert evaluation, after an application period of 4 months.

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### INTRODUCTION

**H**air loss disorders or alopecia cause significant impacts on patients' quality of life, reduce self-esteem, and increase stress.<sup>1</sup> To some extent, this is a natural phenomenon that results in the shedding of up to 80 to 100 telogen hairs per day in a healthy adult.<sup>2</sup> Nonetheless, a severe increase in this number or the loss of anagen hairs are pathological signs.<sup>3</sup>

Alopecia can be categorized as cicatricial and non-cicatricial, with female androgenetic alopecia (AGA) and female pattern hair loss (FPHL) included in the latter category.<sup>4</sup> Their incidence rises with age and is closely related to the emergence of menopause.<sup>5,6</sup> The imbalance between androgens and estrogens that occurs during this stage affects the proliferative capacity of the dermal papilla itself, and also greatly impairs the vascular microenvironment of the follicle, leading to overall decreased density, thickness, and altered texture.<sup>6,7</sup>

With hair as a key aesthetic-defining feature, FPHL has a noticeable psychological burden. Different non-cosmetic approaches are available to reduce its impact, such as drug administration, aesthetic camouflage techniques, or, most recently, hair transplantation.<sup>8</sup>

Nonetheless, side effects, invasiveness, lack of universality, and incomplete hair restoration capacity of these interventions require the development of novel treatments for AGA patients. In this regard, extensive efforts in the cosmetic industry have led to a range of treatments claiming anti-hair loss, hair growth, and scalp rejuvenation properties, with topical serums meeting an important part of these requirements.<sup>9</sup>

Some patented ingredients have shown efficacy in this field, such as Redensyl, Capixyl, Procapil, or Anagain, resulting in even more beneficial results than the benchmark minoxidil in some contexts.<sup>10-12</sup> Thus, the inclusion of such ingredients, together with botanical extracts, antioxidants, and anti-inflammatory molecules for which evidence exists that supports a healthy scalp, can be proposed as a rationale for new formulations to treat AGA.<sup>13-16</sup> For this reason, this prospective clinical trial aimed at evaluating the clinical effectiveness of the combined application of a two-step cosmetic serum system developed by KilgourMD at reducing female hair loss in a predominantly menopausal-aged cohort.

**TABLE 1.**

Relevant Clinical Data of the Study Population							
VOLUNTEERS' DATA							
N° Volunteer	Gender	Age	Ethnicity	Skin Sensitivity	Skin Type	Skin Phototype	Sensitive Scalp
1	Female	43	Latin	AC / M- / GT-	Combination	IV (moderate brown)	0,6
2	Female	57	Caucasian	AC- / M- / GT-	Dry	II (white)	0
3	Female	55	Latin	AC- / M+ / GT+	Dry	III (light brown)	-0,4
4	Female	65	Caucasian	AC- / M- / GT-	Combination	II (white)	0
5	Female	39	Latin	AC- / M- / GT-	Combination	IV (moderate brown)	-0,4
6	Female	46	Latin	AC- / M- / GT-	Dry	IV (moderate brown)	0
7	Female	56	Caucasian	AC / M- / GT-	Combination	II (white)	0
8	Female	34	Caucasian	AC- / M- / GT-	Combination	III (light brown)	0,8
10	Female	55	Caucasian	AC / M- / GT-	Dry	III (light brown)	0
11	Female	51	Caucasian	AC / M+ / GT+	Dry	II (white)	0
12	Female	39	Caucasian	AC+1 / M- / GT-	Combination	III (light brown)	-0,4
13	Female	58	Caucasian	AC- / M- / GT-	Combination	II (white)	0
14	Female	44	Caucasian	AC- / M- / GT-	Combination	III (light brown)	-0,2
15	Female	38	Latin	AC+1 / M+ / GT	Combination	IV (moderate brown)	-0,2
16	Female	36	Caucasian	AC- / M- / GT-	Oily	II (white)	0
17	Female	59	Latin	AC+1 / M+ / GT-	Combination	III (light brown)	0
18	Female	48	Caucasian	AC / M+ / GT+	Combination	III (light brown)	0,8
20	Female	52	Caucasian	AC / M- / GT-	Dry	II (white)	0
21	Female	51	Caucasian	AC+1 / M- / GT-	Combination	II (white)	-0,2
22	Female	54	Caucasian	AC- / M- / GT-	Dry	III (light brown)	0
23	Female	64	Caucasian	AC / M- / GT-	Combination	II (white)	-0,2
24	Female	41	Latin	AC- / M- / GT-	Dry	IV (moderate brown)	0
25	Female	49	Caucasian	AC- / M- / GT-	Dry	III (light brown)	0,8
26	Female	55	Caucasian	AC+ / M+ / GT+	Combination	II (white)	1,4
27	Female	57	Caucasian	AC- / M- / GT-	Dry	III (light brown)	-0,2
28	Female	40	Latin	AC- / M- / GT-	Dry	IV (moderate brown)	-0,2
29	Female	39	Latin	AC / M- / GT-	Dry	IV (moderate brown)	0
30	Female	48	Caucasian	AC- / M+ / GT+	Dry	III (light brown)	0
31	Female	42	Latin	AC- / M- / GT-	Combination	III (light brown)	-0,4
33	Female	33	Caucasian	AC- / M- / GT-	Combination	II (white)	0,4
34	Female	60	Caucasian	AC- / M- / GT-	Dry	II (white)	0
35	Female	56	Latin	AC+2 / M- / GT+	Dry	III (light brown)	0,6
36	Female	22	Latin	AC+2 / M- / GT+	Combination	IV (moderate brown)	0
37	Female	65	Caucasian	AC+2 / M- / GT-	Dry	III (light brown)	0
38	Female	61	Caucasian	AC+2 / M- / GT-	Dry	III (light brown)	1,2
40	Female	52	Caucasian	AC- / M- / GT-	Dry	III (light brown)	0
41	Female	34	Latin	AC- / M- / GT-	Combination	III (light brown)	-0,2
42	Female	47	Caucasian	AC+1 / M- / GT-	Dry	III (light brown)	-0,2
43	Female	53	Caucasian	AC / M- / GT-	Combination	III (light brown)	0
44	Female	40	Caucasian	AC+1 / M- / GT-	Dry	II (white)	1
45	Female	66	Caucasian	AC / M+ / GT+	Dry	II (white)	0
46	Female	63	Caucasian	AC- / M- / GT-	Dry	III (light brown)	0
47	Female	49	Caucasian	AC+2 / M- / GT+	Dry	III (light brown)	-0,2

## MATERIALS AND METHODS

### Study Design

This clinical trial was a prospective, non-randomized, pretest-posttest study, conducted between August 2025 and December 2025 in an outpatient study center (Dermaclaim Lab, Valencia, Spain). Subjects were assessed at baseline, days 45, 90, and 120 after the start of the treatment. The study was conducted following International Conference on Harmonization Good Clinical Practice guidelines, and in accordance with the Declaration of Helsinki. Additionally, all the volunteers included in this study had previously read, understood, and signed the Protection of Personal Data and Communication written consent.

### Study Population

The study cohort was composed of 43 female volunteers (Table 1) aged from 22 to 65 years (mean  $48.1 \pm 10.0$ ), suffering from moderate to excessive hair shedding (grades 3–6 in the Sinclair Hair Shedding Scale, shown by Kovacevic and colleagues<sup>17</sup>) confirmed through combing test, low hair density (grades 3–6 in customized female Ludwig scale, Figure 1) last participation in a clinical study for hair evaluation ending at least two months before the start of this study, being subjected to 15 days of wash-out phase with a neutral shampoo provided by the investigational laboratory, and a willingness to comply with instructions.

**FIGURE 1.** Customized female Ludwig scale. The degrees 1 to 9 are defined on the basis of the area affected by hair shedding, as depicted on pictures.



### Test Sample and Product Application

A two-step, serum formulation-based system (the KilgourMD system) consisting of The Prevention Scalp Serum and The Treatment Scalp Serum was applied for the indicated period. Every other day, participants washed their scalp with the neutral shampoo provided, followed by sequential application of 1 mL of The Prevention Scalp Serum and The Treatment Scalp Serum. One milliliter (1 mL) of each component was directly applied onto the scalp with the dropper applicator, and the product was distributed with a fingertip massage until complete absorption. The total treatment period was 120 days (4 months).

### Instrumental Assessment of Efficacy

Fifteen minutes before every measurement, the volunteers were subjected to an acclimatization period under controlled temperature ( $23 \pm 1$  °C) and controlled relative humidity ( $45 \pm 10$  %). During the acclimatization period, the test area was not covered by clothes. Measurements were conducted on dry hair, without previous treatment application.

Combing Test (CT) and Modified Hair Wash Test (MHWT) were conducted at clinical facilities, according to the protocols explained, for each specific volunteer at each of the timepoints.

Clinical Expert Evaluation (CEE) was conducted by two board-certified dermatologists using Female Ludwig Scale Customized (1–9 score) with 2 independent technical replicates, one conducted live during the visit and the other conducted after the visit using high definition (HD) macroscopic pictures taken with a Nikon D5600 24 Mpx camera and objective 40 mm macro-2.8, using the software CameraScan (Orion).

All the measurements were performed before the start of the treatment (D0), after 1.5 months of treatment (D45), after 3 months of treatment (D90), and after 4 months of treatment (D120).

### Combing Test (CT)

Participants attended the research facility after a 48-hour period free of hair washing or combing. Their hair was combed in a standardized way on the hairdresser's washing chair, protected by a dense weft fabric. Three different combs were sequentially used: (1) a thick flat brush was used once in each hair strand; (2) a medium brush was used once in each strand of hair; (3) a fine comb was used in each strand of hair, as many times as needed until no hair shed.

Shed hairs were collected onto dense weft fabrics conveniently labelled. Fabrics were let dry for 48–72 hours, hairs were transferred to plastic boxes and photographed, and hair fibers were manually counted.

### Modified Hair Wash Test (MHWT)

Participants were requested to avoid shampooing for 48 hours. After that, hair was thoroughly washed with neutral shampoo in a sink for 5 minutes and rinsed. This protocol was repeated twice to ensure a complete wash. The hairs were trapped onto a dense, wet fabric and allowed to dry for 48–72 hours. Subsequently, hairs were classified by length (>/< 3 cm), pictures were taken, and a manual count was performed.

### Statistical Analysis

Parameter values of an individual at a given time point were normalized versus average baseline measurements for the whole cohort. This way, the inter-individual random variation was corrected, and the statistical power of the results increased.<sup>18</sup>

The individual results were expressed in percentage relative to baseline values (D0) for all the parameters studied. Mean ± Standard Error of the Mean (SEM) was calculated and shown in the graphs. \* denotes statistical significance with  $P < 0.05$ . \*\* denotes statistical significance with  $P < 0.01$ . \*\*\*

denotes statistical significance with  $P < 0.001$ . \*\*\*\* denotes statistical significance with  $P < 0.0001$ .

GraphPad Prism V10.6.2 software was used for graph plotting and statistical analysis through one-way analysis of variance (ANOVA) with Dunnett's multiple comparisons test.

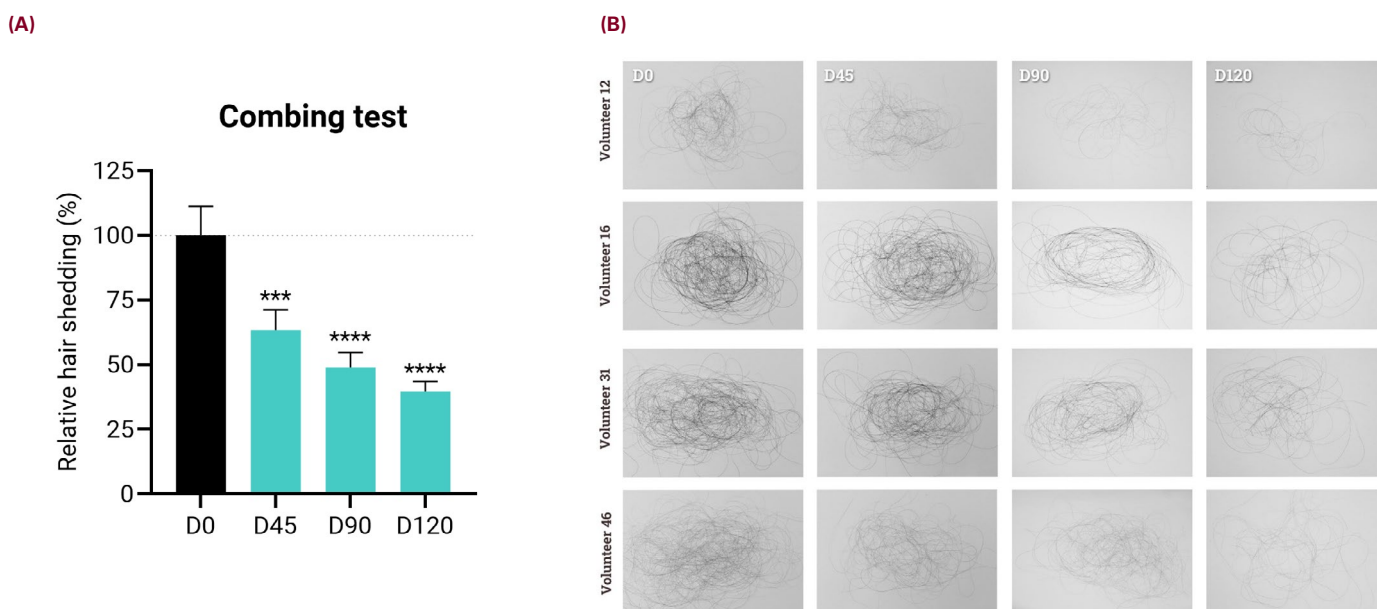
## RESULTS

### Combing Test Efficacy

The Combing Test (CT) is a well-established protocol used in cosmetic and dermatological clinical testing to evaluate the anti-hair loss efficacy of topical treatments, supplements, or formulations. It provides quantitative data on hair shedding, which is a key indicator of hair loss or hair retention improvements.<sup>19</sup>

In this study, results displayed a clear time-dependent trend, with significant decreases in the number of shed hairs versus the untreated control. In this regard, a statistically significant reduction in the relative percentage of hair shedding was observed after 45 days (-33.8% vs D0), 90 days (-51.0% vs D0), and 120 days (-60.3% vs D0) (Figure 2). In total, 81.4% (35/43) of the trial participants demonstrated

**FIGURE 2.** Hair anchoring effect of The KilgourMD Bundle measured by the Combing Test (CT). (A) Graphical representation of the number of shed hairs counted before (D0), after 1.5 months (D45), 3 months (D90), and 4 months of treatment (D120), with the test sample, in the study cohort. (B) Representative HD macroscopic pictures obtained from hairs shed in the CT at each time point.



a decrease from baseline in hair shedding count by day 45, reaching 97.7% (42/43) at day 120, as measured by the CT.

### Modified Hair Wash Test Efficacy

The Wash Test or Hair Wash Test provides valuable insights into the ability of a product to minimize hair loss under conditions that simulate real-world activities such as shampooing.<sup>20</sup> To assess the progression in hair loss of the participants in a more daily life scenario, this test was implemented during the application of treatment. For results readout, the global number of shed hairs (> 3 cm) was interpreted as the severity of hair loss (telogen effluvium), while the percentage of vellus hairs (≤ 3 cm) was interpreted as the severity of androgenetic alopecia.<sup>1</sup>

Interestingly, the application of the test formula significantly reduced the relative number of shed hairs by 68.2 % at day 45 of treatment and by 50.7 % at day 120. In addition, it also non-significantly reduced this parameter by 50.6 % after 3 months of treatment (D90) (Figure 3A). In total, 95.3% (41/43) of the trial participants demonstrated a decrease from baseline in terminal hair shedding count by day 45, as measured by the MHWT.

In contrast, no significant reductions were seen in the percentage of vellus hairs. Only a non-significant reduction of 22.5 % was detected on day 45 and a non-significant

increase of 77.0 % on day 90, with high variability that precludes drawing solid conclusions on the data trend (Figure 3B).

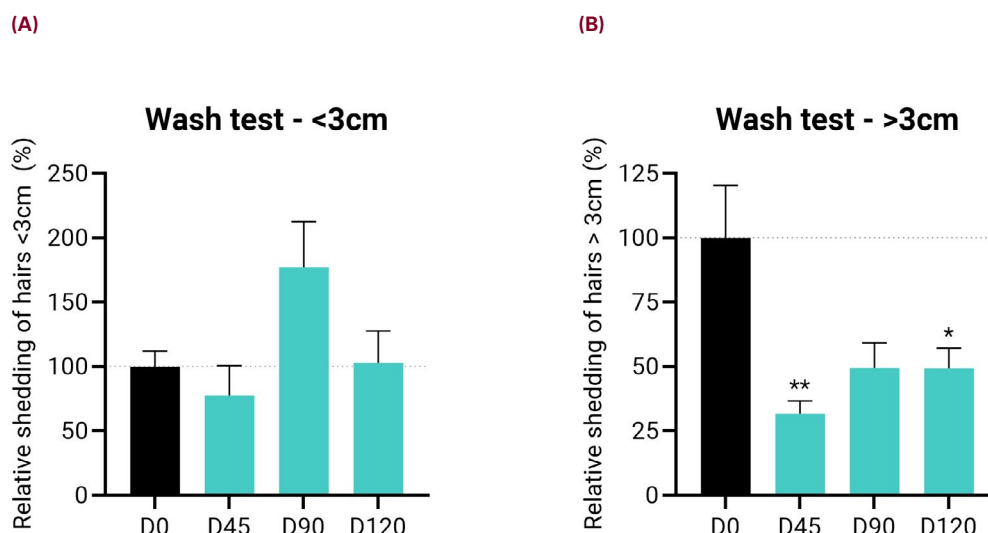
### Macroscopic Evaluation of Scalp

Apart from the objective, count-based measurements of CT and MHWT, the most important parameter from a self-esteem point of view is the overall appearance of the individual receiving the hair loss treatment. For this reason, macroscopic pictures and Clinical Expert Evaluation play a key role in claiming efficacy for an anti-hair loss product.

Concerning this question, scoring from Clinical Expert Evaluation revealed a statistically significant decrease in the degree of hair loss perceived after 90 days (-8.2 % vs baseline) and 120 days (-11.1 % vs baseline; Figure 4A). By day 120, 53.5% (23/43) of the trial participants demonstrated at least a 0.5 grade improvement in their Ludwig score from baseline, with 25.6% (11/43) reaching a 1.0 or greater improvement.

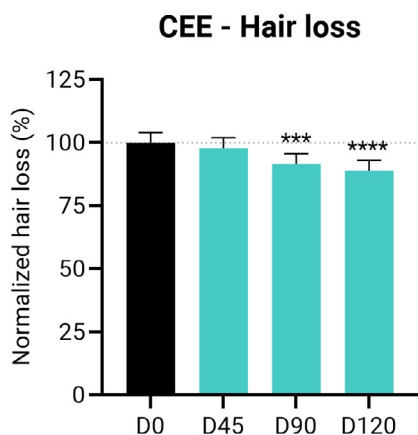
This decrease in hair loss was clearly reflected in the macroscopic perception of hair density in the scalp of the study participants, with a progressively denser aspect throughout time, especially between time points day 90 and day 120 (Figure 4B).

**FIGURE 3.** Hair strengthening effect after Modified Hair Wash Test (MHWT). Graphical representation of the number of hairs, shorter than 3 cm (A) and longer than 3 cm (B), counted after 2 replicates of MHWT before (D0), after 1.5 months (D45), 3 months (D90), and 4 months of treatment (D120), with the test sample, in the study cohort.

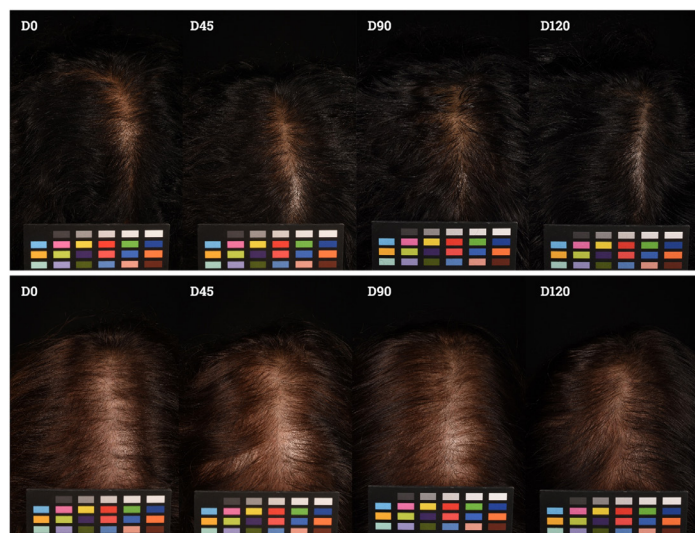


**FIGURE 4.** Clinical Expert Evaluation (CEE) of volunteers' scalp in the study cohort. (A) Graphical representation of the hair loss scored using the Female Ludwig Scale (modified), before (D0), after 1.5 months (D45), 3 months (D90), and 4 months of treatment (D120), with the test sample. (B) Representative HD macroscopic pictures obtained with Nikon D5600 camera in HeadScan Bench Light Face at each of the timepoints.

(A)



(B)



## DISCUSSION

Androgenetic and female pattern alopecia are hair loss conditions that pose significant psychological distress, and are increasingly being recognized in the peri- and post-menopausal female population.<sup>5</sup> Both topical minoxidil and orally administered antiandrogens are first-line therapy to manage this condition, but their efficacy, variability of response, and side effect profiles remain important limitations.<sup>21</sup>

Over the last few years, some help to overcome these limitations has been obtained from cosmetic formulations that are administered topically, thus reducing the risk of side effects and rendering appearance changes in shorter periods.<sup>21,22</sup>

The inclusion of newly developed ingredients with well-known agents with beneficial effects against overall aging symptoms has led to the formulation of the KilgourMD cosmetic serum system, tested in this prospective trial for a total treatment period of 4 months. Its application on a

panel composed of females, predominantly of menopausal age, has led to a dramatic decrease in hair shedding after daily activities such as combing and washing. Moreover, the overall hair density perceived in macroscopic pictures and evaluated by clinical experts became noticeably greater, thus reinforcing the most important factor of psychological distress, which is the aesthetic appearance.

The application of Redensyl, Capixyl, and Procapil has previously shown noticeable clinical benefits in male AGA patients in comparison with the benchmark Minoxidil 5%, after six months of treatment.<sup>10</sup> The data described herein, with the above-mentioned ingredients included in the tested formula, reinforce these previous studies and demonstrate an evident amelioration after 4 months of topical application, a shorter time window. Additional research is needed to elucidate the possible synergy between the active ingredients of the formula, given its multi-substance composition.

Further reinforcing the feasibility of this kind of combined formulation, the data presented herein are also consistent with the reported benefits of combining Redensyl and Sepicontrol A5 in a mixed population of males and females.<sup>11</sup>

From a perspective of the study demographics, the data presented above make sense: the whole study was conducted on females, for whom the telogen effluvium has a more significant impact than AGA. Thus, it is more likely to observe improvements in the first condition -and that was indeed the aim of the formulation.

All in all, these data and those provided by others support the use of novel topical solutions for female androgenetic and female pattern alopecia, different from the classical use of minoxidil or oral anti-androgens. Future research will elucidate to what extent these kinds of interventions are useful as alternatives themselves or as adjuvant tools to the use of first-line drugs to overcome hair loss.

In conclusion, this prospective clinical trial provides strong evidence that the application of a novel cosmetic topical formula, containing a mixture of botanical ingredients with demonstrated efficacy against alopecia, meaningfully improves both objective shedding and the clinical appearance of menopausal women suffering from non-scarring alopecia.

## DISCLOSURES

CQ, SA, ARP, and JMK are employees of KilgourMD, Inc., which developed the investigational scalp serum products. DGF, LFG, MC, EN, and APF are employees of Dermaclaim Lab, a contract research organization that conducted the clinical study.

Authors affiliated with Dermaclaim Lab declare no personal or financial conflicts of interest beyond conducting the study as a CRO.

The sponsor had no role in data collection, statistical analysis, or interpretation of the results, which were performed independently by Dermaclaim Lab.

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