

A DOUBLE-BLIND RANDOMIZED CONTROLLED CLINICAL TRIAL COMPARING PLANT-BASED SERUM CONTAINING SAW PALMETTO VS 2% TOPICAL MINOXIDIL IN FEMALE PATTERN HAIR LOSS

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ABSTRACT

Background: Female pattern hair loss (FPHL) is a common hair disorder among women that can negatively affect quality of life. This study compared the efficacy and safety of a plant-based serum containing saw palmetto with 2% topical minoxidil in women with FPHL. **Methods:** This 12-week, double-blind, randomized controlled trial included 26 women with FPHL, randomly assigned to receive either saw palmetto serum (n=13) or 2% topical minoxidil (n=13), applied twice daily. Mean hair count and hair shaft diameter were assessed at baseline and weeks 4, 8, and 12. Global photographic assessment, participant satisfaction, and adverse events were also evaluated. **Results:** Both groups demonstrated significant increases in mean hair count and hair shaft diameter from baseline to week 12 (both $p < 0.001$). In the saw palmetto group, mean hair count increased from 84.02 ± 6.61 to 90.56 ± 6.64 hairs/cm², while hair shaft diameter increased from 70.27 ± 4.87 to 76.12 ± 4.60 μ m. In the minoxidil group, hair count increased from 88.48 ± 9.32 to 95.76 ± 8.89 hairs/cm², and hair shaft diameter increased from 70.38 ± 4.57 to 76.18 ± 3.58 μ m. No significant between-group differences were observed in hair count, hair shaft diameter, photographic assessment, or participant satisfaction. No adverse effects were reported. **Conclusions:** The saw palmetto serum significantly improved hair count and hair shaft diameter over 12 weeks. It may represent a well-tolerated botanical treatment option for FPHL.

Keywords: Plant-Based Serum, FPHL, Saw Palmetto, Minoxidil, Hair Loss

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INTRODUCTION

Female pattern hair loss (FPHL) is a common nonscarring hair disorder characterized by progressive follicular miniaturization and a patterned reduction in hair density. The pathogenesis of FPHL is complex and multifactorial. Alterations in the hair cycle, including a shortened anagen phase, prolonged telogen phase, and delayed re-entry into anagen, may result in an extended kenogen phase and progressive follicular miniaturization (Guarrera & Rebora, 2005; Messenger & Sinclair, 2006). Although the contribution of androgens to FPHL remains incompletely understood, androgen-mediated effects on genetically susceptible hair follicles have been implicated in its development (Ludwig, 1977). In addition, nutritional deficiencies, oxidative stress, and metabolic abnormalities may contribute to disease onset and progression, further supporting the multifactorial nature of FPHL (Redler et al., 2017).

Topical minoxidil remains an established treatment for FPHL. However, the requirement for continuous treatment and the potential for local adverse effects may limit treatment adherence and patient acceptance (Olsen et al., 2002). Consequently, there has been increasing interest in botanical-based interventions as potential therapeutic alternatives or adjunctive approaches for hair loss. Several plant-derived compounds have been investigated for their potential effects on hair growth through multiple biological mechanisms, including inhibition of 5 α -reductase, anti-inflammatory activity, antioxidant effects, and modulation of the follicular microenvironment (Dhariwala & Ravikumar, 2019). Saw palmetto (*Serenoa repens*) is of particular interest because its bioactive constituents, including fatty acids and phytosterols, have demonstrated inhibitory effects on 5 α -reductase activity (Abe et al., 2009). These pharmacological properties provide a biological rationale for investigating saw palmetto as a topical therapeutic approach for androgen-related hair disorders.

Despite growing interest in botanical interventions for hair loss, evidence regarding the clinical efficacy and safety of topical saw palmetto in women with FPHL remains limited. Therefore, this double-blind, randomized controlled trial aimed to compare the efficacy, safety, and participant satisfaction of a topical plant-based serum containing saw palmetto with 2% topical minoxidil in women with FPHL. Treatment efficacy was assessed objectively by changes in hair count and hair shaft diameter, while global photographic assessment and participant satisfaction were evaluated as additional outcomes.

LITERATURE REVIEW

Female pattern hair loss

Female pattern hair loss (FPHL) is a common nonscarring alopecia characterized by progressive reduction in hair density and follicular miniaturization. The condition results from a gradual decrease in the proportion of terminal hairs relative to finer, shorter hairs, predominantly affecting the vertex, upper parietal, and frontoparietal scalp while generally preserving the frontal hairline (Messenger & Sinclair, 2006). FPHL is considered the most common form of alopecia in women, although reported prevalence varies considerably among populations, partly because of differences in diagnostic criteria and assessment methods (Vaño-Galván et al., 2019). The prevalence increases with age, with clinically significant pattern hair loss reported in a substantial proportion of women after menopause (Bertoli et al., 2020).

The clinical presentation of FPHL is heterogeneous. The characteristic pattern consists of diffuse thinning over the vertex and upper biparietal regions with preservation of the frontal hairline. The Ludwig classification remains one of the commonly used systems for grading the severity of this pattern and comprises three stages, ranging from mild reduction in hair density to extensive scalp

hair loss (Ludwig, 1977). Other classification systems, including the Sinclair and Savin scales, have also been developed to provide greater gradation of disease severity (Dinh & Sinclair, 2007). In addition to its clinical manifestations, FPHL can have considerable psychosocial consequences. Hair is closely associated with appearance, femininity, and personal identity, and women with FPHL may experience reduced self-esteem, social anxiety, emotional distress, and impaired quality of life (Rencz et al., 2016). Consequently, effective management of FPHL should consider both objective improvement in hair growth and patients' perceptions of treatment outcomes.

Saw palmetto (*Serenoa repens*)

Among botanical agents investigated for hair loss, saw palmetto has received particular interest because of its potential antiandrogenic activity and its relevance to pathways implicated in follicular miniaturization. Saw palmetto (*Serenoa repens*) is a small palm native to the subtropical southeastern United States. Its fruit extract contains a high proportion of fatty acids (approximately 70-95%), along with phytosterols like β -sitosterol (0.1%), β -carotene, vitamin E derivatives, and polysaccharides (Booker et al., 2014). The pharmacological properties of these constituents have led to investigation of saw palmetto as a potential therapeutic agent for androgen-related disorders. The proposed antiandrogenic activity of saw palmetto is by directly interfering with the binding of dihydrotestosterone (DHT) and androstenediol cytoplasmic androgen receptors, and by the inhibition of 5 α -reductase, the enzyme responsible for conversion of testosterone to DHT. Saw palmetto extracts have demonstrated inhibitory effects on both type I and type II isoforms of 5 α -reductase, potentially reducing local DHT production (Kreutzkamp, 2006; Schantz et al., 2008). Additional proposed mechanisms include modulation of androgen receptor activity and conversion of DHT to less potent metabolites. Beyond its antiandrogenic activity, saw palmetto may exert effects through additional biological pathways relevant to hair growth. Experimental evidence suggests potential effects on transforming growth factor- β signaling (Zhu et al., 2018), while studies in human keratinocytes have demonstrated anti-inflammatory activity (Chittur et al., 2011). These multiple mechanisms may be relevant to the multifactorial pathophysiology of FPHL.

The present study was designed to compare a topical plant-based serum containing saw palmetto with 2% topical minoxidil in women with FPHL, using changes in hair count and hair shaft diameter as objective measures of treatment efficacy, together with global photographic assessment, participant satisfaction, and safety outcomes.

RESEARCH METHODOLOGY

Study design and participants

This study was designed as a double-blind, randomized controlled clinical trial to evaluate the efficacy and safety of a topical plant-based serum containing saw palmetto compared with 2% topical minoxidil in women with female pattern hair loss (FPHL). The study was conducted at Mae Fah Luang University Hospital, Bangkok. Thirty female volunteers were enrolled, and 26 participants completed the 12-week study. Eligible participants were women aged 20–60 years with FPHL classified as Ludwig pattern I or II, with good general health, and are not using medication which affect hair growth. Exclusion criteria included pregnancy, postpartum or breastfeeding status; other causes of hair loss, including alopecia areata and telogen effluvium; medical conditions potentially associated with hair loss or affecting study participation, including cardiac disorders, uncontrolled hypertension, diabetes mellitus, hypothyroidism, and hyperthyroidism; serious medical conditions such as cancer, autoimmune diseases, or immunosuppressive states; and a positive patch test result of grade ++ or higher. All participants provided written informed consent before enrollment.

The study protocol was reviewed and approved by IRB-EC of Mae Fah Luang University; protocol No: EC 25270-20 in compliance with international guidelines such as Declaration of Helsinki, the Belmont Report, CIOMS Guidelines and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use - Good Clinical Practice (ICH - GCP).

Randomization, blinding, and intervention

Following medical history, physical examination, and patch testing, participants were randomly allocated in a 1:1 ratio to receive either the plant-based serum containing saw palmetto or 2% topical minoxidil. The randomization sequence was created using a computer-generated random sequence generator (random.org). Allocation concealment was strictly maintained by an independent third party who was not involved in participant recruitment, intervention delivery, or outcome assessments. This independent party generated the sequence, prepared the treatments, and kept the allocation list confidential until the study's conclusion. Participants received sequentially numbered containers corresponding to their enrollment order. To maintain the double-blind protocol, both investigational products were dispensed into identical, opaque containers under aseptic conditions. These containers were pre-labeled by the independent third party with only a participant code number and standardized usage instructions in English and Thai. Consequently, neither the participants nor the investigators were aware of the treatment allocation for the duration of the 12-week trial.

Test Intervention

Participants were randomized to receive either a plant-based topical serum containing saw palmetto (*Serenoa repens*) extract or 2% topical minoxidil. The plant-based serum contained saw palmetto extract obtained by supercritical carbon dioxide (CO₂) extraction and specified to contain 80% fatty acids and 2% β -sitosterol. The comparator intervention was 2% topical minoxidil. Both interventions were dispensed in coded, identical opaque containers and were administered according to the same application schedule. Participants were instructed to apply 1 mL of the assigned treatment to the affected scalp area twice daily for 12 weeks. After application, participants were instructed to spread the product over the scalp using their fingertips and to avoid washing the scalp for 4 hours.

Outcome assessment

Hair count and hair shaft diameter were objectively assessed using the Aramo SG Skin and Hair Diagnosis System at baseline and weeks 4, 8, and 12. Global photographic assessment was performed using standardized photographs and independently evaluated by three dermatologists using a 7-point scale ranging from -3 to +3. Participant satisfaction was assessed using the 7-point rating scale, and adverse effects were recorded throughout the study.

Statistical analysis

The reliability of the dermatologists' assessment scale was evaluated using Cronbach's alpha. Data analysis between groups were analyzed using independent t-test at each time point, and within group were analyzed using repeated measures of ANOVA test. Participants' satisfaction score and GPA scores were analyzed using Fishers' Exact test. Data was analyzed using IBM SPSS Statistics, and a two-sided $p < 0.05$ considered statistically significant.

RESULTS

Characteristics of the Participants

A total of 30 female volunteers with female pattern hair loss (FPHL) were recruited and 26 completed the 12-week study. Mean age of the participants was 31.73 ± 4.26 years. Regarding

occupational status, 14 participants were students, while 12 were employed. Based on the Ludwig classification, 20 participants presented with FPHL Grade I and 6 participants with FPHL Grade II. All participants reported no underlying medical conditions, history of allergy, or current use of medications at the time of enrollment.

Table 1 Participant's demographic characteristics

Demographic data	Plant-Based Serum (n = 13)	2% Minoxidil (n = 13)
Age (years)		
mean $\pm$ SD	31.54 $\pm$ 3.95	31.92 $\pm$ 4.71
Min-Max	25-41	26-42
Occupation (n)		
Student	6	8
Employee	7	5
Female Pattern Hair Loss Grade		
I	11	9
II	2	4
Family History of AGA		
No history	8	9
Father	2	2
Mother	3	2
Current Medication		
YES	0	0
NO	13	13
History of allergy		
YES	0	0
NO	13	13

Hair Density Assessment Evaluated by Aramo SG

Mean Hair Count

Table 2 Mean Hair Count Assessment

Follow-up	Plant-Based Serum, Mean $\pm$ SD (n=13)	2% Minoxidil, Mean $\pm$ SD (n=13)	p value ^a
Baseline	84.02 $\pm$ 6.61	88.48 $\pm$ 9.32	0.172
4 th week	85.95 $\pm$ 6.63	90.66 $\pm$ 9.48	0.155
8 th week	87.80 $\pm$ 6.64	92.96 $\pm$ 9.12	0.113
12 th week	90.56 $\pm$ 6.64	95.76 $\pm$ 8.89	0.104
p value ^b	<0.001	<0.001	

Data were analyzed with independent t-test^a, Repeated measures of ANOVA^b

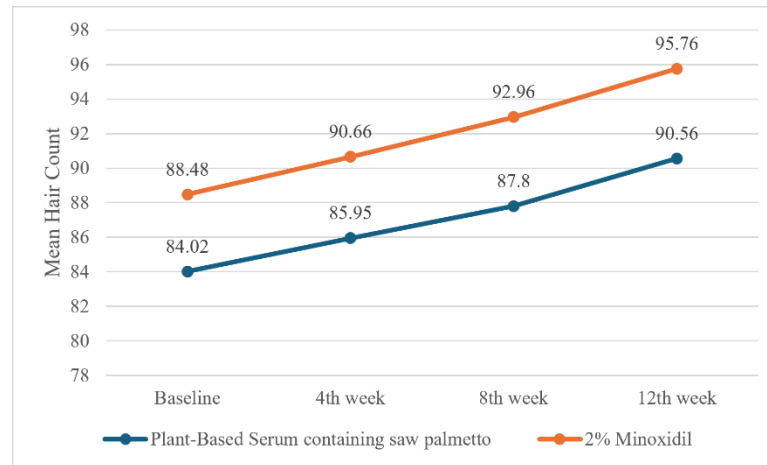


Figure 1 Line graph illustrating mean hair count at baseline, 4th week, 8th week, and 12th week for plant-based serum containing saw palmetto and 2% topical minoxidil

According to **Table 2**, the mean hair count demonstrated a progressive increase over the 12-week study period in both treatment groups. In the plant-based serum group, the mean hair count was 84.02 ± 6.61 at baseline and increased to 85.95 ± 6.63 , 87.80 ± 6.64 , and 90.56 ± 6.64 at Weeks 4, 8, and 12, respectively. The increase in mean hair count over time was statistically significant ($p < 0.001$). Similarly, in the 2% topical minoxidil group, the mean hair count increased from 88.48 ± 9.32 at baseline to 90.66 ± 9.48 , 92.96 ± 9.12 , and 95.76 ± 8.89 at Weeks 4, 8, and 12, respectively. This increase was also statistically significant ($p < 0.001$).

However, comparison of the mean hair counts between the two treatment groups at each assessment time point revealed no statistically significant differences ($p > 0.05$).

Table 3 post-hoc test for mean hair count (Plant-based serum)

Timepoint Comparison	Plant-based serum (n=13) Mean Diff. (p)	Lower Bound	Upper Bound
Baseline vs. Week 4	-1.93* ($p < 0.001$)	-2.06	-1.80
Baseline vs. Week 8	-3.78* ($p < 0.001$)	-3.94	-3.62
Baseline vs. Week 12	-6.54* ($p < 0.001$)	-6.70	-6.39
Week 4 vs. Week 8	-1.85* ($p < 0.001$)	-1.99	-1.70
Week 4 vs. Week 12	-4.61* ($p < 0.001$)	-4.83	-4.39
Week 8 vs. Week 12	-2.76* ($p < 0.001$)	-2.99	-2.53

Table 4 post-hoc test for mean hair count (2% Topical Minoxidil)

Timepoint Comparison	2% Topical Minoxidil (n=13) Mean Diff. (p)	Lower Bound	Upper Bound
Baseline vs. Week 4	-2.17* ($p = 0.015$)	-3.97	-0.37
Baseline vs. Week 8	-4.47* ($p < 0.001$)	-6.53	-2.43
Baseline vs. Week 12	-7.28* ($p < 0.001$)	-9.25	-5.31
Week 4 vs. Week 8	-2.30* ($p < 0.001$)	-3.49	-1.10
Week 4 vs. Week 12	-5.10* ($p < 0.001$)	-6.97	-3.24
Week 8 vs. Week 12	-2.80* ($p < 0.001$)	-4.42	-1.18

Multiple comparisons were analyzed using Bonferroni method.

Mean Hair Shaft Diameter

Table 5 Mean Hair Shaft Diameter Assessment

Follow-up	Plant-Based Serum, Mean $\pm$ SD (n=13)	2% Minoxidil, Mean $\pm$ SD (n=13)	p value ^a
Baseline	70.27 $\pm$ 4.87	70.38 $\pm$ 4.57	0.954
4 th week	72.06 $\pm$ 3.84	71.66 $\pm$ 3.99	0.793
8 th week	74.32 $\pm$ 4.34	73.83 $\pm$ 3.98	0.766
12 th week	76.12 $\pm$ 4.60	76.18 $\pm$ 3.58	0.970
p value ^b	<0.001	<0.001	

Data were analyzed with independent t-test^a, Repeated measures of ANOVA^b

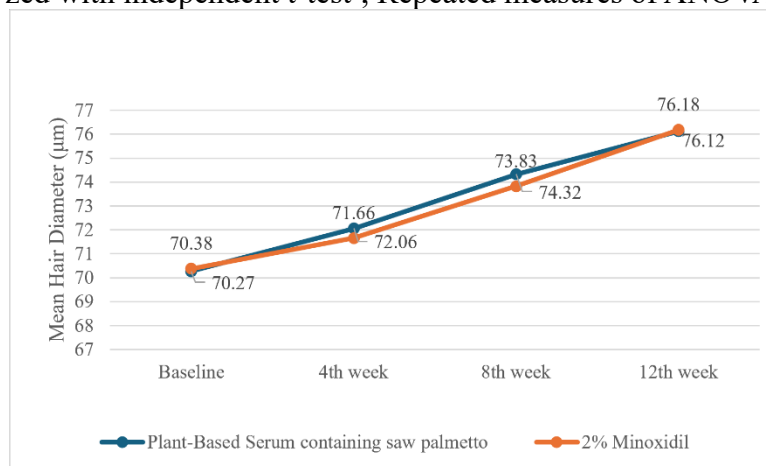


Figure 2 Line graph illustrating mean hair shaft diameter (µm) at baseline, 4th week, 8th week, and 12th week for plant-based serum containing saw palmetto and 2% topical minoxidil

According to **Table 5**, the mean hair diameter demonstrated a progressive increase over the 12-week study period in both treatment groups. In the plant-based serum group, the mean hair shaft diameter (µm) was 70.27 $\pm$ 4.87 at baseline and increased to 72.06 $\pm$ 3.84, 74.32 $\pm$ 4.34, and 76.12 $\pm$ 4.60 at Weeks 4, 8, and 12, respectively. The increase in mean hair diameter over time was statistically significant ($p < 0.001$). Similarly, in the 2% topical minoxidil group, the mean hair shaft diameter increased from 70.38 $\pm$ 4.57 at baseline to 71.66 $\pm$ 3.99, 73.83 $\pm$ 3.98, and 76.18 $\pm$ 3.58 at Weeks 4, 8, and 12, respectively. This increase was also statistically significant ($p < 0.001$). However, comparison of the mean hair shaft diameter between the two treatment groups at each assessment time point revealed no statistically significant differences ($p > 0.05$).

Table 6 post-hoc test for mean hair shaft diameter (µm) (Plant-based serum)

Timepoint Comparison	Plant-based serum (n=13) Mean Diff. (p)	Lower Bound	Upper Bound
Baseline vs. Week 4	-1.79* ($p=0.23$)	-3.37	-0.21
Baseline vs. Week 8	-4.04* ($p<0.001$)	-5.75	-2.33
Baseline vs. Week 12	-5.84* ($p<0.001$)	-7.70	-3.98
Week 4 vs. Week 8	-2.25* ($p<0.001$)	-3.34	-1.15
Week 4 vs. Week 12	-4.05* ($p<0.001$)	-5.34	-2.67
Week 8 vs. Week 12	-1.80* ($p=0.002$)	-2.93	-0.66

Table 7 post-hoc test for mean hair shaft diameter (μm) (2% Topical Minoxidil)

Timepoint Comparison	2% Topical Minoxidil (n=13) Mean Diff. (p)	Upper Bound	Lower Bound
Baseline vs. Week 4	-1.27* ($p=0.032$)	-2.46	-0.08
Baseline vs. Week 8	-3.44* ($p<0.001$)	-5.26	-1.62
Baseline vs. Week 12	-5.80* ($p<0.001$)	-8.07	-3.52
Week 4 vs. Week 8	-2.16* ($p=0.017$)	-4.00	-0.33
Week 4 vs. Week 12	-4.52* ($p<0.001$)	-6.23	-2.81
Week 8 vs. Week 12	-2.35* ($p=0.013$)	-4.25	-0.45

Multiple comparisons were analyzed using Bonferroni method.

Global Photographic Assessment

A global photographic assessment (GPA) was conducted to evaluate the improvement of hair growth after 12 weeks of treatment using a 7-point standardized scale. The average scores from three independent dermatologists were calculated for each patient and categorized into a binary outcome to assess research efficacy. The reliability of the assessment scale was evaluated using Cronbach's alpha, which yielded a coefficient of 0.758. This value exceeded the generally accepted threshold of 0.70, indicating satisfactory internal consistency among the assessment items. These findings suggested that the assessment criteria were applied consistently by the participating dermatologists.

A mean score of 2.0 or higher was categorized as a "High Score", while a mean score below 2.0 was categorized as a "Low Score".

Table 8 Global photographic assessment for plant-based serum containing saw palmetto and 2% minoxidil at 12th week

Treatment Group	Low Score (<2.0) (n=13)	High Score (≥ 2.0) (n=13)	p value
Plant-Based Serum	5	8	0.673
2% Topical Minoxidil	3	10	

Data were analyzed with Fisher's Exact test

A Fisher's Exact test was conducted to determine if there was a statistically significant difference in the proportion of patients achieving a High Score (≥ 2.0) between the two treatments, as detailed in **Table 8**. Descriptively, the 2% topical minoxidil group displayed a higher proportion of clinical improvement, with 76.9% ($n = 10$) of participants achieving a High Score compared to 61.5% ($n = 8$) in the plant-based serum containing saw palmetto. Conversely, Low scores (<2.0) were recorded for 23.1% ($n = 3$) of the minoxidil group and 38.5% ($n = 5$) of the plant-based serum group. However, the analysis indicated that there was no statistically significant difference in hair growth improvement between the plant-based serum containing saw palmetto and 2% topical minoxidil treatment ($p=0.673$). While the 2% topical minoxidil group displayed a slightly higher percentage of High Scores descriptively, this difference was not large enough to be statistically significant within this sample size.

Participants' Satisfaction Score

Table 9 Participants' satisfaction assessment for plant-based serum containing saw palmetto and 2% minoxidil at 12th week

Satisfaction levels	Plant-based serum (n=13)	2% topical minoxidil (n=13)	p value
Minimally improved	2	5	0.378
Moderately to significantly improved	11	8	

Data were analyzed with Fisher's exact test

Participant satisfaction at week 12 was assessed in both the plant-based serum containing saw palmetto and 2% topical minoxidil groups using a 7-point standardized satisfaction scale. As presented in **Table 9**, the distribution of satisfaction scores between the two treatment groups was compared using Fisher's exact test. No statistically significant difference was observed between the groups ($p = 0.378$). Descriptively, the majority of participants in both groups rated their condition as "Moderately to significantly improved," accounting for 84.6% ($n = 11$) of participants in the plant-based serum group and 61.5% ($n = 8$) in the 2% topical minoxidil group. Conversely, "Minimally improved" was reported by 15.4% ($n = 2$) of participants in the plant-based serum group and 38.5% ($n = 5$) in the 2% topical minoxidil group.

Adverse effects

No adverse effects were reported in any participants during the study with plant-based serum containing saw palmetto and 2% topical minoxidil.

DISCUSSION & CONCLUSION

The present 12-week randomized controlled trial demonstrated progressive and statistically significant improvements in mean hair count and hair shaft diameter in both plant-based serum containing saw palmetto and 2% topical minoxidil groups. However, no statistically significant differences between groups were observed in hair count, hair shaft diameter, global photographic assessment, and participant satisfaction. These findings suggest that both interventions were associated with improvements in the assessed hair parameters during the 12-week treatment period. However, the absence of statistically significant between-group differences should be interpreted cautiously given the small sample size and limited statistical power of the study.

The observed improvement is consistent with previous clinical evidence supporting the potential of saw palmetto containing preparations for hair growth, including studies reporting increased hair counts following topical or oral saw palmetto treatment. For instance, a 24-week prospective cohort study by Wessagowit et al. evaluating a topical saw palmetto lotion in 50 men reported increased total hair counts at the 12-week mark, alongside high self-perceived patient satisfaction (Wessagowit et al., 2016). Similarly, a randomized clinical trial by Morganti et al. demonstrated that the topical application of a saw palmetto-containing lotion resulted in a 17% increase in hair count and an approximate 20% increase in hair mass and caliber by week 10 (Morganti et al., 1998). Although these studies differed from the present study in terms of study population, formulation, and study design, their findings provide supportive clinical evidence for the potential role of topical saw palmetto-containing preparations in promoting hair growth.

The mechanism behind the efficacy of the plant-based serum is likely multifaceted. The primary clinical benefit of saw palmetto is attributed to its antiandrogenic properties; it acts as a competitive, non-selective inhibitor of 5 α -reductase isoforms, thereby blocking the nuclear uptake of dihydrotestosterone (DHT) and decreasing its binding capacity to androgen receptors by nearly 50%. Furthermore, localized inflammatory properties and potential angiogenic stimulation, which have been demonstrated in vitro (Moon et al., 1999), likely contribute to the favorable follicular responses and sustained anagen phase observed in our participants.

Importantly, the global photographic assessment also requires cautious interpretation. Although the difference between treatment groups was not statistically significant (Fisher's exact test, $p = 0.673$), a descriptively higher proportion of participants in the 2% topical minoxidil group achieved a high photographic assessment score compared with the plant-based serum group (76.9% vs. 61.5%). Given the small number of participants in each group, this descriptive difference should not be interpreted as evidence of superiority of either treatment, but it further emphasizes the need for adequately powered comparative studies.

Overall, the plant-based serum containing saw palmetto demonstrated promising improvements in hair count and hair shaft diameter over 12 weeks. No statistically significant differences between groups were detected compared with 2% topical minoxidil. Nevertheless, the present findings do not establish equivalence or non-inferiority between the two treatments. The results should therefore be regarded as preliminary and hypothesis-generating evidence supporting further investigation of the plant-based serum in FPHL.

Limitations and suggestions for future study

The present study has several limitations that should be considered when interpreting the findings. Firstly, the relatively small sample size, with 13 participants in each treatment group completing the 12-week intervention, limited the statistical power to detect between-group differences and increased the possibility of a Type II error. Therefore, the absence of statistically significant differences between treatments should not be interpreted as evidence of equivalence or non-inferiority. This limitation is particularly relevant to the global photographic assessment, in which a descriptively higher proportion of participants in the 2% topical minoxidil group achieved a high score compared with the plant-based serum group (76.9% vs. 61.5%), despite the difference not reaching statistical significance. Second, the treatment period was limited to 12 weeks. Because hair growth is a gradual process and FPHL is a chronic condition, a longer follow-up period may provide a more comprehensive assessment of sustained treatment response and safety. Third, the study was conducted with a relatively homogeneous and limited study population, which may restrict the generalizability of the findings to broader populations of women with FPHL.

Future studies should therefore include larger sample sizes based on an appropriate sample size calculation and should employ longer treatment and follow-up periods. Larger randomized controlled trials should also consider predefined primary endpoints and, where the objective is to establish comparable efficacy, an appropriately designed non-inferiority or equivalence framework with a prespecified clinically meaningful margin. Further studies may also evaluate the long-term efficacy and safety of the plant-based serum and investigate whether treatment response varies according to FPHL severity or other relevant clinical characteristics.

Conflict of Interest

The author declared no conflict of interest.

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