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Clinical Efficacy and Mechanisms of Microneedling Alone or Combined With Drugs in the Treatment of Androgenetic Alopecia

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ABSTRACT

Objective: To investigate the clinical efficacy, safety, and underlying mechanisms of microneedling alone or combined with drugs for androgenetic alopecia (AGA), so as to provide evidence for the standardized clinical treatment.

Methods: A total of 60 male AGA patients admitted to our hospital from January 2023 to June 2025 were enrolled and stratified into mild, moderate, and severe groups (20 cases each) based on the Hair Loss Severity Score (HLSS). The mild group received microneedling alone, the moderate group received microneedling combined with minoxidil, and the severe group received microneedling combined with a mixed solution of minoxidil and finasteride. All patients were treated with a pen-type electric microneedle at a needling depth of 1 ± 0.5 mm (tolerated by patients), once weekly. The treatment course was 8 weeks for the mild group, 12 weeks for the moderate group, and 16 weeks for the severe group. Efficacy was evaluated using HLSS, hair density detection, and patient satisfaction (Visual Analog Scale, VAS) before and after treatment, with adverse reactions recorded.

Results: Before treatment, significant differences in HLSS and hair density were observed among the three groups (all $p < 0.001$), showing a gradient distribution of mild group < moderate group < severe group (for HLSS) and mild group > moderate group > severe group (for hair density). After treatment, HLSS significantly decreased (all $p < 0.001$) and hair density significantly increased (all $p < 0.001$) in all groups. Intergroup comparisons revealed that HLSS was mild group < moderate group < severe group, while hair density was mild group > moderate group > severe group (all $p < 0.001$). The moderate group had the highest patient satisfaction (8.5 ± 0.8 points), with significant differences among the three groups ($p = 0.004$). No severe adverse reactions occurred in all 60 patients; only 3 cases (5.0%) developed mild scalp erythema and swelling, which resolved spontaneously within 24–48 h.

Conclusion: Microneedling exerts therapeutic effects by regulating hair growth signaling pathways and promoting transdermal drug delivery. It is effective for mild AGA when used alone, and achieves more significant efficacy in moderate to severe AGA when combined with drugs, with high safety. Thus, it is worthy of clinical promotion. However, this study has limitations such as a small sample size and male-only participants, and further multi-center, large-sample RCTs are needed for validation.

Guorui Li, Junjun Geng, and Jujing Liang contributed equally to this work, both regarded as the first authors.

1 | Introduction

Androgenetic alopecia (AGA) is the most common non-scarring alopecia worldwide, affecting approximately 50% of men and 30% of women, with an increasingly younger age of onset [1]. Characterized by progressive hair thinning, AGA presents as frontal hairline recession and vertex hair loss in men, and diffuse vertex thinning in women, which severely impairs patients' self-esteem and quality of life [2]. Its pathophysiological mechanism is complex, with the core link being 5α-reductase-mediated conversion of testosterone to dihydrotestosterone (DHT). DHT has a 5-fold higher affinity for hair follicle androgen receptors (AR) than testosterone; their binding induces follicular miniaturization and growth cycle disorders (shortened anagen phase and prolonged telogen phase), ultimately leading to gradual follicular atrophy and loss [3].

Current clinical treatments mainly consist of drug therapy and surgical intervention. First-line drugs, oral finasteride (a type II 5α-reductase inhibitor) and topical minoxidil (which improves local blood circulation), have proven efficacy but require long-term use, and some patients may experience adverse reactions or have poor tolerance [4]. Hair transplantation is limited by donor scarcity, high costs, and graft survival rates, restricting its clinical application [5]. In recent years, microneedling, as an emerging therapeutic approach, has shown promising prospects in AGA treatment by regulating the hair growth cycle through mechanical stimulation and assisting drug delivery [6]. Based on clinical practice, this study adopted stratified treatment according to alopecia severity to explore the efficacy and safety of microneedling alone or combined with drugs, providing data support for clinical standardized treatment.

2 | Materials and Methods

2.1 | Study Participants

A total of 60 male AGA patients aged 22–55 years (mean age: 38.6 ± 7.2 years) diagnosed in the Department of Medical Cosmetology of our hospital were enrolled. *Inclusion criteria*: ① Consistent with AGA diagnostic criteria (typical clinical manifestations + follicular miniaturization on pathological examination); ② HLSS of 3–8 points; ③ No prior alopecia treatment within 3 months; ④ No coagulation disorders, scalp infections, or drug allergies. *Exclusion criteria*: ① Scarring alopecia; ② Hepatic or renal insufficiency; ③ Pregnant or lactating males (note: finasteride is contraindicated in women of childbearing age, so only males were included); ④ Inability to complete the treatment course. Patients were stratified into three groups based on HLSS: mild group (3–4 points, $n = 20$), moderate group (5–6 points, $n = 20$), and severe group (7–8 points, $n = 20$). There were no significant differences in general data such as age and disease duration among the three groups ($p > 0.05$), indicating comparability. However, significant differences in pre-treatment HLSS and hair density were observed among the groups (all $p < 0.001$), meeting the gradient requirement for stratification.

2.2 | Treatment Protocols

2.2.1 | Equipment Selection

A pen-type electric microneedle with a needle length of 0.5–2.5 mm (Guangzhou Feijia Medical Devices Co. Ltd., Model: FJ-MN01) was used. The actual needling depth was adjusted to 1 ± 0.5 mm based on scalp thickness and patient tolerance.

2.2.2 | Treatment Regimens

- *Mild group*: Microneedling alone. The scalp was cleaned and disinfected before treatment. The pen-type microneedle was operated in a linear point-lifting manner in the alopecic area, with mild erythema as the treatment endpoint. Treatments were performed once weekly for 8 consecutive weeks.
- *Moderate group*: Microneedling combined with minoxidil. Microneedling was performed as in the mild group. Immediately after microneedling, 1 mL of 5% topical minoxidil solution (Johnson & Johnson, USA; Approval No.: H20140113) was topically applied once daily. Microneedling was conducted once weekly for 12 consecutive weeks, and minoxidil was continued until the end of the course.
- *Severe group*: Microneedling combined with a mixed solution of minoxidil and finasteride. Microneedling was performed as described above. Immediately after treatment, 1 mL of a mixed solution containing 5% minoxidil and 0.1% finasteride (prepared by the Pharmaceutical Preparation Department of our hospital; Batch No.: 20230106) was topically applied once daily. Microneedling was performed once weekly for 16 consecutive weeks, and the mixed solution was continued until the end of the course.

2.2.3 | Operational Standards

The procedures strictly followed the *Expert Consensus on Clinical Application of Microneedling in Hair Regeneration (2025 Edition)* [1]: ① Routine scalp disinfection and sterile drape placement before treatment; ② Uniform force application with linear point-lifting using the pen-type microneedle, avoiding repeated puncture of the same area (interval: approximately 1 mm); ③ Treatment endpoint controlled as mild erythema or pinpoint bleeding to avoid excessive damage to the deep dermis; ④ Immediate scalp cleaning and topical application of corresponding drugs after operation. Patients were advised to avoid hair washing, scalp scratching, direct sunlight, and spicy diets within 24 h.

2.3 | Efficacy Assessment Indicators

- *Hair Loss Severity Score (HLSS)*: Evaluated by two dermatologists in a blinded manner before and after treatment. Comprehensive scoring (3–8 points, higher scores indicating more severe alopecia) was based on hair thinning range

(0–3 points), density (0–3 points), and distribution (0–2 points). Discrepancies were resolved through consultation.

- *Hair Density Detection*: Hair density (hairs/cm^2) in the alopecic area was measured using a hair follicle detector (CK Electronics GmbH, Germany; Model: MPA10). The average value of three regions (vertex, forehead, and temporal area) was calculated under standardized conditions (20× magnification, room temperature: 22°C–25°C).
- *Patient Satisfaction*: Assessed using the Visual Analog Scale (VAS), with scores ranging from 0 (completely dissatisfied) to 10 (completely satisfied). Patients self-rated after treatment.
- Adverse Reactions: The occurrence and duration of adverse reactions such as scalp erythema, pain, infection, and bleeding were recorded during treatment.

2.4 | Statistical Analysis

Data were analyzed using SPSS 26.0 statistical software. Continuous data were presented as mean ± standard deviation ($x \pm s$). Intragroup comparisons before and after treatment were performed using paired *t*-tests, and intergroup comparisons were conducted using one-way analysis of variance (ANOVA) followed by LSD-t post hoc tests. Categorical data were expressed as rates (%) and analyzed using the χ^2 test. $p < 0.05$ was considered statistically significant.

3 | Results

3.1 | Comparison of HLSS Among the Three Groups Before and After Treatment

Before treatment, there were significant differences in HLSS among the three groups ($F = 286.419$, $p < 0.001$), showing a gradient distribution of mild group < moderate group < severe group. After treatment, HLSS significantly decreased in all groups compared with baseline (all $p < 0.001$). Intergroup comparisons revealed the lowest HLSS in the mild group, followed by the moderate group, and the highest in the severe group (2.1 ± 0.4 vs. 3.2 ± 0.5 vs. 4.3 ± 0.6 points), with significant differences among the three groups ($F = 128.735$, $p < 0.001$). Post hoc pairwise comparisons showed significant differences in HLSS between the mild and moderate groups, mild and severe groups, and moderate and severe groups (all $p < 0.001$). Detailed data are presented in Table 1.

3.2 | Comparison of Hair Density Among the Three Groups Before and After Treatment

Before treatment, significant differences in hair density were observed among the three groups ($F = 136.825$, $p < 0.001$), showing a gradient distribution of mild group > moderate group > severe group. After treatment, hair density significantly increased in all groups compared with baseline (all $p < 0.001$). Intergroup comparisons revealed the highest hair density in the mild group, followed by the moderate group, and the lowest in the severe group (118.6 ± 15.3 vs. 105.7 ± 13.6 vs. 82.4 ± 11.2 hairs/cm^2), with significant differences among the three groups ($F = 68.937$, $p < 0.001$). Post hoc pairwise comparisons showed significant differences in hair density between the mild and moderate groups, mild and severe groups, and moderate and severe groups (all $p < 0.001$). Detailed data are presented in Table 2.

As shown in the Figure 1, mild, moderate, and severe alopecia all achieved favorable outcomes after treatment. Subjectively, the improvement in moderate and severe groups was more pronounced, leading to higher patient satisfaction.

3.3 | Patient Satisfaction and Adverse Reactions

The VAS scores for patient satisfaction were (7.2 ± 1.1) points in the mild group, (8.5 ± 0.8) points in the moderate group, and (7.8 ± 1.0) points in the severe group, with significant differences among the three groups ($F = 5.832$, $p = 0.004$). Post hoc comparisons showed that satisfaction in the moderate group was significantly higher than that in the mild group ($p = 0.002$), while no significant differences were observed between the moderate and severe groups ($p = 0.061$) or between the mild and severe groups ($p = 0.185$).

No severe adverse reactions occurred in any patient. Mild scalp erythema and swelling were reported in 3 cases (5.0%) (1 case in the mild group and 2 cases in the moderate group), without significant pain or infection. These symptoms resolved spontaneously within 24–48 h without special treatment. No long-term adverse reactions such as scarring or hyperpigmentation were observed.

TABLE 1 | Comparison of HLSS among the three groups before and after treatment ($x \pm s$, points).

Group	Number of cases	Before treatment	After treatment	*t*-value	Intragroup *p*
Mild	20	3.6 ± 0.5	$2.1 \pm 0.4^{\#}$	13.267	< 0.001
Moderate	20	5.8 ± 0.6	$3.2 \pm 0.5^{\#}$	18.932	< 0.001
Severe	20	7.5 ± 0.7	4.3 ± 0.6	21.548	< 0.001
F-value	—	286.419	128.735	—	—
Intergroup *p*	—	< 0.001	< 0.001	—	—

Note: Post hoc pairwise comparisons (LSD-*t*-test): Compared with the mild group after treatment, $p < 0.001$; compared with the moderate group after treatment, $^{\#}p < 0.001$.

TABLE 2 | Comparison of hair density among the three groups before and after treatment ($x \pm s$, hairs/cm^2).

Group	Number of cases	Before treatment	After treatment	*t*-value	Intragroup *p*
Mild	20	86.4 ± 12.5	118.6 ± 15.3$^{\#}$	8.724	< 0.001
Moderate	20	62.3 ± 10.8	105.7 ± 13.6$^{\#}$	12.351	< 0.001
Severe	20	38.5 ± 9.6	82.4 ± 11.2	15.679	< 0.001
F-value	—	136.825	68.937	—	—
Intergroup *p*	—	< 0.001	< 0.001	—	—

Note: Post hoc pairwise comparisons (LSD-*t*-test): Compared with the mild group after treatment, $p < 0.001$; compared with the moderate group after treatment, $^{\#}p < 0.001$.

FIGURE 1 | Comparison of hair loss of different severities before and after treatment with different grades of AGA.

4 | Discussion

4.1 | Pathophysiology and Treatment Status of AGA

AGA pathogenesis involves multiple factors including genetics, hormones, and signaling pathway regulation, with DHT-mediated follicular miniaturization as the core [3]. Binding of DHT to follicular AR inhibits the Wnt/β-catenin signaling pathway (critical for maintaining the anagen phase) and activates the abnormal expression of the Shh/Gli signaling pathway, and downregulates hair follicle stem cell activity, resulting in shortened anagen phase, prolonged telogen phase, and ultimately thin, fragile hair and hair loss [4]. In traditional treatment, finasteride reduces DHT production by inhibiting type II 5α-reductase, while minoxidil exerts effects by improving local blood circulation and promoting follicular metabolism. However, both have limitations: finasteride may cause adverse reactions such as sexual dysfunction (incidence: approximately 2.1%) [5], and minoxidil has low transdermal absorption efficiency (only 1%–3%), requiring long-term use (at least 6 months) to achieve visible efficacy [6]. Although hair transplantation can quickly improve appearance, it is limited by donor availability (scarce healthy follicles in the occipital region), high surgical costs (approximately 10 000–30 000 RMB per case), and graft survival rates (approximately 80%–90%), making it unable to meet the needs of all patients [7].

4.2 | Mechanisms of Microneedling in AGA Treatment

Microneedling exerts anti-alopecia effects through a multidimensional mechanism involving mechanical stimulation, biological response, and drug synergism, with two core mechanisms that exhibit synergistic effects: ① Regulation of the hair growth cycle via mechanical stimulation: Controlled micro-injuries induced by microneedling (depth:0.5–2.5 mm) in the scalp and surrounding dermal tissues activate the skin wound healing pathways, promote overexpression of hair growth-related genes such as vascular endothelial growth factor (VEGF), β-catenin, and Wnt3a, activate the Wnt/β-catenin signaling pathway, prolong the anagen phase, and reverse follicular miniaturization [8]; ② Enhancement of transdermal drug delivery: Microneedling creates uniformly distributed microchannels in the scalp, breaking the stratum corneum barrier and increasing the transdermal absorption rate of drugs such as minoxidil and finasteride to 20%–30% [9], significantly improving targeted drug delivery to hair follicles. Additionally, microneedling stimulates local blood circulation and growth factor

release, providing a favorable microenvironment for follicular regeneration [10].

4.3 | Clinical Application and Standardized Operation of Microneedling

This study demonstrated that microneedling alone significantly improves mild AGA (41.7% reduction in HLSS, 37.3% increase in hair density), and combination with drugs achieves superior efficacy in moderate to severe AGA (44.8% reduction in HLSS in the moderate group, 42.7% reduction in the severe group), consistent with the findings of previous randomized controlled trials (RCTs) [6, 11]. Two studies involving 94 and 60 male AGA patients respectively confirmed that hair density increase in the roller microneedling combined with minoxidil group was significantly higher than that in the minoxidil alone group ($p < 0.05$) [5, 12]. A study by the team from Affiliated Hospital of Yangzhou University further showed that microneedling combined with PRP and minoxidil in the treatment of refractory severe AGA increases hair density by 36% and reduces vellus hair ratio by 25%, with high safety [3].

Standardized operation is critical for ensuring the efficacy and safety of microneedling. According to the *Expert Consensus on Clinical Application of Microneedling in Hair Regeneration (2025 Edition)* [1], recommended equipment includes pen-type electric microneedles (0.5–2.5 mm) or roller microneedles (1.5–2.0 mm), with attention to differences in actual needling depth: the actual penetration depth of roller microneedles is 50%–70% of the needle length, while that of pen-type electric microneedles is close to the needle length at 0.25–1.00 mm and shorter than the needle length at 1.5–2.5 mm. In this study, a pen-type electric microneedle was used with a controlled needling depth of 1 ± 0.5 mm, and mild erythema or pinpoint bleeding as the treatment endpoint, ensuring therapeutic efficacy while minimizing adverse reaction risk (total incidence: only 5.0%), consistent with consensus recommendations.

4.4 | Clinical Selection and Prospects of Microneedling

Microneedling has a broad range of applications: it can be used alone for mild AGA, combined with drugs for moderate to severe AGA, and serves as an alternative for patients who refuse or are intolerant to drugs [13]. In this study, the moderate group had the highest patient satisfaction (8.5 ± 0.8 points), possibly due to significant therapeutic effects and few adverse reactions; although the severe group showed better efficacy than the mild group, lower baseline hair density resulted in slightly lower satisfaction than the moderate group. The low adverse reaction rate (5.0%), all mild erythema and swelling, indicates high safety and good patient tolerance, consistent with literature reports [14].

4.5 | Study Limitations and Future Perspectives

This study has several limitations: ① Small sample size: Restricted by single-center hospital scale and patient recruitment volume, only 60 patients (20 per group) were enrolled, which may affect statistical power and lead to undetected differences in some secondary outcomes; ② Male-only participants: Female AGA differs from male AGA in pathophysiology (e.g., androgen levels, follicular sensitivity to DHT) and clinical manifestations (diffuse vertex thinning), potentially resulting in different treatment responses [15]. Thus, the results cannot be directly generalized to females; ③ Limited treatment protocol design: To improve patient satisfaction, the mild group only received microneedling alone without a microneedling + drug control subgroup, precluding the evaluation of the potential synergistic effect of combination therapy in mild AGA; ④ Study design limitations: This was a single-center, before-after self-controlled study lacking multicenter, randomized, parallel-controlled design, which may introduce selection bias and fail to fully exclude the influence of natural disease course or placebo effect [16]; ⑤ Short follow-up duration: The treatment course was only 8 weeks for the mild group and up to 16 weeks for the moderate to severe groups, with no long-term follow-up (e.g., 6 months, 1 year) to assess the stability of long-term efficacy and recurrence rate.

Based on these limitations, future research should focus on: ① Expanding the sample size to improve statistical power and further verify the efficacy and safety of microneedling; ② Including female patients in gender-stratified studies to explore the efficacy and optimal treatment parameters of microneedling in female AGA; ③ Optimizing study design with multi-center, randomized, double-blind, parallel-controlled RCTs, including multiple control groups (drug alone, microneedling alone, microneedling + drug) to reduce bias; ④ Adding a mild combination therapy group to evaluate the efficacy of microneedling + drugs in mild AGA, providing more comprehensive clinical treatment options; ⑤ Extending follow-up duration to at least 1 year to observe long-term efficacy persistence and late adverse reactions; ⑥ Exploring personalized treatment protocols by optimizing microneedling parameters (needle length, treatment frequency, course) and combined drug regimens based on patient age, alopecia severity, and follicular status.

5 | Conclusion

Microneedling has definite therapeutic effects on AGA by regulating hair growth signaling pathways and promoting transdermal drug delivery. It is suitable for mild AGA when used alone, and achieves more significant efficacy in moderate to severe AGA when combined with minoxidil or a mixed solution of minoxidil and finasteride. With safe operation, few adverse reactions, and high patient satisfaction, it is worthy of clinical standardized promotion and application. However, this study has limitations such as a small sample size and male-only participants, and further multi-center, large-sample RCTs are needed for validation.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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