



TREATMENT OF ALOPECIA AREATA WITH ORAL METHYLPREDNISOLONE COMBINED WITH FRACTIONAL MICRONEEDLE RADIOFREQUENCY

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ABSTRACT

Objective: To evaluate the efficacy and safety of fractional microneedle radiofrequency combined with oral methylprednisolone in the treatment of alopecia areata.

Subjects and Methods: A total of 40 patients with alopecia areata were enrolled and randomized into two groups. The study group was comprised of 20 patients (7 males, 13 females) who received combined treatment of oral methylprednisolone and ablative fractional microneedle radiofrequency (five sessions at 4-week intervals). The control group included 20 patients (9 males, 11 females) received monotherapy with oral methyl prednisolone. Treatment efficacy was determined based on clinical improvement and the Severity of Alopecia Tool (SALT) score, laboratory improvement was evaluated using trichoscopy analysis from the baseline and after 12 weeks.

Results: Significant improvements in SALT score, hair density, mature hair rate, and hair regrowth were observed at baseline, week 12, and week 24 of treatment ($p < 0.001$). Comparison between the two groups showed no significant difference in mean SALT score at week 12, whereas hair density and mature hair rate at weeks 12 and 24 were significantly higher in the study group than in the control group ($p < 0.05$). However, patients experienced increased hair shedding after 24 weeks, with an increase in mean SALT score and decrease in hair density and mature hair compared with week 12 ($p < 0.05$). In the fractional microneedle radiofrequency group, 100% of patients reported pain during treatment, no infections or skin ulcerations were recorded. Adverse effects of oral corticosteroids included folliculitis and acne in 21/40 patients (52.5%), hypertrichosis in 40%, abdominal pain or discomfort in 35%, weight gain in 57.5%, fasting hyperglycemia in 12.5%, menstrual irregularities in 19.4%, Cushing's syndrome features 12.5%, and decreased serum cortisol in 2 out of 15 patients (13.3%).

Conclusion: Ablative fractional microneedle radiofrequency is an effective adjunctive therapy for severe alopecia areata when combined with oral methylprednisolone.

Keywords: *alopecia areata, ablative fractional microneedle radiofrequency, methylprednisolone.*



INTRODUCTION

Alopecia areata (AA) is a chronic, organ-specific autoimmune disorder, affecting approximately 0.2% of the global population. Despite being indolent, it often results in significant cosmetic concerns, with substantial psychological impact and reduced quality of life.^{1,2,3,4} Spontaneous resolution of AA occurs in approximately 80% of patients, particularly in mild cases with a disease duration of less than one year.^{5,6}

Evidence indicates that alopecia universalis, alopecia totalis, and linear alopecia are frequently associated with poor treatment outcomes and high risks of relapse. The 2012 UK clinical guidelines identify systemic corticosteroids as a preferred therapeutic option for alopecia totalis, while concerns regarding the adverse effects of prolonged oral corticosteroid administration substantially restrict their long-term application.^{5,6,7}

Scalp-directed procedures inducing micro-injury have been documented in several studies investigating their therapeutic efficacy in alopecia areata. However, they are primarily regarded as adjunctive interventions, typically employed in combination with other therapeutic modalities.⁷ Although the underlying mechanism remains unclear, prevailing hypotheses propose that scalp micro-injury sparks the wound-healing cascade, thereby stimulating hair follicle regeneration while concurrently mitigating perifollicular inflammation through T lymphocyte apoptosis, migration, or cytokine diffusion.^{11,12} In addition to inducing controlled micro-injuries on the scalp surface, fractional microneedling RF transduces thermal effects to targeted tissue, thereby exerting a superior effect over conventional microneedling. Furthermore, compared with fractional CO₂ laser, fractional microneedling RF offers an advantage in scalp applications by minimizing the risk of undesirable tissue ablation in areas with hair shafts. Therefore, this study was conducted to evaluate the therapeutic efficacy of combining oral methylprednisolone with fractional microneedle RF in the management of alopecia areata.

MATERIALS AND METHOS

Study participants

Patients with AA who presented for examination and treatment at the Stem Cell Research and Application Technology Department, National Hospital of Dermatology and Venereology, from January 2022 to March 2024 were included in the study.



The inclusion criteria were as follows: patients were diagnosed with alopecia areata, characterized by one or more round or oval patches of non-scarring hair loss with a smooth scalp surface and without associated pruritus or scaling. In cases requiring differential diagnosis, trichoscopy evaluation was performed, revealing features such as exclamation mark hairs, yellow dots, black dots, or vellus hairs. Eligible patients had AA affecting more than 25% of the scalp surface area. Patients were 12 years of age or older, and had not received any topical or systemic treatments for alopecia areata, or other therapies with potential efficacy for the condition, within the preceding three months.

The exclusion criteria included: pregnant or breastfeeding women; individuals with hypersensitivity to topical anesthetics, pacemakers, or metallic implants; those with coagulation disorders or receiving anticoagulant therapy; individuals with autoimmune connective tissue diseases or localized scalp infections at alopecia sites; individuals with chronic systemic illnesses such as hypertension, diabetes mellitus, cardiovascular disease, renal or hepatic failure, or severe immunodeficiency.

Study design

A randomized controlled trial was conducted at the Stem Cell Research and Application Technology Department, National Hospital of Dermatology and Venereology, from January 2022 to March 2024.

Participants meeting the eligibility criteria underwent clinical and trichoscopy examination of both the lesional and perilesional sites. In cases of extensive lesions (alopecia totalis), trichoscopy images were taken from three regions: the vertex, occipital, and temporal areas. The examined sites were marked to ensure that follow-up assessments were taken at the exact same locations.

Both groups received oral methylprednisolone at a dose of 0.3 mg/kg/day, tapered by three-quarters every two weeks over a 12-week period, followed by maintenance with gradually reduced alternate-day dosing for an additional month before discontinuation. In the intervention group, the alopecia patches were treated with fractional microneedle RF once every four weeks for a total of 20 weeks (needle length 1.5–2 mm, energy level 3–4). The study utilized the INTRAcel device (Jeisys, Korea) equipped with an invasive tip comprising 49 microneedles arranged over a 1 cm² surface area. The microneedles were non-conductive except for the distal 0.3 mm of each

tip. Topical anesthesia was achieved using 10% lidocaine in either spray or cream form. Oral methylprednisolone (Medrol, 16 mg and 4 mg tablets) was manufactured by Pfizer, Italy. Esomeprazole (Nexium Mups, 40 mg) was produced by AstraZeneca, Sweden. Topical fusidic acid cream (Fucidin) was manufactured by Leo, Denmark. Dermoscopic imaging was performed with the Fotofinder system (Germany). A square-grid ruler, with each square measuring 1 cm², was used for hair density assessment, and clinical photographs were obtained using an iPhone 13 Pro Max.

Evaluation of treatment outcomes

Treatment efficacy was assessed by evaluating changes in the Severity of Alopecia Tool (SALT) score, hair density, and the proportion of terminal hairs, as well as recording any adverse events. Assessments were performed at baseline and at 4, 8, 12, and 24 weeks after treatment initiation.

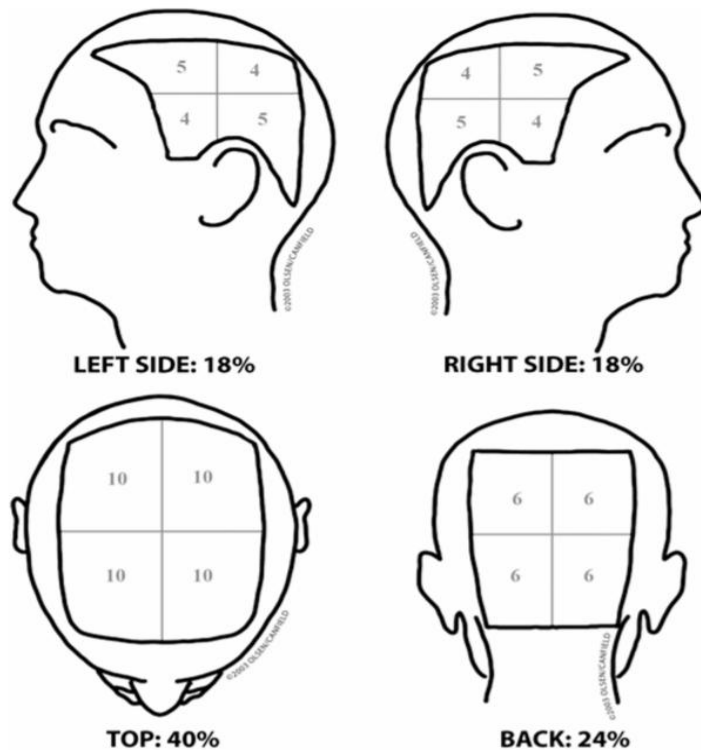


Figure 1: Scalp area

Assessment of the SALT score

The scalp was divided into four quadrants, and the percentage of hair loss in each section was estimated. The percentage of hair loss in each quadrant was calculated as: *percentage of hair*

loss \times percentage of scalp surface area represented by that quadrant. The overall SALT score was obtained by summing the calculated hair loss percentages across all quadrants.

Treatment response was further classified according to the criteria proposed by Gita & Mohammadreza (2013):

- Good response: > 75% hair regrowth.
- Moderate response: 51–75% hair regrowth.
- Poor response: 26–50% hair regrowth.
- No response: 0–25% hair regrowth

Data analysis

Data were analyzed using SPSS version 20.0. Variables were presented appropriately as mean \pm standard deviation (SD), deviation, median, minimum value, maximum value, percentage, and frequency. Statistical tests used for comparing two means included the *t*-test for normally distributed variables and non-parametric tests (Wilcoxon and Mann–Whitney U or rank-sum test) for non-normally distributed variables. For qualitative variables, Fisher's exact test or the Chi-square test was applied. A *p*-value < 0.05 was considered statistically significant.

Institutional Review Board

The study was conducted in accordance with the principles outlined in the Declaration of Helsinki. All patients provided the written informed consent before enrollment and had the right to withdraw from the study at any time without any impact on their ongoing treatment. Patient's confidentiality was strictly maintained. All participants were informed of the potential effects of the medications, monitored throughout the study, and assured that their health would not be adversely affected by participation.

RESULTS

Demographic and clinical characteristics

Table 1. Demographic and clinical characteristics (N=40)

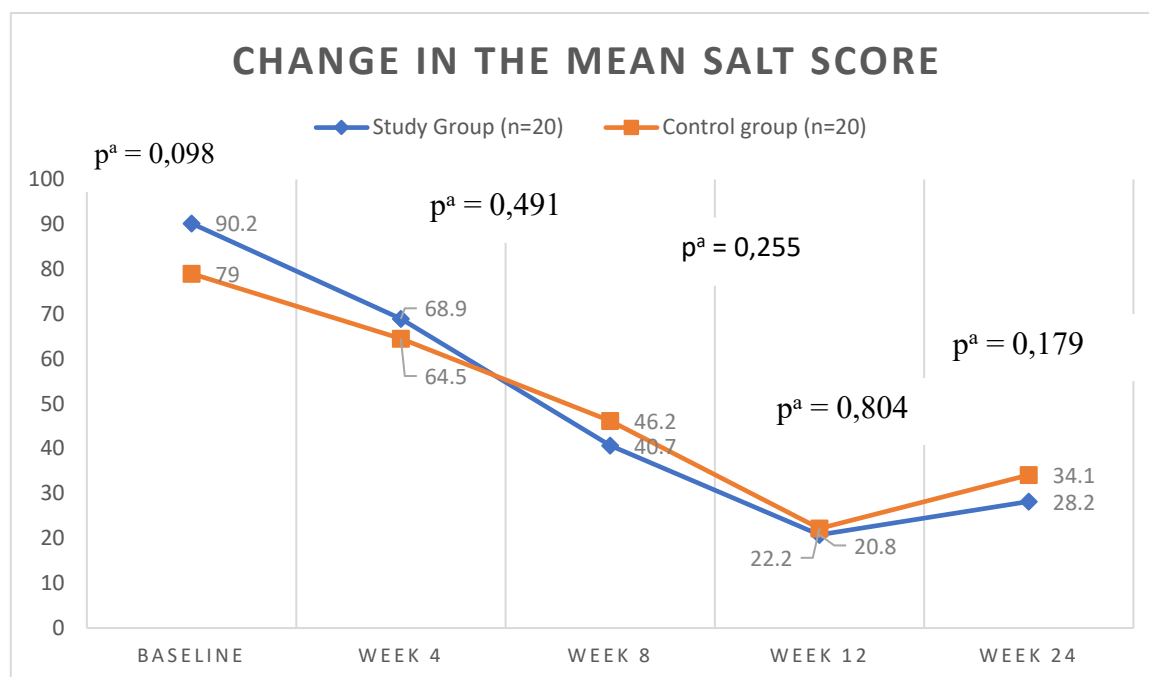
Index	Study group (N1=20)	Control group (N2=20)	p- value
Age (years)			
$\bar{X} \pm SD$	$32.4 \pm 14,1$	28.1 ± 11.4	0.289 ^a

Disease duration (months)			
$\bar{X} \pm SD$	25.2 \pm 32.4	26.3 \pm 38.2	0.922 ^a
SALT score			
$\bar{X} \pm SD$	90.2 \pm 16.2	79 \pm 24.5	0.098 ^a
Hair density	12.6 \pm 14.9	17.2 \pm 15.2	0.345
$\bar{X} \pm SD$			
Sex - n (%)			
Male	7 (35%)	9 (56.3%)	0.374 ^b
Female	13 (65%)	11 (45.8%)	
History of Alopecia Areata-			
n (%)	6 (30%)	5 (25%)	0.723 ^c
Yes	14 (70%)	25 (75%)	
No			
History of family- n (%)			
Yes	4 (20%)	2 (10%)	0.331 ^c
No	16 (80%)	18 (90%)	

^aRank sum test, ^bChi-square test, ^cFisher's exact test

Twenty patients were enrolled in the intervention group, with the mean age of 32.4 ± 14.1 years; males accounted for 35% and females for 65%. 25.2 ± 32.4 months. In the control group, there were 20 patients with the mean age of 28.1 ± 11.4 years; males accounted for 56.3% and females for 45.8%. The mean ($\pm SD$) disease duration was 26.3 ± 38.2 months. There were no significant differences between the two groups in terms of sex distribution, mean age, mean disease duration, SALT score, or personal and family history of alopecia areata ($p > 0.05$) (Table 1).

Change in the mean SALT score



^aRank sum test

Figure 2. Changes in mean SALT scores between the two treatment groups at baseline and after 4, 8, 12, and 24 weeks (N=40).

The mean SALT score was markedly decreased over time in both groups, at 4, 8, and 12 weeks compared to baseline. At 24 weeks, patients began to exhibit a varied increase in hair loss, with mean SALT scores mildly rising at 28.2 and 34.1 in the intervention and control groups, respectively; however, these values remained significantly lower than the baseline SALT scores. There were no statistically significant differences in mean SALT scores between the two groups at baseline, week 4, week 8, week 12, or week 24.

Mean reduction in SALT scores between the two groups

Table 2. Comparison of mean SALT score reduction between the two groups (calculated as the difference in SALT scores at weeks 4, 8, 12, and 24 versus baseline) (N=40).

Index	Study group (n1=20)	Control group (n2=20)	p-value ^a
Week 4 ($\bar{X} \pm SD$)	21.2 \pm 5.2	14.5 \pm 5.3	< 0.001
Week 8 ($\bar{X} \pm SD$)	49.5 \pm 11.9	32.8 \pm 13.5	< 0.001
Week 12 ($\bar{X} \pm SD$)	69.3 \pm 23.1	56.8 \pm 27.2	0.125

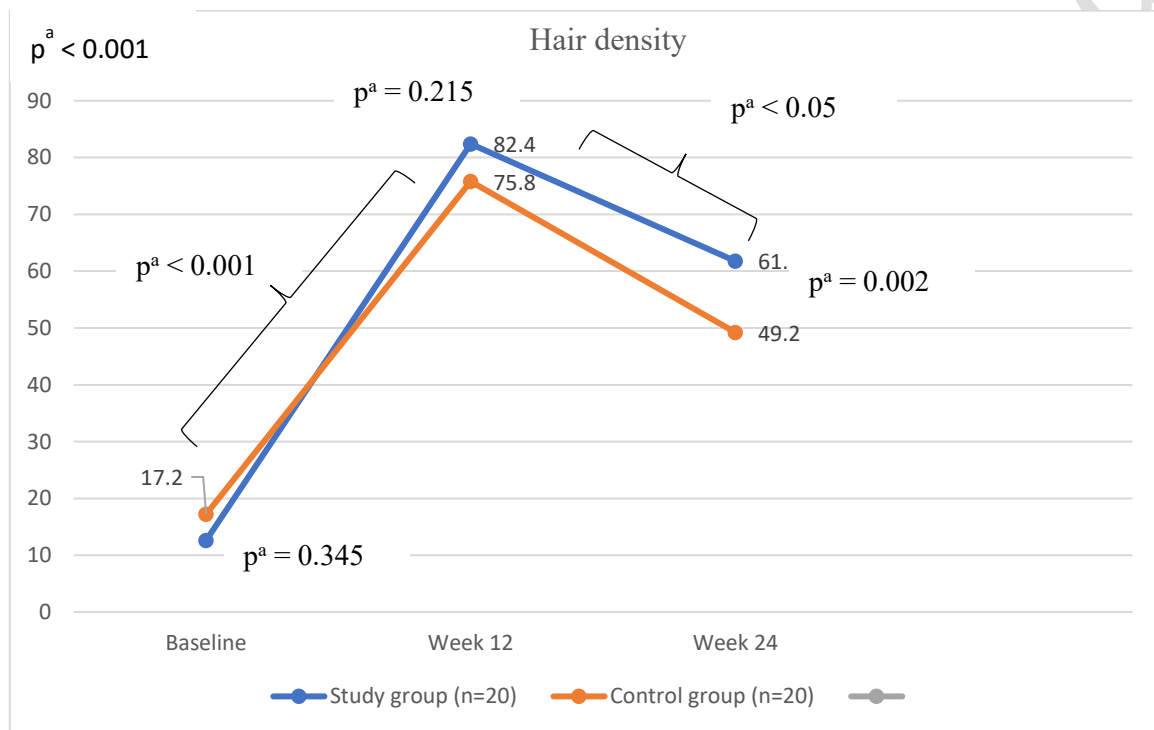


Week 24($\bar{X} \pm SD$)	61.9 \pm 16.3	44.9 \pm 17.2	0.003
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^aRank sum test

The reduction in mean SALT scores (calculated as the difference between the mean SALT score at weeks 4, 8, 12, and 24 with week 0) was greater in the intervention group than in the control group, with statistically significant differences observed at weeks 4, 8, and 24 ($p < 0.05$).

Changes in hair density assessed by trichoscopy

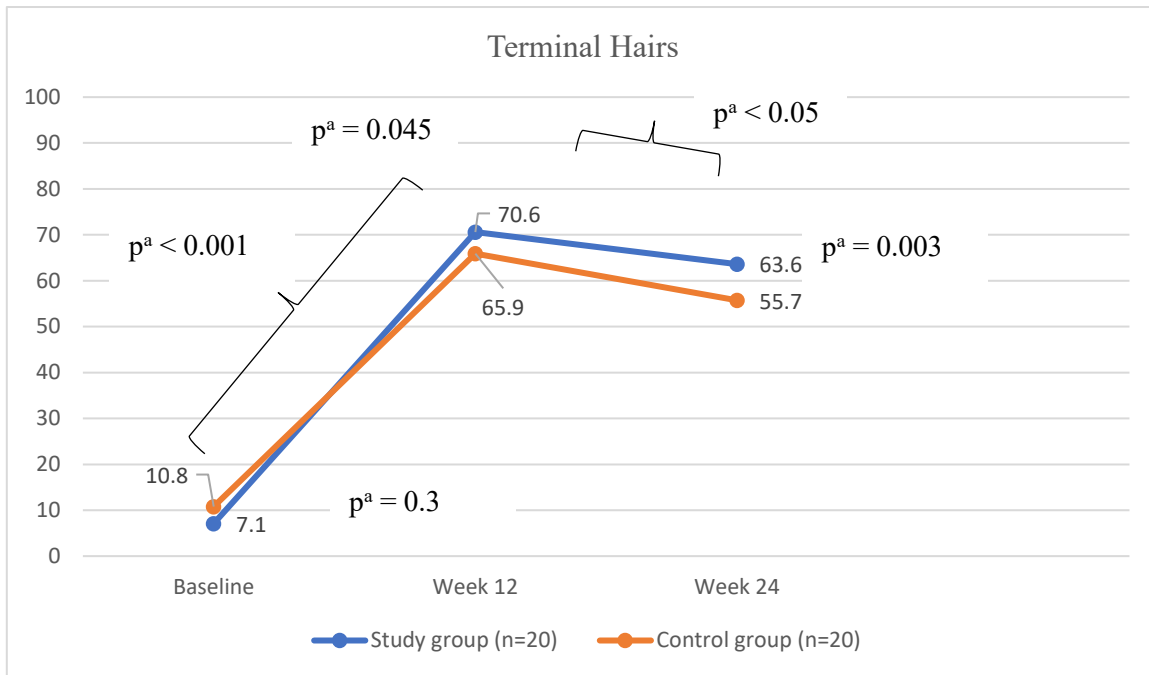


^aRank sum test

Figure 3. Mean changes in hair density on dermoscopy in the two treatment groups at baseline, week 12, and week 24 (N=40).

Hair density at week 12 was significantly increased compared with baseline in both groups ($p < 0.001$). At week 24, hair shedding was observed, and hair density was markedly reduced compared with the 12-week time point ($p < 0.05$), yet remained significantly higher than baseline levels. Comparison of hair density between the intervention and control groups revealed no significant difference at 12 weeks, whereas at 24 weeks, hair density was significantly higher in the intervention group ($p = 0.002$).

Changes in terminal hairs

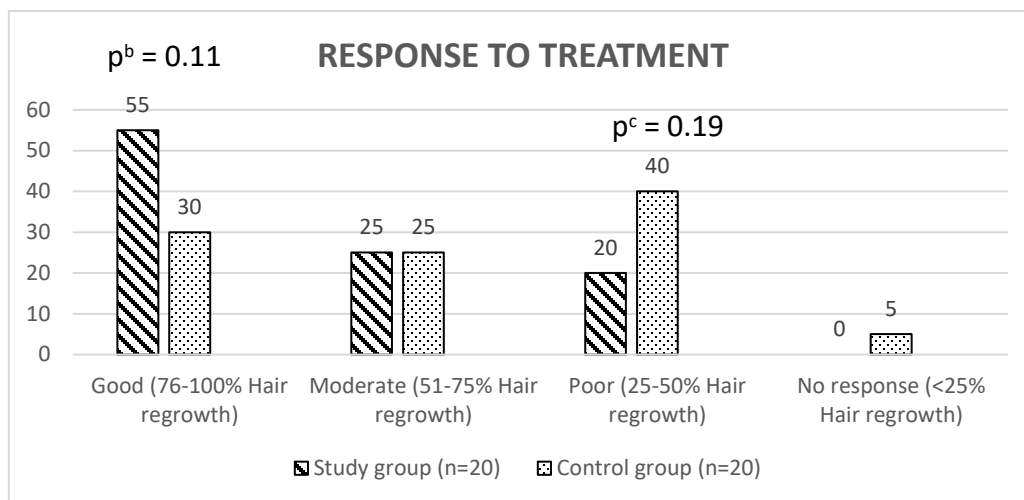


^aRank sum test

Figure 4. Mean changes in terminal hair count on trichoscopy in the two treatment groups at baseline, week 12, and week 24 (N=40).

The fraction of terminal hairs after 12 weeks was substantially elevated in both groups compared with baseline ($p < 0.001$). At week 24, hair shedding occurred, and the proportion of terminal hairs decreased compared with the 12-week time point ($p < 0.05$). Comparison between the intervention and control groups showed a statistically significant difference at both 12 and 24 weeks, with p-values of 0.045 and 0.003, respectively.

Response to treatment



^bChi square test, ^cFisher's exact test

Figure 5. Treatment response based on the Gita & Mohammadreza (2013) grading system (N=40)

In the intervention group, 55% of patients achieved a good response, 25% achieved a moderate response, 20% had a poor response, and no patients were classified as non-responders. In the control group, 30% achieved a good response, 25% had a moderate response, 40% had a poor response, and 5% were non-responders.

Association between disease duration and treatment response

Table 3. Association between disease duration and treatment response (N=40)

	Duration < 5 years	Duration > 5 years	p-value ^c
Good response	17 (51.5%)	0	0.009
Moderate response	7 (21.2%)	3 (41.9%)	
Poor response	9(27.3%)	3(42.9%)	
No response	0	1 (14.3%)	

^cFisher's exact test

There was a significant association between disease duration and treatment response. Patients with a disease duration of less than five years showed better treatment outcomes, with the difference reaching statistical significance ($p = 0.009$).

Association between alopecia phenotype and treatment respons

Table 4. Relationship between alopecia phenotype and therapeutic response (N = 40)

	Alopecia Totalis	Linear Alopecia	Patch Alopecia	p-value ^c
Good response	13 (50%)	0	4 (66.7%)	0.000
Moderate response	8 (30.8%)	0	2 (33.3%)	
Poor response	5 (19.2%)	7 (87.5%)	0	
No response	0	1 (12.5%)	0	

^cFisher's exact test

There was a correlation between alopecia phenotype and treatment response. Patients with the linear pattern exhibited poorer or no response to therapy, whereas those with patchy AA achieved good to moderate outcomes with the treatment regimen.

Adverse events

Table 5. Adverse events (N=40)

Symptom	n (%)
Pain	20/20 (100%)
Cutaneous infection	0
Ulceration	0
Folliculitis / Acne	14 (52.5%)
Gain weight	23 (57.5%)
Hypertrichosis	16 (40%)
Abdominal pain / discomfort	14 (35%)
Gastric and duodenal ulcers	0
Fasting hyperglycemia > 7 mmol/L	5 (12.5%)
Menstrual irregularities	6/31 (19.4%)
Cushing's syndrome features	5 (12.5%)
Decreased serum cortisol	2/15 (13.3%)

In the intervention group, 100% of patients experienced pain during the procedure; no cases of infection or skin ulceration at the treatment site were observed. Folliculitis and acne occurred in 21 out of 40 patients (52.5%). Weight gain was reported in 57.5% of patients, Hypertrichosis in 40%, abdominal pain or discomfort in 35%, fasting hyperglycemia in 12.5%,

menstrual irregularities in 19.4%, Cushing's syndrome features 12.5%, and decreased serum cortisol in 2 out of 15 patients (13.3%).

DISCUSSION

Systemic corticosteroid therapy, administered either orally or via injection, is recommended for severe alopecia areata (AA) in most current treatment guidelines.^{2,5,7,8,9} However, localized procedures for AA have been reported by a limited number of small-scale studies and are generally regarded as adjunctive measures to primary treatments.^{13,14,15}

In our study, sex distribution, age at onset, disease duration, severity of hair loss (SALT score), and dermoscopic parameters were comparable between the two groups. Both groups demonstrated significant improvements in SALT scores, hair density, terminal hair ratio, and hair regrowth at baseline, week 12, and week 24. When comparing the two groups, no significant difference was found in the mean SALT score at week 12. However, hair density and the terminal hair fraction at weeks 12 and 24 were higher in the intervention group compared to the control group ($p < 0.05$). However, by week 24, a recurrence of hair shedding was observed, accompanied by an increase in the mean SALT score and a significant reduction in both hair density and the terminal hair fraction compared with week 12. At week 12, the intervention group demonstrated good, moderate, and poor response rates of 55%, 25%, and 20%, respectively, compared with 30%, 25%, and 40% in the control group, based on the treatment response grading system of Gita and Mohammadreza (2013). However, these differences did not reach statistical significance. Analysis of factors influencing treatment outcomes revealed that a disease duration greater than five years and a linear pattern of hair loss were associated with poorer responses. This finding is consistent with the findings reported by Hee Jeong Han 2023¹⁰.

Overall, the intervention group demonstrated improvements in SALT scores and treatment response rates comparable to those of the control group, but achieved higher hair density and terminal hair proportion. This may be explained by the mechanism of fractional microneedle RF, which delivers energy through an array of ultrafine needles, inducing controlled micro-injuries in the affected scalp areas. This stimulation may promote apoptosis of pathogenic T lymphocytes, recruit inflammatory cells and cytokines into the follicular microenvironment, and disperse perifollicular T-cell infiltrates. In addition, the wound-healing cascade and enhanced microcirculation, similar to the mechanism of minoxidil, may further activate follicular growth.

Finally, the microchannels generated by RF facilitate transdermal delivery of topical agents, thereby augmenting hair regrowth.¹¹

Adverse events were assessed during treatment. In the fractional microneedle RF group, all patients (100%) reported pain during the procedure, but no cases of infection or ulceration at the treated sites were observed. Analysis of adverse effects from oral corticosteroids showed that 21/40 patients (52.5%) developed folliculitis or acne, 57.5% experienced weight gain, 40% reported hypertrichosis, 35% had abdominal pain or discomfort, 12.5% developed fasting hyperglycemia, 19.4% reported menstrual irregularities, 12.5% exhibited Cushingoid features, and 2/15 patients (13.3%) had decreased serum cortisol levels.

In a controlled trial conducted by Olsen (1992), 30–47% of patients with AA presenting from patchy to totalis forms, responded to a 6-week tapering course of oral prednisolone. More than 47% achieved hair regrowth, with the main adverse events being weight gain and acne.¹² Kurosawa et al. (2006) conducted a comparative study in Japan, evaluating three treatment regimens: oral dexamethasone 0.5 mg/day for 6 months (Dex group), intramuscular triamcinolone acetonide 40 mg/month for 6 months followed by 40 mg every 6 weeks for 1 year (TAC group), and oral prednisolone 80 mg/day for 3 consecutive days every 3 months (Pred group). Response rates were 37%, 74%, and 66% in the Dex, TAC, and Pred groups, respectively. Adverse effects included gastrointestinal discomfort, weight gain, acne, and muscle weakness, with incidence rates of 10% (Pred group), 41% (TAC group), and 30% (Dex group). No patients developed hypertension, peptic ulcer disease, or hyperglycemia. Adrenal suppression, characterized by elevated ACTH and reduced serum cortisol, was observed in 2/27 patients (7%) in the Pred group, 5/22 (23%) in the TAC group, and 4/6 (67%) in the Dex group¹³.

Colin Michael Kincaid (2023) analyzed several studies investigating the efficacy of RF in promoting hair regrowth and found that this modality was effective in both androgenetic alopecia and AA¹⁵. Issa et al. (2015) compared the use of CO₂ laser with fractional microneedle RF combined with topical triamcinolone in patients with AA and reported complete hair regrowth after 3–6 treatment sessions.¹⁶

The combination of fractional microneedle RF and oral methylprednisolone in our study demonstrated favorable therapeutic outcomes. Future studies with larger sample sizes are warranted to further characterize the safety profile of RF, particularly given that, in addition to its

hair-growth-promoting effect, RF can also induce hair removal, which may paradoxically exacerbate hair loss. Moreover, a more comprehensive evaluation of the adverse effects of daily low-dose oral methylprednisolone is needed. Finally, our follow-up period was limited to 24 weeks; thus, long-term recurrence rates could not be accurately determined.

CONCLUSIONS

In the treatment of AA, the combination of fraction microneedle RF with oral methylprednisolone demonstrated superior therapeutic efficacy, showing significant improvement from baseline as well as over oral methylprednisolone monotherapy. Fractional microneedle therefore represents a promising adjunctive modality for enhancing hair regrowth and managing AA.

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Conflict of Interest Statement: The authors declare no conflicts of interest related to this work.

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