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Original Article
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# Effect of Biodegradable Microneedle Acupuncture in Mild to Moderate Atopic Dermatitis: a single-blinded randomized controlled pilot trial

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**Objectives:** The need for alternative therapies for atopic dermatitis (AD) has emerged due to the side effects of conventional therapies. Biodegradable microneedle acupuncture (BMA) is a novel medical device that overcame the shortcomings of traditional intradermal acupuncture (IDA), such as foreign body feeling and allergic dermatitis. This study aimed to evaluate the efficacy and safety of BMA for patients with Mild to Moderate AD compared with the IDA.

**Methods:** An assessor-blinded, parallel, non-superiority, randomized controlled pilot trial was conducted. Thirty adult participants were recruited from a single hospital and were equally divided into the experimental or control group. They were treated with BMA or IDA on both sides of LI11, ST36, and PC6 for four hours. Over four weeks, both interventions were performed eight times in total. The primary endpoint was the objective scoring AD (O-SCORAD) index. The secondary endpoints were visual analog scale (VAS) for itch and sleep disturbance, dermatology life quality index (DLQI), skin hydration, and transepidermal water loss (TEWL).

**Results:** Enrolled thirty participants completed the trial. After the trial, all endpoints remarkably improved compared with the baseline in both groups, except for the TEWL. Between the two interventions, there were no remarkable differences in the fourth week, except for the VAS score for itch and DLQI. No serious adverse events occurred during the study period.

**Conclusion:** Both BMA and IDA were effective in improving Mild to Moderate AD, and they were safe. BMA can be an alternative to conventional acupuncture for patients with sensitive skin, including metal allergies.

**Keywords:** atopic dermatitis, biodegradable microneedle acupuncture, thumbtack needle, randomized controlled trial, efficacy

## INTRODUCTION

The pathogenesis of atopic dermatitis (AD), a common chronic eczema, is complex [1]. Although topical corticosteroids are the most representative medications for treating inflammatory AD lesions in Western medicine [2], they have various side effects, including skin atrophy, drug-induced skin abnormalities, secondary infection, hormone disruption, and growth delay in children [2, 3]. Because immediate interruption can cause a rebound phenomenon, corticosteroids should be stopped carefully [4]. Moreover, the safety of long-term topical corticosteroid use is not established because, in most clinical trials, they have been applied for four weeks. Because of these side effects, doctors and patients are reluctant to use conventional therapies, and alternatives are needed [5].

Like Western medicine, Korean medicine traditionally suggests that AD pathogenesis is based on hereditary and environmental factors. Korean medicine considers innate constitution

as the fundamental AD etiology. Additionally, classics in Korean medicine suggest immoderate dietary habits or dissolute lifestyles as external AD causes. Mechanistically, an eczematous lesion is typically provoked by external wind, dampness, and heat infiltration into a body with excess dampness and heat [6]. In Korean medicine, various methods, including acupuncture, herbal medicine, and external therapy, are used to treat AD [7].

Intradermal acupuncture (IDA), a traditional acupuncture method, is generally used to treat various diseases in clinical practice by inserting a small needle into skin acupoints and leaving it in place for a relatively long time [8].

Despite its many benefits, IDA still faces some barriers that can limit its popularity. For example, medical-grade stainless steel IDA acupuncture needles are commonly used because of enhanced corrosion resistance and the mechanical strength provided by chromium, nickel, and molybdenum alloying. Although their composition ensures suitability for various biomedical applications, including implants and medical devices [9], during treatment, IDA needles are attached to the skin for many hours, and chromium and nickel release through corrosion or prolonged exposure can provoke immune responses. By binding to proteins and forming hapten–protein complexes, nickel triggers a dendritic and T cell cascade, which results in hypersensitivity, inflammation, and elevated levels of proinflammatory cytokines, such as IL-1β and TNF-α. Hexavalent Chromium (Cr6+) is especially reactive, generating reactive oxygen species, which can exacerbate inflammation by inducing oxidative stress and damaging cellular structures. This is particularly concerning in patients with AD, who have a heightened immune activity [1, 10-12].

To address these concerns, innovative wearable acupuncture needles like biodegradable microneedle acupuncture (BMA), a newly developed medical device that overcomes the shortcomings of conventional metal needle acupuncture, are a safer, biodegradable alternative. As illustrated in Image 1, the BMA patch (left) has five biodegradable microneedles, while the IDA device (right) has one steel needle. However, both have 1.2 mm-long needles. BMA's microneedles are composed of hyaluronic acid, which is clinically validated and commonly used for microneedle applications [13-16]. The device used in this study was developed by RAPHAS, and when open, the patch remains dry, which ensures adequate rigidity for skin penetration. After approximately four hours, which is enough acupoint stimulation, the microneedles soften after absorbing skin moisture, and they pose minimal injury or environmental harm risk upon removal (Fig. 1).

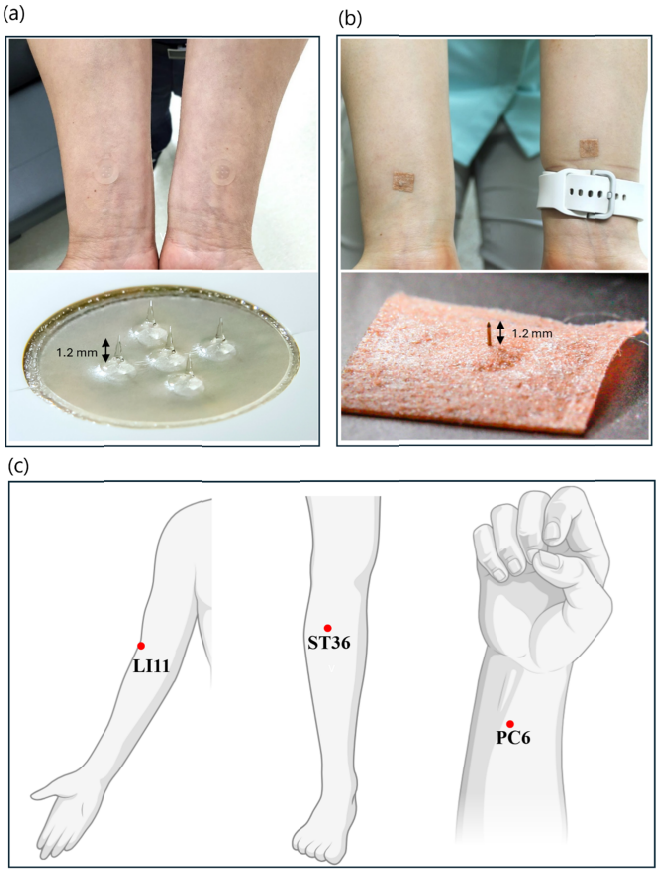


**Figure 1.** Participants were treated with each intervention. (a) The BMA, made from programed biodegrade material, 5 needles per patch, was attached to both sides of the PC6 acupoint of a male participant. (b) The IDA with the metal needle, was attached to the same acupoints of a female participant. (c) Three commonly targeted acupuncture points—LI11 (on the arm), ST36 (on the lower leg), and PC6 (on the forearm). BMA, biodegradable microneedle acupuncture; IDA, intradermal acupuncture.

The BMA system addresses some of the most significant barriers to acupuncture adoption by mitigating the risks associated with metal-induced immune responses. By making self-treatment more convenient and less intimidating, its user-friendly biodegradable microneedles ultimately broaden acupuncture access and foster greater public acceptance. This study evaluated BMA's efficacy and safety in patients with mild-to-moderate AD.

## MATERIALS AND METHODS

### 1. Study design and ethics

This study was a single-center, investigator-initiated, asses-

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sor-blinded, parallel, non-superiority, randomized controlled trial. Patients with mild-to-moderate AD, who willingly participated in this trial were examined for eligibility as per the study protocol. On visit 1, eligible participants were randomly separated into the experimental (BMA-AD) or control (IDA-AD) groups, which were treated with BMA and IDA, respectively. Both groups were treated twice a week during the four-week trial. Four weeks after visit 1, the investigators evaluated all endpoints within three days from treatment termination.

The study protocol for the use of an experimental medical device was approved by the Ministry of Food and Drug Safety, Republic of Korea (approval number 1350). This trial was approved by the Institutional Review Board of Naju Dongshin University Korean Medicine Hospital (approval number NJ-IRB-016) and it was registered with the Clinical Research Information Service on July 25, 2022 (identifier: KCT0007546). This clinical trial's protocol adhered to the Consolidated Standards of Reporting Trials and Standards for Reporting Interventions in Clinical Trials of Acupuncture guidelines [17, 18]. The investigators gave detailed study information to willing participants, and all participants gave written informed consent before enrollment.

## 2. Participant recruitment

Because this study was planned as a pilot trial, the sample size was set at twelve patients based on Julious' suggestion [19]. Considering a 20% dropout rate, each group required fifteen participants, for a total sample size of thirty. Participants were recruited at one hospital.

## 3. Study population

Adults with AD (age: 19-60 years) were enrolled. AD was diagnosed by a Korean medicine dermatologist based on the Hanifin and Rajka criteria. According to Objective Scoring AD (O-SCORAD) index results, patients with scores of ≤ 40 were determined eligible. However, patients who recently took medications like antibiotics, oral or topical corticosteroids, immunosuppressants, interferons, or antipsychotics, were excluded. Patients with unstable AD symptoms, a high infection risk, severe internal diseases, adhesive allergy, as well as those who were pregnant, breastfeeding, or planning for pregnancy, were excluded.

## 4. Randomization and allocation concealment

Block randomization was performed using SPSS Statistics 21 (IBM, NY, USA). With a block size of 4, 30 participants were randomly assigned into two groups at a 1:1 ratio. Randomization results were sealed in opaque envelopes and deposited in a double-locked cabinet. Investigators allocated the group by opening the envelope in front of the participant. Unsealed envelopes were stored separately.

## 5. Interventions

The BMA-AD group was treated with disposable sterilized BMAs (RMD-PN1, RAPHAS Co. Ltd., Seoul, Republic of Korea). BMA's structure is similar to an IDA needle. Five biodegradable hyaluronic acid microneedles are arranged in an X shape on a circular hydrocolloid film. For treatment, Korean medicine specialists or residents used the BMA on the LI11, ST36, and PC6 acupoints and applied it to the same acupoints on both the right side and left haft of the body (Fig. 1b). The IDA-AD group was treated with disposable sterilized IDA needles (T-press needle DB130A, Dongbang Medical, Seongnam, Republic of Korea). A 0.18 mm × 1.2 mm stainless steel needle is affixed to the center of a small paper plaster. The same practitioner applied treatment with IDA at the same acupoints as BMA (Fig. 1b). The attached needles were torn off after four hours. Both groups received each intervention eight times over four weeks.

## 6. Prohibited and permitted concomitant treatments

Except for rescue medication, concurrent treatments were restricted during the study period. In consultation with the principal investigator, a corticosteroid cream containing prednisolone valeroacetate (Sama Lidomex cream 0.15%, Sama Pharm Co., Ltd., Wonju, Republic of Korea) was restrictively allowed as rescue medication for severe itching. In such cases, investigators allowed the application of rescue medication using the fingertip unit method and checked medication use at every visit.

## 7. Study schedule

This study was executed between May 19, 2022, and July 15, 2022. During the trial, participants visited ten times. Screening

visit 1 and visits 8-9 were permitted to be planned on the same day. The study's general schedule is presented in Fig. 2.

On the screening visit, patients were informed about the study by the investigators and voluntarily gave written consent. Next, the investigators examined the participants' eligibility and eligible participants received identification codes.

Allocation and treatment were conducted on visit 1, which was planned for within seven days after the screening visit. Eligible participants were allowed to proceed to visit 1 on the screening visit day. After the screening visit, investigators checked the participants' medical and medication history changes, as well as rescue medicine usage. Before treatment, investigators examined itch and sleep disturbance, dermatology life quality index (DLQI), skin hydration, and transepidermal water loss (TEWL) based on the Hanifin and Rajka criteria, O-SCORAD index, and visual analog scale (VAS). Participants were treated with BMA or IDA depending on assignment results.

During visits 2-8, investigators checked vital signs, medical and medication history changes, adverse events, and rescue

| | SCREENING* | TREATMENT & OBSERVATION | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Enrolment | Allocation | Post-allocation | | | | | | | Close-out |
| TIMEPOINT (week) | | 1st | | 2nd | | 3rd | | 4th | | |
| TIMEPOINT (visit) | | 1* | 2 | 3 | 4 | 5 | 6 | 7 | 8* | 9*† |
| ENROLMENT: | | | | | | | | | | |
| *Written consent* | X | | | | | | | | | |
| *Sociodemographic information* | X | | | | | | | | | |
| *Medical history check* | X | | | | | | | | | |
| *Physical examination* | X | | | | | | | | | |
| *Eligibility criteria* | X | | | | | | | | | |
| *Randomization* | | X | | | | | | | | |
| INTERVENTIONS: | | | | | | | | | | |
| *BMA* | | X | X | X | X | X | X | X | X | |
| *IDA* | | X | X | X | X | X | X | X | X | |
| ASSESSMENTS: | | | | | | | | | | |
| *Vital signs* | X | X | X | X | X | X | X | X | X | X |
| *Changes in medical and medication history* | | X | X | X | X | X | X | X | X | X |
| *The Hanifin and Rajka criteria* | X | X | | | | | | | | |
| *O-SCORAD index* | X | X | | | | X | | | | X |
| *VAS for itch and sleep disturbance* | | X | | | | X | | | | X |
| *DLQI* | | X | | | | X | | | | X |
| *Skin hydration* | | X | | | | X | | | | X |
| *TEWL* | | X | | | | X | | | | X |
| *Adverse events* | | X | X | X | X | X | X | X | X | X |
| *Check rescue medication use* | | X | X | X | X | X | X | X | X | X |

**Figure 2.** Study schedule. *The visits are allowed to be scheduled on the same day: screening visit and visit 1, visits 8 and 9; †visit 9 was scheduled for within three days from when four weeks passed since visit 1. O-SCORAD, objective scoring atopic dermatitis; VAS, visual analog scale; DLQI, dermatology life quality index; TEWL, transepidermal water loss.

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medicine usage. Treatment was continuously provided to the participants on every visit and a midterm assessment was conducted on visit 5. Endpoints, including the O-SCORAD index, VAS for itch and sleep disturbance, DLQI, skin hydration, and TEWL, were examined before the day's treatment.

Visit 9 was scheduled within three days from four weeks after visit 1. Investigators checked vital signs, medical and medication history changes, adverse events, and rescue medicine usage. The final endpoint assessment was conducted. Participant compliance was also investigated.

## 8. Outcomes

The O-SCORAD index, a modified version of the SCORAD index that does not include questions on subjective symptoms [20, 21], was the primary outcome. The total score was calculated based on lesion extent and symptom severity scores, with scores of < 15, 15-40, and > 40 indicating mild, moderate, and severe AD, respectively.

VAS for itch and sleep disturbance, DLQI, skin hydration, and TEWL were the secondary outcomes. VAS was adopted to assess subjective itch severity and sleep disturbance. Participants marked severity discomfort on a 100 mm-long line calibrated from 0-10. The Korean version of the DLQI, which surveys the participants' symptoms, feelings, daily life, leisure activities, job performance, personal relations, and treatment was used to survey the participants' quality of life (QOL) [22] and the response to each question was rated 0 to 3. The maximum total score was 30, with higher scores suggesting negative AD effects on the QOL [22]. This study received a free DLQI license from the School of Medicine, Cardiff University (License ID: CUQoL1766).

Skin hydration and TEWL were measured using a Corneometer CM825 and Tewameter TM300 (Courage + Khazaka electronic GmbH, Köln, Germany), respectively. To determine the test area for the two endpoints, the measurer searched the participant's extremity for a suitable area that was very dry and had AD lesions. Next, a 5 cm-long test area was marked using a sterile skin marker, imaged, and its location recorded using anatomical structures. Before the examinations, the participants relaxed for 30 minutes under constant temperature (20-25℃) and relative humidity (40%-60%). Skin hydration was measured five times, and the average of medium three values was calculated. For TEWL, the stable value obtained 30 seconds after beginning the measurement was recorded. TEWL was measured thrice and their average was calculated.

## 9. Outcome analyses

SPSS Statistics 21 (IBM, NY, USA) was used to analyze all

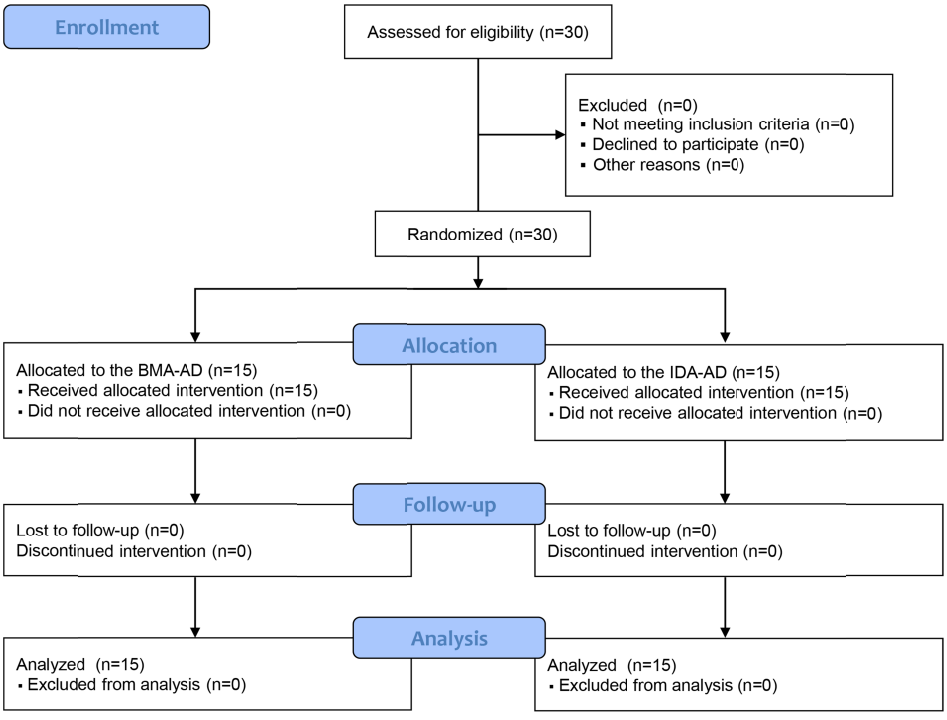


**Figure 3.** The CONSORT flowchart of the study. BMA-AD, treated with biodegradable microneedle acupuncture for atopic dermatitis; IDA-AD, treated with intradermal acupuncture for atopic dermatitis.

outcomes using the same method. In the second and fourth weeks, the Wilcoxon signed-rank test was used to compare the differences between the baseline and each checkpoint. Differences between the two groups were compared using the Mann–Whitney test. A p-value of $< 0.05$ was considered statistically significant.

## RESULTS

### 1. General characteristics

The first participant was enrolled on May 19, 2022, and the study was completed on July 15, 2022. The 30 enrolled participants finished the trial without any dropouts (Fig. 3). The participants' main characteristics, including mean age and gender ratio, were similar between the BMA-AD and IDA-AD groups (Table 1). Although rescue medication was allowed, no one used it throughout the study period.

### 2. O-SCORAD index reduction

Both interventions significantly reduced the O-SCORAD index after the trial. After four weeks, the declines were 9.2 ± 3.73 and 7.2 ± 3.91 in the BMA-AD and IDA-AD groups, re-

**Table 1.** General characteristics of the participants

| | BMA-AD (n = 15) | IDA-AD (n = 15) | Total (n = 30) |
|---|---|---|---|
| Age (mean ± SD) | 34.1 ± 7.73 | 34.0 ± 7.72 | 34.2 ± 7.62 |
| Gender (%) | | | |
| Male | 7 (46.7) | 7 (46.7) | 14 (46.7) |
| Female | 8 (53.3) | 8 (53.3) | 16 (53.3) |
| Final education (%) | | | |
| ≤ Middle school | 0 (0) | 0 (0) | 0 (0) |
| High school | 1 (6.7) | 4 (26.7) | 5 (16.7) |
| University | 12 (80) | 10 (66.7) | 22 (73.3) |
| ≥ Graduate school | 2 (13.3) | 1 (6.7) | 3 (10.0) |
| Height (mean ± SD, cm) | 166.0 ± 7.73 | 166.5 ± 7.92 | 166.4 ± 7.81 |
| Weight (mean ± SD, kg) | 63.8 ± 16.35 | 64.8 ± 16.21 | 64.2 ± 16.22 |
| Occupation (%) | | | |
| Profession | 9 (60.0) | 7 (46.7) | 16 (53.3) |
| White collar | 5 (16.7) | 3 (20.0) | 8 (26.7) |
| Student | 1 (3.3) | 0 (0) | 1 (3.3) |
| Blue collar | 0 (0) | 5 (33.3) | 5 (16.7) |
| Smoking (%) | | | |
| Smoker | 1 (6.7) | 4 (26.7) | 5 (16.7) |
| Non-smoker | 12 (80.0) | 9 (60.0) | 21 (70.0) |
| Past smoker | 2 (13.3) | 2 (13.3) | 4 (13.3) |
| Drinking (%) | | | |
| Drinker | 8 (53.3) | 9 (60.0) | 17 (56.7) |
| Non-drinker | 7 (46.7) | 6 (40.0) | 13 (43.3) |
| Menstrual history (%) | | | |
| Menopause | 0 (0) | 1 (6.7) | 1 (3.3) |
| Menstruation | 8 (53.3) | 7 (46.7) | 15 (50.0) |
| Not applicable | 7 (46.7) | 7 (46.7) | 14 (46.7) |

BMA-AD, treated with biodegradable microneedle acupuncture for atopic dermatitis; IDA-AD, treated with intradermal acupuncture for atopic dermatitis; SD, standard deviation.

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spectively. Although the BMA-AD decrease in the second and fourth weeks was bigger than that of IDA-AD, the two interventions had no statistical differences (Fig. 4a).

### 3. Reduction in itch and sleep disturbance VAS

After the trial, both interventions significantly reduced itch VAS scores, and the declines after four weeks were 3.3 ± 0.88 and 2.3 ± 1.10 in the BMA-AD and IDA-AD groups, respectively. However, in the second and fourth weeks, the decline in the BMA-AD group was significantly larger than in the IDA-AD group (Fig. 4b). Both interventions also significantly reduced sleep disturbance VAS scores after four weeks. The declines after four weeks were 3.1 ± 0.92 and 2.7 ± 1.23 in the BMA-AD and IDA-AD groups, respectively. However, the two interventions did not have significant differences in any visit (Fig. 4c).

### 4. DLQI improvements

During the trial, QOL improvement was generally more remarkable in the BMA-AD group than in the IDA-AD group. In the second week, only the BMA-AD group presented a significant decrease in the intragroup and intergroup comparisons. However, both interventions significantly decreased the score on the final visit. The declines after four weeks were 4.9 ± 3.34 and 2.3 ± 2.35 in the BMA-AD and IDA-AD groups, respectively (Fig. 4d).

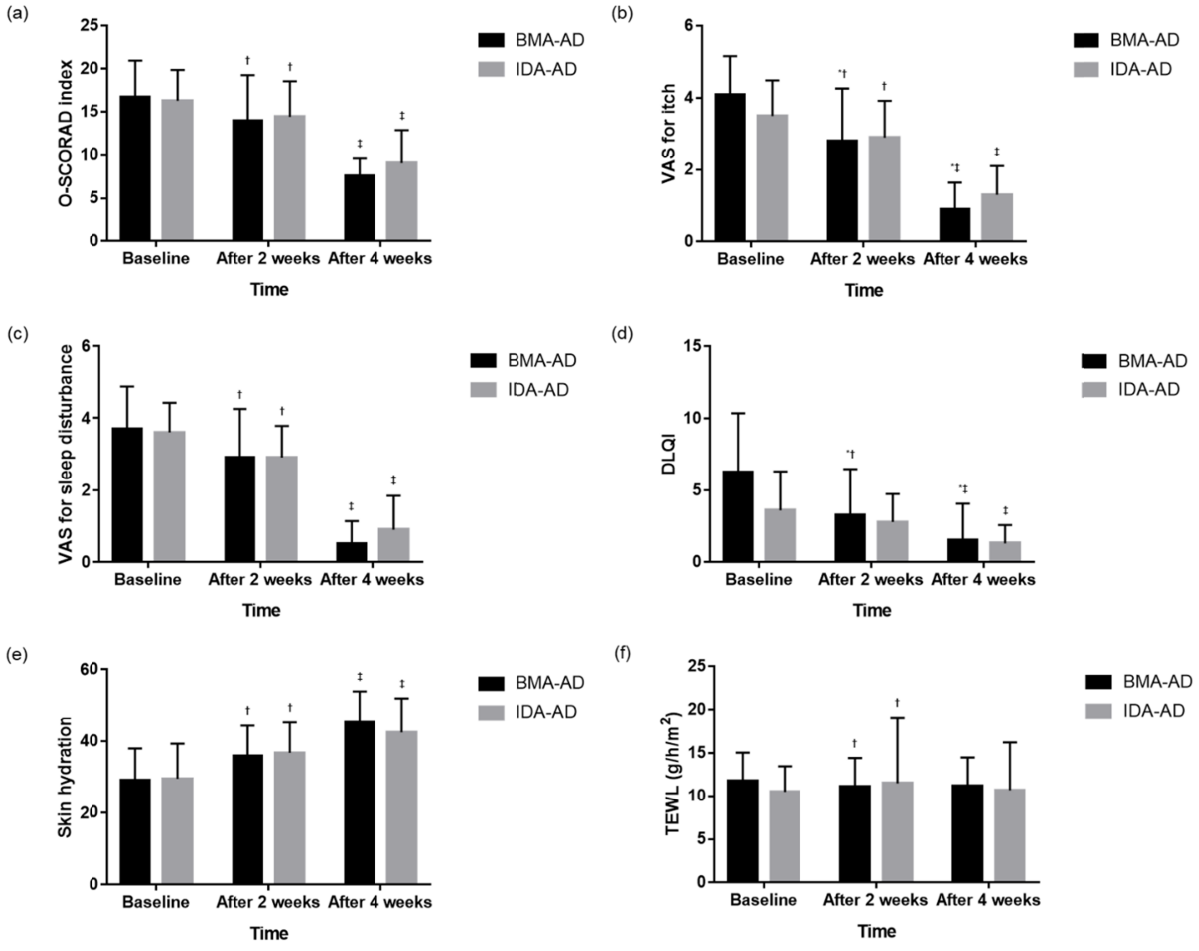


**Figure 4.** The results of the primary and secondary endpoints. Values were presented as mean ± standard deviation. (a) Objective scoring atopic dermatitis (O-SCORAD). (b) Visual analog scale (VAS) for itch. (c) VAS for sleep disturbance. (d) Dermatology life quality index (DLQI). (e) Skin hydration. (f) Transepidermal water loss (TEWL). BMA-AD, treated with biodegradable microneedle acupuncture for atopic dermatitis; IDA-AD, treated with intradermal acupuncture for atopic dermatitis. *$p < 0.05$ in intergroup comparisons; †$p < 0.05$ on comparing the result after two weeks with baseline; ‡$p < 0.05$ on comparing the result after four weeks with baseline.

### 5. Increase in skin hydration

The two treatments significantly moisturized the skin, and the increments after four weeks were 16.3 ± 7.37 and 13.0 ± 9.99 in the BMA-AD and IDA-AD groups, respectively. However, the two interventions had no significant differences in any visit (Fig. 4e).

### 6. Indistinct TEWL shifts

The value of the BMA-AD significantly decreased in the second week. However, the value of the IDA-AD significantly increased. There was no statistical difference between the two interventions. In the fourth week, the values of the two interventions returned to baseline levels. No statistical significance was observed in the final visit (Fig. 4f).

### 7. Safety

Serious adverse events did not occur during the study period. However, four adverse events with a causal relationship between IDA metal allergies were observed during the study, although they were not severe.

## DISCUSSION

BMA is based on IDA and microneedle patch technology. In IDA, a small needle is inserted into the skin for acupoint stimulation with a prolonged soft stimulus. It originated from combining "shallow needling" with the "needle retention method", acupuncture techniques defined in Korean medicine classics [23]. Although the needle is inserted into the skin, IDA is less painful than usual acupuncture and does not disturb physical movement. Because of these characteristics, IDA is beneficial in caring for chronic diseases that require prolonged needle stimulation [24, 25]. To date, previous studies have mainly focused on IDA's pain-relieving effects [26-28]. Recent studies have explored IDA use for neuropsychiatric diseases, such as major depressive disorder and insomnia [8, 29, 30]. However, there are few studies on IDA use against skin diseases, including AD. Nonetheless, based on previous studies that have demonstrated the effectiveness of acupuncture in alleviating inflammation and AD, IDA may also be useful against chronic skin diseases [31-34].

Despite its merits, IDA has shortcomings. It may result in a foreign body feeling if inserted too long or cause allergic dermatitis because of the metal needle. BMA was developed to overcome the IDA needle's shortcomings by adopting biodegradable hyaluronic acid microneedle patch technology. Initially, the patch was invented to encourage efficient transdermal drug delivery by piercing the skin with microneedles [35]. Because BMA and the microneedle patch look similar to the conventional IDA needle, BMA was predicted to ameliorate AD as effectively as IDA. Fundamentally, the three needles have the same structure as a small needle fixed on a substrate film. The difference is the number of needles and their material. The needle material was changed from conventional stainless steel to biodegradable hyaluronic acid, which is widely applied in medicine and cosmetics because of its safety. Additionally, because BMA microneedles completely decompose in the skin, they do not trigger skin allergies when compared with steel needles [36].

In this study, acupuncture was performed on both sides of the LI11, ST36, and PC6 acupoints. The treatment was done twice weekly, for four weeks. Based on frequently used variables in AD treatment with acupuncture [25, 33, 36], the endpoints were the O-SCORAD index, VAS, DLQI, skin hydration, and TEWL.

Many previous studies have proposed acupuncture potential against skin diseases. One study suggested that for type I hypersensitivity itching, acupuncture has the same antipruritic effect as antihistamine therapy [32]. Another clinical trial suggested that in patients with AD, LI11 acupressure improves pruritus and lichenification [37]. In a randomized controlled trial comparing verum and sham acupuncture for AD treatment, treatment with acupuncture alone alleviated AD symptoms in patients with mild-to-moderate AD [33]. A systematic review also concluded that acupuncture was effective in improving dermatitis, chloasma, pruritus, urticaria, hyperhidrosis, and skin elasticity [38]. The two acupuncture methods used in this study also remarkably improved all endpoints in patients with AD.

For TEWL, long-term large-scale clinical trials may be necessary to validate BMA's efficacy. Since low TEWL implies healthy skin, participants' TEWL should decrease after finishing treatment. However, in this study, TEWL shifts were irregular. In the BMA group, TEWL declined consistently over four weeks. However, in the IDA group, it increased in the second week and declined in the fourth week. Previous microneedle device studies suggest that the TEWL can temporarily increase because of the skin damage caused by microneedles [39]. However, in this

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study, acupuncture was not directly performed on AD lesions. Therefore, the TEWL shifts in this study are challenging to explain using this hypothesis.

This study has a few limitations. One is single-blinding. Because of the distinct appearances of the two needles, the participants and therapist could know the assigned treatment based on their appearance, hence, double-blinding was impossible. Therefore, in this study, the assessor was blinded. The assessor was restricted from meeting the participants except for the evaluation. Moreover, the assessor was provided with a different evaluation form that could not identify the participants. Another limitation was the absence of a placebo control group, such as sham acupuncture. Because this study focused on BMA efficacy, the authors compared BMA with a similar medical device, IDA. Further studies should include a sham control group. The other limitation was the small participant number (30 patients were recruited). In intergroup and intragroup comparisons, most endpoints presented consistent results, and both interventions improved the endpoints equally after four weeks. However, a few endpoints presented results that needed to be more consistent. Based on this study, a large-scale study should be conducted to confirm BMA's efficacy and superiority.

In conclusion, after four weeks, BMA and IDA remarkably improved endpoints, including the O-SCORAD index, VAS for itch and sleep disturbance, DLQI, and skin hydration. Between the two interventions, there were few efficacy differences. Serious adverse events did not occur during the study period. Therefore, BMA is safe and as effective as IDA at ameliorating mild-to-moderate AD. BMA can be used as an alternative to IDA, and it may be beneficial for patients with metal allergies.

## CONCLUSION

BMA and IDA significantly improved clinical symptoms and QOL in patients with mild-to-moderate AD after four weeks of treatment. No significant differences in efficacy were observed between the two interventions, except for better outcomes in itch severity and QOL improvements with BMA. Additionally, BMA, which exhibited excellent safety without adverse events, offers a promising alternative for patients who are sensitive to metal needles or prone to allergic reactions. These findings suggest that BMA is an effective and safe option for mild-to-moderate AD management warranting further investigation in larger, long-term studies.

## AUTHORS' CONTRIBUTIONS

Soo-Yeon Park was responsible for the study's conceptualization and methodology. Ji-Hoon Song and Soo-Yeon Park conducted the clinical trial. Soo-Yeon Park oversaw the study's administration. Gihyun Lee supervised the study's progress. Soo-Yeon Park analyzed the study data. Ji-Hoon Song and Soo-Yeon Park drafted the initial manuscript. All authors approved the final manuscript. Nguyen Cong Duc and Soo-Yeon Park revised the manuscript and managed its submission to the journal for publication.

## DATA AVAILABILITY

All data generated or analyzed during this study are included in this published article.

## CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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