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Clinical trial

The efficacy of insulated-microneedle radiofrequency in keratosis pilaris: a randomized, double-blind, sham irradiation-controlled trial

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ABSTRACT

Radiofrequency, including insulated-microneedle radiofrequency, has facilitated progress in the field of dermatology, but clinical data in treating keratosis pilaris (KP) are limited. To compare the efficacy of radiofrequency and sham irradiation for reducing skin roughness, erythema, and hyperpigmentation and to evaluate the physician-grading scale, visual-analogue scale, and side effects. Twenty patients with KP on the outer upper arms received 3 consecutive treatments at 4-week intervals. Radiofrequency showed higher skin roughness mean improvement compared to sham irradiation (0.42 ± 0.54 *vs* -0.20 ± 0.72, respectively; *p*<0.001), a higher mean improvement on the physician-grading scale compared with sham irradiation (2.70 ± 0.45 vs 0, respectively; *p*<0.001) and higher mean improvement on the visual-analogue scale compared with sham irradiation (21.05 ± 2.96 vs 99.47 ± 0.53, respectively; p <0.001). Erythema mean improvement and hyperpigmentation mean improvement of both groups were not statistically different. Side effects of both protocols, such as erythema and itching, were minor and transient. Insulated-microneedle radiofrequency is an effective treatment for KP with no significant side effects.

INTRODUCTION

The most common follicular condition in children is keratosis pilaris (KP). It is characterized by multiple keratotic papules in a folliculocentric distribution containing keratinous plugs and twisted hair. Perifollicular erythema and hyperpigmentation may occur (1-3). The pathogenesis of the disease is still unknown. However, the most accepted theory for the pathogenesis proposes defective keratinization of the follicular epithelium resulting in a keratotic infundibular plug and hair shaft defects (2-3). Histopathologic findings are dilated vellus hair follicles containing keratinous plugging and coiled vellus hair with mild perifollicular and mononuclear cell infiltration (3). KP mainly affects the extensor surfaces of the arms and legs but may also involve the face, buttocks, and trunk. It does not affect general health, but it has a negative impact on the patient's quality of life, especially if the lesions are on exposed body parts (1-4).

Treatments included topical moisturizers, exfoliants, anti-inflammatory medicines, and topical corticosteroids. However, regardless of the procedures used, the results remain temporary and have side effects (1-5). The energy-based technologies used to cure KP include an 810-nm Diode laser, a Pulsed Dye laser (PDL), a Carbon dioxide laser (CO2), a Q-switched (QS) 1064-nm Nd: YAG laser, and an intense pulse light (IPL). There are several effective medicinal and energy-based device therapies available, however, there is no definite treatment to prevent a clinical relapse (6-19); this leads to the study of insulated microneedle radiofrequency, which may generate large amounts of heat and promote keratinocyte and fibroblast migration and proliferation while also dissolving follicular plugging and twisted vellus hair with no serious adverse event (20-23). This is the first study to evaluate the efficacy and safety of insulated-microneedle radiofrequency for KP treatment.

MATERIALS AND METHODS

Study design

A prospective, randomized, double-blind, controlled intra-individual trial was conducted on twenty Thai patients (11 males and 9 females). The trial was reviewed and approved by the Srinakharinwirot University

Human Research Ethics Committee, which was in accordance with the guidelines of the International Conference on Harmonization Good Clinical Practice and the Declaration of Helsinki (Approval number EC515/63) and was registered at Thai Clinical Trials Registry with registration number TCTR20210412005 on April 12th 2021, retrospectively registered.

Participants and setting

Patients who were diagnosed by dermatologists with KP on the upper outer arm from March to July 2021 were included in this study. Patients with a history of severe underlying conditions, such as severe heart disease, active or recent malignancy, immune suppression, history of surgery with a metal-containing device, and history of hypertrophic scar or keloid, were excluded from this study. In addition, patients that received any topical medication affecting keratinization (e.g., topical retinoid, topical steroid, topical salicylic acid, vitamin D analogues) or emollients within the past 4 weeks or oral medication affecting keratinization (e.g., steroids, isotretinoin, acitretin) within past 6 months or energy-based devices within the past 6 months were also excluded.

Study protocol

On the first visit, all patients' medical histories were taken, and they were given a physical examination and received treatment at weeks 0, 4, and 8. Patients had appointments for a follow-up at weeks 4, 8, and 12. Each patient served twice as an experimental unit of insulated-microneedle radiofrequency and sham irradiation, and one arm of each patient was included in the study. The upper and lower regions of the arms were separated into 25 cm^2 each. The arm that received insulated microneedle radiofrequency treatment was determined by the condition where the KP lesion was evenly distributed; the left arm was chosen because most human populations are right-handed, making examination and post-procedure care easier. If the KP lesion was asymmetrically distributed, the right arm was treated with radiofrequency instead.

Patients were randomized using a sealed opaque envelope method in a 1:1 allocation ratio to decide which part of the arm should be treated with radiofrequency or sham irradiation. The monopolar insulated microneedle radiofrequency (6 MHz, 15 watts maximum power) approach is an insulated microneedle radiofrequency method (AcGen, Jeisys Medical Inc., Korea) with an energy level 3, a 2-second pulse duration and a 2-second delay time. A 0.3 mm insulation layer covered the needle tip's edge, protecting the epidermis from thermal heat. The treatment involved minimal pain as a 1.5 mm long and 34 gauge needle was used. The radiofrequency and sham irradiation procedures were performed without local or topical anaesthetic. On the chosen arm, no topical creams or substances were allowed to be used to observe the results and consequences of each treatment.

The sham-irradiation approach used the same procedure as the radiofrequency therapy, except the microneedle was not charged. As a result, the needle's energy at the tip was depleted, so it no longer provided radiofrequency treatment.

Outcome evaluation

The Antera 3D camera (Miravex Limited, Dublin, Ireland), digital photography, physician grading scale, and side effects at weeks 4, 8, and 12 of follow-up compared to baseline were used to evaluate and assess the efficacy of radiofrequency and sham irradiation (Week 0) by blinded dermatologists.

The Antera 3D camera has good sensitivity, specificity, repeatability, and reliability and can distinguish between skin erythema and melanin. Thus, this study used the Antera 3D camera to analyze the value of skin roughness, erythema, and hyperpigmentation of KP (24-25). The skin roughness, erythema, and hyperpigmentation results from Antera 3D camera provide a data value with no units of measure.

The physician grading scale consists of a 4-point quartile grading scale from 3 to 0, with 3 indicating good improvement (76-100%), 2 indicating significant improvement (51-75%), 1 indicating moderate improvement (26-50%), and 0 indicating no change (0-25%). In addition, patients were asked to rate their subjective improvement and satisfaction using a visual analogue scale at 12 weeks compared to baseline (Week 0).

In order to evaluate the visual analogue scale, patients were asked to rate their overall improvement and satisfaction (0-100%) when comparing their baseline (100%) to their current skin lesion. For example, 0% = no residual lesions and much better than before, 50% = the lesions were better than the baseline at 50%, and 100% = no improvement and the lesions are the same as baseline.

Statistical analysis

The sample size was estimated by two dependent means for a pair-matched study. From the efficacy of the Intense-pulsed light therapy study in 24 Thai KP patients, the mean skin roughness of the treatment group at baseline to week 12 was 6.50 ± 0.96 and 5.59 ± 0.66, respectively. The mean skin roughness of the control group at baseline to week 12 was 6.45 ± 1.32 and 6.47 ± 1.16, respectively (19).

$$n = \frac{(z_{1-\frac{\alpha}{2}} + z_{1-\beta})^2 \sigma^2}{\Delta^2}$$

Alpha (α)= 0.05, Beta (β)= 0.20, Delta(Δ) corresponds to the mean skin roughness of the IPL treatment group from week 12 compared to baseline or 6.50- 5.59 = 0.91. The standard deviation (σ) is the variance of differential response to therapy which is calculated from the differential of skin roughness found in the control group of KP patients in the study of the efficacy of IPL = 1.32

A sample size of 17 patients was required for each group, with the minimum sample size required to achieve 95% confidence and 80% power. The sample size was calculated using the Power and Sampling Size program (PS Power and Sampling Size program version 3.1.6). The number of samples that had to be recruited = 17 x (1+0.2) = 20.4. Thus, a sample of 20 patients was required.

Baseline characteristics of patients were described using mean ± SD or median (interquartile range) for the continuous data and frequency and percentage for the categorical data. All patients were included in the analyses (intention to treat analysis). We performed an intention-to-treat analysis and entered missing data by the latest patient visit (Last observation carried forward method).

Skin roughness, erythema, hyperpigmentation, and physician grading scale were described using mean ± SD Multi-level data analysis (Mixed linear model) was used to compare the difference between treatment groups and the difference between each visit. In addition, paired *t*-test was used to compare the visual analogue scale between treatment groups.

RESULTS

Clinical characteristics of patients

Twenty Thai patients (11 males and 9 females) were randomized at enrollment (Radiofrequency n=20; sham irradiation n=20). One patient dropped out of the study because of the COVID-19 pandemic before 8 weeks of follow-up. The data were obtained from the excluded patient at weeks 0 and 4 (Fig. 1).

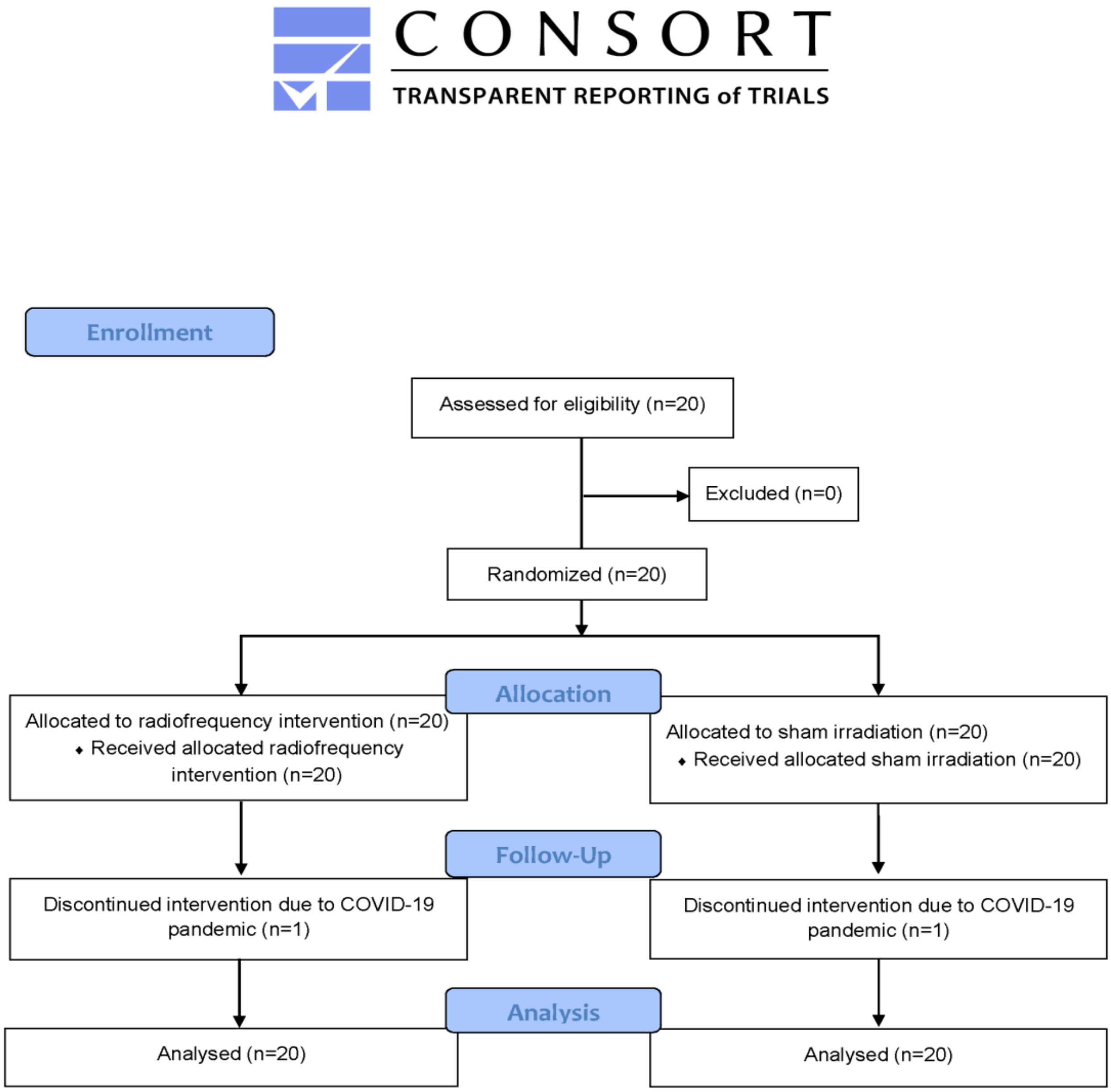


Fig. 1. *Study flow diagram.*

The patient's average age was 30.25 years (30.25 ± 3.48), ranging from 26 to 41 years. The subjects are entirely Thai (100%). Fifteen patients (75%) are Fitzpatrick skin type III, and five patients (25%) are Fitzpatrick skin type IV. The individuals' average BMI was 24.45 kg/m^2, ranging from 18.03 to 35.16 kg/m^2 (24.45 ± 4.02). Fourteen patients (70%) had no history of KP treatment, and six patients (30%) had a history of treatment. Two patients (10%) had applied topical treatments such as urea and AHA creams. Four patients (20%) had energy-based devices treatment such as QS 1064-nm Nd:YAG and Picosecond laser.

Primary outcomes

The primary outcomes are to evaluate skin roughness from Antera 3D.

Skin roughness

The mean improvement in skin roughness on the insulated microneedle radiofrequency area was 0.42 ± 0.54 at weeks 4, 8, and 12, compared to -0.20 ± 0.72 on the sham irradiation area ($p<0.001$) (Table I). The skin roughness mean improvement by radiofrequency was statistically significant and higher than that of sham irradiation (Fig. 2A, 2B). Thus, the insulated microneedle radiofrequency treatment was more effective than sham irradiation measured by Antera 3D skin roughness.

Secondary outcomes

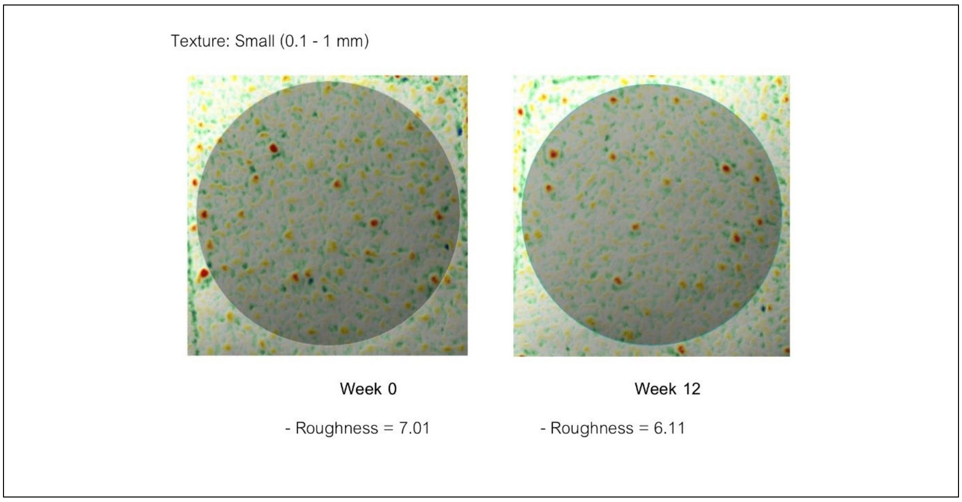
Secondary outcomes are to evaluate erythema, hyperpigmentation from Antera 3D, physician grading scale, visual analogue scale, and side effects.

Erythema

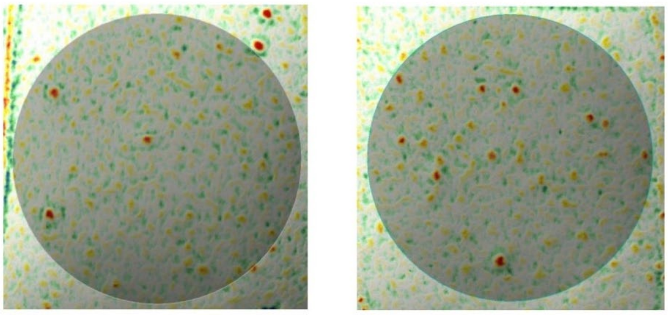
Erythema improved by insulated microneedle radiofrequency treatment, while sham irradiation worsened. At weeks 4, 8, and 12 of follow-up, erythema mean improvement on the insulated microneedle radiofrequency area was 0.06 ± 0.11 compared to 0.00 ± 0.11 on the sham irradiation area with no statistical significance ($p=0.382$) (Table II, Fig. 2C, 2D).

Hyperpigmentation

Hyperpigmentation improved on the insulated microneedle radiofrequency area, while the sham irradiation worsened. At weeks 4, 8, and 12 of follow-up, hyperpigmentation mean improvement on the insulated microneedle radiofrequency area was 0.01 ± 0.02 compared to -0.00 ± 0.03 on the sham irradiation area without statistical significance ($p=0.879$) (Table III, Fig. 2E, F).



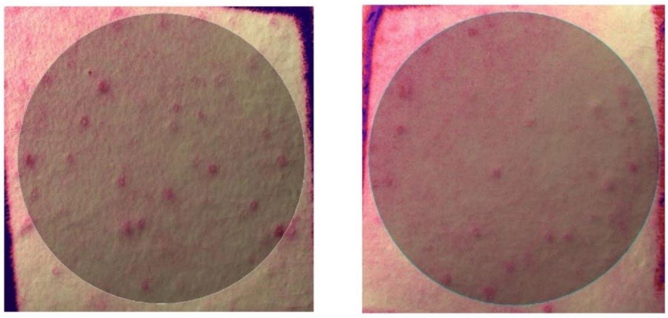
Texture: Small (0.1 - 1 mm)



Week 0 | Week 12

- Roughness = 6.35
- Roughness = 6.38

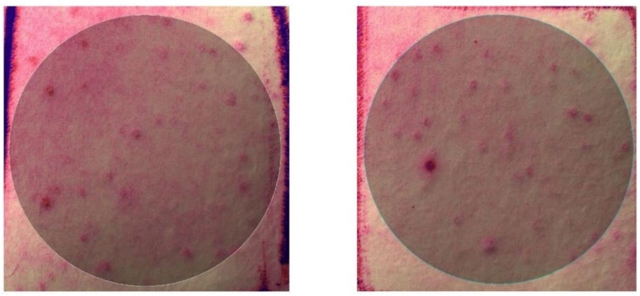
Haemoglobin: Level and Variation



Week 0 | Week 12

- Average level = 1.00
- Average level = 1.15

Haemoglobin: Level and Variation



Week 0 | Week 12

- Average level = 1.23
- Average level = 1.10

Fig. 2. *Subject 1, Antera 3D report at weeks 0 and 12. Subject 1, Antera 3D report of insulated microneedle radiofrequency skin roughness (**A**), sham irradiation skin roughness (**B**), insulated microneedle radiofrequency erythema (**C**), sham irradiation erythema (**D**), insulated microneedle radiofrequency hyperpigmentation (**E**), and sham irradiation hyperpigmentation (**F**), at weeks 0 and 12.*

Table I. *Mean skin-roughness score by Antera 3D camera and mean skin-roughness improvement score of Insulated microneedle RF and Sham irradiation.*

Week	Mean skin roughness score by Antera 3D camera (Mean ± SD)		Mean skin-roughness improvement score (Mean ± SD)		*p*-value*
	Insulated microneedle RF	Sham irradiation	Insulated microneedle RF	Sham irradiation	
Week 0	5.79 ± 0.93	5.43 ± 0.95	0	0	<0.001
Week 4	5.60 ± 1.01	5.59 ± 1.03	0.18 ± 0.56	-0.17 ± 0.62	
Week 8	5.30 ± 1.03	5.64 ± 1.10	0.47 ± 0.71	-0.19 ± 0.73	
Week 12	5.36 ± 1.03	5.66 ± 1.06	0.42 ± 0.54	-0.20 ± 0.72	

Table II. *Mean erythema score by Antera 3D camera and erythema mean improvement score of Insulated microneedle RF and Sham irradiation.*

Week	Mean erythema score by Antera 3D camera (Mean ± SD)		Erythema mean improvement score (Mean ± SD)		*p*-value*
	Insulated microneedle RF	Sham irradiation	Insulated microneedle RF	Sham irradiation	
Week 0	1.01 ± 0.11	0.99 ± 0.15	0	0	0.382
Week 4	1.00 ± 0.12	0.98 ± 0.13	0.01 ± 0.11	0.01 ± 0.10	
Week 8	0.96 ± 0.15	0.93 ± 0.16	0.04 ± 0.12	0.05 ± 0.11	
Week 12	0.94 ± 0.11	0.98 ± 0.11	0.06 ± 0.11	0.00 ± 0.11	

** Multi-level data analysis (Mixed linear model)*

Table III. *Mean hyperpigmentation score by Antera 3D camera and mean-hyperpigmentation mean improvement score of Insulated microneedle RF and Sham irradiation.*

Week	Mean hyperpigmentation score by Antera 3D camera (Mean ± SD)		Mean Hyperpigmentation improvement score (Mean ± SD)		*p*-value*
	Insulated microneedle RF	Sham irradiation	Insulated microneedle RF	Sham irradiation	
Week 0	0.50 ± 0.07	0.50 ± 0.08	0	0	0.879
Week 4	0.50 ± 0.08	0.51 ± 0.09	-0.00 ± 0.02	-0.03 ± 0.14	
Week 8	0.53 ± 0.18	0.51 ± 0.13	-0.03 ± 0.14	-0.01 ± 0.09	
Week 12	0.49 ± 0.07	0.50 ± 0.08	0.01 ± 0.02	-0.00 ± 0.03	

** Multi-level data analysis (Mixed linear model)*

Physician grading scale

The physician grading scale improved on the insulated microneedle radiofrequency area, while the sham irradiation worsened. At 12 weeks of follow-up, the physician grading scale on the insulated microneedle radiofrequency area was 2.70 ± 0.45 compared to 0 on the sham irradiation area ($p<0.001$) (Table IV). Thus, the insulated microneedle radiofrequency treatment was more effective than sham irradiation by physician grading scale assessment.

Table IV. *The physician grading scale of insulated microneedle RF and sham irradiation.*

Week	Insulated microneedle RF (Mean ± SD)	Sham irradiation (Mean ± SD)	*p*-value*
Week 4	1.70 ± 0.47	0	
Week 8	2.50 ± 0.50	0.21 ± 0.42	<0.001
Week 12	2.70 ± 0.45	0	

** Multi-level data analysis (Mixed linear model)*

Visual analogue scale

After a radiofrequency treatment, the severity of KP lesion in 12 patients (63%) remained 0-20% from 100% at baseline, 6 patients (32%) remained at 21-40% from 100% at baseline, and one patient (5%) remained at 41-60% from 100% at baseline. The visual analogue scale of radiofrequency treatment provided a statistically normal distribution with a mean ± SD of 21.05 ± 2.96 and a confidence interval of 14.85-27.25.

After sham irradiation, the severity of the KP lesions in 19 patients (100%) remained about 81-100% from 100% at baseline. The visual analogue scale of sham irradiation provided a statistically normal distribution with a mean ± SD of 99.47 ± 0.53 and a confidence interval of 98.37-100.58 (Table V and VI).

Table V. *Visual analogue scale of Insulated microneedle RF and Sham irradiation reported as the number of patients and percentage.*

Visual analogue scale	Insulated microneedle RF Number of patients (Percentage)	Sham irradiation Number of patients (Percentage)
0-20%	12 (63%)	0
21-40%	6 (32%)	0
41-60%	1 (5%)	0
61-80%	0	0
81-100%	0	19 (100%)

Table VI. *Paired t-test was used to compare visual analog scale between treatment groups.*

Visual analog scale	Mean ± SD	95% Confident interval
Insulated microneedle RF	21.05 ± 2.96	14.85-27.25
Sham irradiation	99.47 ± 0.53	98.37-100.58

Thus, radiofrequency treatment provided a higher rate of patient satisfaction or visual analogue scale than sham irradiation due to the higher success rate of the clinical outcome of radiofrequency treatment. The visual analogue scale of radiofrequency treatment had statistically significant improvement and was higher than that of the sham irradiation (p <0.001) (Fig. 3).

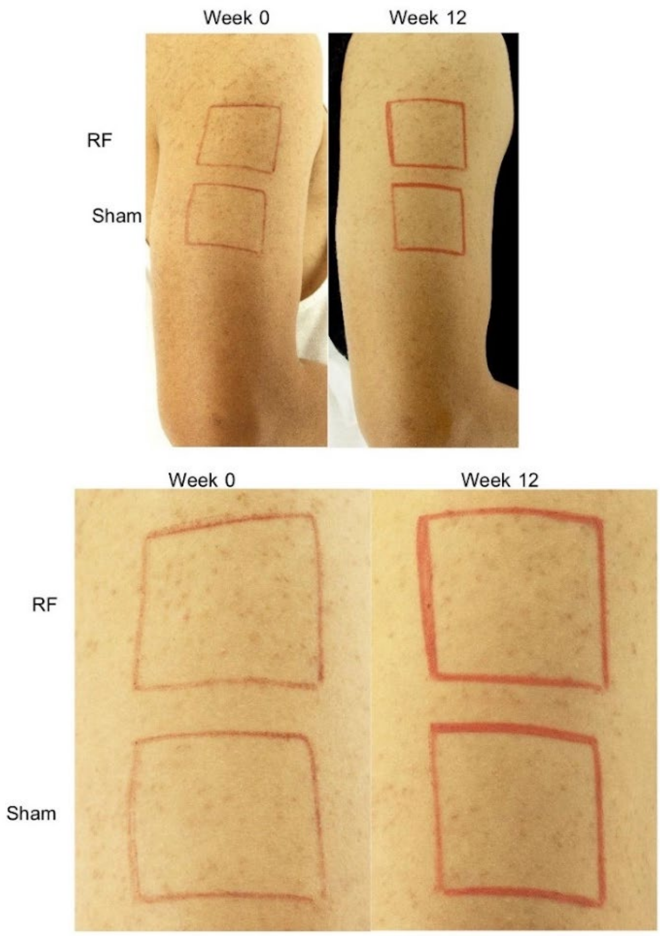


Fig. 3. *Subject 1, the right arm treated with insulated microneedle radiofrequency and sham irradiation at weeks 0 and 12.*

Side effects

The side effects of both methods in weeks 4, 8, and 12 were minor and transient, with no irreversible or harmful side effects. In the radiofrequency treatment, 14 patients from a total of 20 patients (70%) had erythema, and 3 patients (15%) had itching, while in the sham irradiation, 15 patients from a total of 20 patients (75%) had erythema, and 2 patients (10%) had itching.

DISCUSSION

In this study, we administered three sessions (weeks 0, 4, 8) of insulated microneedle radiofrequency and sham irradiation to treat KP with three follow-up sessions (weeks 4, 8, 12). The results of radiofrequency, when compared to sham irradiation, indicate that skin roughness improvement was statistically significant, but erythema and hyperpigmentation improvement was not statistically significant. The physician grading scale and the visual analogue scale of radiofrequency treatment had statistically significant improvement and were higher than that of sham irradiation.

Several energy-based devices have been used for KP skin roughness and dyspigmentation treatment, such as QS 1064-nm Nd: YAG, PDL, Diode Laser, Fractional CO2 laser, and IPL.

Park et al., using the QS Nd:YAG found that 50% of the patients showed more than 50% improvement in skin texture, and 41.7% showed more than 50% improvement in dyspigmentation (14). Kim et al.'s study on Low fluence QS Nd: YAG with a high pulse rate (10 Hz) found that clinical outcome improvement was statistically significant ($p<0.05$) (15). Pichai Saelim, et al.'s study evaluated the efficacy of the long pulse 1064 nm Nd: YAG laser in reducing the affected hair follicle sizes with a significant improvement in global assessment, erythema, and in the number of keratotic papules. ($p<0.05$) (16). Sobhi *et al.*'s study compared using fractional CO2 laser, QS Nd: YAG laser (1064 nm), and combined its use for treatment. Their results showed that all techniques improved keratotic plugs and pigmentation. In addition, one of 20 patients showed hypopigmented macules in combination and QS Nd:YAG laser areas with improvement after one month (18).

Lee et al. evaluated the combination of 595-nm PDL, long-pulsed 755-nm Alexandrite laser, and microdermabrasion. The combined treatment had a positive therapeutic effect on twisted hair shafts trapped within keratin materials, and 595-nm PDL positively affected erythema. On the other hand, our study did not show a positive effect on the erythema of KP. They found post-therapy erythema in all treatment sites. Five of the 26 patients who developed prolonged posttherapy scaling recovered within 2 weeks by recommendation of using emollients (11).

Alcántara González, et al.'s study found that 585-nm Diode laser only improved erythema but not skin roughness in keratosis pilaris rubra (9). Also, from Ibrahim et al.'s study, an 810-nm Diode laser significantly improved skin texture and roughness but not erythema (6). Diode laser aimed selectively at melanin targets inflammatory condition of vellus hair follicles. However, perifollicular erythema with follicular papules should be combined with a vascular laser procedure. Two of the 23 patients from the 810-nm Diode laser withdrew from the study due to post-inflammatory hyperpigmentation.

Vachiramon et al.'s study evaluated the fractional CO2 laser, showing that 30% of the lesions on the laser-treated side had moderate to good improvement ($p = 0.02$). Four patients had post-inflammatory dyspigmentations. All patients with hypo- and hyperpigmentation were Fitzpatrick skin type V, received special care and resolved by 12 weeks of follow-up (12). Ismail et al.'s fractional CO2 laser study showed clinical and dermoscopic improvement because it targets follicular papules, keratinous plugs, and brown pigments (13).

Maitriwong et al. compared IPL to sham irradiation on the other part of the arm. An objective clinical evaluation was performed using Antera 3D camera to measure skin roughness, erythema, and hyperpigmentation, the same as in our study. In addition, subjective clinical evaluation was performed using Global Improvement Score to measure skin roughness, erythema, hyperpigmentation, and global appearance. As in our study, they used a physician grading scale and a visual analogue scale for evaluation (19). IPL significantly reduced skin roughness when compared to the control group ($p<0.001$), similar to the result in our study ($p<0.001$). Both devices can reduce skin roughness by reducing hyperkeratotic papules and hair reduction of IPL and dissolving the follicular keratin plugging and vellus hair from massive thermal heat of insulated microneedle radiofrequency. However, neither IPL nor radiofrequency significantly reduced dyspigmentations compared to the two groups. Because the chosen cut-off filter in the IPL study was 645–950 nm to focus on the melanin in the hair shaft and hair follicle to reduce skin roughness and removal but no ability to reduce dyspigmentation. Radiofrequency does not affect epidermal chromophores or chromophore absorption, making it not ideal for treating skin erythema and hyperpigmentation.

Limitations

Further randomized controlled studies should be conducted over a more extended research period to detect the procedures' long-term consequences and side effects. In addition, histopathology from tissue biopsy should be provided to certify the outcome of the investigation. Also, local anaesthesia should be accommodated for patients to reduce the bias of radiofrequency treatment and sham irradiation. Moreover, a larger number of patient samples and diverse nationalities and skin types are needed to support our conclusions. Lastly, to reduce bias in the study and to see the results of before and after treatment more clearly, photography should be modified to take one treatment lesion per frame.

CONCLUSIONS

In conclusion, insulated microneedle radiofrequency significantly improves skin roughness, but erythema and hyperpigmentation improvement was not statistically significant in keratosis pilaris patients. Therefore, it should be considered an alternative choice in treating KP, with no major side effects.

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Conflicts of interest

The authors have no conflicts of interest to declare relevant to this article's content.

Author contributions

All authors contributed to the study conception: study design, material preparation, data collection and analysis.

Ethics approval

Reviewed and approved by Srinakharinwirot University IRB; approval SWUEC-515/2563

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