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**Original Article**

# Treatment of cutaneous leishmaniasis with radiofrequency microneedling

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## Abstract

***Objective*** To assess the efficacy of radiofrequency microneedling in the treatment of cutaneous leishmaniasis particularly in preventing or at least minimizing the potential scarring.

***Methods*** This is an open interventional therapeutic trial and was conducted in a private dermatology clinic in Missan province, Iraq between the period from January 2019 to December 2021. Sixty patients diagnosed with cutaneous leishmaniasis participated in this study. A detailed history and examination were done on every patient. We used a radiofrequency microneedling machine (NBW-FR200)© to treat lesions of CL. The depth of microneedles used in this study ranged from 2 to 3 mm according to the area treated and the degree of lesional induration. The interval between sessions was one week. The status of each lesion was documented every week including size and degree of erythema and of induration.

***Results*** Only 54 patients completed the trial period, their age was 15.4±13.3 years. The male to female ratio was 0.8:1. The duration of lesions ranged from 25 days to 5 months. A solitary lesion was encountered in 23 patients, the total number of treated lesions was 125 and the upper limbs were the most commonly affected area. The size of lesions ranged from 0.5 to 6 cm in diameter with a mean±SD of 2.46±1.17 cm. and ulcerative type was seen in 75 (60%) lesions. Two to six therapeutic sessions were done for all patients and the cure rate was 88.8%. Most patients encounter minor side effects after therapeutic sessions. All treated patients were followed up every month for 6 months. No recurrence has been detected in all cases.

***Conclusion*** Radiofrequency microneedling has a high cure rate for cutaneous leishmaniasis with minimal side effects.

***Key words***
Cutaneous leishmaniasis; Radiofrequency; Microneedling.

## Introduction

Cutaneous Leishmaniasis (CL) is caused by the vector-borne protozoan parasite *Leishmania* and is transmitted via the bite of an infected female sandfly (*Phlebotomus and Lutzomyia*). It is endemic in more than 98 countries.[1] More than 90% of the cutaneous cases appear in Afghanistan, Saudi Arabia, Algeria, Brazil, Iran, Iraq, Syria, and Sudan.[2] Clinically C.L. can be seen as a dry and wet types.[3] The incubation period is relatively short (1-4 weeks) for wet type and longer (2-8 months or more) for the dry type. The lesion presents as an asymptomatic violaceous papule, with time it

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might enlarge to become a nodule or a plaque. This stage is called dry (non-ulcerative) type leishmaniasis. The lesion may become crusted at the center and then ulcerate forming the wet (ulcerative) type of leishmaniasis.[4]

Cutaneous leishmaniasis is usually diagnosed on clinical bases (supported by epidemiologic data) and confirmed by laboratory testing. Variable diagnostic methods have been described with a huge variation in diagnostic accuracy, including the direct parasitologic examination (microscopy, histopathology, and parasite culture) and/ or indirect testing with serology and molecular diagnostics.[5]

Although CL is a self-limiting disease, it is disfiguring, therefore, the main objectives of treatment of CL are shortening the duration of the disease, improving the cosmetic results of its scar, and cutting short the psychological impact on the patients.[6] There are different ways of treating CL that may include:

***A. Local treatment*** heat therapy has proven to be effective but requires special equipment,[7-9] cryotherapy,[10] $CO_2$ laser,[11] local infiltration with sodium stibogluconate,[6] hypertonic sodium chloride,[12] chloroquine,[13] zinc sulfate solution[14] and rifamycine solution,[15] topical application of paromomycin[16] and azole antifungal agents.[17]

***B. Systemic treatment*** like pentavalent antimonials,[18] antifungal drugs,[3,19,20] rifampicin,[21] azithromycin,[22] dapsone,[23] oral zinc sulphate,[24] and interferon c.[25]

The above therapeutic options have been associated with variable success rates and may have different side effects during or after treatment. The main parameters governing the choice of the best mode of treatment are efficacy, cost, availability, adverse effects, and the local experience. Drug resistance is an emerging problem in the control of CL.[26]

CL has the ability to induce little immune stimulation through the continuous variation of antigenic epitopes and immunosuppressive mechanisms.[27] To the best of our knowledge, there is no human vaccine available for CL used in vaccination programs despite many trials.

This study aims to assess the efficacy of radiofrequency microneedling in the treatment of cutaneous leishmaniasis particularly in preventing or at least minimizing the potential scarring.

## Patients and Methods

This is an open interventional therapeutic trial to assess the efficacy of microneedling radiofrequency in the treatment of CL. Several patients diagnosed with CL were enrolled in this study. The study was conducted in a private dermatology clinic in Missan province in the southern part of Iraq during 3 seasonal outbreaks between January 2019-December 2021. The primary outcome measure was the complete healing of lesions. All patients diagnosed with cutaneous leishmaniasis during the period of trial were enrolled in the present study except those who previously received any form of anti-leishmanial therapy within the last 6 months before enrolment, those who had more than 5 lesions, immune-compromised patients, pregnant women, and infants below one-year-old.

Ethical approval has been obtained from the ethical committee at the University of Missan after fulfilling all requirements of medical research stipulated by the committee.

A detailed history was taken from every patient including age, gender, residence, duration of the lesion(s), history of any previous treatment, and

family history of similar lesions.

The diagnosis was primarily clinically based, however in query cases, investigations were arranged accordingly. All patients have been examined for the number of lesion(s), their sites, size, consistency, and morphology (ulcerative and non-ulcerative). The number of sessions and parameters of the microneedling radiofrequency machine (intensity, pulse duration, depth, and the number of shoots) were documented for every case and session. The status of each lesion was documented every week including size, degree of erythema, and degree of induration. However, the main parameter of assessment was the size of the lesion according to our grading system as follows:

Grade I: Non-significant result.

Grade II: Mild improvement: reduction in the size up to 50%.

Grad III: Good improvement: reduction in the size >50% up to 75%.

Grade IV: Excellent improvement: reduction in the >75- 100%.

Photos before and after starting treatment were taken for all cases by Sony camera H300 after obtaining the patient`s or his/her parents' or guardian's permission. Written informed consent was taken from all patients or their guardians before starting treatment. We used a radiofrequency microneedling machine (NBW-FR200) with a maximum energy production of 15 joules that generates heat of 50 °C within the dermis. The depth of microneedles used in this study ranged from 2 to 3 mm according to the area treated and the degree of lesional induration. The interval between sessions was one week. The number of shoots (pulses) was adjusted according to the size, depth, and site of the lesion and it was broadly within the range of 1–6 shoots per lesion per session. The duration of one shoot was 2 milliseconds. For descriptive and analytical analysis, we used the SPSS program (version 21).

**Results**

A total of 60 patients with CL were enrolled in this study. Fifty-four patients completed the trial period whereas 6 patients defaulted at variable times during the trial for an unknown reason, therefore the data of those defaulted 6 patients were omitted from the study.

The age of patients ranged from one year to 41 years with a mean age of 15.4 years (SD ±13.3) **Figure 1**. Twenty-four (44%) patients were males whereas 30 (56%) patients were females. The male to female ratio was 0.8:1. The duration of lesions ranged from 25 days to 5 months **(Table 1)**. A solitary lesion was encountered in 23 patients, 7 individuals had two lesions, 12 patients had three lesions and 12 had more than 3 (4-5) lesions. The total number of trialed lesions was 125.

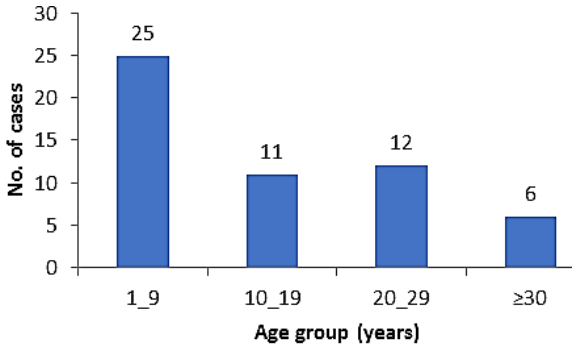



**Table 1** Frequency distribution of CL cases according to the duration of lesion.

| *Duration (months)* | *No. of patients* | *Percentage* |
|---|---|---|
| 1 | 7 | 12.96 |
| 2 | 23 | 42.59 |
| 3 | 11 | 20.37 |
| >3 | 13 | 24.07 |
| Total | 54 | 100% |

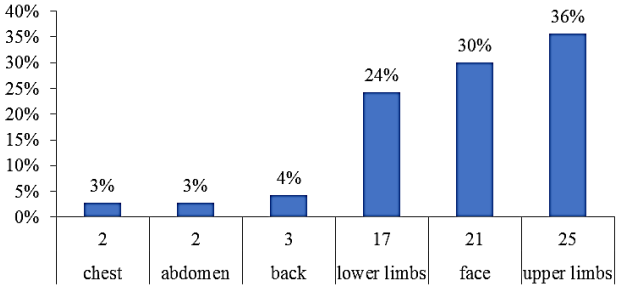



**Figure 2** Frequency distribution of CL cases according to body sites involved.

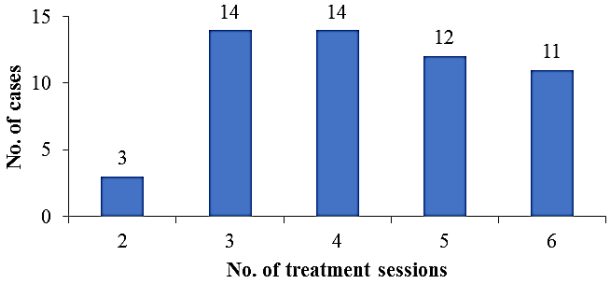



**Figure 3** Number of treatment sessions per CL cases.

Regarding sites involved by CL, our study revealed that the upper limbs were the most commonly affected area (figure 2). The size of lesions ranged from 0.5 to 6 cm in diameter with a mean±SD of 2.46±1.17 cm). According to the morphology of lesions, there were 50 (40%) non-ulcerative lesions in form of papules, nodules, or plaques whereas 75 (60%) lesions were ulcerative.

The number of therapeutic sessions per case ranged from 2 to 6 sessions **(Figure 3)**. The number of treated CL lesions that have attained grade III and IV therapeutic responses and the number of sessions required is shown in **Table 2** and **Figures 3, 4**. Only six cases had grade I–II therapeutic responses at the end of trial period.

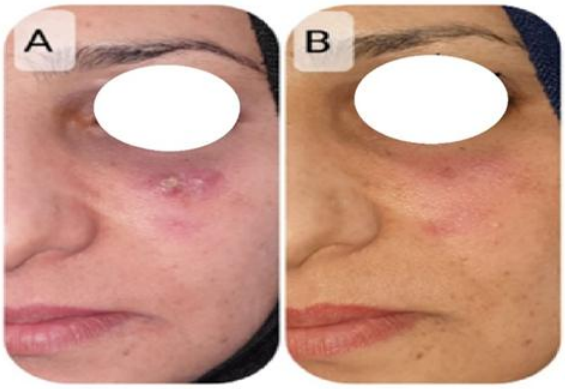
Most of our patients had a mild degree of pain during therapeutic sessions with transient erythema (lasting less than 72 hours), however, these mild unwanted effects didn't interfere with completing treatment sessions. About 40 (74%) patients noticed pinpoint bleeding of minor degree and that was expected due to the traumatic nature of microneedling and had given no importance due to its mild degree and transient nature. Blistering was suffered only by one patient and during only one session. It was mild and transient and disappeared within a few days and the patient completed further sessions uneventfully.

**Table 2** Frequency distribution of successfully treated cases (grade III and IV) according to number of sessions required.

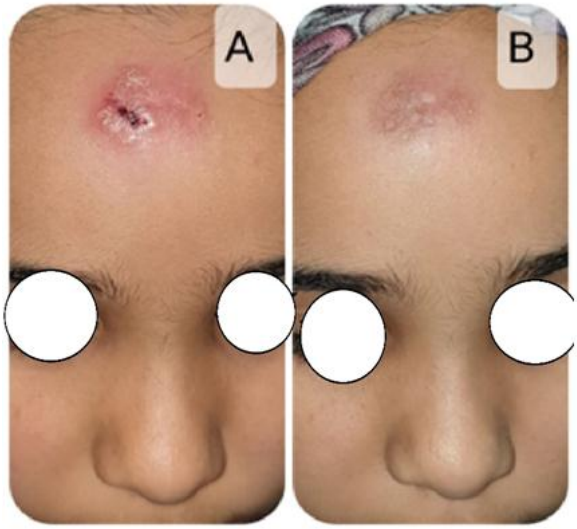
| No. of sessions | No. of cured cases | % |
|---|---|---|
| 2 | 2 | 4.16 |
| 3 | 10 | 20.83 |
| 4 | 16 | 33.33 |
| 5 | 10 | 20.83 |
| 6 | 10 | 20.83 |
| Total | 48 | 88.8 |

Among all treated patients, noticeable or marked scaring of atrophic type was suffered by 8 patients (6 of them are those who had shown a non-significant effect to mild improvement (grade I–II), whereas, only 2 patients of 48 (grade III and IV) responded patients have noticeable scars. All patients enrolled in this study were diagnosed with CL clinically, however, only 2 query cases necessitated skin biopsy to confirm the diagnosis histologically.

After the first session, the patients were assessed every one week and according to the response, the parameters of the radiofrequency machine were adjusted for further sessions.




**Fuqure 4** Results of RF microneedling after 3 sessions A) before treatment; B) after treatment.




**Fuqure 5** Results of RF microneedling after 4 sessions. A) before treatment; B) after treatment.

All treated patients were followed up every month for 6 months to one year. No recurrence has been detected in all cases.

CL is an endemic parasitic infestation in Iraq, especially in southern rural provinces. Missan province is one of the most endemic areas with CL in Iraq. So, this disease might impose a great social and economic burden on the population. CL if untreated, might result in massive tissue destruction with a bad or ugly cosmetic outcome.[2]

Our study aimed to introduce (to the best of our knowledge) a new treatment method to overcome unavailability of therapeutic medicines (shortage of supply). Also to overcome therapeutic resistance which has been noticed in many cases treated with traditional treatment.[26]

Leishmania parasite is a delicate microorganism that can be killed easily, however, clinical lesions produced by this parasite might result in significant tissue destruction with an ugly atrophic scar, especially in exposed parts of the body. Regarding age group affected, gender, duration, number, involved sites, and the size and type of lesions found in our study are generally in agreement with other published studies.[3,4,6,7,15,16]

Radiofrequency microneedling technique has been used as a therapeutic tool in many dermatoses like acne scars, atrophic scars regardless of the causes, and for skin rejuvenation,[28] however, due to its mechanism of action combining microneedling (dermal micro-injury) plus radio frequency (heat delivery to the skin), this gave us a hint to use these combined effects in treating an infectious dermatosis caused by a fragile microorganism and expecting high cure rate, in addition to availability of the machine, easy performance, relatively low cost, and minor or non-significant side effect compared with other therapeutics of CL.

The majority of our patients required 2 to 6 sessions to achieve clinical cure and that is expected with a gentle device producing heat of about 50 C° within the tissue with a short tissue contact time that doesn't exceed 300 milliseconds.

So, this treatment modality proved to be effective with a clinical cure rate approaching 90% with a relatively low number of sessions and minimal or nonsignificant side effects, these results are comparable with other therapeutic modalities.[6-17]

Naomi E Aronous *et al*.[8] have found a 37% efficacy rate in their study using local heat therapy (Themo Med device). We reached a higher cure rate probably due to additional effects of micro-needling to the heat produced by radio frequency. A similar efficacy rate of radiofrequency treatment was reported by others.[29] However, a lower success rate from the same above modality was obtained by other

authors.[30]

Our technique in this study has the advantage of combining two physical modalities including radiofrequency with heat generation to kill the causative parasite in addition to microneedling which has a well-known role in stimulating collagen formation and probably stimulating the immune system that helps in accelerating wound (lesion) healing with minimal or no scar. Only a few minor side effects have been encountered during our study and that is expected with a gentle device working through heat generation that doesn't exceed 50 C° and microneedling with a short contact time.

## Conclusion

Radiofrequency microneedling technique proved to be effective with a high cure rate for CL treatment with minor side effects profile.

## Recommendations

We recommend another study to assess the two arms of the radiofrequency machine through a comparative study, evaluating the efficacy of radiofrequency with and without microneedling to uncover the real effect of microneedling.

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