



Evaluation of efficacy and safety of microneedling fractional radiofrequency (MnRF) in the treatment of striae distensae

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Abstract

Background: Striae Distensae (SD), represent linear dermal scars with epidermal atrophy of the epidermis that may cause significant cosmetic problems, especially in young women.

Objectives: To study the efficacy and safety of MnRF in the treatment of striae distensae.

Materials and Methods: A total of 20 patients (Male-7, Female-13) aged between 18-40 yrs with SD attending the dermatology OPD, received four sequential MnRF treatments with an interval of 4 weeks between each session. A detailed history, general physical and dermatological examination of the striae, along with photographs, of each patient was taken before and after the procedure with emphasis on striae distensae. Clinical assessment of improvement of striae was done based on Global Improvement Scale at their first visit & at the end of 1 month after the last session. In addition, patients were asked to provide their opinion on improvement of striae using the patient satisfaction score.

Results: Out of our 20 patients (n=20), subjected to 4 consecutive MnRF sessions, four weeks apart, 6 patients showed 'marked improvement', while 12 patients showed 'moderate improvement', and 2 had 'minimal improvement'. According to the patient satisfaction score, 6 out of the twenty patients were 'very satisfied' with the treatment, while 8 were 'satisfied' and 6 were 'slightly satisfied' with their treatment outcome. No significant adverse effects were reported.

Conclusion: In our study, MnRF was found to be a safe and effective modality in the treatment of striae distensae.

Keywords: problems, epidermal, satisfaction, modality

Introduction

Striae Distensae [SD] or stretch marks are common disfiguring skin condition characterized by linear atrophic plaques that are initially erythematous (striae rubra), and overtime become progressively atrophic and hypopigmented (striae alba) [1] Although, SD do not pose any serious medical problems but may have significant aesthetic and psychological/ psychosocial impact on affected patients, especially in young women [2].

Improving the appearance of SD, particularly striae alba, has always been a challenge, owing to the limited availability of efficacious and low risk treatment options. A variety of treatment modalities have been advocated for the treatment of SD, including topical preparations like topical tretinoin (0.1%), trofolastin cream, peels such as trichloroacetic acid (13%,20%,30%) and glycolic acid (50%,70%) peels. Lasers and light-based devices like 308 nm excimer laser, 585-nm pulse dye laser,1064-nm Nd-Yag laser, ablative/ non-ablative lasers and intense pulse light have also been tried for treatment of SD, but, with inconsistent results [3]. However, no definitive gold standard treatment modality for the treatment of SD has been determined till date and hence, there is a need for newer therapeutic modalities that are more efficacious and safer with minimal downtime.

A recently developed minimally invasive novel technique is microneedling fractional radiofrequency (MnRF). It has been used to treat various dermatological indications like wrinkles and atrophic/ hypertrophic scars. Microneedling fractional radiofrequency treatment has demonstrated

significant clinical improvement in acne scars, open pores and skin rejuvenation [4]. The histopathological analysis of SD, especially striae alba, being similar to a scar [5], MnRF provides a very promising option. With extensive review of literature, there has been no report describing the efficacy of microneedling RF device alone for the treatment of striae distensae in Indian population. Hence, this study was conducted to assess the efficacy and safety of MnRF in the treatment of SD.

Materials and Methods

Participants: A total of twenty randomly selected patients (M:F=1:2), aged between 18-40 years, with Fitzpatrick skin type III-V, having striae over the arms, abdomen, back, thighs, chest and gluteal region, attending the OPD at the Department Of Dermatology, Venereology and Leprosy, Adichunchanagiri Hospital and Research Centre, B.G. Nagara, Nagamangla Taluk, Mandya District, were enrolled in the study. Approval was obtained from institutional ethical committee and a written informed consent was taken from all the patients before enrolling them in the study. A detailed dermatological examination of the striae along with photographs of each patient was taken before and after the procedure with emphasis on striae distensae.

Pregnant/ lactating women and patients with active infections like Herpes, Type I/ II were excluded from the study. Patients with history of photosensitive disorders like lupus erythematosus, dermatomyositis or who are on anti-coagulants, anti-platelet therapy, immunosuppressive drugs and platelet disorders weren't considered for the study.

Patients with Cushing's disease/ Ehlers-Danlos syndrome or patients with history of propensity for keloid formation and vitiligo were excluded.

Patients with implants, like pacemaker or cochlear implants or who had received treatment for laser skin resurfacing in the past 6-12 months on the striae were also not considered.

Treatment: Microneedling Fractional Radiofrequency Device and Treatment Protocol

Patients with striae distensae were subjected to receiving four sequential microneedling radiofrequency (DERMA INDIA MR 16-2SB) treatments with an interval of 4 weeks between each session. The energy delivery system consists of a disposable tip with 25 gold-plated insulated microneedle electrodes with a maximum energy output of 50W. The depth of the needle can be adjusted from a minimum of 0.5mm to a maximum of 3.5mm. When the needles reach the pre-defined insertion depth, the RF is emitted selectively heating the dermis while sparing the epidermis. The time of needles being out was 450ms and the time difference of radiofrequency and needles being out was 10ms for each session.

Prior to each treatment session, EMLA cream (Lignocaine 2.5% and Prilocaine 2.5%) was applied to the targeted regions of striae distensae for 40 minutes followed by gentle cleansing. The procedure area was painted with povidine iodine and cleaned with 70% isopropyl alcohol as a disinfectant, using sterile precautions.

In each session, two passes were administered. Penetration depth was individualized for each striae, ranging from 1.5mm to 2.5mm. Disposable micro radiofrequency needles were used for every patient in each session.

Post procedure, the sites were wiped gently with cold water and an ice pack was applied for 5 mins to alleviate discomfort and minimize swelling.

Patients were advised to apply hyaluronic acid-based emollients. Any post procedure erythema was treated with topical steroid antibiotic cream provided by the investigator and post procedure pain was managed with non-steroidal anti-inflammatory drugs.

Evaluation: Assessments were made by photographing the striae by a digital camera (SONY CYBERSHOT). Objective clinical assessment was carried out by comparing before and after photographs using the Global Improvement Scale, viz. Grade 0- Worsened, Grade I- Minimal improvement (0-30%), Grade II- Moderate improvement (31-50%), Grade III- Marked improvement (51-80%), Grade IV- Near total improvement (>81%) at baseline, that is their first visit and 1 month after the last session [11].

In addition, the patients were asked to provide their opinion about the improvement of striae, using the patient satisfaction Visual Analogue Scale (0- Not satisfied, 1- Slightly satisfied, 2- Satisfied, 3- Very satisfied, 4- Extremely satisfied) at the end of one month, after 4 treatment sessions [11].

Patients were assessed for side effects, such as tear, erythema, pain, burning, bleeding and post inflammatory hyperpigmentation. One month after the final session, patients were again evaluated for any possible side effects.

Data collected was entered into Microsoft Excel 2016 and analyzed using SPSS 20.0. Descriptive statistics was expressed using mean and SD. For test of significance, paired t test and chi square test were used. *P* value < 0.05 was considered significant at 95% confidence interval.

Results

Out of the 20 patients (n=20) (M: F=1:2), subjected to 4 consecutive MnRF sessions, four weeks apart, 6 patients showed marked improvement, while 12 patients showed moderate improvement, and 2 demonstrated minimal improvement. According to the patient satisfaction score, 6 out of the twenty patients were 'very satisfied' with the treatment, 8 were 'satisfied' and 6 were 'slightly satisfied'.

Amongst the three groups of outcome, viz. minimal improvement, moderate improvement and marked improvement groups; no conclusive significant difference could be established between the minimal and marked groups using the ANOVA test ($p=0.059$). However, while the analysis of variance between the minimal group and moderate group ($p=0.0152$) and moderate group and marked group ($p=0.0154$) showed a significant difference.

In a few patients, post procedure erythema was present, which was transient and subsided eventually. There was no significant adverse effects reported.



Fig 1

Discussion

Striae distensae, commonly referred to as stretch marks, was described as a dermatological entity in 1889 [6]. It is a common disfiguring skin condition characterized by linear smooth bands of atrophic skin, appearing in areas of stretching due to dermal damage. They tend to occur in areas of maximum stretching and initially develop opposite to the skin tension lines [7]. It is found in both genders, across all races and are usually located on the gluteal region, thighs, knees, calves, and lumbo-sacral areas. A genetic predisposition is presumed, as SD has been reported in monozygotic twins [1]. It has been postulated that, infection/inflammation trigger the release of "striatoxin" that damages tissue and creates linear atrophic depressions [8]. Although, SD do not pose any serious medical problems but may have significant aesthetic and psychological/psychosocial impact on affected patients, especially in young healthy women.

Most commonly, striae develop during pregnancy, followed by in adolescence, rapid weight gain/loss, obesity, prolonged use of systemic and topical corticosteroids and Cushing's syndrome or Marfan syndrome. Females are 2.5 times more susceptible to develop SD than their male counterparts [3].

Striae Distensae over thighs of a 27-year-old male patient. Fig (a) shows the striae at baseline, before commencement of treatment. Fig (b) showing significant improvement of striae after 4 MnRF sessions.

Histologically, striae are similar to scars, but the lesions in striae distensae mature from striae rubra to stria alba. The

natural evolution of striae is from red/ purple raised wavy lesion to white atrophic lesion with a wrinkly texture. In striae rubra, lesions are deep with superficial perivascular lymphocytic infiltrate. With time, reticular dermis collagen bundles, get stretched parallel to the skin, causing flattening of the epidermis along with elongation of the rete ridges [4]. This is followed by loss of collagen and elastic fibres in the dermis. Also, messenger RNA expression of collagen, elastin and fibronectin gene is markedly reduced in SD [9]. In early stages, inflammatory changes are less conspicuous, with elastolysis accompanied by mast cell degranulation, followed by activated macrophages that envelope fragmented elastic fibres. In later stages, the dermal collagen is layered in thin eosinophilic bundles oriented in straight lines [1].

Various topical agents have been advocated in the management of striae. Tretinoin and retinoic acid have been found to be useful in several studies. In early SD, it is believed to act upon by stimulation of fibroblasts leading to increase tissue collagen levels. Combination of tretinoin and glycolic acid, or a combination of glycolic acid and ascorbic acid, shows some improvement in striae rubra [7]. Hyaluronic acid is also found to be effective in SD as it increases collagen production. Other agents used with varying success are trofolastin (*Centella asiatica*), silicone, glycolic acid, ascorbic acid, alphasia, bio-oil fortified with vitamin C/E, topical retinoids, and peels like TCA/ salicylic acid peels [10]. Microderm abrasion has a possible stimulatory effect on Type I procollagen formation.

Several light based and laser modalities have been implicated. The usefulness of these sources lie in their ability to induce changes in collagen and elastin, as well as delivering energy that selectively target oxyhemoglobin in dilated vessels of striae rubra [8]. Ablative lasers of wavelength more than 1000 nm are readily absorbed by tissue water, results in cell vaporization, tissue heating and remodeling. The commonly used ablative lasers for SD are CO₂ (10,600 nm) and Er:YAG (2940 nm). Non ablative lasers like Erbium glass laser has also been used for fractional photo thermolysis [1]. Generally, repetitive treatments (4–6 sessions) are required. Other lasers like Pulse dye laser, 308nm excimer laser, Nd:YAG 1064nm, and diode laser have been tried in the treatment of SD.[8] In spite of availability of various treatment modalities, the results and outcomes in SD are unsatisfactory, hence, there is a need for a newer modality which is more efficacious and safe with minimal downtime.

A recently developed minimally invasive novel technique is microneedling fractional radiofrequency. In MnRF, microneedles penetrate into skin with minimal injury to epidermis and once within the dermis, radiofrequency energy is delivered through needles. The heat generated by the resistance offered to passage of radiofrequency energy causes dermal remodelling, neoelastogenesis and neocollagenogenesis resulting in dermal thickening and skin rejuvenation [11]. The mechanism of action is related to the fact that water, melanin, collagen, dermal microvasculature can absorb energy from the device producing a bulk heating effect to release growth factors like VEGF, PDGF, EGF, TGF beta resulting in dermal remodeling [4].

Our data showed that, MnRF induced clinical improvement of SD without causing serious side effects. This, to the best of our knowledge, with extensive review of literature is the first study of its kind using microneedling radiofrequency in

the treatment of SD that showed statistically significant improvement in the texture and size of striae in the Indian population.

Conclusion

In conclusion, MnRF could be an effective treatment for striae distensae, resulting in significant reduction in the appearance and width of SD without serious adverse effects.

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