TREATMENT OF DEPRESSED ACNE SCARS AND DEEP WRINKLES WITH A NOVEL MULTISOURCE FRACTIONAL RADIOFREQUENCY DEVICE - HISTOLOGICAL AND CLINICAL RESULTS ON 50 PATIENTS WITH LONG TERM FOLLOW-UP

Yoram Harth, Klaus Fritz

AMERICAN SOCIETY FOR LASER MEDICINE & SURGERY, Inc.

TREATMENT OF DEPRESSED ACNE SCARS AND DEEP WRINKLES WITH A NOVEL MULTISOURCE FRACTIONAL RADIOFREQUENCY DEVICE - HISTOLOGICAL AND CLINICAL RESULTS ON 30 PATIENTS WITH LONG TERM FOLLOW-UP

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Background and Objectives

Acne scars and deep wrinkles are among the most difficult disorders to treat in aesthetic dermatology. Although microsurgery and dermabrasion may be efficacious in some cases their use is limited due the significant downtime and risks associated. In the recent years fractional lasers were used for scars and wrinkles. The results of these lasers were not optimal most probably to the fact they generate low volume of non ablative heat . The optimal treatment system will provide minimal downtime resurfacing for the epidermis and non ablative deep volumetric heating for collagen remodeling in the dermis. (1-8) A novel therapy system (EndyMed Ltd., Cesarea , Israel) uses phase controlled **multisource** radiofrequency (RF) to provide simultaneous one pulse microfractional resurfacing with simultaneous volumetric deep dermal heating for collagen remodeling of scars and deep wrinkles.

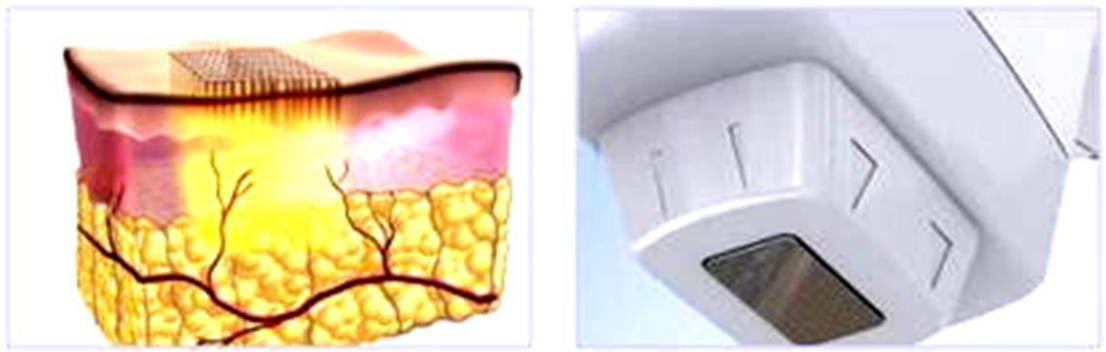

Fig. 1: EndyMed's 3DEEP technology uses 6 or more independent RF sources with controlled polarities to achieve simultaneously epidermal fractional microablation (112 contact points , diameter of 300micron and 100% coverage deep dermal heating of up to 2.9 mm.

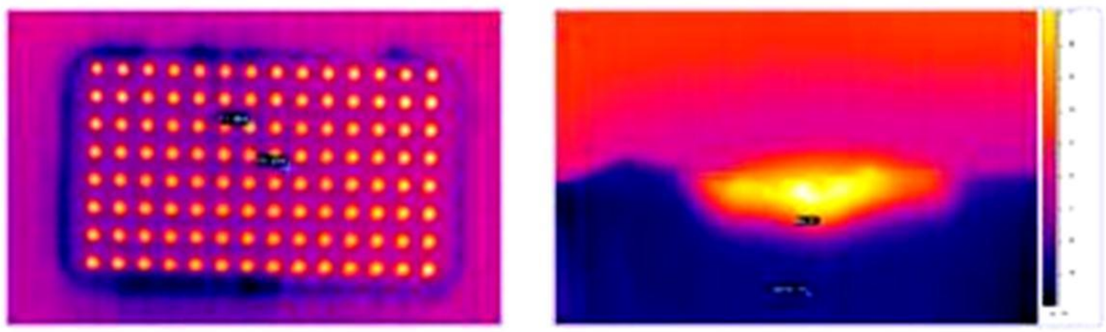

Fig. 2: Left : Fractional Microablation of the epidermis (Diameter 300 micron, depth 100-200 micron) **Right:** Deep dermal heating up to 2.9 mm.

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Travel expenses, salary, stockholder, equity position, intellectual property rights with EndyMed; FDA Approved: N/A; Off-Label Use: N/A; Opt-In Online: Yes

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Patients and methods

Paients, Materials and Methods: In the first stage of the study we treated in vivo animal skin. Skin specimens from the treatment area were harvested for histology immediately after, 3 days and 14 days after the treatment. In the clinical study, thirty subjects (Fitzpatrick's skin types 2 to 5) with moderate to deep wrinkles (Fitzpatrick's scale > 3) and twenty subjects with depressed acne scars were enrolled. Treatment was repeated each month up to a total of 3 treatment session. Patients photographs were graded according to accepted improvement scale by two uninvolved blinded evaluators. (Table 1.).

Results:

In vivo histologies showed various degrees of ablation, coagulation and dermal heating according to power settings.

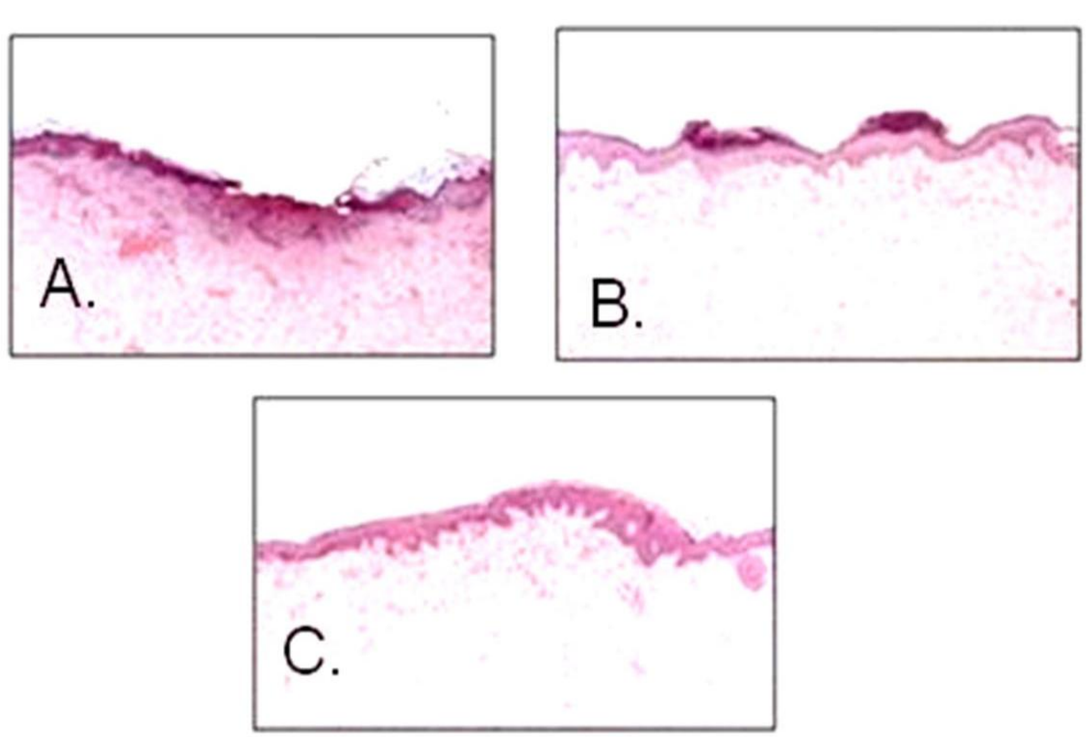

Fig. 3: In Vivo treatment of animal skin. **A**. Immediately after Fractional treatment - Ablation and coagulation. **B.** 3 Day after treatment - Dry crusts with complete healing of dermis and epidermis . **C.** 14 days after treatment. clear skin with complete healing of dermis and epidermis .

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Results

All treated subjects experienced mild-moderate edema and erythema as an immediate response to treatment. Edema resolved after up to one hour post treatment and mild erythema lasted up to 2 days. Micro ablative crusts lasted up to 5 days. In all 50 patients a significant reduction in the depth of wrinkles and acne scars was noted 4 weeks after therapy with further improvement at the 3 months follow up.

Table 1: Scale of Clinical Improvement

0	No improvement
1	1-25% Improvement
2	26-50% Improvement
3	51-75% Improvement
4	76–100% Improvement

Analysis revealed improvement (according to the quartile scale) in all (100%) patients according to both reviewers. Average clinical improvement at 1 month follow-up was 2.5 (±0.78) according to first reviewer and 1.83 (±0.70) according to the second reviewer. Furthermore, analysis of the frequency of improvement degree reveal that both reviewers found that the degree of improvement is moderate to good (25%-75% improvement) in most of the study participants (83.3% according to first reviewer and 66.7% according to the second reviewer); These results support significant improvement in skin texture as a result of the treatment. (Figure 4,5).

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Fig. 4: Significant decrease in number and depth of deep perioral wrinkles with tightening effects over the cheeks and jaws. Before and 1 months after two Endymed Fractional Skin resurfacing treatments.

Fig. 5: Significant decrease in number and depth of atrophic and ice pick acne scars. Before and 2 months after three Endymed Fractional Skin resurfacing treatments.

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Conclusions:

Our data show the histological impact and clinical beneficial effects of simultaneous RF fractional micro ablation and volumetric deep dermal heating for treatment of wrinkles and acne scars.

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