

Revolutionary Fractional RF Microneedling Enables Deep Tissue Penetration Without Full Needle Insertion for Skin Rejuvenation and Fat Reduction.

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Abstract

The Exion Fractional RF applicator is a new technology used in RF microneedling, a minimally invasive cosmetic treatment that improves the skin's appearance. The applicator uses a unique combination of monopolar radiofrequency, AI-controlled energy delivery, and Extended mode allowing for both deep tissue penetration without needle insertion and a single pass procedure. This technology overcomes intense pain sensation associated with traditional RF microneedling by creating a thermal gradient below the needle to affect subdermal tissue up to 8 mm in depth. Clinical studies have shown that this breakthrough technology yields great results in treating stretch marks, acne, acne scars, as well as overall skin rejuvenation and fat reduction. It improves the patient's perception of the treatment while providing impressive results with high patient satisfaction rates.

Keywords: AI-controlled energy delivery, Deep tissue penetration, Single pass procedure, Thermal gradient, RF microneedling

Introduction

RF microneedling is a minimally invasive aesthetic procedure without significant downtime or serious complications. In the last few years, microneedling procedures have seen the highest growth among other skin rejuvenation treatments. Standard non-energetic microneedling has been rapidly replaced by fractional radiofrequency, which brings significant benefits to patients and provides the ability to treat a wider range of indications ^{1,2}.

Generally, RF microneedling uses the application of radiofrequency energy through a set of small needles that are inserted into the skin. This treatment is designed to improve the appearance of the skin by inducing controlled thermal damage in the deeper layers of the dermis or subcutaneous fat tissue; in addition to mechanical damage via the penetrating needles.

When the needles penetrate into the deep layers of the skin, they create microchannels in the tissue to which the RF energy is delivered. The RF is used to generate heat of up to 60-80°C which leads to controlled thermal damage in the dermis. Such intense heating results in coagulation and denaturation of old collagen and elastin fibres. This process stimulates the body's natural healing response, leading to the formation of new collagen and elastin fibres ³⁻⁶.

Although the microneedling RF has become a widely popular procedure yielding great results, the major drawback of existing technologies lies in high treatment discomfort. Due to the needles penetrating the skin and the RF heating the treatment is often perceived as very painful even when using numbing creams. The painful and uncomfortable perception is further enhanced by treatments requiring multiple passes, when the already micro injured skin is again penetrated with

needles and RF. Pain perception is especially associated with bodily treatments, where it is desired to treat subdermal layers, thus requiring deep needle penetrations of up to 8 mm. It is not uncommon that patients refuse to come for additional treatments after a single session⁷.

Exion Fractional RF

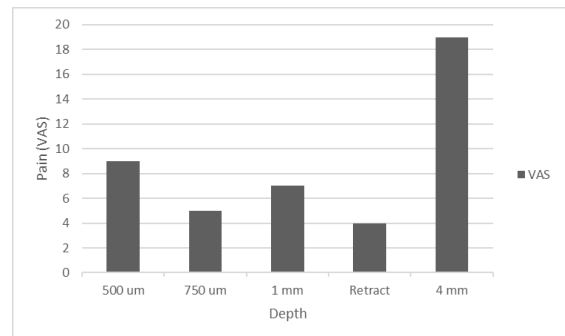
Exion Fractional RF technology has been designed to revolutionise this approach by tackling the major drawbacks to provide the major benefits of the microneedling RF but with significantly more comfortable experience. A unique combination of monopolar radiofrequency and AI controlled energy delivery has enabled deep tissue penetration without requiring full needle insertion, allowing for a single pass procedure.

Deep tissue treatment without full needle insertion

The depth of needle penetration during microneedling RF procedures is directly related to the intensity and frequency of pain experienced; the deeper the penetration, the greater the sensation of pain. Which is logical, because the pain receptors are present throughout all layers of the skin, thus with deeper penetration more pain receptors are stimulated along the needle. Such needle insertion generates a potent mechanical stimulus that triggers the activation of several types of mechanoreceptors located in the dermis, including pressure-sensitive Ruffini endings, movement-sensitive hair follicle receptors (Pacinian corpuscles), and mechanoreceptors innervated by single nerve endings⁸⁻¹⁰.

Although the pain sensation generally increases with needle penetration depth, there is a significant escalation in perceived pain intensity when needles are inserted to depths of 4 mm or greater.. The induction of heightened pain sensation is primarily attributed to the nerve

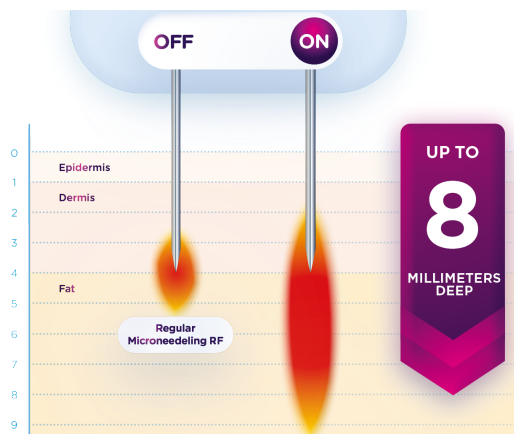
pain receptors rather than superficial receptors⁷. These are highly concentrated at the subcutaneous and dermal layers. Local anaesthetics are able to block impulses from the superficial receptors but their effect is very limited on larger nerve endings localised in the depth at around 4 mm¹¹.



The absolute VAS pain scores associated with the insertion of microneedles into the skin indicate a significant difference in pain perception intensity when inserting needles to depths of 4mm or more⁷.

Exion Fractional RF addresses the issue of intense pain sensation associated with deep tissue treatments by limiting needle penetration to 4 mm and creating a thermal gradient extending 4 mm below the needle. This approach bypasses the deep mechanical pain receptors enabling the subdermal tissue to be affected up to a depth of 8 mm.

The generation of thermal gradient is linked to the AI controlled energy delivery and monopolar nature of used radiofrequency, which requires the use of a neutral electrode located in the back of the patient. Therefore, when a long enough RF pulse is brought to the needle tip, the RF energy is directed towards the neutral electrode and as the energy passes through the tissue, it creates an additional thermal gradient below the needle. The built-in AI adjusts the pulse duration and power delivery automatically, optimising the energy flow to create the thermal gradient. This approach enables treatment of deep subdermal tissue without requiring full insertion of the needles.



The Extended mode delivers RF energy up to 4 mm beyond the needle tip, allowing for greater depth and tissue penetration without the need for physical puncturing of the tissue.

AI for Single pass treatment

However, such deep penetration may not be desired for facial treatments or when only skin remodelling is desired since it requires precise energy delivery. While deep tissue penetration is desirable in some treatments, facial treatments, and skin remodelling procedures require precise energy delivery rather than deep penetration. To ensure this precision, the device offers the option to switch off the Extended mode and provide greater control over energy delivery to the targeted depth.

When the mode is turned off, the device generates RF pulses that are of higher intensity but shorter duration, which physically does not allow energy to be directed towards the neutral electrode. The energy is localised only along the needles without a deep thermal gradient below the needle tip, which resembles traditional FRF devices that have been used for many years.

However, unlike any other currently available microneedling RF technologies, Exion Fractional RF has been enhanced with an AI pulse control system, eliminating the need for multiple passes during treatment. Since the skin parameters

differ from patient to patient and even from one body area to another, the AI retrieves impedance measurement from every single needle and during each pulse, when the skin and needles come into contact. Then, the AI evaluates this information and uses it to adapt the major pulse parameters to optimise the energy delivery for highest efficacy.

Many parameters are automatically set for each pulse of the device including the RF power, pulse length, and delivery rate. The technology ensures that the required energy is delivered during each pulse and from each needle based on individual needs of each patient and treatment area. The AI guarantees consistency and homogeneity of the delivered energy, which eliminates the need for repeating the application on already treated areas.

This single pass approach avoids excessive micro-injuries and prevents irritation of once-injured spots which significantly increases the comfort perception of the treatment.¹²

Increased comfort does not mean less results

Without in-depth knowledge it could be assumed that without full needle insertion or multiple passes it is not possible to achieve the “microneedling-like” results, however, the clinical studies suggest otherwise.

Duncan et al. assessed the effectiveness of single pass therapy on the face and the thermal gradient treatment on the body. The study involved three therapy sessions, and the results are impressive. 90% of subjects self-reported improved facial appearance. Also 98% expressed their satisfaction with the results¹³.

Clark-Loeser & Halaas reported that 82% of subjects found the treatments comfortable, and there was a 41% reduction in acne scars, as shown through 3D photo analysis. The efficacy of the treatment on the cellular level has been confirmed in a study by Bernardy et al. who showed significantly increased levels of collagen, which was elevated by 2.5 times ¹⁴.



53-years old female at 1 months after facial wrinkle treatment.



53-years old male at 3 months after facial treatment.

Solution For All Skin Types

To take into account the skin specifics related to skin types, the Exion Fractional RF is compatible with two types of needle tips: non-insulated and insulated microneedles tips. Non-insulated microneedles deliver energy along the entire length of the needle during one insertion, resulting in a more profound clinical effect along the entire microchannel wound. This approach affects the entire skin layer. However, this may not be suitable for higher skin types, where irritation of the upper layer of the skin may lead to hypo- or hyperpigmentation. Insulated microneedles were thus designed to deliver the energy only at the needle tip, allowing the physician to target specific depths of the dermis while protecting the epidermis

from heat and thermal damage. This approach is compatible with all skin types (I-VI) and allows for procedures that are less aggressive and safe from pigmentation changes ¹⁵.

The availability of both treatment approaches and the adjustable needle depth from 0.5 to 4 mm provides high versatility for the operator allowing to tailor the treatment according to the various conditions and their severity and also to fit the patient's expectations.

What happens in tissue?

During the microneedling RF treatment the affected tissue is heated to temperatures of 60-80°C leading to coagulation and denaturation of old collagen and elastin fibres. Mechanical and thermal injuries trigger a successive wound healing cascade of inflammation, proliferation, and remodelling of the skin's collagen and elastin fibres ^{3,16}.

The healing process starts with a release of potassium and proteins that alter intracellular resting potential. The first phase of the cascade is the inflammation phase, which begins shortly after the injury with the release of chemotactic factors from platelets; resulting in invasion of other platelets, neutrophils, and fibroblasts. Thus shortly after the application; the skin erythema and edema can be observed at the place where the needles penetrated the skin.

In the second phase, proliferation phase, monocytes replace neutrophils and change into macrophages with subsequent release of numerous growth factors, including platelet-derived growth factor, fibroblast growth factor (FBF), and transforming growth factors; stimulating the fibroblasts to synthesise new fibrous structures. Keratinocytes then start to re-establish the basement membrane by enhancing the production of laminin and collagen types IV and VII. The studies have also shown up-regulation of a cytokine that prevents aberrant scarring, increased gene

expression for collagen type I, and elevated levels of vascular endothelial growth factor. The levels of metalloproteinases, which are crucial for long-term remodelling, showed an increase in correlation with histological findings.

The last phase, the remodelling phase, which is mainly achieved by the fibroblasts, continues for months after the injury, and collagen is formed in the upper dermis over a period of a year or longer. After the cutaneous injury, a fibronectin network is created, providing a matrix for collagen type III deposition, which is eventually replaced by Type I collagen. This transition occurs over several weeks, resulting in clinical skin tightening and rhytide reduction. Over the next several months a more gradual tightening effect, called “secondary tightening” is observed, which translates into increased dermal thickness, density, firmness and elasticity, and even epidermal thickness^{2,12,17,18}.

Multiple clinical and histological studies investigating the synergy effects of RF and microneedling on skin have shown significant effects not only for skin tightening, reduction of wrinkles, or improving skin tone and texture, but they have also found improvement of conditions such as hyperhidrosis¹⁹, acne, acne scars, body scars, stretch marks and many more indications are being investigated^{20–28}.

In conclusion

Exion Fractional RF is a breakthrough technology in the field of microneedling RF as this is the first approach that allows treating deep subdermal layers without full needle insertion. The technology uses advanced artificial intelligence to achieve consistent results with a single pass technique, without the need for additional passes. Designed to change the paradigm of microneedling being a horrifyingly painful procedure it improves the patient's perception of the treatment, while yielding great results when treating both the face and body.

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