

Safety and clinical results using a novel radiofrequency microneedling device with 9 different needle array configurations for skin revitalization and tightening (via soft-tissue coagulation)

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Background

- Radiofrequency (RF) technology has seen a rapid expansion in indications for nonsurgical skin improvement.
- Delivery of RF energy through a microneedle to enhance energy penetration is a very active area of development.
- This study evaluates the use of a highly customizable RF microneedle device with 9 different needle array configurations for use in various aesthetic applications.

Methods

- 55 subjects underwent 3 treatments with a novel RF microneedle device at 4-week intervals.
 - Indications for treatment included improvement of blemishes, skin revitalization and skin tightening (via soft-tissue coagulation).
- Energy, needle depth, needle tip impact speed, RF frequency (1Mhz vs. 2Mhz) and polarity (monopolar vs. bipolar modes) were modified at the discretion of the physicians based on their expertise.
- Subject satisfaction, physician evaluation, treatment tolerability, standardized photography and adverse events were assessed.

Results

- Skin tightening (via soft-tissue coagulation) of either jawline or abdomen was the most common treatment performed, followed by skin revitalization.
- 88% of subjects reported they were satisfied with their treatment results 1 month after their initial treatment.
- Improvement was noted by physicians and subjects in a majority with continued improvement after subsequent visits.
- The treatment was well tolerated by subjects with an average discomfort score of 4/10.
- Adverse events reported were expected for RF microneedling treatment but were mild and resolved within two days on average.

Conclusion

- High subject satisfaction and aesthetic improvement were noted by the physician and subjects even after the first treatment. The treatment was considered tolerable and adverse events reported were mild and transient in nature.
- This study validates the safety and efficacy of a highly customizable RF microneedle device with 9 needle tip configurations for use in an extensive variety of indications and for multiple body sites. Further data collection is in progress to determine long-term efficacy and best needle configurations for optimized outcomes.

Figure 1. Results 1 month post 2 treatments of the abdomen with a customizable radiofrequency microneedle device compared to baseline

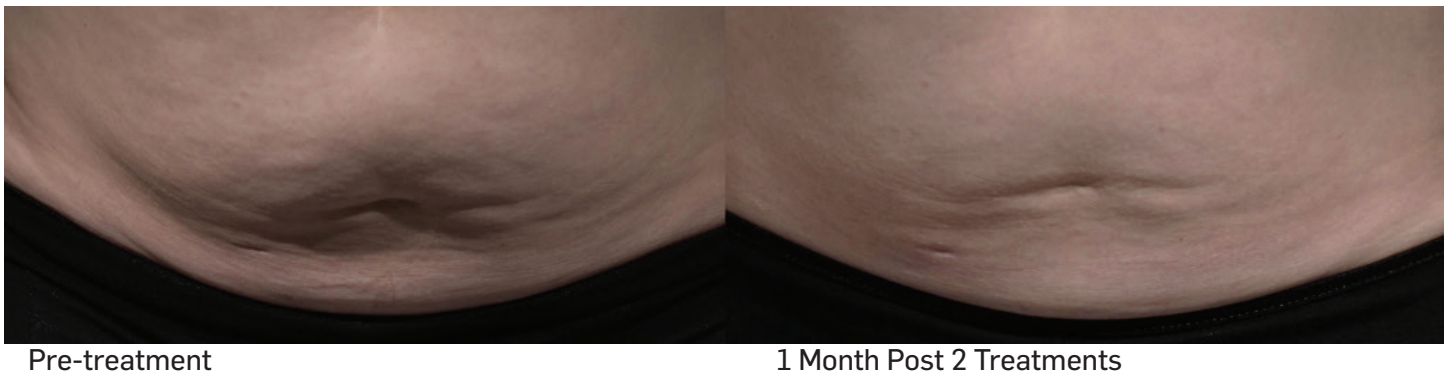


Figure 2. Results 1 month post 3 treatments of the abdomen with a customizable radiofrequency microneedle device compared to baseline

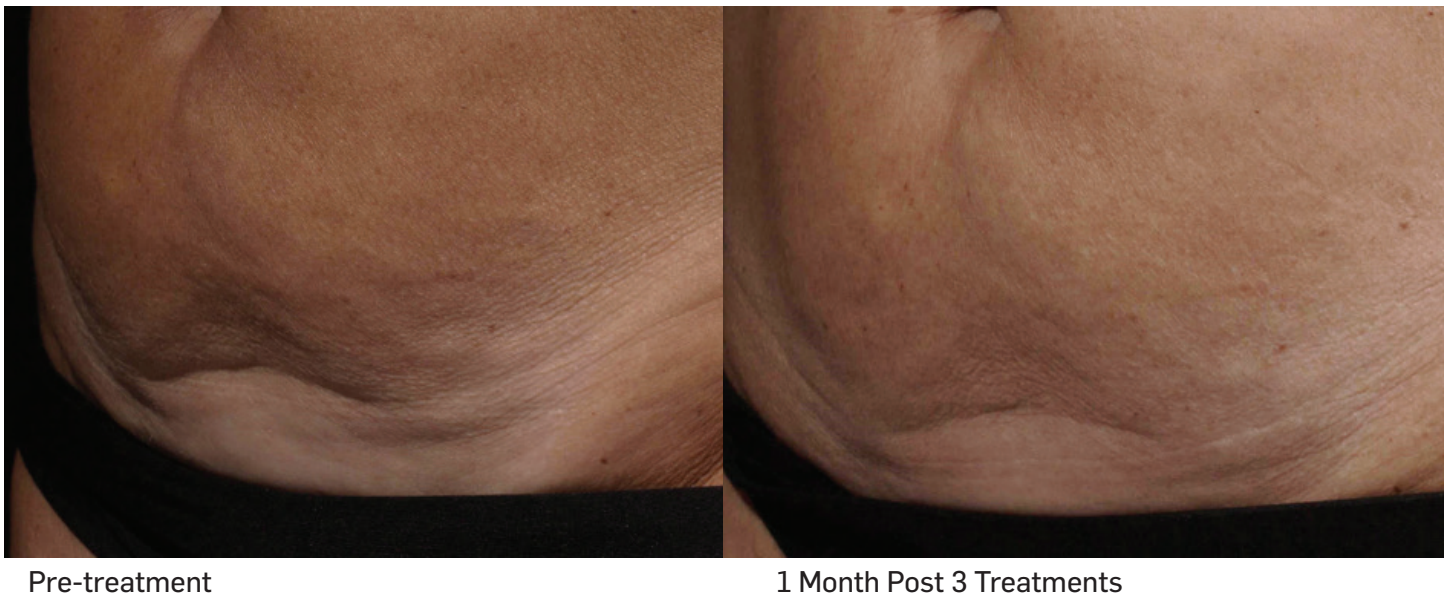


Figure 3. Results 3 months post 2 treatments with a customizable radiofrequency microneedle device compared to baseline



Pre-treatment

3 Months Post 2 Treatments

Figure 4. Results 1 month post 2 treatments with a customizable radiofrequency microneedle device compared to baseline



Pre-treatment

1 Months Post 2 Treatments

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The Potenza radiofrequency microneedling device is intended for electrocoagulation and hemostasis of soft tissues for dermatologic conditions. Common side effects include redness, heat sensation and tingling while receiving treatment. Other side effects may include swelling, blistering, burns, hives and lightening and darkening of the skin. Like all medical procedures, not all patients are suitable for the treatment. A qualified practitioner is solely responsible for evaluating each subject's suitability to undergo treatment and for informing those being treated about any risks involved with the treatment, pre-and postoperative care, and any other relevant information. Individual results may vary and are not guaranteed. Agile PN 921-7043-048 PRD_3553

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