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 ORIGINAL ARTICLE

Consensus Recommendations for 4th Generation Non-Microneedling Monopolar Radiofrequency for Skin Tightening: A Delphi Consensus Panel

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ABSTRACT

Importance: The demand for non-invasive methods for facial and body rejuvenation has experienced exponential growth over the last two decades. While multiple treatment systems exist, device specific guidelines to help guide clinicians to achieve the best outcomes are lacking.

Objective: To develop expert consensus on the use of 4th generation non-microneedling monopolar radiofrequency.

Design: In a modified Delphi process, a panel of 8 international experts in aesthetic dermatology participated in 3 rounds of consensus building commencing in April 2019. Initially, 32 consensus statements were developed addressing patient selection, patient outcomes, treatment settings, and practical use of non-microneedling monopolar radiofrequency. By the 3rd round, these had been reduced and refined to a total of 19 statements. The consensus process was completed in June 2019 and the data were analyzed in July 2019.

Results: In 3 Delphi rounds, the 8 panelists achieved consensus on 19 recommendations on the use of 4th generation non-microneedling monopolar radiofrequency and developed additional explanatory guidance to support 12 of the consensus statements including those related to patient selection, procedural technique, and anticipated treatment outcomes.

Conclusions and Relevance: Although guidelines will never replace individual clinical judgment, as the demand for noninvasive tissue tightening increases, so too does the need for positive, reproducible outcomes. Careful patient selection, pre-treatment counseling, treatment planning, and good technique, are all critical for success. These consensus statements should assist clinicians in each of these areas.

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INTRODUCTION

The increasing demand for safe and effective, non-surgical, skin rejuvenation modalities has resulted in a paradigm shift in the fields of dermatology and aesthetic medicine. Although surgical procedures and ablative laser technology produce dramatic results, many patients opt for procedures with minimal or no downtime, minimal discomfort, and a lower risk of side effects and complications. Several minimally invasive skin rejuvenation procedures help improve skin texture, reducing the appearance of fine lines, wrinkles, and acne scars. The goal of most non-invasive skin rejuvenation procedures is to trigger a wound repair response, encouraging the body to replenish or remodel old or damaged tissues. The process may be mechanical, chemical, or thermal.

Non-surgical thermal skin tightening procedures work by using targeted energy to heat deeper layers of skin, which stimulates collagen and elastin production and gradually improve skin texture. Non-invasive options for skin tightening include focused ultrasound, non-ablative lasers, and radiofrequency (RF).

One such system, a non-microneedling monopolar RF system (Thermage FLX®, Solta Medical) is a capacitively coupled monopolar radiofrequency system that utilizes a reverse thermal gradient that has been in use since 2002. The fourth generation system, approved by the U.S. FDA in 2017, includes enhanced features such as optimized energy delivery, shorter treatment times, uniform energy delivery over the tip, multiple tip sizes, enhanced multi-directional vibration, a universal handpiece for all tips, and a larger 4cm tip size that reduces treatment time

by 25 percent. Its FDA cleared indications include non-invasive treatment of facial and periorbital wrinkles and rhytids, including lower and upper eyelids, and temporary improvement in the appearance of cellulite.

Given the absence of high-quality evidence or peer-reviewed published practical guidance, the aim of this research was to develop a set of clinician-led consensus statements on the use of this novel 4th generation non-microneedling monopolar RF device.

METHODS

A literature review was conducted by an independent observer to obtain published material on the use of non-microneedling monopolar RF. Following completion of the literature review, an on-line survey of 32 open-ended questions was developed. These questions were divided into three sections: background information, clinical information, and other information.

In parallel with development of the online survey, a panel of eight international experts were invited, and agreed, to participate in an online collaboration to develop consensus statements. The experts were all practicing aesthetic dermatologists. Seven were located in the U.S. while one was based in Hong Kong. All had clinical experience treating patients with one or more generations of non-microneedling monopolar RF (mean, 12.7 years) and the 4th generation device (mean, 12 months/50-100 patients).

The questionnaire was delivered electronically, and complete responses were received from 7 of 8 members of the expert consensus panel.

Based upon the responses to the Round 0 survey, 32 consensus statements were developed by the independent observer and reviewed by two independent third parties with subject matter expertise to confirm clinical accuracy.

These consensus statements were then distributed and reviewed by the panel in accordance with a modified Delphi technique[1] — a group communication process that aims to achieve a convergence of opinion on a specific real-world issue.[2] The Delphi technique has been validated and widely used for medical research[3-9] and has been shown to be particularly valuable for consensus building[2,3] and when there are gaps or contradictions in knowledge.

An iterative approach was employed where sequential surveys were presented to the expert panel of experts to gain consensus.[10] Participants reviewed and commented on the statements in isolation and all responses were anonymous, ensuring each participant provided their own opinion without influence, peer-pressure, or the potentially coercive effect of dominant individuals within the group.[3]

For each statement, all eight participants were asked to judge whether the statement was clear ('yes' or 'no'), whether they believed that the statement should be included (1 = 'definitely do not include' to 9 = 'definitely include'), and finally to provide any comments, in the form of free text, that might help clarify the meaning of the statement (Figure 1).

Using the criteria in Table 1, all statements were analyzed to determine whether the statement should be considered for in-

FIGURE 1. Overview of consensus statement development and the Delphi technique

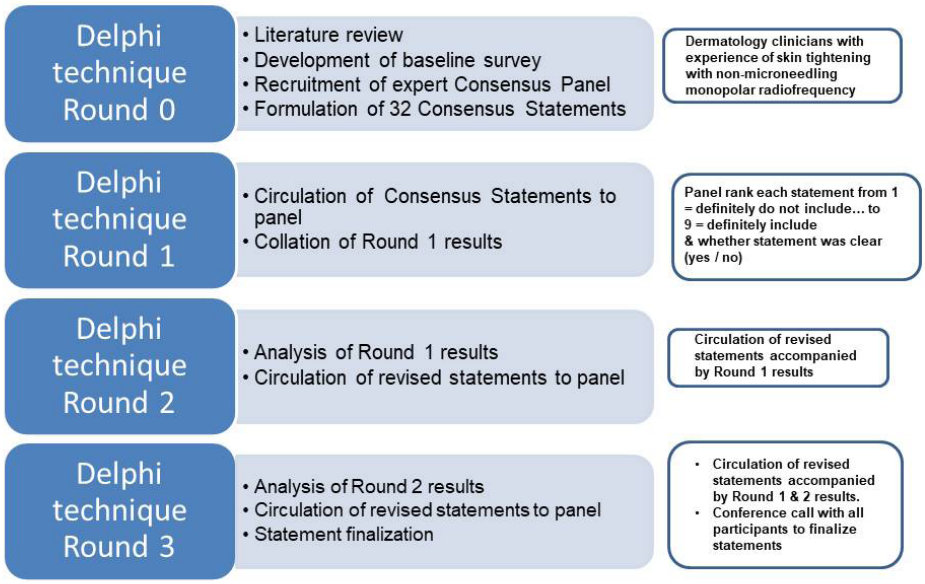


TABLE 1.

Delphi Technique – Consensus Statement Inclusion Criteria	
Statement Result	**Threshold Applied**
Definitely Include	(i) >80% of consensus panel rate statement as =9 OR (ii) Median rating of >8
Maybe Include	(i) >70% of consensus panel rate statement as =9 OR (ii) Median rating of >7
Definitely Exclude	(i) <70% of consensus panel rate statement as =9 AND 100% of consensus panel said statement was clear OR (ii) Median rating of <6 AND 100% of consensus panel said statement was clear*
Revise	(i) Major revisions suggested OR (ii) <70% of panel rate statement as =9 AND <100% of consensus panel said statement was clear*

*suggesting that low scores are not due to lack of understanding of proposed Consensus Statement

clusion, with or without modification. Following the first round of the Delphi technique, participants were provided with the results from the entire panel. Where statements remained unmodified, participants were shown individual ratings and the group ratings. This included the percentage of the group that agreed the statement was clear, median rating for inclusion, percentage of the group who rated the statement as 'definitely include', and combined comments. This summation of comments made each participant aware of the range of opinions and the reasons underlying those opinions.

Where a statement was modified, participants were shown the same information and asked to re-rate the revised statements. Deleted statements were not presented to the panel in subsequent rounds. Non-responders were sent weekly follow-up email reminders to complete the online survey.

All online surveys were built and distributed using SurveyMonkey® software. Data collection for all three rounds took place over 3 months; however, data collection per round lasted no longer than two weeks. All eight clinicians participated in Rounds 1 and 2 and the subsequent conference call.

The feedback process allowed and encouraged the participants to reassess their initial judgments about the information provided in previous iterations based on their ability to review and assess the comments and feedback provided by the other consensus panelists.

RESULTS

The comprehensive MedlinePlus[11] search failed to identify any peer reviewed clinical studies or consensus guidelines on the use of the 4th generation non-microneedling monopolar RF device. Consensus Statements had been published for the first generation device,[12] but given the technical advances that have occurred over the past 15 years, and the absence of clinical studies comparing each generation device, these may not be relevant or applicable for the 4th generation of non-microneedling monopolar RF.

The Round 0 online questionnaire resulted in the development of 32 statements. These addressed patient selection, patient outcomes, treatment settings, and practical use of non-microneedling monopolar RF.

Following Round 1 review of the 32 statements, 12 were unmodified, 7 statements were deleted, and 13 statements were revised based on participants comments. Two statements were added as a result of revisions that split subject matter from one previous statement into two new statements and one statement – *Patients who are treated with 4th generation non-microneedling monopolar RF every 1-2 years may experience prolonged, consistent skin tightening that helps to prevent future sagging* – was added, as one of the panelists felt strongly that this had been omitted from the original list, resulting in a total of 28 statements being submitted for review in Round 2.

Round 2 results revealed 19 statements that met the threshold for inclusion; 3 that were classified as *maybe include*; 2 that could be excluded; and 4 for which revisions were suggested. A conference call was then conducted between all members of the consensus panel and the independent observer to review and discuss the "maybe include" and "revise" statements from Round 2, which resulted in the acceptance of 19 final Consensus Statements.

Final Consensus Statements

1. *Skin quality, degree of laxity and extent of photoaging are more important than chronological age when selecting the ideal candidate for 4th generation non-microneedling monopolar RF.* Although some clinicians suggest the ideal candidate is between 30–65 years old, patients outside of this age range (ie, over 65 years old) can also benefit. As 4th generation non-microneedling monopolar RF addresses skin laxity through immediate collagen contraction and secondary collagen remodeling, it is possible better results will be achieved in patients without extensive collagen damage (ie, sun damage, acne scarring).

2. *The ideal 4th generation non-microneedling monopolar RF patient should have no more than mild-moderate skin laxity.* People who have mild-to-moderate sagging skin are more likely to benefit from this treatment than people with severe facial sagging. The consensus panel agreed that although even severe laxity may improve, the results are less predictable. (It is important to note that there is no FDA or dermatology society agreed definition of mild, moderate, or severe laxity. Thus, these terms are largely subjective and based on physician and patient experience and expec-

tations. While there is a comprehensive grading scale for assessment of rhytides, laxity, and photodamage,[13] this is mainly used to assess the efficacy of cosmetic treatment modalities in the context of a clinical study rather than in routine clinical practice.)

3. *Discussing/managing patient expectations prior to treatment with 4th generation non-microneedling monopolar RF is essential.* It is always important for patients to have realistic expectations when undergoing any cosmetic procedure. While 4th generation non-microneedling monopolar radiofrequency may improve overall appearance, it is not a surgical treatment and typically does not result in dramatic changes. Managing expectations through frank and honest discussion prior to treatment will lead to improved patient satisfaction. Equally important is to prepare patients for the timing of results. Patients should expect some immediate improvement with continued tightening and smoothing of the skin over the next 2–6 months as new collagen forms.

4. *Patients with severe sun damage are not ideal candidates for 4th generation non-microneedling monopolar RF.* The panel noted that patients with poor skin quality and mild dyschromia can achieve good results, especially when 4th generation non-microneedling monopolar radiofrequency is used in combination with other treatment modalities.

5. *Greater than 90% of properly selected patients may achieve positive results with 4th generation non-microneedling monopolar RF.* Based on their 1–2 years of clinical experience with 4th generation non-microneedling monopolar RF, the expert panel feels that their patients are achieving results equivalent or better than with previous generations. The panel recommends repeating the groundbreaking, 5,700 patient satisfaction survey study undertaken with the first-generation device in 2005, which showed that 87% of patients experienced immediate tightening, 92% observed skin tightening 6 months after treatment, and 94% of patients found the treatment results met their expectations.[14]

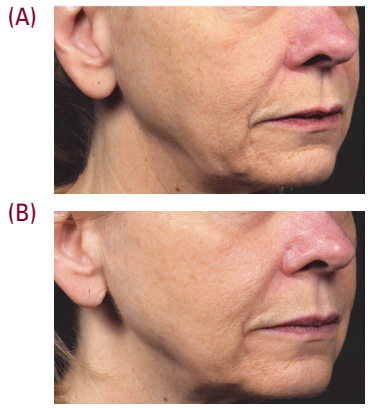
6. *Patients in whom positive results are seen may benefit from additional treatments with 4th generation non-microneedling monopolar RF, as results appear to be cumulative.* The collagen changes induced by 4th generation non-microneedling monopolar RF don't go away but the aging process continues, so the skin that was tightened will eventually show signs of laxity again. Repeat treatments will help to keep skin tightened and may postpone the need for surgery.

7. *4th generation non-microneedling monopolar RF can be used safely and effectively to treat eyes, face, submentum, and body.*

8. *Most appropriately selected patients see visible improvements after a single 4th generation non-microneedling monopolar RF treatment.*

9. *Most patients expect to achieve some contouring after 4th generation non-microneedling monopolar RF treatment.* Contouring is a subjective term, but may equate to firming, improved elasticity, or "shrink-wrapping." As applied to the jawline, it may imply more definition or angularity (Figures 2A and 2B).

FIGURE 2. (A) Jaw line before non-microneedling monopoloar RF treatment. (B) Jaw line contouring after non micro-needling monopolar RF treatment.



10. *Patient feedback on heat sensation scale should be used to select 4th generation non-microneedling monopolar RF treatment settings.* It should be hot, but easily tolerable. The discomfort of treatment is related to RF energy converting to heat energy in the skin. Tissue properties such as dermal thickness, fat thickness, fibrous septae, and adnexal structures affect local impedance. Additionally, the ability to tolerate pain varies from patient to patient and by treatment location. The expert consensus panel agreed that 4th generation non-microneedling monopolar RF is more tolerable than previous generations, due to the larger tip size, multi-directional vibration, and cooling cryogen spray. Most sensitive patient's discomfort can be mitigated by pre-medicating with 800 mg of ibuprofen or 500 mg acetaminophen. For patients with lower pain thresholds, adding low dose oral anxiolytics may be effective. It should be noted that the manufacturer does not recommend the use of sedatives, regional blocks, or narcotic pain medications, as these may prevent the patient from providing accurate heat sensation feedback, which could potentially increase the risk of adverse events. The manufacturer recommends starting with clean, dry skin and then applying a generous amount of the provided Coupling Fluid to the targeted site before beginning treatment and reapplying throughout treatment.

11. *Energy settings can be titrated up or down based on the patient's comfort level.* Use a 0–4 patient feedback scale with a target goal of 2–2.5 (Figure 3).

12. *4th generation non-microneedling monopolar RF treatments should be repeated approximately every 12 months to maintain results and to continue to induce further skin tightening and smoothing.* Some patients may choose to "touch-up" in 6-months, others may wait up to 2 years to repeat. Treatment interval decisions may be based on patient age, what the patient wants to achieve / avoid and financial considerations.

13. *4th generation non-microneedling monopolar RF can be used in patients who have, or will, receive neurotoxins, dermal fillers and fractionated skin resurfacing ablative and/or non-ablative laser modalities, based on medical judgment.*

14. *When adding therapies, 4th generation non-microneedling monopolar RF may be done before, or after the other treatment depending on medical judgment, schedules, and convenience for the patient.* Should not be done on erythematous skin, ie, immediately post fractional laser.

15. *The wait period between 4th generation non-microneedling monopolar RF and injecting dermal fillers is based on patient preference and clinician judgment.*

16. *The wait period between 4th generation non-microneedling monopolar RF and injecting neurotoxins is based on patient preference and clinician judgment.*

17. *4th generation non-microneedling monopolar RF treatment-related side effects are very rare and generally mild.* To prevent superficial burns or other tissue damage, clinicians are urged to inspect the treatment tip membrane before, and periodically during, treatment to ensure integrity and to regularly apply generous amounts of coupling fluid. Of note, the historical concerns about fat atrophy, associated with earlier generations of the device, have not been observed with the current generation device. Furthermore, since the launch of the 4th generation non-microneedling monopolar radiofrequency device, the overall incidence rate of adverse events reported to the manufacturer, based on their sales of treatment tips equates to less than 0.05%.[15]

18. *Patients who are treated with 4th generation non-microneedling monopolar RF every 1-2 years may experience prolonged, consistent skin tightening that could help to prevent future sagging.*

19. *Achieving favorable results with 4th generation non-microneedling monopolar RF is dependent upon following proper patient selection and treatment guidelines, together with good technique.* Good technique constitutes 2–4 passes using moderate treatment levels, using the patient feedback scale where the treatment goal is *hot but tolerable*. The multiple passes are followed by 5–10 vector and contouring passes, treating to the clinical endpoint of visible or palpable tightness.

FIGURE 3. 4th generation non-microneedling monopolar RF treatment–Patient feedback scale.

DISCUSSION

Skin laxity and wrinkling are major findings associated with aging. The demand for noninvasive methods to decrease skin laxity and smooth irregular body contours has experienced exponential growth over the last two decades. Non-ablative aesthetic RF treatments have established a good safety record and are associated with minimal to zero downtime. The mechanism of action is based on an oscillating electrical current, forcing collisions between charged molecules and ions, which are then transformed into heat. RF generated tissue heating has different biologic and clinical effects, depending on the depth of tissue targeted, the frequency used, and specific cooling of the dermis and epidermis. A study that examined the thermoelastic response of cutaneous and subcutaneous tissues to RF heating demonstrated that there is greater power absorption in the fibrous septa filaments than in fat.[16] Heat disrupts hydrogen bonds of collagen molecules resulting in conformational changes. The denatured collagen fibrils immediately contract and then act as a tightened scaffold over which new collagen is laid down in the secondary/repair phase of wound healing, giving rise to skin tightening.[17] RF device settings and the number of treatment passes were shown in one study to have an important effect on collagen fibril change.[18] Increases in pass number at the same setting dramatically increased the extent of irrevers-

ible collagen fibril change, specifically, increase in diameter, as did increases in energy setting at a standard pass number.[18] The depth of penetration of RF energy is inversely proportional to the frequency. Consequently, lower frequencies of RF are able to penetrate more deeply into the dermal layers to stimulate collagen contraction and neocollagenesis.[19]

RF devices may be monopolar, bipolar, tripolar, polypolar, or combination. Monopolar systems deliver current through a single contact point with an accompanying grounding pad that serves as a low resistance path for current flow to complete the electrical circuit. Monopolar electrodes concentrate most of their energy near the point of contact and energy rapidly diminishes as the current flows toward the return pad.

The 4th generation non-microneedling RF system uses a high-frequency generator that produces a 400W, 6.78MHz monopolar current signal. A disposable membrane tip with a treatment area of 0.25, 3.0, 4.0, or 16.0cm^2 is used with a disposable adhesive return pad that serves as the passive electrode. The depth of heating is dependent upon the size and geometry of the treatment tip being used. A conductive coupling fluid is used during the treatment to enhance the thermal and electrical contact between the treatment tip and the skin. The treatment tip creates an electrical field within the tissue by alternating its charge from positive to negative 6 million times per second with electrons and ions simultaneously attracted and repelled from the surface. The movement of these ions generates heat, which results in immediate collagen denaturation with resultant fibril contraction and tissue thickening.[20] A secondary inflammatory wound healing response follows, resulting in collagen neogenesis, deposition, and remodeling along with gradual reduction in rhytides, tissue tightening, and improvement in skin texture in most patients. Skin surface cooling is maintained through the use of a cryogen gas spray, while comfort is improved by use of vibration and adjusting energy level of the handpiece according to patient feedback.

Recommended treatment algorithms with the RF device have significantly changed since their introduction to the U.S. marketplace nearly 18 years ago. Initially, patients were treated with a single pass of the RF device at high-energy settings, sometimes resulting in mixed clinical results and significant treatment discomfort. Subsequent treatment guidelines used a multiple pass technique with reduced energy settings, resulting in superior clinical results and significant reduction in patient discomfort.[12,19,21]

In developing these Consensus Statements, we aimed to provide clear, unambiguous, practical guidance for clinicians. However, we have steered away from providing numerical recommendations for treatment settings or retreatment intervals. For example, energy level selection is best determined by continuously evaluating the level of heat tolerance for individual patients during the procedure. Not only do patients have different pain tolerance but they also vary in skin composition, which in turn affects RF penetration, resistance, and thermal deposition within tissues. As such, each patient's feedback regarding tolerability is vital during treatment to avoid excessive thermal delivery to the skin.

Although there is an extensive body of clinical literature to support non-microneedling monopolar RF, and consensus panel recommendations have been published for previous generations of the device, these consensus statements represent the first, real-world, practical treatment guidelines for the 4th generation non-microneedling monopolar RF. While we recognize that each patient is unique and that guidelines will never replace individual clinical judgment, as the demand for noninvasive tissue tightening increases, so too does the need for positive, reproducible outcomes. Although improvement in skin laxity is not as pronounced as that observed with surgical lifting procedures, the advantages of RF procedures include a virtually nonexistent postoperative recovery period and extraordinarily low risk of serious adverse effects. Careful patient selection, pretreatment counseling, managing patient expectations regarding potentially modest results, thorough treatment planning and good technique, are all critical for success.

Doctors routinely rely on the scientific literature in addition to their own knowledge and experience when optimizing treatment for their patients. However, when no such literature exists, and a device is new to the market, additional tools, including these Consensus Statements, will assist clinicians to achieve successful outcomes for their patients.

Limitations

All guidelines have potential limitations, the most important of which is that recommendations may be incorrect for individual patients. Although these Consensus Statements were developed by internationally recognized experts in aesthetic dermatology, following a precise and transparent methodology, development of Consensus Statements is less rigorous than for evidence-based Clinical Guidelines. Furthermore, we lacked a systemic review of the literature, simply because the literature did not exist.

Given that patient expectations and outcomes represent an important aspect of this RF treatment modality, it could be argued that we should have diversified our expert to include other contributors, including patients.

Other limitations relate to the selected methodology. Although there are many advantages to using the Delphi technique, there are some important drawbacks. First, judgments in the second and subsequent rounds may be influenced by feedback given

over the course of the rounds because overall feedback is given to each participant. Second, is the lack of face-to-face collaboration, coupled with the increased potential for participant burnout as the number of rounds increases.

Finally, although these Consensus Statements provide clinicians with recommendations, further work is necessary to generate the data that would be needed to develop evidence-based guidelines. We encourage the manufacturer to support the development of a patient registry that would allow prospective collection of outcomes data from both patients and treatment data from clinicians.

DISCLOSURES

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Solta Medical had no role in the design or conduct of the study nor collection, management, analysis, or interpretation of the data; nor in the preparation, review, or approval of the manuscript.

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