

Tolerability of a Monopolar Radiofrequency Facial Skin Tightening Procedure: An Observational Study

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Monopolar radiofrequency (RF) treatment has generated interest among practitioners for patients seeking nonsurgical skin tightening procedures. However, adoption of this technology has been limited by a perceived lack of efficacy and pain associated with older devices. This prospective observational study assessed the tolerability of the newest generation Thermage CPT (comfort pulse technology) System (Solta Medical) for facial skin tightening. Upgrades of the device include integrated pulsed cryogen cooling, a vibrating tip, and an updated electrode that distributes RF energy over the entire surface of the tip. Twenty consecutive patients electing to undergo monopolar RF treatment for cheek, jawline, and upper neck tightening were enrolled in the study (mean age, 53.7 years; 95% female). Treatment was associated with mild to moderate discomfort caused by heat, which was assessed using a 5-point comfort rating scale. Six (30%) participants described the discomfort as mild to moderately hot (graded as a 2), while the remaining 14 (70%) participants described it as warm (graded as a 1). No adverse events were noted. All 20 participants expressed that the level of discomfort they experienced would not preclude them from undergoing future treatments. *Cosmet Dermatol.* 2011;24:327-330.

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Monopolar radiofrequency (RF) treatment has generated considerable interest among physicians and patients seeking nonsurgical skin tightening procedures. Radiofrequency devices utilize the principle of volumetric heating, whereby resistance to the flow of an electrical current generates heat in the targeted tissue. Tissue impedance varies based on body site, which directly affects the amount of energy delivered.¹ The resulting heat modifies collagen in the tissue, creating a contracted and denatured conformation that leads to subsequent tightening of the skin.^{2,3} Although the efficacy of RF tightening has been

established,³⁻⁹ widespread adoption of the technology has been limited by seemingly inconsistent results and pain associated with earlier-generation devices.

Technologic upgrades in the Thermage CPT (comfort pulse technology) System (Solta Medical) purportedly afford improved patient tolerability of monopolar RF treatment. Extensive data confirm the consistency of the results.⁷ In comparison to older devices, the new Thermage CPT System interweaves cryogen cooling bursts throughout the pulsed RF delivery. To enhance patient comfort, a vibrating mechanism is activated when the treatment tip comes in contact with the skin. The noninvasive electrode is designed to deliver RF energy more evenly over the entire surface of the tip to minimize focused RF heating at the edges. This prospective observational study assessed the tolerability of the device in tightening skin on the cheeks, jawline, and upper neck.

MATERIALS AND METHODS

Twenty consecutive patients at one practice site (SkinCare Physicians, Chestnut Hill, Massachusetts) electing to undergo monopolar RF treatment for cheek, jawline, and upper neck tightening were enrolled in the study. Patients were required to consent to providing pain feedback to participate in the study. Exclusion criteria included prior surgery in the treatment area, presence of a pacemaker, and history of silicone injections.

After vital signs were obtained, one 60-mg intramuscular ketorolac tromethamine injection was administered. Participants were subsequently instructed on the 5-point (0=no warmth [no pain]; 4=intense warmth [intolerable]) comfort rating scale (Table 1). After 45 to 60 minutes, treatment was initiated with the multiple-pass, low-fluence technique using the 3-cm² CPT vibrating tip.^{7,10} Participants were started at a treatment level of 2 (14 J/cm²) with vibration set at 1, and pain was assessed at the end of each pulse. If a participant's discomfort was rated a 2 or higher, the treatment level was decreased by a 0.5 increment and pain was assessed again after the subsequent pulse. Prior to beginning the treatment, participants were instructed that the optimal sensation with each pulse is a feeling of intense warmth or a slight pinch but no substantial pain. If participants were uncomfortable with the vibration, it was set to 0 (no vibration).

Immediately following the procedure participants were asked to assess their maximum level of pain during the treatment based on the intensity of the heat they experienced. Participants also were asked to respond yes or no to whether the discomfort they experienced would preclude them from undergoing future treatments.

TABLE 1

Comfort Rating Scale

Score	Heat Intensity	Comfort Description
0	No warmth	No pain
1	Warm	Tolerable
2	Mild to moderately hot	Tolerable
3	Very hot	Intolerable
4	Intense warmth	Intolerable

RESULTS

All 20 participants who were enrolled completed the study. The mean age of the cohort was 53.7 years (range, 38–71 years). Nineteen participants were female (95%) and 1 was male (5%)(Table 2).

Treatment level settings ranged from 0.5 (7 J/cm²) to 3 (19 J/cm²). Treatment times ranged from 44 to 63 minutes. Of the 20 participants, 6 (30%) described the discomfort as mild to moderately hot (graded as a 2), while the remaining 14 (70%) participants described it as warm (graded as a 1). No adverse events were noted. All 20 participants expressed that the maximum level of discomfort they experienced would not preclude them from undergoing future treatments. Two (10%) participants preferred to be treated without vibration. Of the remaining 18 (90%) participants, all were treated with a vibration level of 1.

COMMENT

Discomfort associated with monopolar RF skin tightening treatments is due to the conversion of RF energy to heat energy in the skin. Consequently, the comfort rating scale used to assess pain monitors the intensity of the heat patients experience throughout the procedure. In the past, pain experienced during RF tightening treatments substantially limited the widespread utilization of the technology. To achieve procedural tolerability using the original high-energy, single-pass technique, clinicians

TABLE 2

Participant Demographics

Participant No.	Age, y	Sex	Comfort Rating Score ^a
1	49	M	1
2	49	F	2
3	57	F	1
4	57	F	1
5	55	F	1
6	61	F	1
7	60	F	2
8	71	F	1
9	53	F	1
10	68	F	1
11	48	F	1
12	48	F	1
13	57	F	2
14	56	F	1
15	61	F	1
16	47	F	2
17	49	F	2
18	38	F	1
19	46	F	2
20	44	F	1

Abbreviations: M, male; F, female.

^aComfort rating scale: 0=no warmth [no pain]; 1=warm (tolerable); 2=mild to moderately hot (tolerable); 3=very hot (intolerable); 4=intense warmth (intolerable).

utilized topical anesthesia as well as nerve blocks. One study of 86 patients reported that despite measures for analgesia, 11% (19/172) of the cohort experienced severe pain (graded as a 3) and 2% (4/172) described it as intolerable (graded as a 4).¹¹ It is important to note that the employment of local anesthesia can compromise safety by eliminating the patient's awareness of intense heat. A study of 14 physicians who treated 5700 patients found that 45% of patients characterized the high-energy, single-pass procedure as too painful, while the low-energy and multiple-pass algorithm reduced the percentage of patients to 5%.⁷

The technologic upgrades of the Thermage CPT System that improve treatment tolerability include integrated pulsed cryogen cooling, a vibrating tip, and an updated electrode that distributes RF energy more evenly over the entire surface of the tip. The concept of vibration as a means of pain reduction is based on the gate-control theory of pain, which was introduced by Melzack and Wall¹² in 1965. This theory finds that stimulation of the large nerve fibers responsible for the transmission of vibrations would inhibit the summation of pain impulses transmitted by small nerve fibers.¹² Counterstimulation, whether a noxious or painless stimulus, is now well-known to reduce the perception of pain.¹³⁻¹⁷

The aforementioned study of 5700 patient treatments did not seek to address efficacy. The survey found that 94% of patients felt the treatment results met their expectations.⁷ Efficacy of the procedure is well-established,³⁻⁹ and in our experience, patient satisfaction mirrors the 94% reported by Dover and Zelickson.⁷

The newest generation Thermage CPT System as employed in this study was associated with mild to moderate discomfort, and none of the participants described the procedure as too painful. There were no adverse events recorded in this cohort, which is consistent with the reported levels of adverse events (0.05%–2.7%) associated with the multiple-pass, low-fluence technique.^{18,19}

The selection of appropriate candidates is important to achieve a positive outcome. Obese patients or those with severe skin redundancy should not be treated. The ideal candidate is aged 30 to 60 years with mild to moderate laxity of the jowls, midface, and upper neck/jawline.

This study group is representative of our cumulative experience with this monopolar RF device utilizing the CPT vibrating tip. Given the fact that monopolar RF is now a relatively pain-free procedure, the number of patients who may benefit from it has increased. In the past, efficacy limitations and pain precluded widespread use of monopolar RF for skin tightening. With the use of the multiple-pass, low-fluence technique, efficacy has

improved.⁵⁻⁷ The new CPT vibrating tip has dramatically reduced procedural pain. In the past, narcotic analgesia, such as meperidine, was routinely administered, along with sedation in the form of diazepam, to ensure patient comfort during Thermage CPT treatments. This regimen required the patient to secure a chaperone for transportation home after the procedure. With the new vibrating tip, pain medications that alter mental status are no longer needed. Intramuscular ketorolac is employed in some patients to allow for a more pleasant procedural experience. Although the entire cohort received ketorolac in this study, in our experience many patients have been treated without it with minimal to no variation in treatment settings. The procedure is associated with mild to moderate discomfort that is well-tolerated and patients can drive home afterward.

Monopolar RF is now accepted as an effective treatment of mild to moderate skin laxity. Although it will never replace or approximate the efficacy of a surgical facelift, RF can be a useful adjunct to a comprehensive skin rejuvenation program. As physicians better understand the efficacy of RF skin tightening, an interesting concept is being developed to consider using monopolar RF as a laxity prevention tool. Clinicians may now consider introducing the concept of preventative RF tightening, whereby treatment is instituted at the earliest sign of laxity to delay or altogether preclude the necessity for surgical intervention. Further studies are needed to investigate this potential new strategy for preventative monopolar RF skin tightening.

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