

“Deep Heating” Noninvasive Skin Tightening Devices: Review of Effectiveness and Patient Satisfaction

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ABSTRACT

Non-surgical aesthetic devices intended for treatment of lax and loose skin have gained popularity due to their ability to non-invasively improve patient's aesthetic condition and its low side effect profile. This study is intended to review available peer reviewed literature about Ultherapy, ThermoCool, and Exilis Ultra 360 non-invasive skin tightening devices to compare their treatment efficacy and patient subjective satisfaction.

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INTRODUCTION

Aesthetic improvement in the appearance of facial wrinkles, redundant facial, neck, or body laxity is a major feature of aging. Monopolar radiofrequency (RF) and ultrasound sources became a treatment of choice for non-ablative tissue tightening by volumetric tissue heating of the deep dermis.

Non-ablative radiofrequency devices have gained popularity because of their ability to offer improvement of skin laxity without the postoperative recovery or financial burden of surgical procedures. It remains in demand secondary to its lower side effect profile and remarkably short post procedural downtime.

This continuing shift away from ablative and invasive aesthetic procedures continues to be driven largely by patient and clinician preferences.¹ According to the American Society Aesthetic Plastic Surgery, 526,000 non-surgical skin tightening procedures (annual growth of 11 %) were performed in 2016 in the United States.²

The aim of this clinical paper is to review available literature for selected aesthetic devices utilizing deep tissue heating (Ultherapy, ThermoCool, Exilis Ultra 360). The data reported herein are based on a retrospective review of peer-reviewed clinical studies. Aforementioned devices are evaluated for safety and efficacy. In everyday practice, patient's perceived improvement typically outweighs the practitioner's scoring. Therefore, most of the clinical studies utilize subjective patient satisfaction scores.

DISCUSSION

Ultherapy (Ulthera, Merz North America, NC)

The Ultherapy procedure is indicated for use in: lifting skin on the neck, on the eyebrow and under the chin as well as improving lines and wrinkles on the décolletage.

The first aesthetic use of high intensity focused ultrasound (HIFU) was introduced in 2008 and it was FDA cleared for brow-lifting a year later. Currently, the microfocused ultrasound (MFU) is being used for non-invasive tissue remodeling.

Currently available transducers emit frequencies of 10.0 MHz, 7.0 MHz, and 4.0 MHz with focal depths of 1.5 mm, 3.0 mm, and 4.5 mm, respectively. The higher energy transducers allow energy deposition in smaller anatomical regions. The ultrasound beam is focused to a point less than 1 mm³ in size below the skin surface (in the superficial muscular aponeurotic system) to form “thermal coagulation points.”³ Temperature inside of such points is increased to 65°C. Superficial layer of skin remains unaffected. This results in immediate collagen contraction and initiates collagen synthesis. The device incorporates automatic ultrasound imaging of the tissue for controlled energy delivery and acoustic coupling of the probe. The treatment zone is 25 mm and 14 mm in length, for the standard and the narrow transducers, respectively. Treatment is administered in a “stamping” manner.

A prospective cohort study⁴ described results of facial treatment with the 4 MHz and 7 MHz transducers. At 90 days, 30 patients (86%) showed clinically significant brow-lift with a 1.7 mm mean elevation of the eyebrow. Fabi et al⁵ treated 70 patients on the neck. Quantitative assessment indicated that 72.9% of subjects achieved a visible tissue lift of > 20.0 mm² in the sub-mental area. Three months after, the improvement was still visible for 68.6% of patients treated in sub-mental and neck area, and for 67% of patients treated on face and neck.

The long-term efficacy was studied also by Fabi et al.⁶ At 180 days, physician GAIS score revealed that 77.7% patients achieved improvement in the face and upper neck area, while

patient evaluation resulted in 77.8% improvement. Blinded reviewers assessed photographs with an average score of 67%.

Park et al⁷ treated 20 patients with approximately 420 shots each spread among the supraorbital, zygomatic, infra-orbital, peri-orbital, cheek, pre-auricular, and jawline areas. Physician's GAIS scale evaluation (improvement: 0- none, 1- mild, 2- mild/moderate, 3- moderate, 4- severe) showed 0.9 overall improvement after 90 days, and it stayed unchanged when re-evaluated at 180 days. Patient satisfaction score was 3.80 and 3.65 at 3 months and 6 months, respectively (1- not satisfied; 2- somewhat satisfied; 3- satisfied; 4- very satisfied; 5- extremely satisfied).

Another study investigated improved efficacy when multiple treatment passes had been used.⁸ Neck and face were targeted using the 4 MHz transducer followed by the 7 MHz transducer on 10 patients. Clinicians reported 80% improvement at 90 days, with 20% patients showing no change. Patients reported 90% improvement by self assessment, but the overall outcome was in most cases described as mild or moderate (N=7). The mean pain score was 3.9 ± 1.66 (range, 2-7) on the VIS. No patient reported pain at the follow up.

Oni et al⁹ performed a large Ulthera sponsored study, evaluating improvement in lower face/neck appearance in 93 patients treated with 4 MHz and 7 MHz transducers. At 90 days, 65.6% patients reported their satisfaction with results, the remaining 34.4% saw no improvement. According to masked evaluators, improvement of skin laxity occurred in 54 patients (58.1%). In 16 patients (17.2%) there was no change, and in 23 patients (24.7%) their condition worsened. On a 0-10 scale, the average pain scores were between 5.68 and 6.53 for submandibular region (5- moderate pain, 6- increasing discomfort, 7- significant discomfort).

MFU was also studied for décolletage lifting and rhytids.¹⁰ At 90 days, 96 % patients showed improvement according to PGAIS score, 1 patient showed no results. According to SGAIS score, 100% of patients noticed some kind of aesthetic improvement, all of them were very satisfied (37.5%) or satisfied (62.5%) with provided treatment. At 180 days, they observed a decrease in all aspects of the outcomes. PGAIS decreased to 86 % and SGAIS decreased to 95%. The mean midclavicular-to-nipple distance decreased from 20.9 cm to 19.5 cm at the end of the follow up.

The most common post procedural findings were tenderness, edema, erythema, bruising, numbness, and welts. In a 2014 clinical study on Ultherapy's safety profile,¹¹ most unexpected AEs that happen in <0.4% of cases include pain, nerve irritation, numbness/paresthesia, lumps, swelling, tingling, itchiness, redness, hives/rash, headaches, swollen throat, and could be attributed to incorrect treatment techniques or they are classified as unrelated to the treatment. Gutowski¹² reported only mild side effects which resolved within 7 days, another

study¹³ reported side effects which lasted up to 3 months (skin pigment changes, neuropathic pain, bruising). To overcome pain-related side effects, topical or oral anesthetics were used in numerous studies, improving the somatic experience during the procedure.^{5,8,10,12,14}

Thermage ThermoCool (Solta Medical, San Francisco, CA)

The ThermoCool procedure is indicated for use in: Dermatologic and general surgical procedures for electrocoagulation and hemostasis; non-invasive treatment of periorbital wrinkles and rhytids including upper and lower eyelids; and non-invasive treatment of wrinkles and rhytids.

The system is made up of several components that allow delivery of electromagnetic energy to the skin through a single-use treatment tip, which cools down its surface while the RF energy is being delivered. Energy settings are determined based on anatomy of the treated area. Treatment tips come in various sizes, currently 0.25 cm², 1.0 cm², 1.5 cm², and 3.0 cm². Tip heats up the dermis to temperatures of 65–75°C, causing collagen denaturation while the epidermis is kept at 40°C. The cooling is provided by a continuous application of cryogen spray onto the inner surface of the tip membrane.

Initial studies showed modest results, particularly in improvement of wrinkle scores of the face, neck, and brow. These studies demonstrated that outcomes were more significant in younger patients and when treating larger surface area with increased number of treatments. Clinical results improved over time as 4-month scores were statistically higher than the 1-month scores. Areas less responsive to treatments included jowls, mandibular ridge, and neck. Because of significant pain, anesthesia and oral pain medication was needed.^{15,16} A long-term study of the skin tightening effect confirmed that multiple treatments might be beneficial to patients as evidenced by Suh et al.,¹⁷ where 8 patients were observed over 6 years after having an average of 4 sessions over that period.

Fitzpatrick et al¹⁸ investigated periorbital tightening on 86 subjects. Review of photographs showed improvement in 83% cases, with 14% patients seeing no change, and 3% patients worsened. The same evaluation method showed lifting of eyebrows in 62% cases. Patients were satisfied or very satisfied with the treatment outcome in 50% of cases, with 49% patients claiming their appearance improved. According to subjective comfort rating, only approximately 7.5% of treatments (counted for both sides of face) were painless, the remaining 92.5% patients reported mild/moderate/severe/intolerable pain.

Fritz et al¹⁹ treated one group with single treatment (N₁=11) and the second group with two treatments one month apart (N₂ = 9), to evaluate the outcome of multiple treatments to

nasolabial fold improvement. Patients who received two treatments showed higher rate of improvement in self-assessment rating. The overall change noted by physicians and patients was modest, reaching the maximum of 14-16% improvement. Three patients reported less than 10 % of overall improvement. All patients experienced mild or mild-to-modest erythema.

Another study²⁰ focused on cheek and neck laxity treatment found a 35% to 40% subjective improvement of nasolabial and melolabial folds appearance, and 30% to 35% subjective improvement of neck laxity after one treatment session. Patients described the procedure as moderately uncomfortable.

A multi-center study²¹ evaluated low-fluence algorithm intended for facial laxity treatment. At 4 months, 95% of patients showed improvement. Most patients (65%) had reported good improvement (range, 26-50%) or very good improvement (range, 51-75%). Five percent of patients showed no improvement. Results were similar at 6 months when the number of patients with no improvement increased to 8 %. Subjective satisfaction was 78% at 4 months, and decreased to 70% at 6 months post treatment.

Short-lasting post procedural findings, such as erythema and edema, are reported in the majority of patients.²² Edwards et al²³ reported that erythema lasted less than 24 hours in 50% patients; 1 patient had edema that lasted beyond one week. Weiss et al. performed a large-scale retrospective study²⁴ and identified some of the rarer side effects of crusting, oozing, scarring, bruising, pigment alteration, nerve damage, texture change, atrophy, burns, and prolonged swelling, pain, or erythema. There was one case of fat atrophy causing a small depression on the cheek, and one superficial linear crust. These resolved in 3.5 months and one week, respectively.

A degree of pain reported without pain management interventions in the earlier studies was severe (6 of 10 on a 1–10 pain scale)¹⁷ and vibration was added to modify pain fiber recruitment.²⁵ Also the application of topical anesthetics is recommended prior to the treatment to increase tolerability.^{16,18,20,21}

Exilis Ultra 360 (BTL Industries, Boston, MA)

The procedure is FDA cleared for use in: non-invasive dermatologic and general surgical procedures for non-invasive treatment of wrinkles and rhytids, to provide a temporary reduction in the appearance of cellulite.

The system is the latest generation of device based on the Exilis platform. As such the review also includes all evidence relating to the older generations of the device. It is a monopolar RF device with ultrasound component, and a number of built-in safety features, including integrated Peltier cooling. The system has 2 types of different hand applicators, one designed mainly

for the face, and one for the body. During the treatment, the temperature in the treated tissue is raised to 40-45°C while the handpiece is in continuous motion so that areas of skin with the most laxity can be specifically targeted. When targeting deeper layers, the skin is cooled and protected, allowing the heat to reach deeper. Any spikes in RF delivery are automatically eliminated due to constant energy flow monitoring. This virtually eliminates the risk of burns. As such, it allows use of higher power, which then leads to shorter treatment times.

Efficacy of the system on collagen remodeling was first studied by stereological analysis in a veterinary study, which showed large-scale increase of collagen ($P=0.018$) in the treated area.²⁶ The subjects received 4 treatments. Based on evaluation of 54 histological samples of epidermis and dermal-epidermal junction, the collagen content in the tissue increased from 9% to 26% (288% increase) at the 3-month follow-up.

Weiss and McDaniel²⁷ confirmed that modified 2-treatment only protocol is well tolerated by subjects, and produces significant subjective as well as objective improvement. Three months post treatments, 92% of patients showed improvement in skin laxity based on evaluation of photographs. No adverse events were reported. Objectively, skin density increased by 19% at 3 months. Biopsies showed increase in dermal collagen and elastin fibers which correlated with subjective patient evaluation.

A recent study²⁸ proved a high degree of versatility of the system when evaluating efficacy on multiple body parts. Patients (N=34) were divided according to their indication, and were treated for laxity on face, arms, as well as for fat in thighs and abdomen. Four 30-minute treatments were applied. Independent evaluators recognized patient baseline photographs from the 3-month follow-up in 92 % cases, with all groups scoring above 90 % (the highest on facial photographs with 93%, the lowest on arm photographs with 90.5%). On average, 8% patients showed no response. Patients satisfaction averaged 4.15 on a given scale (5- Strong satisfaction to 1- Strong dissatisfaction), and they agreed that the treatment was comfortable with average score of 4.06 (5- Strongly agree, 1- Strongly disagree). There was no post-treatment pain or skin damage.

The efficacy for fat treatments was described by McDaniel et al.²⁹ The study proved that the unit can selectively heat fat, causing apoptosis of adipocytes. The skin surface remained intact, while subcutaneous fat showed apoptotic index increase from 7% to an average of 44% after the last treatment. Study also proved safety through histological analysis, blood chemistry, and hematology samples.

The efficacy has also been investigated when treating laxity of female intimate parts. A study published in *Lasers and Surgery*

TABLE 1.

Comparative Summary of Non-Invasive Skin Tightening Devices

	Ultherapy	ThermaCool	Exilis Ultra 360
Manufacturer	Merz (NC)	Solta Medical (San Francisco, CA)	BTL Industries Inc. (Boston, MA)
Technology	Microfocused Ultrasound	Monopolar RF	Monopolar RF
Mechanism of action	Collagen denaturation and subsequent synthesis ⁹	Collagen remodelling ¹⁸	Collagen remodelling; increase of elastin and collagen fibres (small applicator) ²⁶ , fat apoptosis (large applicator) ²⁹
Treatment Time (Full Face in min)	60-85 ^{9*}	60-120 ^{15*}	45 ²⁸
Number of Treatments	1-2 ⁹	1-2 ¹⁵	2-4 ^{27,28}
Therapeutic Temperatures (°C)	65	65-75	40-45
Anesthetics	YES	YES	NO
Clinical Efficacy	58.1-96.0 % ⁵⁻¹¹	47-95 % ^{18,19,20}	89-93 % ^{28,31}
Patient Satisfaction	65.6-95.0 % ⁵⁻¹¹	53-78 % ^{19,21,22}	77-95 % ^{28,30,32}
Pain (0-10 score)	3.9-6.53 ^{9,10}	6 ¹⁸	No data
Non-responsive Patients	14 - 20.0 % ⁹⁻¹¹	5 - 14 % ^{19,22}	3 - 8 % ^{28,31}
Worsening of Patient's Condition	24.7 % ¹⁰	2.5 % ¹⁹	No Data
Serious Adverse Events	Rare	Rare	None

*Including anesthesia

in Medicine³⁰ presents an average 2.9 point (of maximum 4) improvement in vulvar appearance after 4 treatments, accompanied by increased sexual function measured by FSFI score from initial 75% to 87%. No adverse events were reported. Later on, vaginal treatments have also been studied by other investigators.^{31,32}

In general, post procedural findings included only mild erythema which is also considered the therapeutic endpoint of a proper treatment. No adverse events, nor long-lasting side effects have been reported.

CONCLUSION

A summary of most important disciplines is in Table 1, comparing aspects crucial from both the physician's and patient's perspective. The data is based on available peer-reviewed trials. Quantitative comparison is stated in percentages due to non-uniform approaches to efficacy and safety evaluation in the respective studies.

All 3 devices have solid clinical evidence behind and proved efficacy in tissue laxity treatment. Exact clinical efficacy varies among the devices and also seems to be dependent upon the study design, treated body part and selected outcome measures. Some of the studies have been sponsored by the manufacturers (Oni et al., White et al., Polder et al., etc.), thus leaving room for bias.

Two of the devices leverage higher therapeutic temperatures to achieve results at a smaller number of treatments. This seems to be paid off by increased patient discomfort and the need to use anesthetics, which also prolongs the overall time needed for each session. Exilis Ultra 360 protocol consists of 4 treatments, but shows higher patient comfort. The efficacy of two-treatment protocol was also investigated and proved by Weiss et al. More evidence is likely to appear over time, but as of now there seems to be no clear correlation between the 3 different therapeutic temperatures and clinical efficacy.

None of the studies investigated in more detail how the patient profile influences clinical results. Number of non-responding patients is comparable for Exilis Ultra 360 and ThermaCool devices, ranging from 3% to 8%. Ultherapy studies show slightly higher percentage of non-responders, which was reported by Oni et al. (17.2%), Lee et al. (20%), or Fabi et al. (14%). Oni et al. also reported that after Ultherapy treatment, for 24.7% patients the post-treatment outcome was evaluated as worse against the baseline. Additional research is needed to allow for proper expectation management in patients.

This retrospective review primarily focused on patient satisfaction and treatment efficacy based on comparison of validated peer reviewed articles of three non-surgical skin tightening devices. Despite the slight differences in principles of mechanism

of action, all reviewed devices proved their therapeutic effect on tissue tightening. While the Ultherapy device is specialized mostly on the face, neck and décolletage area, the ThermoCool, and Exilis Ultra 360 are widely used to treat different body parts. The highest rate of versatility offers the Exilis Ultra 360 device, which can be used for treating additional areas such as back, hands, bra fat, forearms, thighs, and female intimate parts.

DISCLOSURES

Dr. Chilukuri is a speaker/consultant for the following companies: Alastin, Allergan Aesthetics, BTL Industries, Cynosure Lasers, Eclipse Micropen, Emvera Lasers, Galderma Aesthetics, PCA Skin, Skin Medica, Suneva Aesthetics, and Theravent Lasers. Dr. Lupton has no conflicts of interest to declare.

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