

Microfocused Ultrasound for Skin Tightening

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KEYWORDS

• Noninvasive skin tightening • Ulthera • Microfocused ultrasound • Thermal injury zones

KEY POINTS

- Noninvasive skin tightening is possible in one treatment session using Ulthera microfocused ultrasound.
- Results may not be seen until 3 to 6 months after treatment.
- Some patients may not see improvement after treatment depending on individual patient treatment response and the energy delivery protocols used.

INTRODUCTION

The continued patient demand for nonsurgical and minimal downtime facial rejuvenation has resulted in more use of injectable neurotoxins and fillers, and skin resurfacing and tightening treatments. Tissue heating either by radiofrequency (RF) or microfocused ultrasound (MFU) can be part of the overall treatment plan to tighten skin and even elevate facial structures. MFU generates heat in deeper dermis and subcutaneous tissue, leading to new collagen synthesis and subsequent skin tightening and elevation.

COLLAGEN DENATURATION AND NEOCOLLAGENESIS

When collagen is exposed to 60°C to 65°C, it becomes denatured. One study showed that new collagen synthesis is observed after 30 days and another study showed new collagen and elastin synthesis at 10 weeks, along with deposition of new hyaluronic acid.^{1,2}

MECHANISM OF ACTION

Ultrasound medical devices use sound waves for diagnostic imaging or medical treatments. Higher ultrasound frequencies have more superficial tissue effects and lower frequencies have deeper

tissue effects. When ultrasound waves are microfocused to a point in living tissue, molecular vibration results and heat is generated creating well-defined thermal injury zones at predetermined depths while leaving the surrounding tissue unaffected. At the resulting tissue temperatures, collagen contraction, and denaturation is seen and neocollagenesis is stimulated.

MFU is different from RF energy in that it can be microfocused to target deeper tissue without affecting more superficial tissue. Unlike RF energy, MFU can heat deeper tissue to between 60°C and 70°C without damaging the skin. For an RF device to achieve high temperatures, surface cooling is needed to protect the skin.

ULTHERA MICROFOCUSED ULTRASOUND SYSTEM

The Ulthera system (Ultherapy) was approved by the US Food and Drug Administration in 2009 for noninvasive eyebrow elevation but is routinely used for panfacial and submental treatments. Depending on the device settings, the target tissue can be set to variable depths:

- 1.5 mm
- 3.0 mm, which targets deep dermis
- 4.5 mm, which targets the superficial muscular aponeurotic system (SMAS) and platysma

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The Ulthera system delivers transcutaneous MFU energy from an operator-controlled hand piece (**Fig. 1**) and a monitor allows direct visualization (**Fig. 2**) of where the energy will be delivered so that specific structures such as bone can be avoided. The focal energy delivery is given in predetermined “lines” results in discrete intervals between 1 mm³ coagulation zones that promote healing.

INDICATIONS

Although the currently approved indications are listed below, other facial and nonfacial areas have been treated:

- Lift eyebrows
- Lift submental tissue (chin and neck)
- Improve lines and wrinkles in décolleté

HISTOLOGIC STUDIES

An early prototype Ulthera device was used on the lateral cheek region in patients who would be undergoing a surgical rhytidectomy within 12 weeks of treatment.³ Skin histology showed consistent and reproducible thermal injury zones in the dermis, without injury to the epidermis, which was absent by 12 weeks. Another study⁴ showed more dermal collagen in the reticular dermis (24% increase) 2 months after treatment resulting in a mean increase in dermal thickening from 1.32 to 1.63 mm. Elastic fibers of the upper and lower dermis were more parallel and straighter.

TREATMENT TIMES

Treatment times for the full face and neck are generally less than 90 minutes, but vary depending on provider experience, aggressiveness of

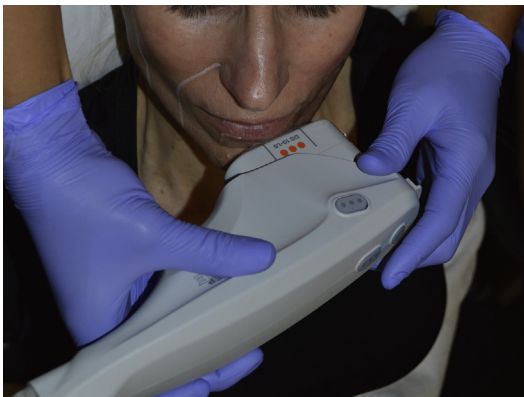


Fig. 1. Patient treatment with Ulthera microfocused ultrasound hand piece.

protocol, patient comfort, and treatment surface area.

- Face – 30 to 60 minutes
- Neck – 30 to 45 minutes

PRETREATMENT

- Topical betacaine/lidocaine/procaine cream for 60 minutes⁵
- Topical lidocaine/tetracaine (7%/7%) for 45 minutes⁶

SPECIFIC APPLICATIONS

Face and Neck

A prospective rater-blinded study of the forehead, temples, cheeks, submental region, and side of neck measured outcomes at 90 days.⁶ Probes used were 4 MHz, 4.5-mm focal depth (source energy 0.75–1.2 J), 7 MHz, 4.5-mm focal depth (source energy 0.75–1.05 J), and 7 MHz, 3.0-mm focal depth (source energy 0.4–0.63 J). Ultrasound pulses were administered every 1.5 mm along each treatment line with 3 to 5 mm between treatment lines. Thirty of 35 patients (86%) had a clinically significant improvement in brow elevation (mean, 1.7 mm). Unfortunately, the imaging used in the study design did not allow for conclusions to be made regarding improvement of other treatment areas.

Periorbital Region

As with any energy device, extreme care is needed when treating the thinner periocular skin. Direct treatment of eyelids over the eye itself is not indicated. Upper eyelid improvement can be seen after treatment of the forehead and brow owing to brow elevation.

Two studies of lower eyelid treatments, both in Asian patients, showed improvement in infraorbital laxity. Quantitative improvement was seen after targeting the lower eyelid skin and orbital septum with 1.5-mm and 3.0-mm probes in a small series of 7 patients.⁹ A larger study of 15 patients^{7,8} also showed improvement in most patients. Histologic analysis confirmed increased collagen and elastin fibers in the reticular dermis, but there was no significant change in the epidermis.

Nasolabial Folds and Jaw Line

A prospective, blinded evaluator study of 22 patients using 7.5- and 4.4-MHz hand pieces, delivering energy to a focal depth of 3.0 and 4.5 mm with linear arrays spaced in parallel at 3 mm, evaluated the nasolabial folds and jaw line.⁴ Two months after treatment of the face and

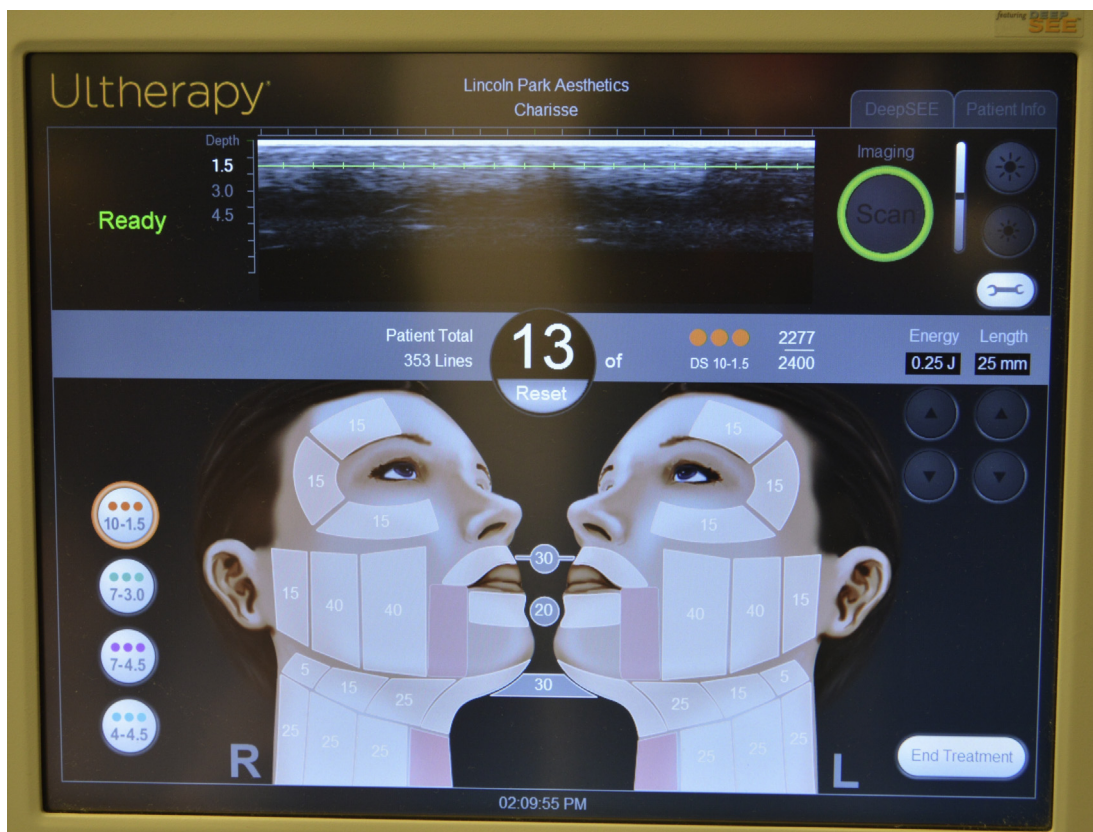


Fig. 2. Ulthera screen display. The upper one-third of the screen shows the depth of tissue treatment.

submental area, all patients demonstrated nasolabial fold and jaw line improvement, 77% and 73% of patients subjectively reported “much improvement,” respectively.

Superficial Musculoaponeurotic System

A cadaver study of transcutaneous Ulthera energy delivery in the face demonstrated thermal injury zones in the SMAS along with SMAS contraction proportional to the amount of energy delivered.⁹ The epidermis and sub-SMAS structures were not affected. These findings suggest that not only dermal contraction, but also deeper support structural improvement contributes to the aesthetic improvements seen after treatment.

Buttocks

A single study evaluated ultrasound skin tightening and smoothing of the buttocks.⁵ Using transducers with 3.0- and 4.5-mm focal depths, an area of twenty-five 1-inch by 1-inch squares was treated. The mean number of treatment lines delivered to the right buttock was 973 (the left buttock served as a control). In most cases, the highest energy

levels were not used owing to patient preference. Standardized blinded assessment and patient satisfaction was measured. Although 17 of 19 patients (89%) showed objective improvement at 180 days, only 68% expressed overall satisfaction and most would not recommend it to family or friends. Furthermore, pain scores were high and may have limited the amount of energy delivered to the treatment area. It is possible that improved treatment protocols and patient selection may yield better results.

Arms, Thigh, and Knee Skin

Because skin aging is not limited to the face, patients (usually women) commonly seek skin tightening of the upper arms, inner thighs, and the area just above the knees. One small study included 6 of each of these areas using 1 (single plane) or 2 (dual treatment depths) treatment passes.¹⁰ After 6 months, blinded assessors found more skin lifting effect in the upper arms and knees than in the inner thighs. The dual treatment depth areas had slightly better clinical improvement scores. Eighty-one percent of patients were highly satisfied and all patients opted to have more treatments at the same site or at other sites. Despite the reported favorable

results, the published before and after images show modest improvements.

Non-Caucasian Ethnic Groups and Skin Types

Most studies were on Caucasian skin types. Chan and colleagues¹¹ reported on 49 Chinese patients with Fitzpatrick skin types III and IV followed for up to 6 months. As in other studies, most patients had transient erythema and edema. Two cases of postinflammatory hyperpigmentation were seen on the forehead at 1 month.

Of 22 Korean patients with Fitzpatrick skin types III to VI treated with Ulthera, 2 developed whitish wheals or striations but no further details were provided.⁴

Pain and Comfort Management

One frequent complaint of the Ulthera system is pain during treatment. Moderate to severe pain may limit the amount of energy delivered, decrease the treatment areas, and increase treatment duration times. Topical anesthetics can provide some relief, but when not used, 54% of patients reported their pain as being "severe." Specific protocols for comfort management during treatment have not been developed but the following options are available and include:

- Nitrous oxide gas
- Oral nonsteroidal antiinflammatory medications
- Oral narcotics
- Oral anxiolytics
- Topical anesthetics
- Injectable anesthetic nerve blocks
- Distraction techniques
- Cool air devices and fans
- Precooled ultrasound gel

These modalities may be used alone or in combination depending on patient tolerance and clinical judgment.

Based on small pilot trials,¹² the following was found during Ulthera treatments:

- No difference in pain relief between 800 mg of ibuprofen versus 10 mg hydrocodone/500 mg acetaminophen given 60 minutes before treatment
- No difference in pain relief between topical liposomal lidocaine and a placebo control
- Lower energy treatment levels had less discomfort that higher energy levels without a difference in clinical outcome at 180 days

Although inflammation is a necessary component of neocollagenesis after Ulthera treatment, it is

unknown if chronic nonsteroidal anti-inflammatory medication use may interfere with the final outcome.

Recovery and Down Time

Other than the mild tissue reactions described elsewhere in this paper, the Ulthera system can be considered to have no down time and a minimal recovery period. No specific aftercare is needed.

Side Effects and Complications

Most published studies reported only mild side effects, typically mild erythema and edema that usually resolves after 2 days but no longer than 7 days.⁶ However, some patients reported transient bruising, skin pigment changes,⁹ and neuropathic pain for up to 3 months, after treatment. A small group of patients also reported numbness of the jawline, which resolved within 3 weeks.⁴ A review of the literature focusing on the safety of MFU confirmed that side effects are generally mild and transient in nature.¹³

RESULTS

Collagen contraction immediately after treatment may result in an initial tissue "lift." There is also mild edema that contributes to the early aesthetic improvement seen by patients. However, the heat-induced collagen synthesis and remodeling can persist for up to 1 year. A typical result is shown in **Fig. 3**. Because ideal candidates tend to have mild to moderate aging, those with more severe aging, sagging skin, and platysmal bands are likely to be better served by surgical treatment.

As with any noninvasive aesthetic treatment, not all patients and clinicians see an improvement. A 2010 study by Ulthera, 51 of 70 patients (73%) had a quantitative improvement in tissue lift in the submental areas after 3 months. Of those 51 patients, 84% (43 patients) had a qualitative improvement as determined by blinded assessors. Therefore, the overall positive response was 61%. Overall patient satisfaction was 67%. Because the energy density settings were about one-half of the density recommended, it is likely that a higher response is possible if more aggressive treatment protocols are used. A follow-up study of 64 patients found 64% to 79% of patients reporting some degree of improvement between 2 and 6 months after treatment. The group that included jowl treatment had lower satisfaction scores.¹⁴

One independent study¹⁵ of 10 patients with standardized photography and blinded, experienced clinician evaluators found that 2 of the patients (20%) did not show any improvement. Patient self-assessment found 1 patient (10%) who



Fig. 3. A 45-year-old woman before (*left*) and after (*right*) ulthera treatment of lower face and submental region.

reported no improvement and 2 patients (20%) who reported only mild improvement. However, treatment protocols, the amount of energy delivered, and individual patient factors make generalizations on expected outcomes difficult. Older patients with less “healing potential” may not respond as well as younger patients.

In the largest Ulthera sponsored study with qualitative and quantitative imaging assessment,¹⁶ 58% of 93 patients had improvement in skin laxity after 3 months, as determined by blinded reviewers. In patients with a body mass index of greater than 30 kg/m², 55% of patients did not have a change, compared with 12% of patients with a body mass index of 30 mg/kg² or less. At the same time, 66% of patients perceived an improvement in skin laxity of their lower half of the face and neck. All patients received a superficial and deep treatment of approximately 295 lines. It is possible that a higher treatment density (more lines) and assessment at 6 to 9 months may have shown more favorable responses.

Duration of Results

Although no skin tightening procedure can claim permanent results, the long-term outcomes of energy-derived skin tightening devices is lacking. Surgical procedures (face and neck lifts), however, have demonstrated continued improvement at up to 10 years.

Physician Oversight

Physicians may administer the treatments themselves, but in most cases, nurses or trained aestheticians provide the service. Specifics of oversight regarding patient evaluation and physician availability vary according to local regulations.

TREATMENT PROTOCOL VARIATION

Because not all patients may not respond to treatments, there is room for increasing the treatment line density. Experienced Ulthera user consensus group participants reported high rates of efficacy when using 600 to 800 lines per treatment. Treatment densities of up to 1500 lines have been used, but there seems to be little clinical return after 1200 to 1500 lines.¹⁷ Therefore, physician assessment and a patient-specific treatment plan should be done for each patient.

Other Treatment Options

Ulthera is only 1 option in the facial rejuvenation armamentarium.

- Brow elevation can be achieved with neuro-modulators and injectable fillers
- Facial and neck skin tightening can also be achieved by a variety of energy devices, including RF
- Injectable fillers and fat grafts can result in mid and lower face elevation
- Lower facial skin laxity and jowls have been treated with conservative laser-assisted liposuction
- Mid and lower face elevation can be achieved with percutaneous barbed “threads”; however, the results are temporary
- Submental fullness can be reduced with deoxycholic acid (Kybella) injections
- Submental fat reduction and skin contraction can be achieved with traditional liposuction (with possibly enhanced results using laser-assisted liposuction)

More invasive and surgical options should always be discussed with patients as more severe

aging may be less responsive to noninvasive treatments.

SUMMARY

MFU is a noninvasive facial skin tightening technology with minimal down time that can complement other noninvasive treatments. However, variability in patient response needs to be considered and future improvements in treatment protocols may improve response rates. Outcomes may be better in patients with mild to moderate facial aging and in those with a body mass index of 30 kg/m² or less.

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