UTIMS

A3 PLUS

SAFEST HIFU SYSTEM

TREATMENT MANUAL

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UTIMS

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SAFEST HIFU SYSTEM

What is **HIFU?**

High Intensity Focused Ultrasound

HIFU History

HIFU is a highly precise medical procedure using high intensity focused ultrasound to heat and destroy pathogenic tissue rapidly. The earliest widespread use of HIFU was a s a treatment for prostate cancer.

UTIMS Features

- Stable power and exact focusing thermal coagulation.
- Various applicable cartridges such as 1.5mm, 3mm, 4.5mm are used for face lifting.
- Good for combination with other treatments such as RF, Fractional Laser, Botox, Filler and so on.
- Face lifting as well as body contouring based on non-invasive treatment.
- The HIFU can be delivereing into target layers for SMAS and dermis without damaging surrounding tissues.
- It is possible to deliver the sophisticated energy for around the eye area using superficial depth cartridge.

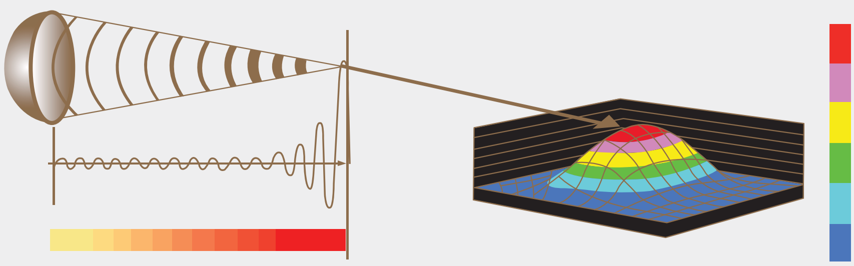
HIFU Fact Sheet

HISTORY: The earliest widespread use of HIFU was initially used for the treatment of prostate cancer. This was a highly precise medical procedure using High Intensity Focused Ultrasound energy transmitted in a mechanical wave form to heat and destroy pathogenic tissue rapidly.

HIFU Principle

Generate HIFU (High Intensity Focused Ultrasound) → Induce a Vibration in Molecules of the Target Area → Lead to Thermal Energy Caused by Friction → Form Thermal Coagulation Zone

Focused Transducer Emitting Ultrasound Waves



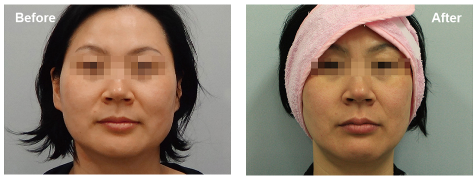
This mechanical wave of energy delivered is focused into thermal injury spots and repeated multiple times along a straight line. Advanced HIFU systems are able to deliver these lines of spot coagulation in both directions of the cartridge for efficient and profitable treatments. Such systems deliver on an average 300 lines in 8 minutes, completing a full face and neck within 30 minutes without operator fatigue. Ultrasound can be focused at frequencies of 1-7MHz with a high degree of precision. An important aspect of HIFU is that the damaging focal point is located several millimetres below the surface of the skin and tissues above and below the focal points remain unaffected. Due to the absorption of this energy, the temperature of tissues rise to more than 60°C with the vibration of cells and this stimulates the cells for collagen production and tissue rejuvenation.

Safe High Speed Treatments

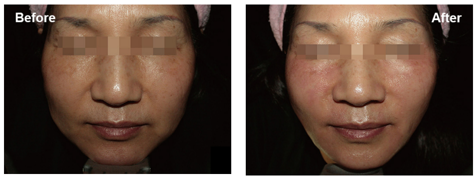
Several Clinical Studies have been done to evaluate the clinical efficacy and safety of HIFU (High Intensity Focused Ultrasound) on Skin Laxity and Wrinkles. **All the experimental data obtained from dermatologists and patients showed that HIFU appears to be a safe and effective modality for skin laxity treatment.** Some of the Clinical Studies also comment on the use of Radio Frequency to be introduced before HIFU so as to reduce the uncomfortable heat (produced in the Thermal Injury Zones) that some patients may feel and also to provide more client satisfaction immediately, as the final results do take up to 90 days to complete the collagen production provided by the HIFU treatment. A mild heat may be felt by the patients post treatment, however it is not uncomfortable and the feeling of tightening also felt for a few days to a week appears to reassure the patient that some cellular activity is happening below the dermis encouraging them to wait to see far more visible results over the following months.

Before & After

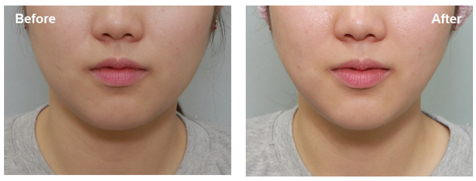
Lower Face After



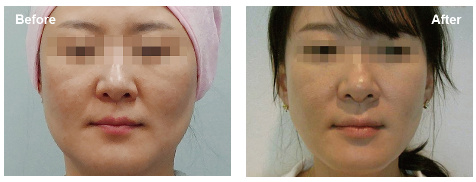
Lower Face After



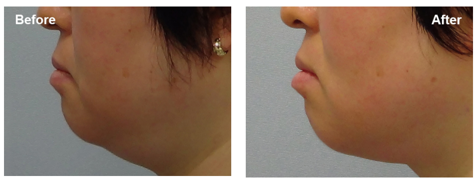
Lower Face After



Lower Face After



Lower Face After



Lower Face After

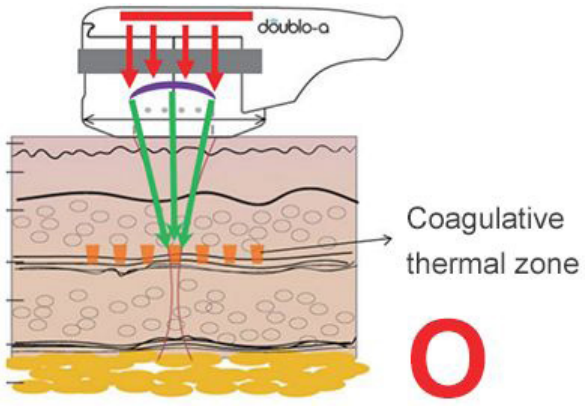
Eyes After

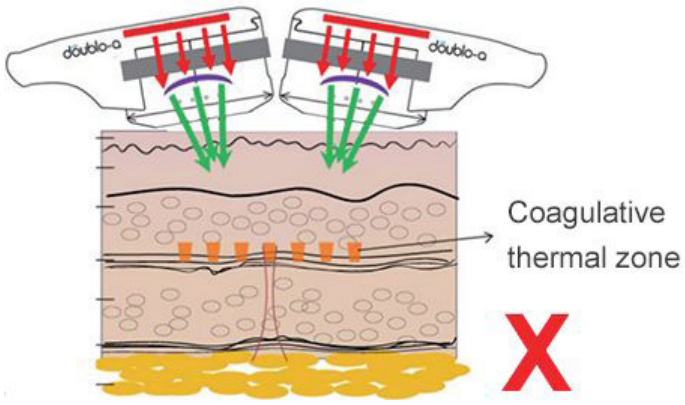
Eyes After

Eyes After

Pre-cautions to take during the HIFU Procedure

1. Make sure that the ultrasound gel is not applied too thickly. Best to apply it to the cartridge directly.
2. Make sure that energy is not directly irradiated on boney areas during the procedure, such as cheek bone & jaw bone.
3. Carry out the procedure in consideration of the locations of the blood vessels and nerves. (Refer to your chart).
4. Make sure that the contact surface between the cartridge and the skin does not move or slip off during the procedure. Use your 2 fingers from your other hand to prevent cartridge slips.





Side effects of the procedure and post-procedure treatment

Pain

1. Pain is caused by heat producing collagen in the thermal injury zones
   - Topical anesthesia / nerve block is not necessary
   - Areas of attention must be paid to: Bony prominence (forehead/cheekbone/jaw)
   - As the soft tissue is relatively thinner, HIFU targets deeper portions often targeting the periosteum.

2. To prevent toothache
   - Avoid treating over dental prosthesis and orthodontic braces.
   - Reduce the power & use D4/M7 to avoid the nerves around the mouth which are more superficial.
   - During the procedure, inflate the cheeks with air to avoid any kind of toothache.
   - Put gauze in the mouth between the lips and front teeth or hold the lips with thumb & index finger while doing the HIFU.

Nerve Injury Protection

The pain or nerve reaction that the patient complains about during the procedure is an important indicator of too much power or too close spacing of dots.

- The nerve block is not recommended.
- If painful, stop the procedure for a moment and do muscular exercise right away for a few seconds or massage the area.
- **Around the mouth:** Pay attention to the Branch Nerves near the mouth of Infraorbital n. and Mental n.
- **Around the eyes:** Pay attention to Supratrochlear n. and Infraorbital n.
- **Around the chin:** Pay attention to the area where the mandibular n. comes around the mandible margin.

Thermal Injury

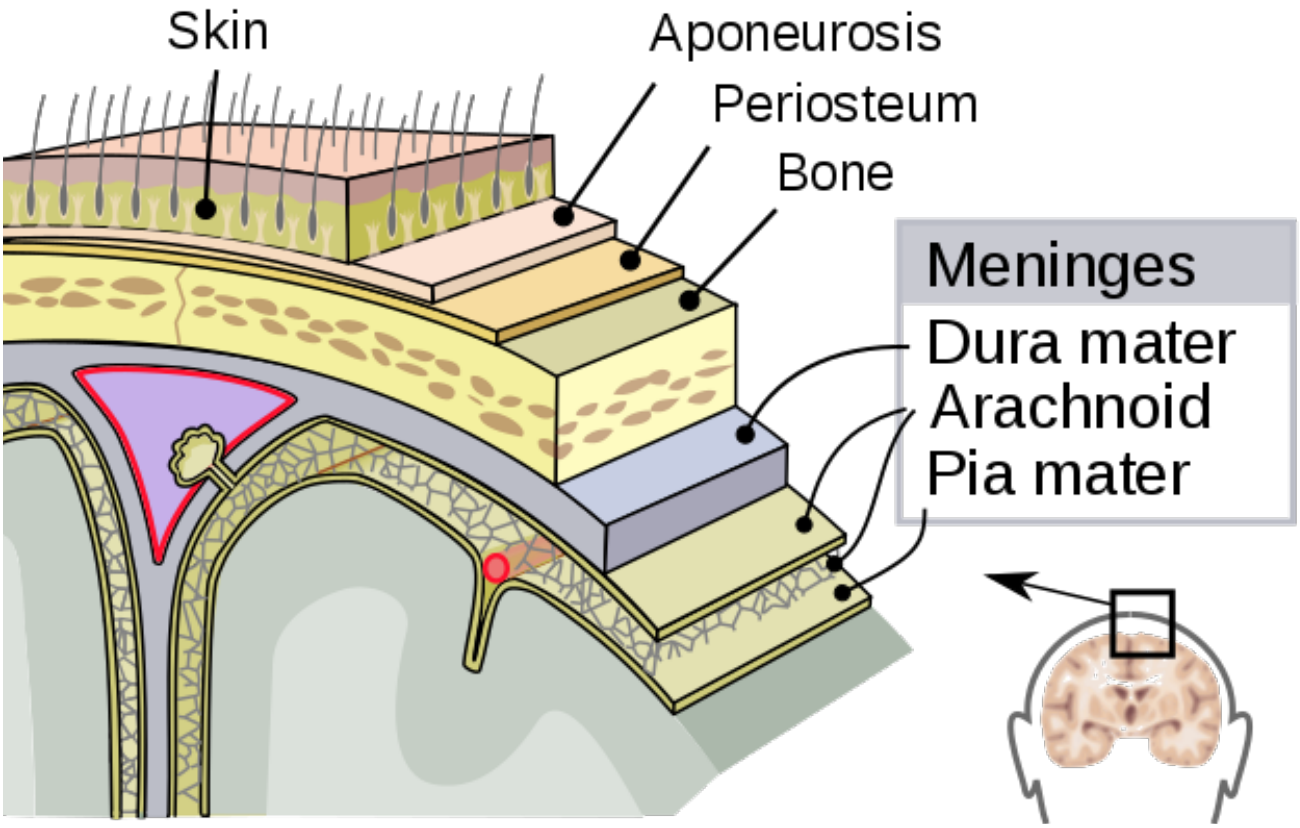
Due to the high level of energy, the thermal injury area increases and may burn the skin surface if spacing between the thermal dots are not increased.

- *Causes of pain or injury
  1. Too strong energy is generated, so reduce power.
  2. Energy is applied continuously to the same area, so move the cartridge as the lines are delivered.
  3. The spacing is too narrow for the energy expansion so increase spacing of the dots.
- Poor contact between the cartridge and the skin, so use more pressure to keep in contact with the skin
- Heat is generated on the ultrasound penetration surface, if contact is lost.

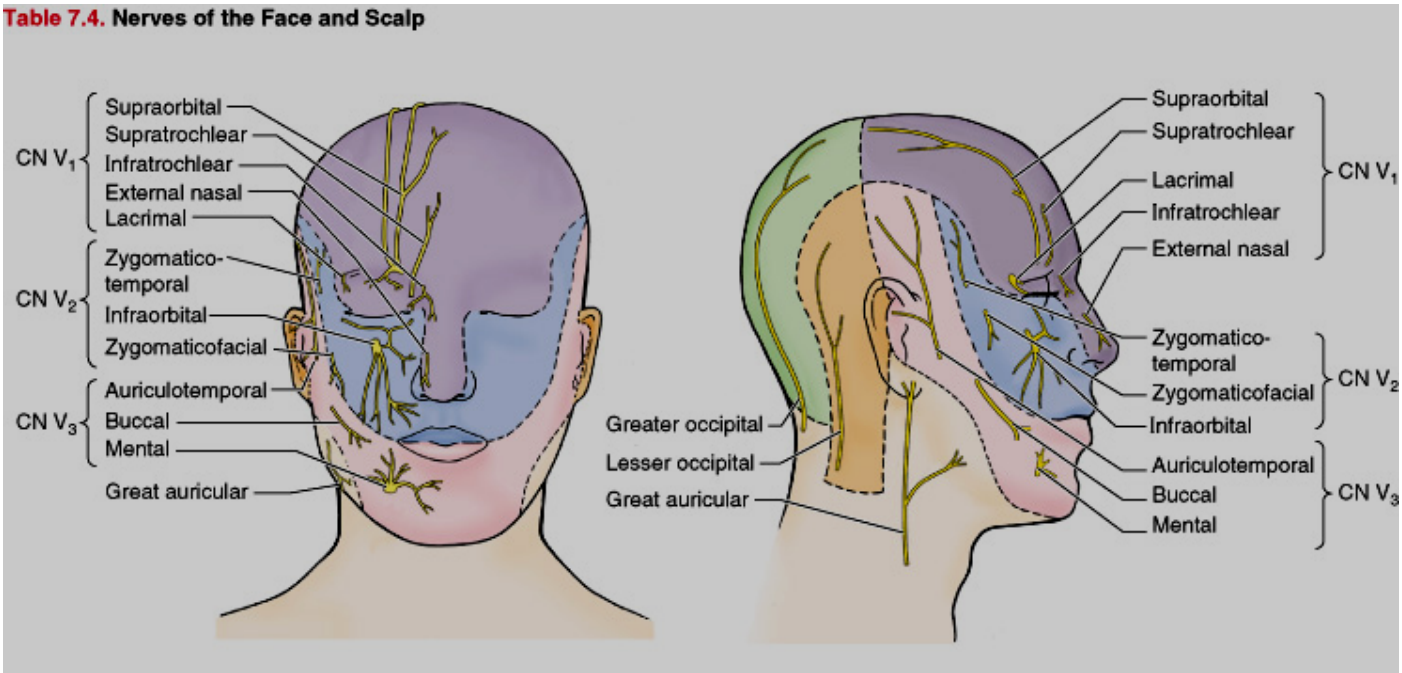
Post-procedure Treatment

1. If the skin becomes red, it will usually disappear in an hour. For maximum effect, use a pack containing minerals or nutritional (regeneration) mask is recommended rather than a cold pack to absorb the extra energy from the thermal injury zones.
2. If the blisters are serious, apply cortozone creme or steroid ointment after treatment only on blisters.
3. Finish off with sun creme (SPF 30+) when client is going out into the sun after the procedure.

Skin Diagram



Nerves Diagram



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THERAPY GUIDELINE

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TRANSDUCERS FOR FACE & NECK

Transducer	Depth	Power (J)	Spacing (mm)
C4D	4.5mm	0.95	1.5
C7D	4.5mm	0.95	1.5
C7M	3.0mm	0.35	1.1
N7M	3.0mm	0.40	1.1
C10S	1.5mm	0.15	1.1
N10S	1.5mm	0.20	1.1

TRANSDUCERS FOR BODY AREAS

Transducer	Depth	Power (J)	Spacing (mm)
C3F	18mm	3.5 ~ 4.0	4.5 ~ 5
C3C	13mm	2.5 ~ 3.0	3.5 ~ 4
C3N	8mm	0.5 ~ 2.0	3 ~ 3.5

Note: The table above represents the default energy settings for the treatment guideline. The user has the ability to adjust these energy settings one step down or two steps up. If adjusted, the system will retain the setting across all regions, for that particular transducer and for the duration of the treatment session.

CONTRAINDICATIONS

The UTIMS System is contraindicated for use in patients with:
- Open wounds or lesions in the treatment area
- Severe or cystic acne in the treatment area
- Active implants (e.g., pacemakers or defibrillators), or metallic implants in the treatment area

PRECAUTIONS

Treatment is not recommended directly over those areas with any of the following:
- Mechanical implants
- Dermal fillers
- Breast implants
- Keloid scars

It is recommended that the following areas should be avoided during treatment:
- Thyroid gland, thyroid cartilage and trachea
- Major blood vessels & nerves
- Breast tissue or breast implants

WARNINGS

- Gap between the transducer and skin
- Excess use of gel
- Gap filled with gel
- Movement of transducer while the shots are being fired

Use by non-trained personnel may cause possible scar formation that may exist for weeks if incorrect treatment technique is used. Do not treat on existing scarring or burn scars.

Note: If any type of side effect appears, please provide ice cooling immediately on the affected area.

POTENTIAL SIDE EFFECTS

Side effects reported in the clinical evaluation of the UTIMS system were mild and transient in nature. These were limited to:

Symptom	Lesion	Duration
Erythema (Redness)	Mid face, neck	Few hours
Edema (Swelling)	Mid face, around mandible	3 to 72 hours
Bruising	Mid face, temple	2 days to 2 weeks
Tenderness	Mid face	2 days to 2 weeks
Numbness	Eye brow, mid face, neck	2 to 6 weeks
Muscle Weakness	Eye brow, mid face, neck	2 to 6 weeks

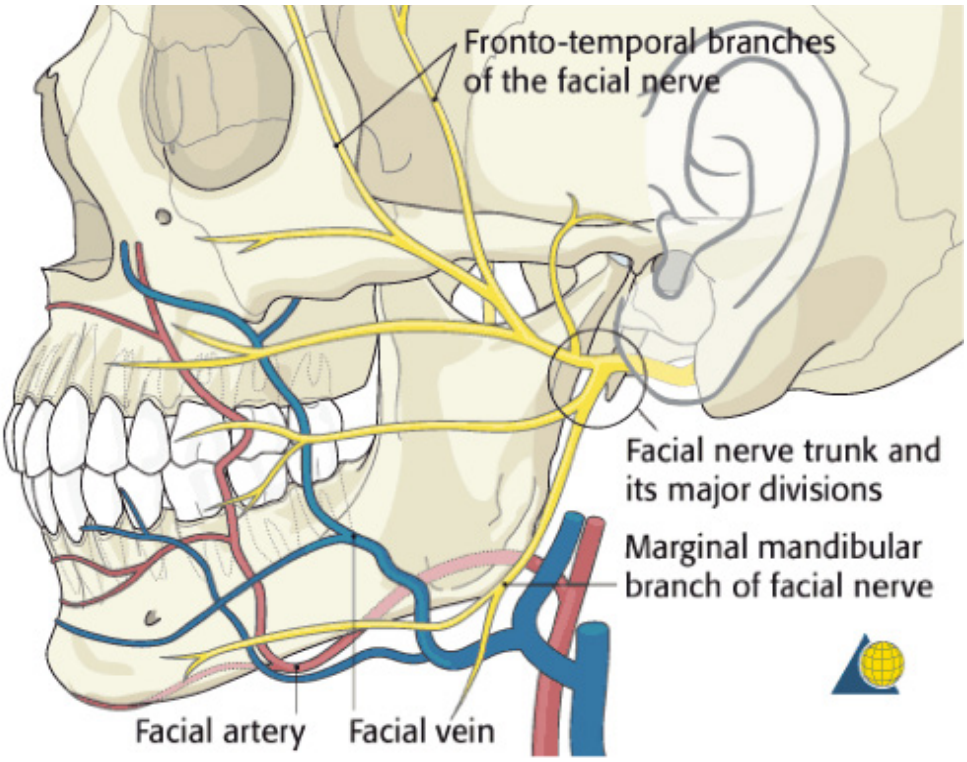
Avoid post-treatment skin care with any acids like AHA, BHA, Vit-A
For 2 days post-treatment, avoid partaking in activities that will heap up your skin, such as going in a hot tub/jacuzzi/sauna, or strenuous exercise.

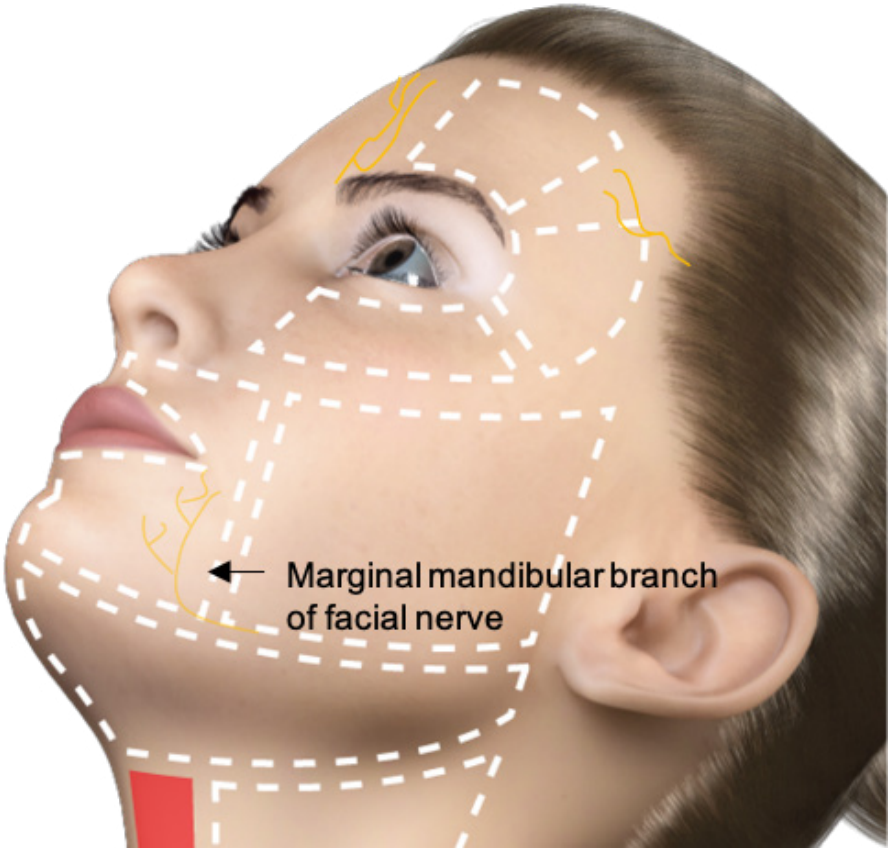
Post-treatment skin care products
All of your skin care products should be non-irritating and non-clogging for the first two weeks. Please do not use any scrubs, toners, glycolic acid, retinoids (RetinA or retinol), or bleaching creams (Hydroquinone) until your skin has healed completely.

Sunscreen
Proper and frequent application of sunscreen is very important. The sunscreen should offer broadband protection (UVA and UVB) and have a sun protection factor (SPF) of 30 or more. You should apply sunscreen 20 minutes before going outside, and again, immediately before. After that reapply your sunscreen every 2hours. If direct sun exposure is necessary, wear a hat and clothing that covers the treated area. Always use this regimen during the healing period.

FACIAL NERVE INJURY AFTER HIFU TREATMENT

Symptom: minor weakness of lower lip depression
Cause of symptom: partial injury to marginal mandibular branch of he facial nerve
Recovery period: from 2 weeks up to 3 months.





QUICK GUIDE

The generation of Ultrasonic wave stops automatically appear if the inner temperature of transducer is over 40˚C + 5˚C. When the temperature is under 40˚C, the message will disappear and you can continue the treatment.

Note:

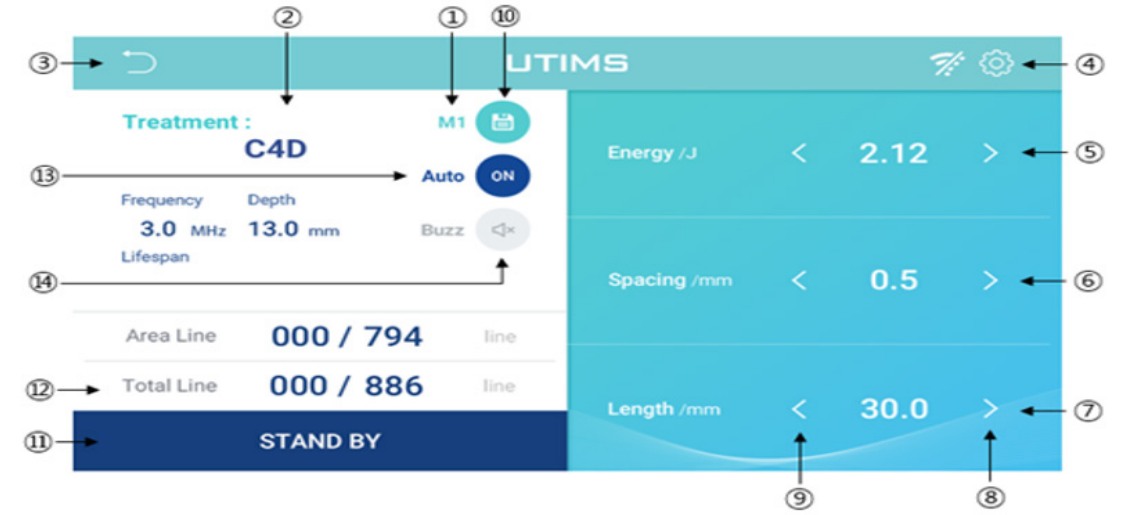
a) TRANSDUCER OVER TEMPERATURE
The message appears when the inner temperature of transducer is over 40˚C + 5˚C.

b) TRANSDUCER CONNECTION HAS LOST
The message appears when the transducer is detached from handpiece.

c) TRANSDUCER END OF LIFESPAN
The message appears when the lifespan of the transducer has ended. You are not able to use the transducer anymore.

d) TRANSDUCER NOT CERTIFICATION
The message appears when the transducer attached is not an authorized transducer.

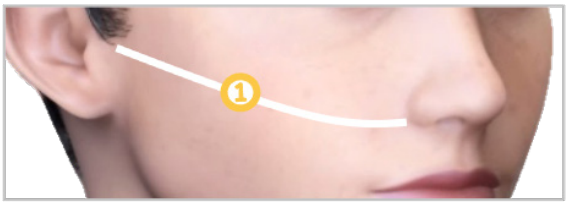
e) TRANSDUCER IS NOT RECOGNIZED
This message appears if the attached transducer is not recognized. The lamp on the handpiece flickers.

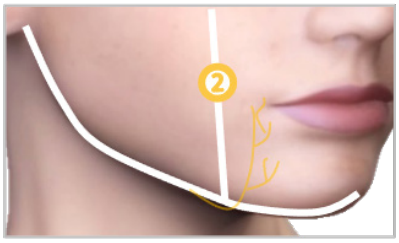


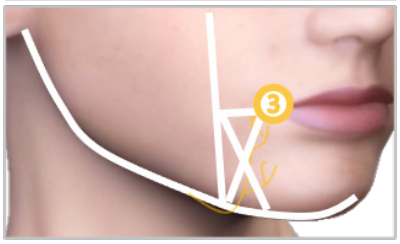
Note:

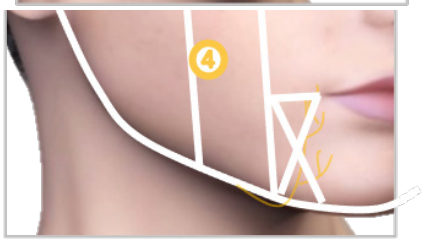
1. **The display of selected treatment mode (APR):** The modes selected on APR screen.
2. **The display of transducer information:** The model name of transducer connected to the handpiece is shown
3. **Back:** The button to move to the APR page
4. **Setting:** The button to move to the system page
5. **Power:** Indicate the level of therapeutic ultrasound energy
6. **Spacing:** Indicate the generation spacing of therapeutic ultrasound (Heat Lesion)
7. **Length:** Indicate therapeutic ultrasound generation length.
8. **Up button:** Increase the value.
9. **Down button:** Decrease the value.
10. **SAVE:** To save the set values.
11. **Stand by / Ready:** pressing the STAND BY button shall activate the READY button and make the equipment ready to generate therapeutic ultrasound
12. **Total Line:** Displays the number of counts; total number of counts available and number of used counts.
13. **AUTO:** It is a button to set up the operation method of operating switch of handpiece.
14. **BUZZ:** It is a button that enables to decide whether to turn on/off BUZZ while the therapeutic ultrasound is generating (Initial state: BUZZ ON).

INSTRUCTIONS FOR HIFU TREATMENT FOR FACE









Patient Preparation

Prior to the start of the treatment, have the patient remove all make-up with water, skin cleanser, and gauze.

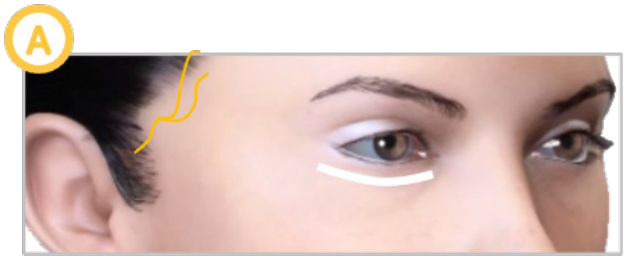
Gently dry the area to be treated and have the patient lie down on the treatment table.

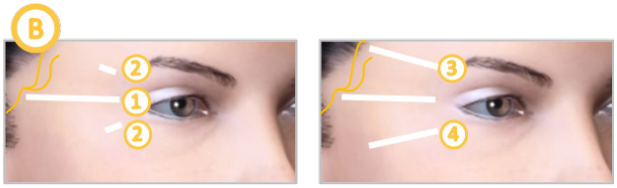
Patient Marking
Lower Face

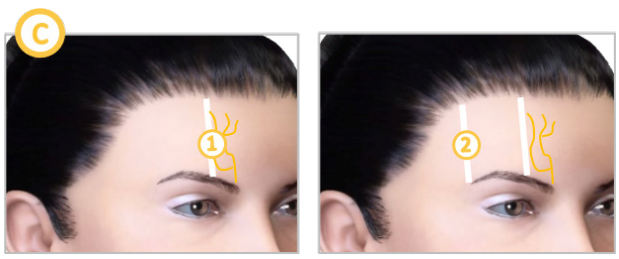
1. Draw a line from the edge of the nose along the apex (peak) of the zygoma (cheek bone) to the top of the tragus (upper middle of ear).
2. Place the ruler vertically against 2cm spacing the corner of the mouth and draw a line on the outside of the ruler (the side closest to the ear), from the cheek bone to the jaw bone.
3. Fill the area by the mouth with X's to clearly indicate not to treat in this area. This is the location of the marginal mandibular nerve.
4. Use the transducer to draw 2-3 columns with 30mm spacing, starting at the outside edge (closest to the ear) of the area you marked with X's.

General Location of Key Facial Nerves

Supraorbital, Temporal Facial and Marginal Mandibular Nerves







Patient Marking
Upper Face

A) Infraorbital Rim

1. Pull the cheek downwards until resistance is met.
2. Palpate the bone below the eye (infraorbital rim) and mark along the edge of it.

B) Lateral Orbit

1. Mark a horizontal line from the outside corner of the eye to the hairline.
2. Place the transducer perpendicular to the line and draw a mark 5 lines below and 5 lines above.
3. Draw a line that angles upward from the top mark.
4. Draw a line that angles downward from the bottom mark. The lines in steps 3 and 4 should create a fan shape that points to the eye.

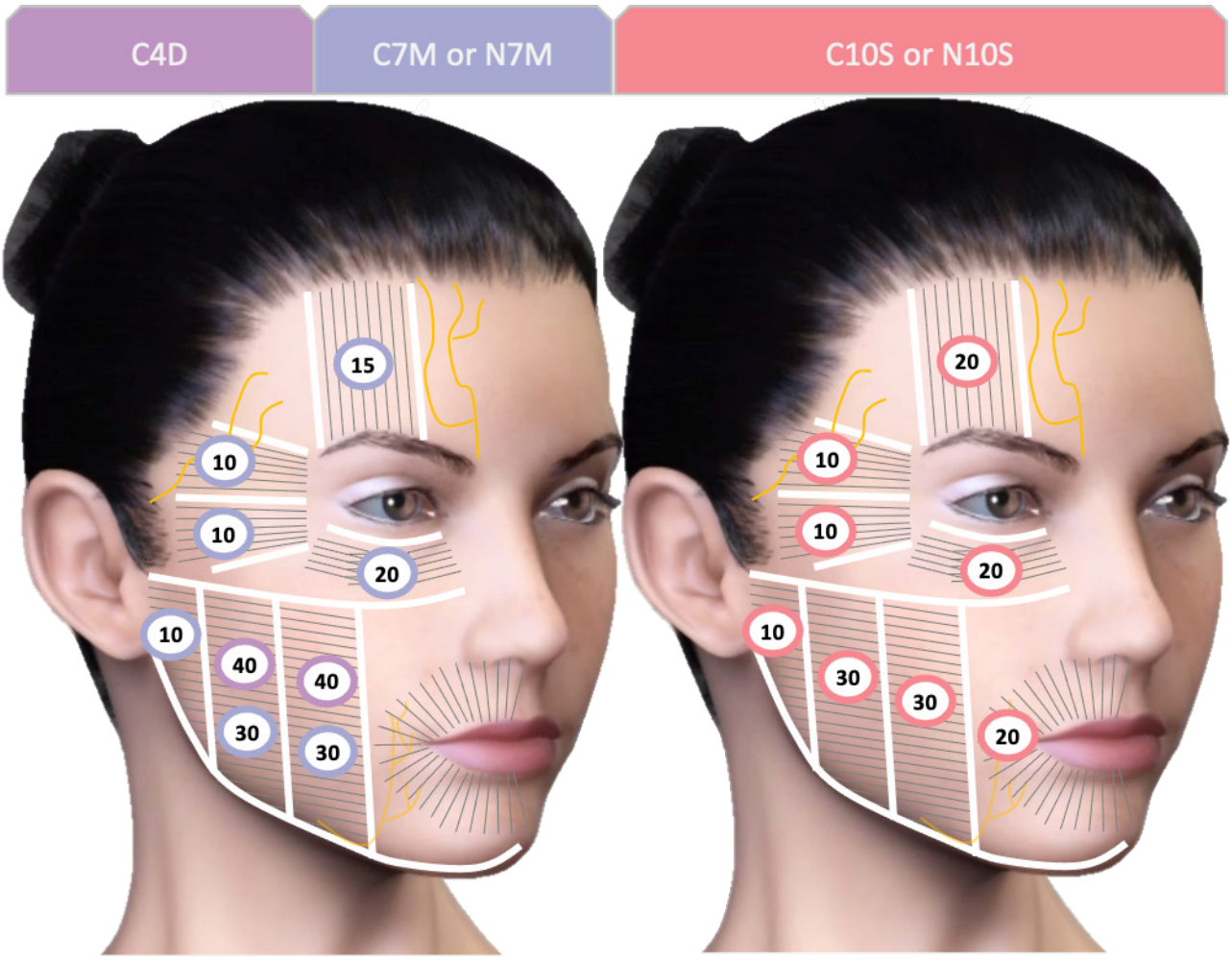
C) Brow

1. Have the patient look straight up and mark the position of the midpupil, from the brow to the hairline.
2. Place the transducer perpendicular to the mid-pupil line, along the eyebrow. Count 10 points towards the ear and draw a vertical line to the hairline.

FACE TREATMENT

Note: When treating multiple layers, treat from deep to shallow in sequential order.

For example: C4D → C7M or N7M → C10S or N10S

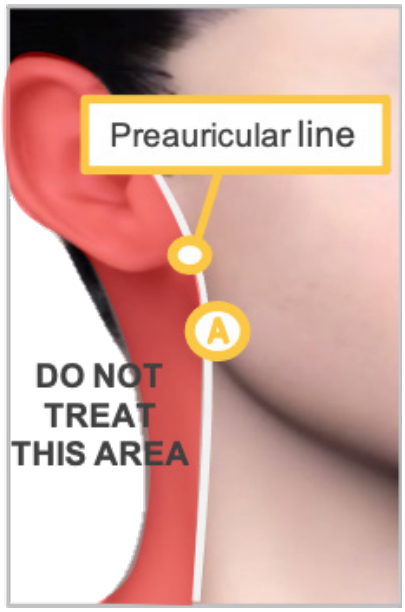


Do not treat this area

General Location of Key Facial Nerves
Supraorbital, Temporal Facial and Marginal Mandibular Nerves

Transducer	Energy	Spacing	Shot
C4D	0.85 ~ 1.00J	1.0 - 1.5mm	80 ~ 100
C7M or N7M	0.35 ~ 0.40J	1.0 - 1.5mm	100 ~ 150
C10S or N10S	0.10 ~ 0.20J	1.0 - 1.5mm	100 ~ 150

INSTRUCTIONS FOR HIFU TREATMENT FOR NECK

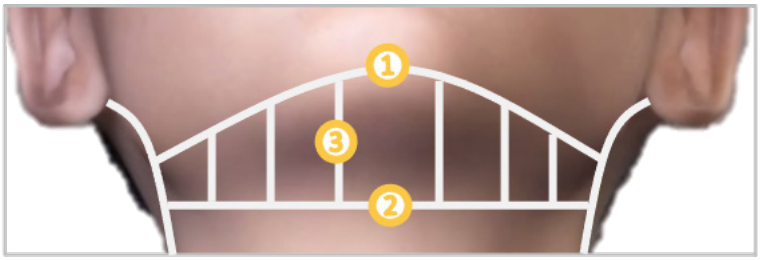


Patient Preparation

Prior to the start of the treatment, have the patient remove all make-up with water, skin cleanser, and gauze.
Gently dry the area to be treated and have the patient lie down on the treatment table.

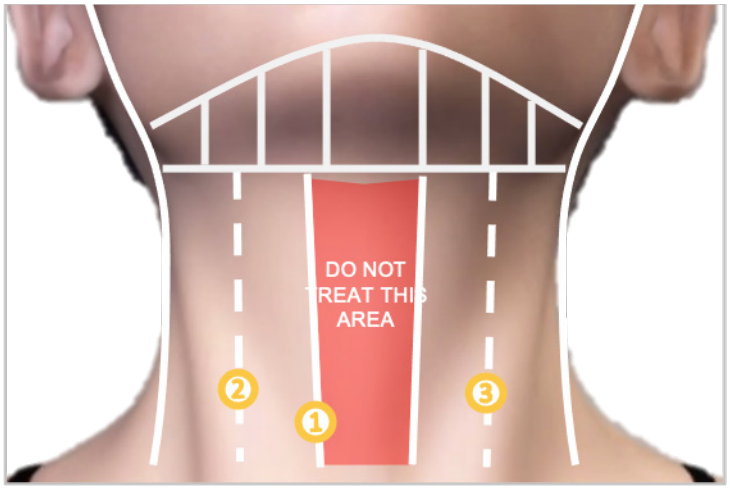
Patient Marking

A) Draw a vertical line in front of the ear. Do not treat behind this line.



Upper Neck

1. Draw a line marking the underside of the mandible
2. Palpate the thyroid cartilage. Draw a line from the top of the cartilage laterally to the preauricular line on both sides.
3. From the center of submental, draw 30mm wide interval lines (vertically downwards).

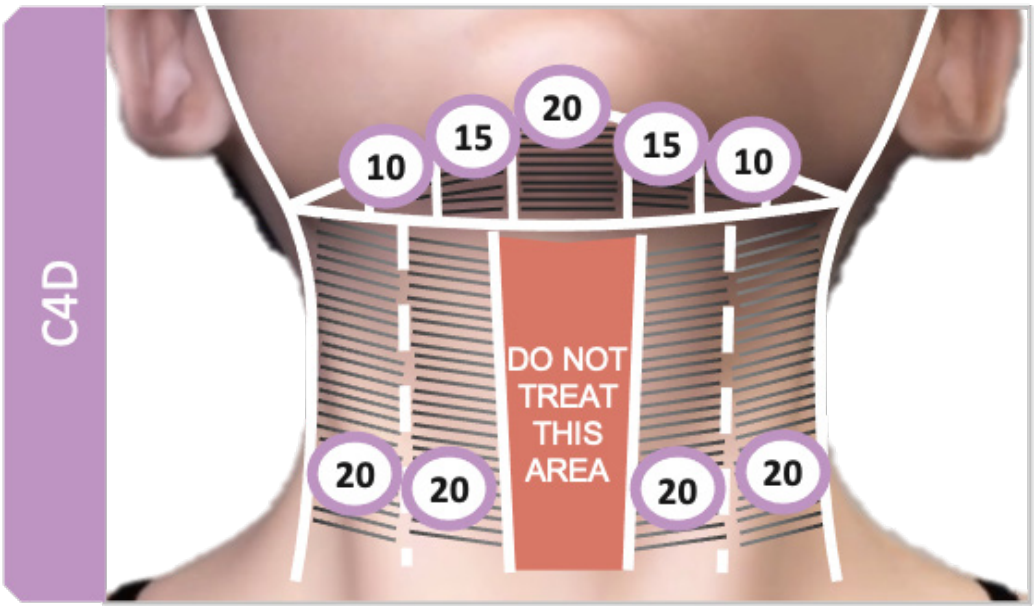


Lower Neck

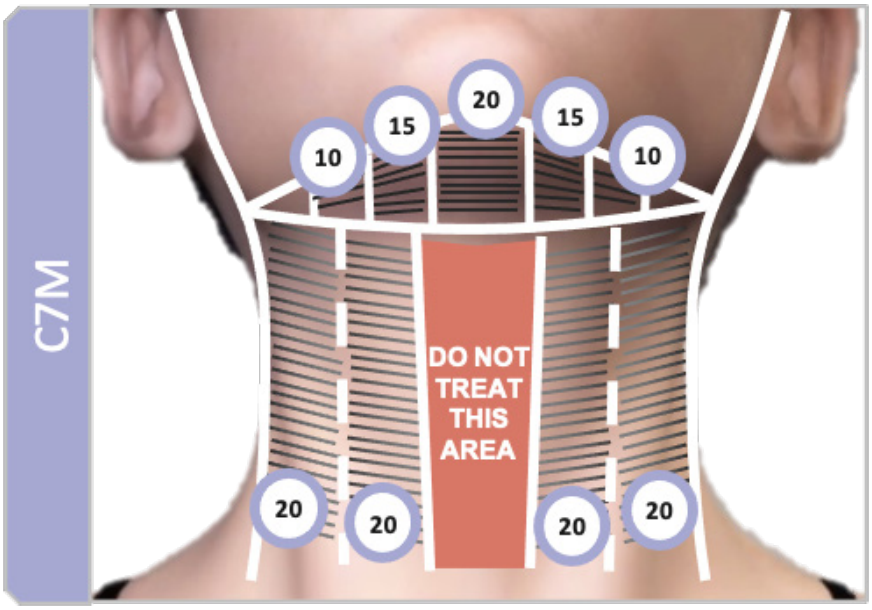
1. Palpate the right edge of the cricoid cartilage (at the side of the trachea). Draw the line down on both side from the cricoid cartilage to the clavicle and be sure to avoid the thyroid.
2. Create at least 1 additional column lateral to the first column. Add columns as needed, but DO NOT pass the preauricular line.
3. Repeat Step 1 - 2 on the left side.

NECK TREATMENT

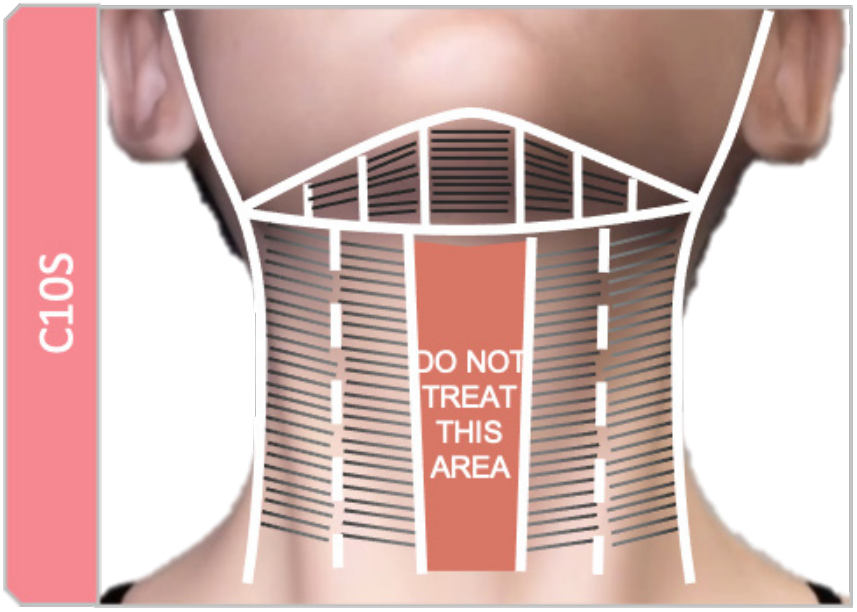
When treating multiple layers, treat from deep to shallow in sequential order.
Ex: C4D ▶ C7M or N7M ▶ C10S or N10S



Transducer	Energy	Spacing	Shot
C4D	0.85 ~ 0.95J	1.0 - 1.5mm	100 ~ 150



Transducer	Energy	Spacing	Shot
C7M	0.25 ~ 0.35J	1.0 - 1.5mm	100 ~ 150



Transducer	Energy	Spacing	Shot
C10S	0.10 ~ 0.20J	1.0 - 1.5mm	100 ~ 150

Note

- The excessive treatment may cause unknown side effects
- Avoid treating directly into bone, as this may increase discomfort
- Do not treat posterior to the preauricular line
- Avoid treating directly into major vessels
- Do not treat over the thyroid gland, thyroid cartilage or trachea
- Pull skin tight when sliding the transducer to prevent dragging the skin

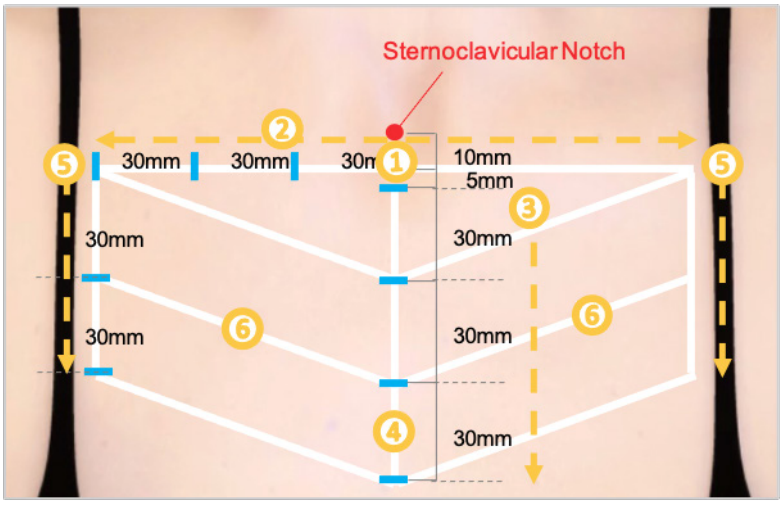
INSTRUCTIONS FOR HIFU TREATMENT FOR CHEST

Patient Preparation

Prior to the start of the treatment, have the patient remove all lotions, creams, and make-up with a gentle skin cleanser, water, and gauze. Gently dry the area to be treated. Have patients sit up during marking to keep skin on the chest stretched tight.

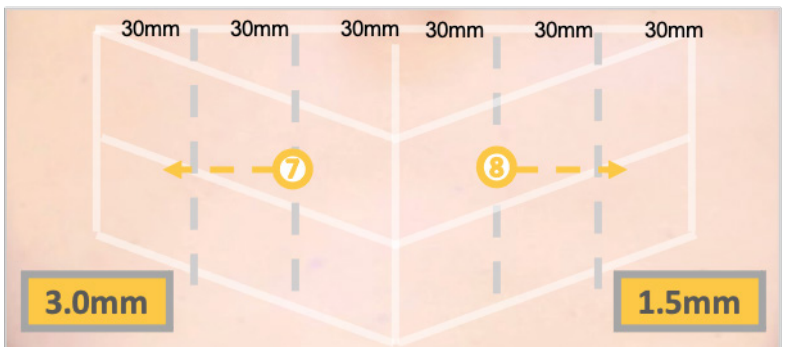
Patient Marking
4.5mm Transducer

1. Draw a horizontal line 10mm below the clavicle notch. The line should be long enough on both sides to the center of the clavicle.
2. Starting from the middle of the sternum, mark three equally spaced 30mm widths laterally on both sides of the horizontal line.
3. Starting from 5mm below the horizontal line, mark three equally spaced 30mm widths down along the middle of the sternum. The final mark should be located above the beginning of the breast tissue.
4. Draw a vertical line at the middle of the sternum, which connects the markers.
5. At both ends of the horizontal line, move two 30mm widths down and mark these two points. Connect these points with the vertical line.
6. Draw three diagonal lines on each side and connect the marks on the center of the sternum and the vertical line at the center of the clavicle.



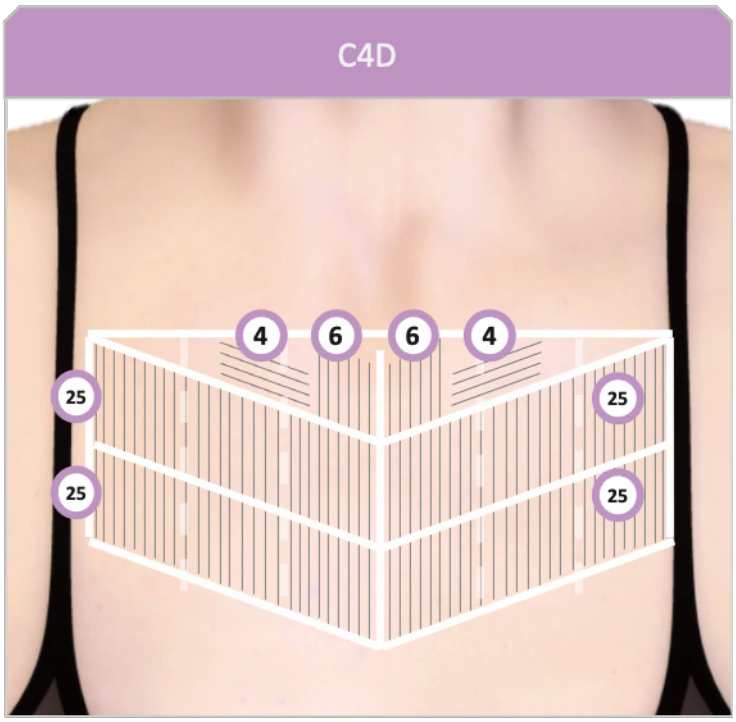
3.0mm Transducer / 1.5mm Transducer

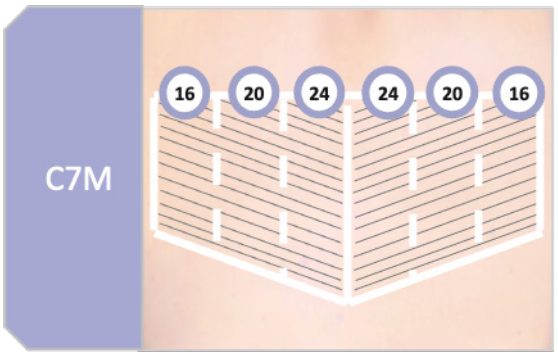
7. Draw a dotted 30mm width dotted line lateral to the center of the sternum. Move on another 30mm to draw next dotted vertical lines.
8. Repeat step 7 on the other side.

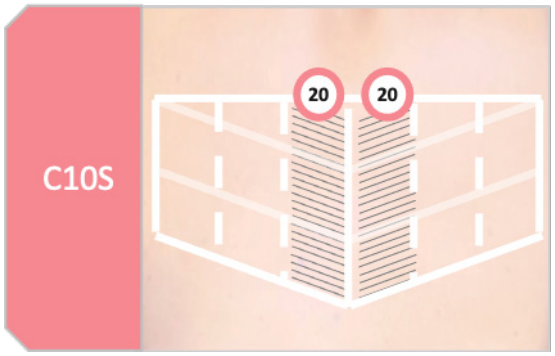


CHEST TREATMENT

When treating multiple layers, treat from deep to shallow in sequential order.
Ex: C4D ▶ C7M or N7M ▶ C10S or N10S







Transducer	Energy	Spacing	Shot
C4D	0.75 ~ 0.85J	1.0 - 1.5mm	100 ~ 150
C7M	0.25 ~ 0.35J	1.0 - 1.5mm	100 ~ 150
C10S	0.10 ~ 0.20J	1.0 - 1.5mm	30 ~ 50

Note

- The excessive treatment may cause unknown side effects
- Avoid treating directly into bone, as this may increase discomfort
- Do not treat directly into breast tissue or a breast implant
- Do not treat directly over an electrical or mechanical device such as a pacemaker
- Do not treat directly over metal screws or wires in the chest

INSTRUCTIONS FOR BODY TREATMENT

Abdomen Treatment

Caution

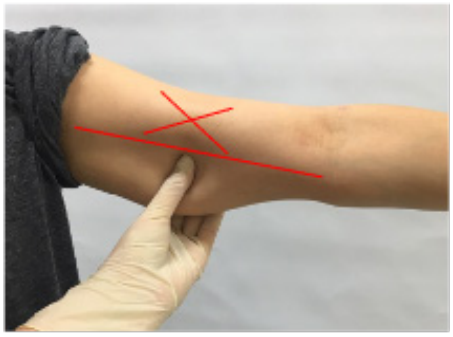
Patient feels the less pain when treatment is done in a sitting position.

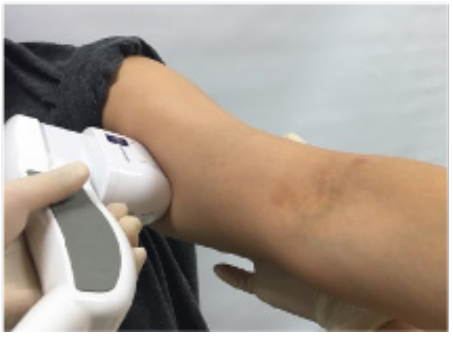
When treatment is done in a lying position, make sure not to push too hard on the stomach.

Arm Treatment

Caution

Do not treat towards the bone.





Cautions when treating to the body in a lying position

Arm Treatment

Caution

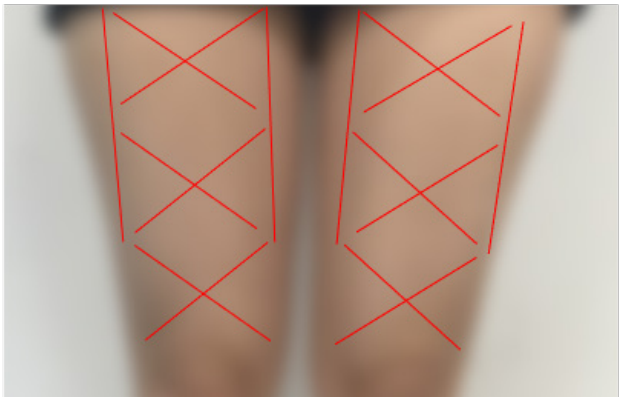
Make sure to pinch the fat to measure and confirm the treatment area prior to the treatment.

It is easier when body treatment is firstly done while patient is in a sitting position.

Thigh Treatment

Caution

Do not treat towards the bone.

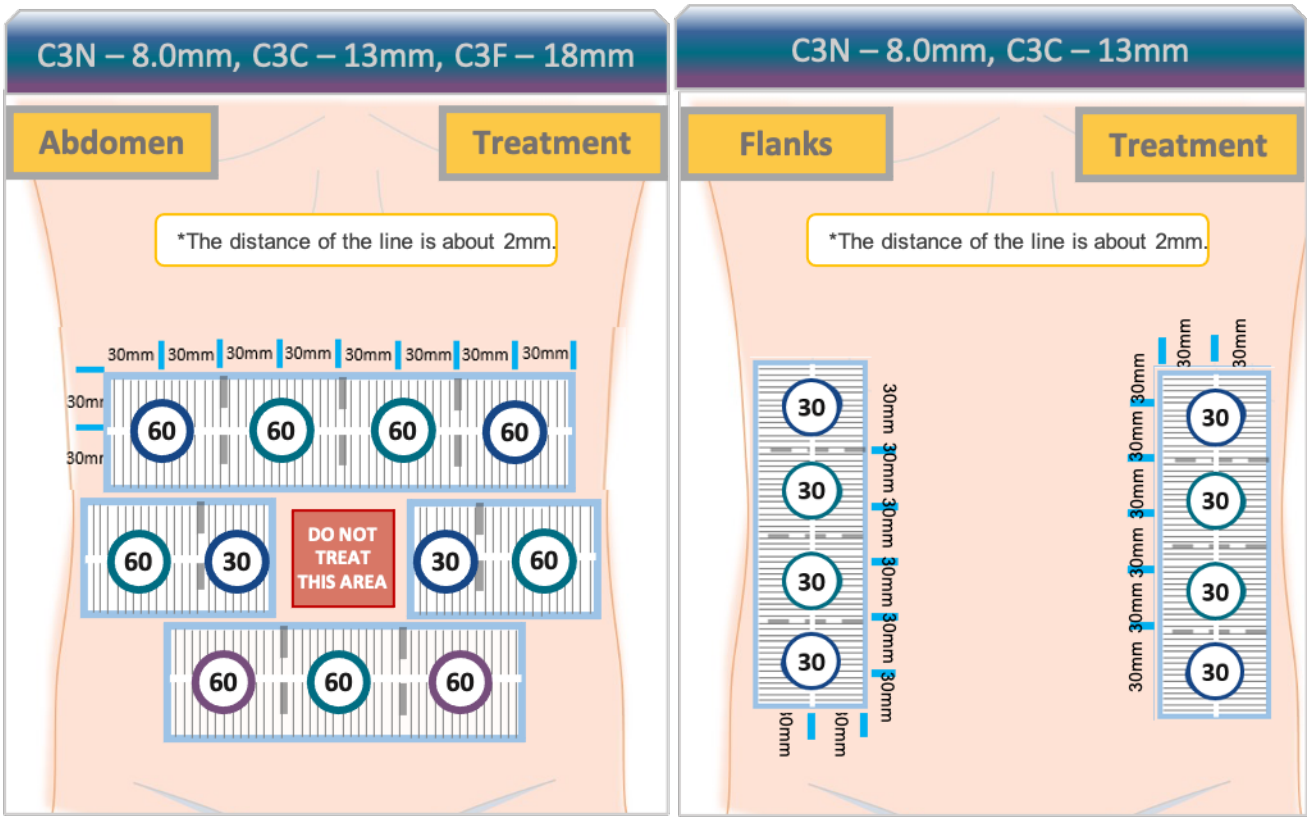


Fat thickness	Recommended Transducer
~1cm	C4D
1cm ~ 2cm	C3N
2cm ~ 3cm	C3N or C3C
3cm~	C3N or C3C or C3F

ABDOMEN & FLANKS TREATMENT

When treating multiple layers, treat from deep to shallow in sequential order.
Ex: C3F ▶ C3C ▶ C3N

Example



Area	Transducer	Energy	Spacing	Shot
Abdomen	C3F	2.50 ~ 3.50J	4.0 - 5.0mm	100 ~ 150
	C3C	2.50 ~ 3.50J	4.0 - 5.0mm	250 ~ 350
	C3N	2.00 ~ 3.00J	3.5 - 4.5mm	150 ~ 200
Flanks	C3C	2.00 ~ 3.00J	4.0 - 5.0mm	50 ~ 80
	C3N	1.50 ~ 2.50J	4.0 - 5.0mm	50 ~ 80

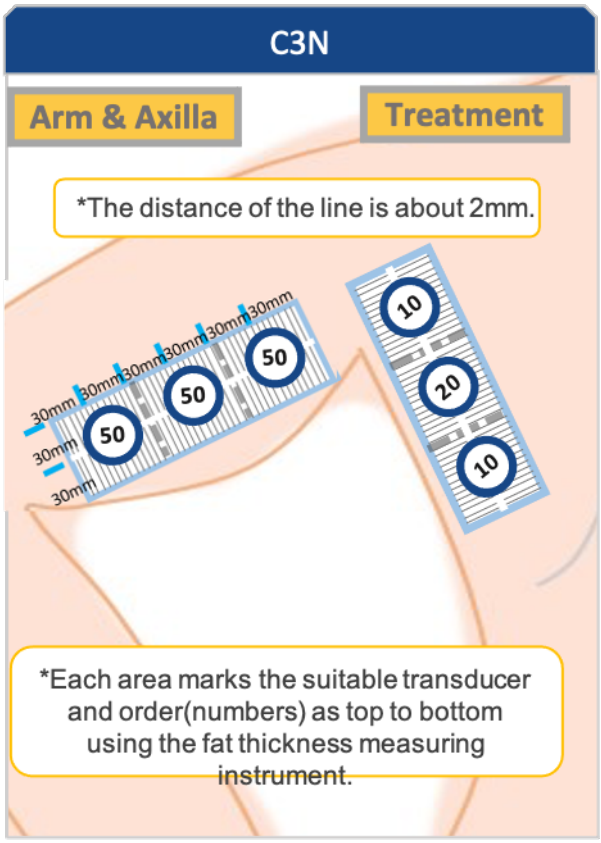
Note

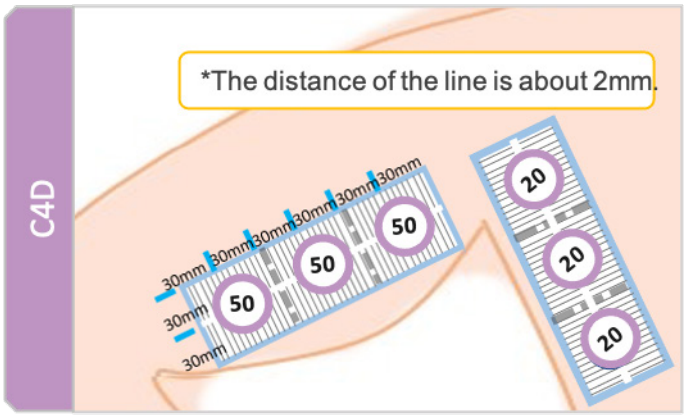
- Do not apply treatment directly on the sensitive areas of the navel, posterior superior iliac spine, or pelvis.
- Make sure to pinch the fat to measure and confirm the treatment area prior to the treatment.
  C3N (8 mm) - depth of at least 1cm
  C3C (13 mm) - depth of at least 2cm
  C3F (18 mm) - depth of at least 3cm

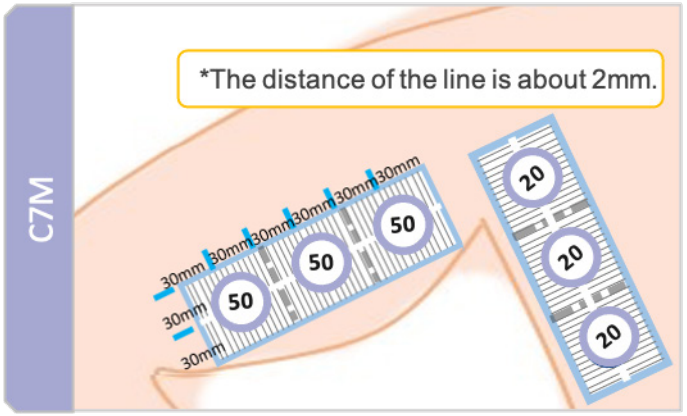
ARM & AXILLA TREATMENT

When treating multiple layers, treat from deep to shallow in sequential order.
Ex: C3N ▶ C4D ▶ C7M

Example







Area	Transducer	Energy	Spacing	Shot
Arm	C3N	1.50 ~ 2.50J	4.0 - 5.0mm	100 ~ 150
	C4D	0.95 ~ 1.00J	1.0 - 1.5mm	100 ~ 150
	C7M	0.30 ~ 0.40J	1.0 - 1.5mm	100 ~ 150
Axilla	C3N	1.50 ~ 2.50J	4.0 - 5.0mm	30 ~ 50
	C4D	0.95 ~ 1.00J	1.0 - 1.5mm	50 ~ 80
	C7M	0.30 ~ 0.40J	1.0 - 1.5mm	50 ~ 80

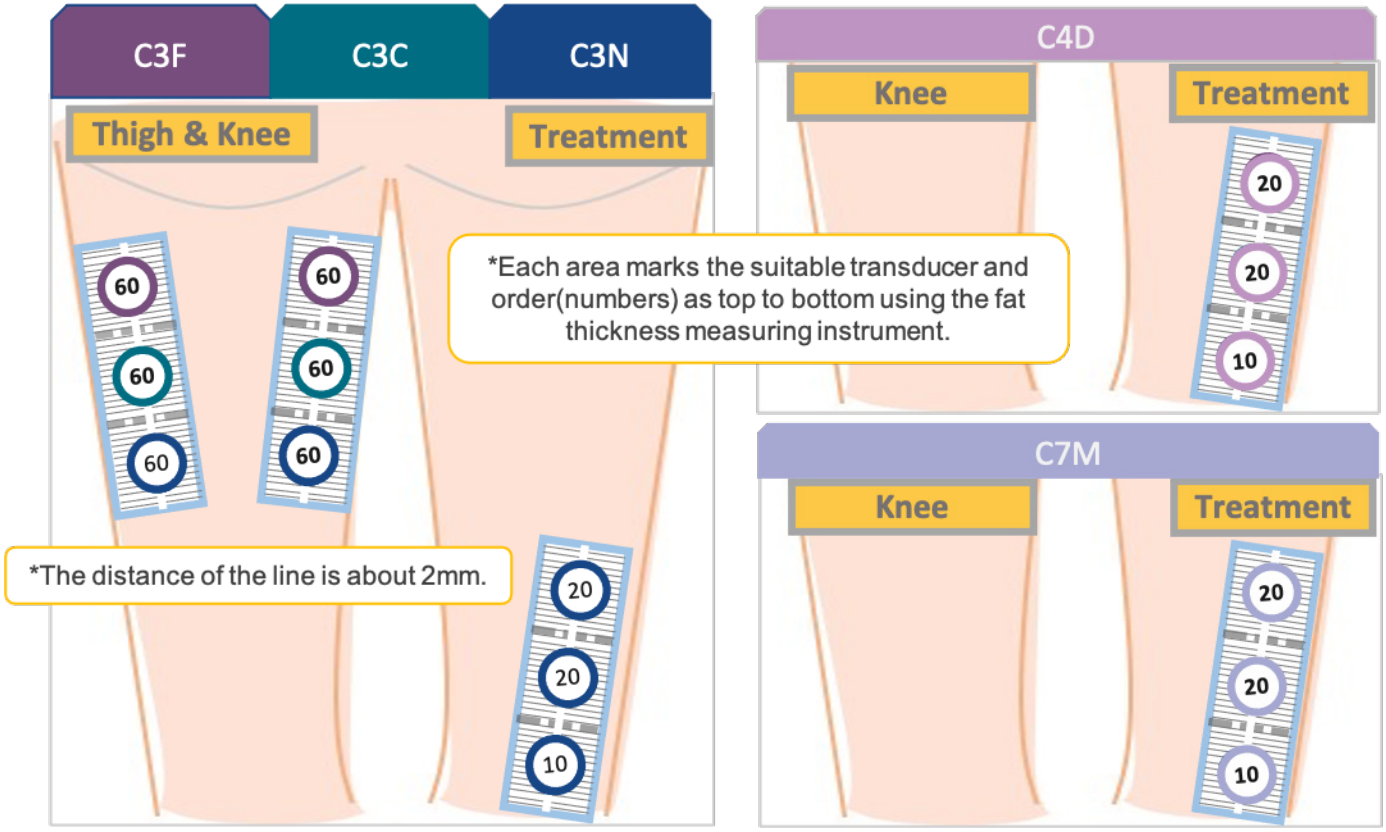
Note

- The excessive treatment may cause unknown side effects
- Avoid treating directly into bone, as this may increase discomfort
- Make sure to pinch the fat to measure and confirm the treatment area prior to the treatment.
  C3N (8 mm) - depth of at least 1cm
  C3C (13 mm) - depth of at least 2cm
  C3F (18 mm) - depth of at least 3cm

THIGH & KNEE TREATMENT

When treating multiple layers, treat from deep to shallow in sequential order.
Ex: C3F ▶ C3C ▶ C3N ▶ C4D ▶ C7M

Example



Area	Transducer	Energy	Spacing	Shot
Thigh	C3F	2.50 ~ 3.50J	4.0 - 5.0mm	100 ~ 200
	C3C	2.50 ~ 3.50J	4.0 - 5.0mm	100 ~ 200
	C3N	2.00 ~ 3.00J	4.0 - 5.0mm	100 ~ 200
Knee	C3N	1.50 ~ 2.50J	3.0 - 4.0mm	30 ~ 50
	C4D	0.85 ~ 0.95J	1.0 - 1.5mm	30 ~ 50
	C7M	0.30 ~ 0.40J	1.0 - 1.5mm	30 ~ 50

Note

- The excessive treatment may cause unknown side effects
- Avoid treating directly into bone, as this may increase discomfort
- Make sure to pinch the fat to measure and confirm the treatment area prior to the treatment.
  C3N (8 mm) - depth of at least 1cm
  C3C (13 mm) - depth of at least 2cm
  C3F (18 mm) - depth of at least 3cm

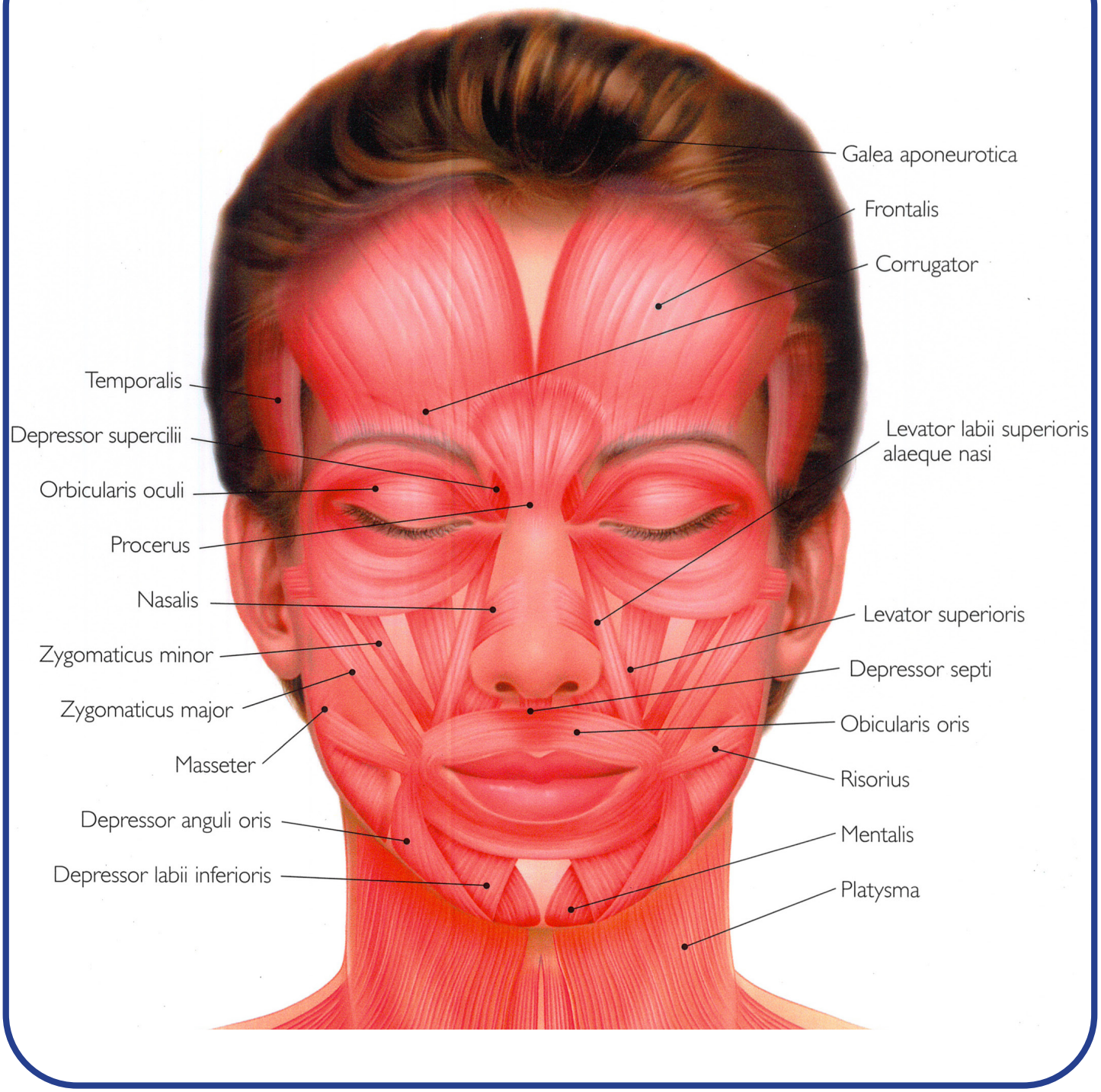
TIGHTENING & ELIMINATING STRETCH MARKS

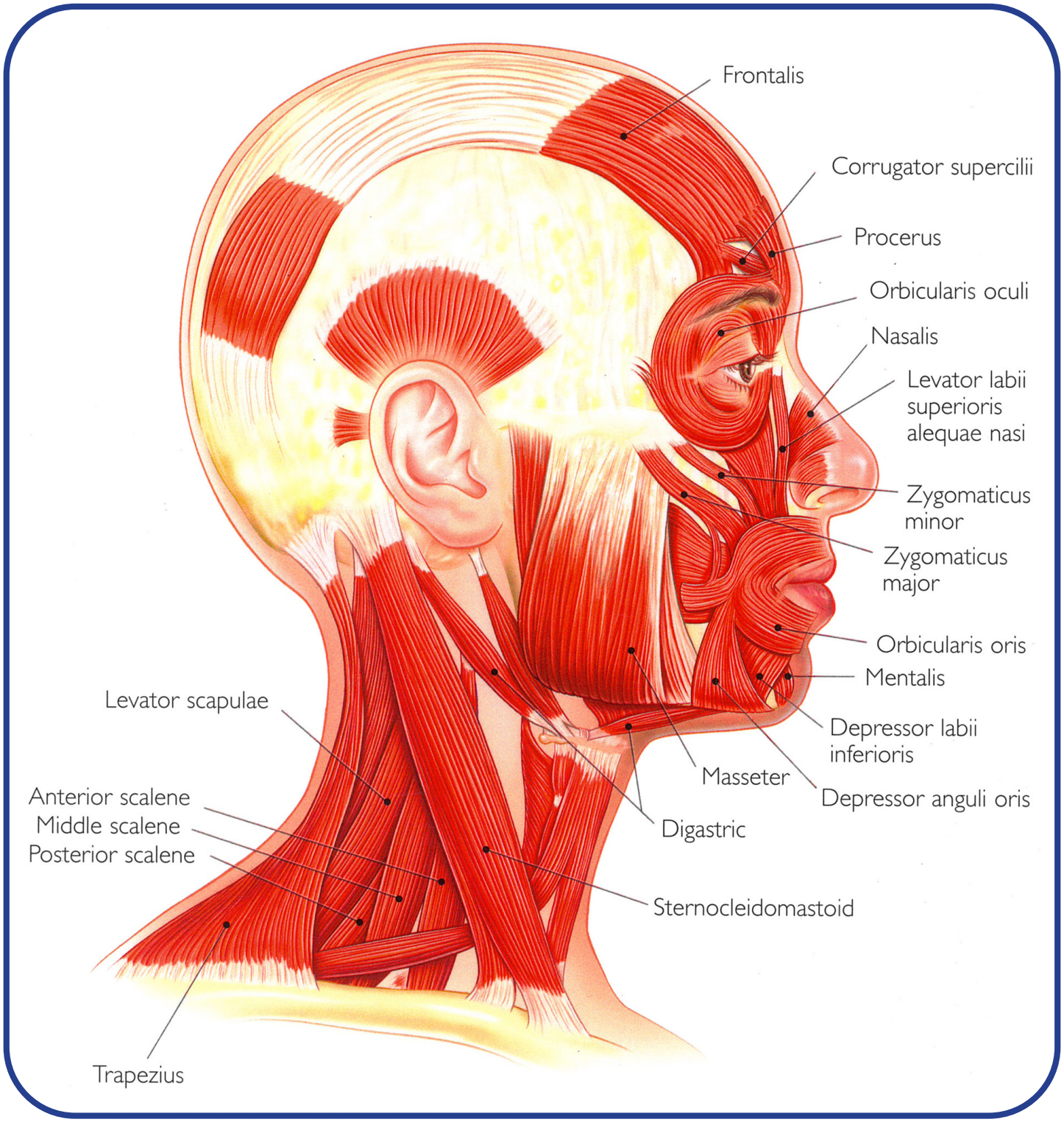
When treating multiple layers, treat from deep to shallow in sequential order.
Ex: C3N ▶ C4D

Transducer	Area	Energy	Spacing	Shot
C3N	Abdomen	2.00 ~ 3.00J	4.0 - 5.0mm	150 ~ 200
C4D		0.95~ 1.00J	1.0 - 1.5mm	200 ~ 300
C3N	Arm	1.50 ~ 2.50J	4.0 - 5.0mm	30 ~ 50
C4N		0.95 ~ 1.00J	1.0 - 1.5mm	30 ~ 50
C3N	Thigh	2.00 ~ 3.00J	4.0 - 5.0mm	150 ~ 200
C4D		0.95 ~ 1.00J	1.0 - 1.5mm	200 ~ 300

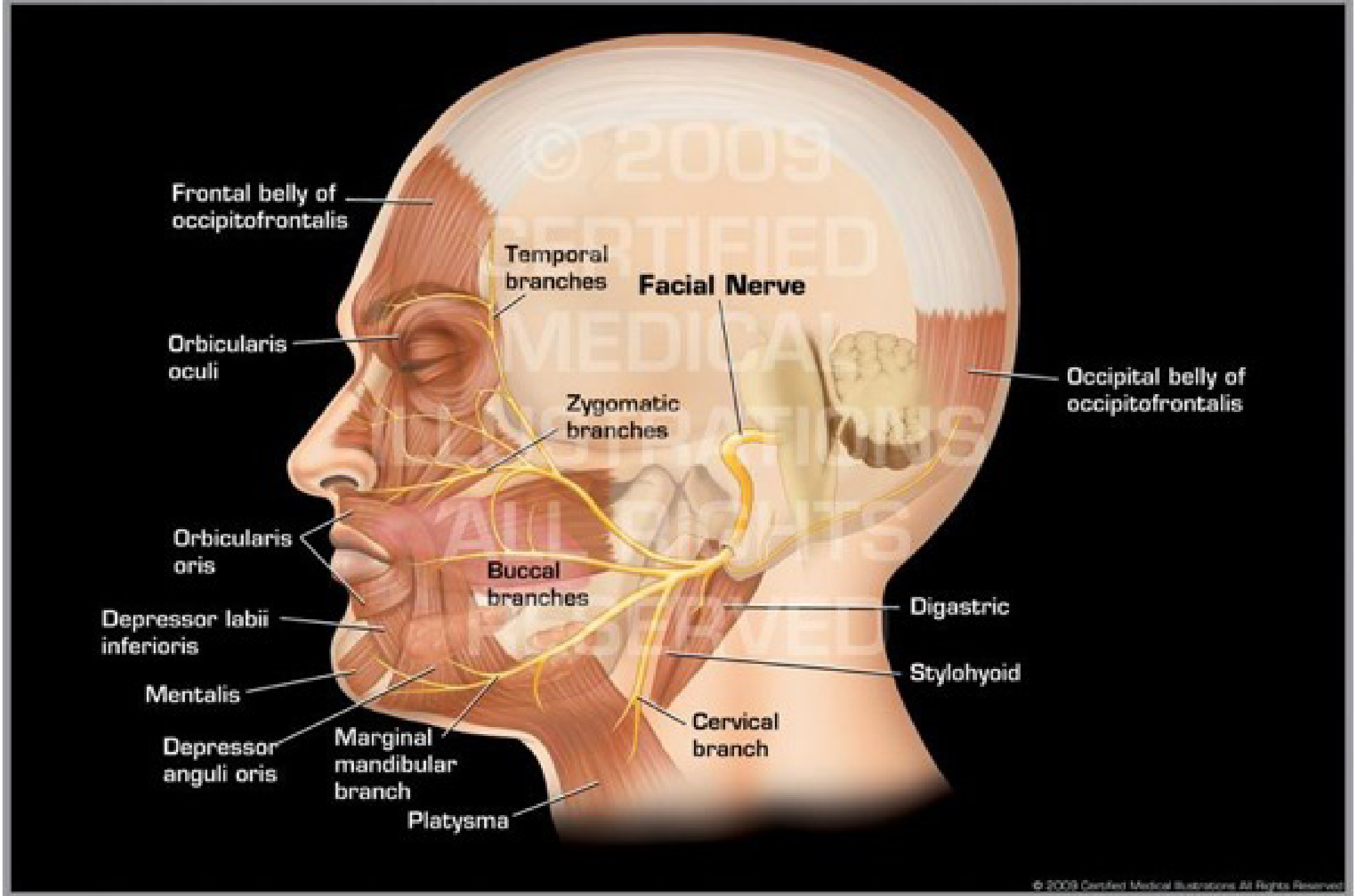
Note

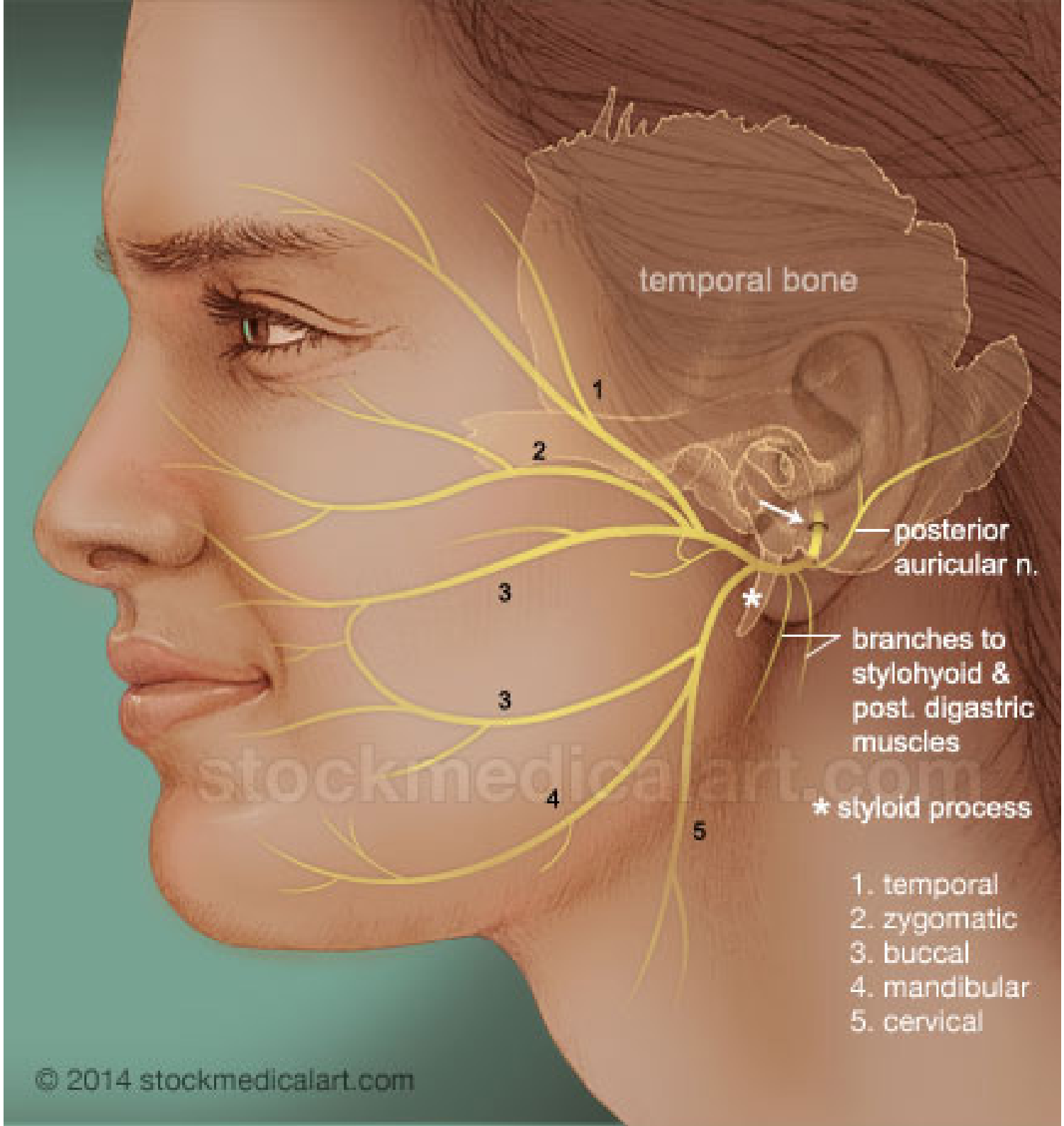
- The excessive treatment may cause unknown side effects
- Avoid treating directly into bone, as this may increase discomfort
- Make sure to pinch the fat to measure and confirm the treatment area prior to the treatment.
  C3N (8 mm) - depth of at least 1cm


Galea aponeurotica
Frontalis
Corrugator
Temporalis
Depressor supercilii
Orbicularis oculi
Procerus
Nasalis
Zygomaticus minor
Zygomaticus major
Masseter
Depressor anguli oris
Depressor labii inferioris
Levator labii superioris alaeque nasi
Levator superioris
Depressor septi
Obicularis oris
Risorius
Mentalis
Platysma


Frontalis
Corrugator supercilii
Procerus
Orbicularis oculi
Nasalis
Levator labii superioris alequae nasi
Zygomaticus minor
Zygomaticus major
Orbicularis oris
Mentalis
Depressor labii inferioris
Depressor anguli oris
Masseter
Digastric
Levator scapulae
Anterior scalene
Middle scalene
Posterior scalene
Sternocleidomastoid
Trapezius

FACIAL NERVE




temporal bone
1
2
3
3
4
5
posterior auricular n.
branches to stylohyoid & post. digastric muscles
* styloid process
1. temporal
2. zygomatic
3. buccal
4. mandibular
5. cervical
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Your Clinic

Address QLD 4xxx Phone: 07 3300 0000

Client Evaluation Card

For Clinical HIFU Treatments

Name:..... **Age Group:** Under 30 / 31-40 / 41-50 / 51-60 / 61+

By completing this Client Profile, you will assist us in evaluating your skin type and condition. The information you will provide will be used to determine what factors may be affecting your skin health and tone for continuous improvement so what we may recommend the proper post care and treatments.

Address: .....

.....

Phone (H) ..... (W) ..... (Mob) .....

Lifestyle

How many hours do you sleep per night? .....

How often do you exercise? .....

On a scale from 1 (low) to 10 (high), how would you rate your stress level?.....

Please list all medications that you take regularly. Include hormones, vitamins etc:

.....

.....

Please check any health conditions which you have had, or are now experiencing:

☐ Alcoholism	☐ Heart Problems	☐ Muscular Conditions	☐ Any Filler Injections
☐ Asthma	☐ Hepatitis	☐ Multiple Sclerosis	☐ Smoking (per day……)
☐ Cancer	☐ Hormonal Disorders	☐ Metal implants, screws	☐ Sugar Diabetes
☐ Claustrophobia	☐ Hypoglycaemia	☐ Pregnant or Recent Pregnancy	☐ Thrombosis or Phlebitis
☐ Epilepsy	☐ Hysterectomy	☐ Recent Operation	☐ Thyroid Disorders
☐ High/Low Blood Pressure	☐ Lack of Normal Skin Sensation	☐ Recent Illness	☐ Whiplash

Comments: .....

.....

.....

Have you ever undergone any surgical treatments recently (last 8-10 years)?

If yes, when? .....

What type of condition?.....

Any negative side effects? .....

Within the last month have you taken or used any of the following?

☐ Retin-A ☐ Antibiotics ☐ Diuretics ☐ Accutane ☐ Oral Contraceptives ☐ Laxatives

Home Skin Care Regime

Describe in detail (using product brand names) exactly how you are presently caring for your skin:

.....

.....

.....

What are your concerns about your face or body health?

What is your specific concern about your skin?.....

.....

How long have you noticed your condition?.....

.....

Is this an ongoing or temporary condition? .....

Have you ever received professional skin care treatment?.....

What were the results?.....

How did you hear about us? .....

Contraindications – Indications for Non-Treatment

If the client has any sever health conditions or if they have any of the following contraindications, treatment cannot be provided during the period of the condition:
Treatment areas that has Mechanical Implants, Derma Fillers, Implanted Electrical Devices, Metal Stents in the face and neck area, Existing Keloid, Open Facial Wounds or Lesions, Severe or Cystic Acne on the face and/ or neck, Patients on anticoagulant treatment plan, Pregnant or Breast Feeding Women, Children, A Hemorrhagic Disorder or Haemostatic Dysfunction, Any Active or Systemic or Local Skin Disease that may delay wound healing, Herpes Simplex, Autoimmune Disease, Diabetes, Epilepsy, Bell's Palsy or if any other conditions not mentioned here and are known to you, please consult your Physician.

- I acknowledge that I have received a thorough, informative consultation regarding the proposed treatment with the use of High Intense Focused Ultrasound. I have had the opportunity to ask questions about this procedure and have had all questions answered to my satisfaction.
- I understand the nature, goals, limitations and possible complications of this procedure and have discussed alternative forms of treatments with the therapist.
- I hereby give my informed consent to proceed with the agreed treatment and I am over 16 years or older and of age to sign my consent to the agreed treatments.
- I voluntarily release this Clinic and the Clinicians of any claims that I have or may have in the future in connection with the agreed treatment.

Name:.....Mobile:.....

Signature:.....Date:.....

Clinician Signature & Name:.....

CLIENT CONSULTATION FORM

All information contained in this form is strictly confidential

Name: D.O.B:

Address: Postcode:

Phone: Mobile: Email:

How did you find us? Internet Yellow Pages Newspaper Radio Street Sign Friend Other

Would you be happy for us to send you appointment reminders/promotions via sms?.....

MEDICAL HISTORY

Please tick any of the following that are applicable to you

( ) Asthma
( ) Bleeding Disorders
( ) Cancer/Tumours
( ) Claustrophobia
( ) Low/High blood pressure
( ) Diabetes
( ) Heart problems
( ) Thyroid disorder
( ) Cold Sores
( ) Sinus Problems
( ) Allergies
( ) Other ……

Please list any medication you are currently taking

Please list any Naturopathic/Homeopathic preparations you are taking

Have you recently undergone any surgical procedures, including x-rays? Yes / No

If yes, please list

Within the last month have you taken or used any of the following –
( ) Retin A ( ) Roacutane ( ) Any Acne preparations ( ) Antibiotics ( ) Glycolic Cremes

Please indicate any areas of concern

( ) Acne/problem skin
( ) Oily/congested skin
( ) Dry/dehydrated skin
( ) Rosacea
( ) Sensitive skin
( ) Broken capillaries
( ) Pigmentation
( ) Scarring
( ) Sun damage
( ) Age spots
( ) Unwanted hair
( ) Ingrown hairs
( ) Fine lines & wrinkles
( ) Cellulite
( ) Other……
( ) Skin Tone
( ) Facial Muscle Tone
( ) Skin Tags & Fibromas
( ) Cholesterol Deposits
( ) Clogged Pores

What is your immediate concern?

How long have you been aware of this concern?

Have you had previous treatments to address this concern?

What is your current skincare routine and product range?

When was your last sun exposure? (i.e. Day at the beach, Sunbathing or Solarium) Days: Weeks: Months:

Women only *Are you pregnant or trying to conceive? Yes / No * Are you lactating? Yes / No
*Are you currently due for or having your period? Yes / No

I hereby state the above information is true and correct to the best of my knowledge.
I am aware that I am to inform the treating Therapist if there are any changes to the above information in the future, during the course of any treatment in this clinic.

Signed: Date:

Name : …….(IN BLOCK LETTERS) Therapist Signature: .....

Date	Treatment Performed	Cost	Products Purchased	Cost	Therapist

MONACO SPECTACULAR FACE LIFT

SPECIAL OFFER

Look Fresh & Natural For Christmas

How to Offer a Monaco Spectacular Face Lift

- Instant lifting & tightening that increases with time
- Long lasting, firming and smoothing over time (90 Days)
- Non-Invasive, energizing and all natural ingredients with safe ultrasound, micro thermal spots to produce your own collagen and filling action.
- Micro collagen induction therapy helps shed some skin cells with peptide wrinkle correction and marine collagen plumping mask to produce visible long lasting results previously only offered via the spectacular Monaco Face Lift surgeons.

"Attend our workshops to see it for yourself"

4 Steps to a Monaco Spectacular Face Lift in just 60 minutes:

- **Step 1 –** Enzymatic Peeling suited to your skin condition and ageing process will remove dead skin cells and stimulate circulation, improving skin texture, tone and glow.
- **Step 2 –** High Intensity Focused Ultrasound (HIFU) energy starts to build up the broken down collagen and elastin network in the SMAS layer. Unlike lasers and RF, which penetrate the skin from the outside, the HIFU therapy delivers energy at 4.5mm to the same foundational layer addressed in a surgical face lift. This stimulates the growth of fresh new collagen and elastin, lifting and tightening the skin over 2-3 months, back to a more youthful and spectacular look!
- **Step 3 –** Mild collagen induction to support skin regeneration quickly by creating multiple surface skin channels to further stimulate collagen and elastin fibroblasts. LED treatment can be added in after step 3 to further enhance the treatment
- **Step 4 –** Cold, soothing marine lift off collagen boosting blend of 10 "plumping" and perfecting peptides that continue to lift, firm, sculpt and smooth your skin to youthful, glowing perfection in just 60 minutes when removing this mask will complete the Monaco Spectacular Face Lift treatment only to keep improving for up to 6 months.

Here is my story on the Monaco Spectacular Face Lift

On one of those staff sick days I was called to consult and treat a client who could not change her appointment as it was too close to her youngest daughter's wedding. She wanted to "look fresh" but not "plastic" for the occasion. Having only 60 days before she flew out to Monaco where the wedding was to take place, I proceeded to perform her treatment using the 4 Steps above. While the client was extremely delighted on the day, I felt she could have benefited tremendously with a bit more time to spare. However, when she sent me her daughter's wedding pictures with a lovely "thank you" card, I was so dumbstruck with the immense improvement the treatment produced in 60 days that I exclaimed:

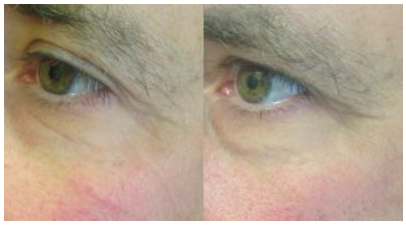
"What a spectacular Monaco Face Lift!
Smooth and Fresh, not Fake and Plastic!"

If you would like to offer this treatment as a **"Christmas Special"** to your " Baby Boomer" clients, please book into our workshops in your city now as this is a hands-on workshop where you will learn the secrets of a successful long-lasting face lift. Workshops to be held in Sydney, Melbourne, Adelaide, Perth and Brisbane.

See you there!

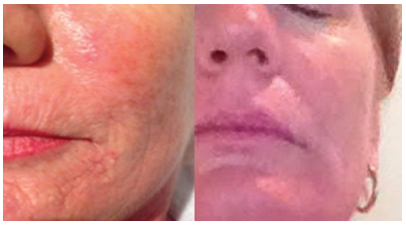
Kind Regards,

Metro



After 1 Visit ($800)

After 2 Visits ($1,200)



After 3 Visits ($1,500)

MONACO
SPECTACULAR
FACE LIFT

SPECIAL OFFER

Look Fresh & Natural For Christmas.

1 visit	$800
2 visits	$1,200
3 visits	$1,500

ClincalPRO
Monaco Spectacular Face Lift

Items to prepare	Professional products & Equipment needed
• Fibrella • Fan brush • Pre- treatment creme • Gloves • Needle cartridge • White marker • Ultrasound gel	● Enzyme peels ● Needling pen & Needle cartridge ● HIFU (High Intensity Focused Ultrasound) ● LED Light ● Q-Switch Laser (optional) ● Collagen Lift off Mask

Patient home care:

- Rosaderm Foaming Cleanser
- EGF/DNA Recovery Concentrate
- RF Tightening Crème
- Sunscreen with Vitamin E
- Skin Tightening Serum
- Depigmentation crème for skin types 4 to 6

Procedure:

1. Client's consent form - needs to be signed prior treatment
2. Take 'Before' photos
3. Cleanse skin with the appropriate cleanser
   - ✔ **Rosaderm Foaming Cleanser** (For Rosacea skin and/or all skin types)
   - ✔ **Discolouration Bar** (For Pigmented skin)

If client has pigmentation, please prepare Q-switch laser equipment.
You can charge an **additional $150 for this step.**

1. Apply **EGF/DNA recovery concentrate** with fan brush, make sure to rub the serum into the skin to prevent reflection during laser treatment
2. Prepare goggles for client and operator
3. Select PTP mode 1064nm, 10mm spot size, 10hz and set the total energy to 800mj
4. Apply 1st pass on pigment only
5. Apply 2nd pass on face (this step rejuvenates and improves laxity of the skin, especially under the eyes region)
6. Cool lightly if necessary before proceeding to next step.
7. Proceed to Enzyme Peel step – allowing peel to stay on for only 2 minutes after a QS Tx.

If client does not have pigmentation, you can proceed to do Enzyme peel after the skin is cleansed

4. **Apply Enzyme peel**
   - ✔ All Skin types: Use **Cherry Berry 20% Enzyme peel** – use fingers to scrub this peel on the skin with a bit of pressure for 2 minutes and then proceed to remove.
   - ✔ Sun damaged skin: Use **Zesty Orange Enzyme 20% Enzyme peel** – apply peel with fan brush, leave on for 3 minutes.
   - ✔ Dry, Ageing skin: Use **Phyto Pumpkin 20% Enzyme peel** – apply peel with fan brush, leave on for 3 minutes

Redness needs to be present after Enzyme peel application (increasing skin micro-circulation)

5. **Using fan brush, neutralize skin with the appropriate solution. Make sure to rub the solution lightly or pat it into the skin until it disappears.**
   - ✔ Cherry Berry 20% Enzyme peel – Use **Cherry Berry Solution**
   - ✔ Zesty Orange Enzyme 20% Enzyme peel – Use **Zesty Orange Solution**
   - ✔ Phyto Pumpkin 20% Enzyme peel – Use **Phyto Pumpkin Solution**
6. **Mark the skin with a white marker – please refer to HIFU chart**
7. Do not work on Cheek and Thyroid region – cross out the danger zone on the face
8. **Select 4.5mm HIFU handpiece for lower face and neck area**
9. **Select 1.5mm HIFU handpiece on forehead and under the eye area**
10. Apply **Ultrasound gel** on HIFU handpiece and you may proceed to work on the marked areas:
    Using 4.5mm handpiece
    - □ Right side neck
    - □ Right side lower face
    - □ Left side neck
    - □ Left side lower face

    Change to 1.5mm handpiece

    - □ Right side forehead
    - □ Right side under eye
    - □ Left side forehead
    - □ Left side under eye
11. **Remove ultrasound gel & apply Pre-cooled skin tightening serum to the treated areas.**
12. Apply **Pre-treatment crème** or Numbing for 5 minutes (if the skin feels sensitive to touch)
13. **Prepare Needling Pen and set the needle depth at 0.3 (**if not numbing is done) **or 0.5 max**
14. Once time is up, remove Pre-treatment crème with **Rosaderm Foaming Cleanser**
15. Refer to chart for needling Procedure application
16. With gloves, infuse **Skin Tightening Serum** with the needling pen

Skin needs to be intact, not necessary to break the skin

17. If bleeding occurs, please clean the skin with chlorexidine solution using gauge
18. If there is no bleeding, please rub the remaining serum into the skin
19. Apply **Collagen Facial Mask** on the skin for 10 – 15 minutes
20. Remove mask and rub the remaining serum into the skin
21. Put LED light for 5 minutes
22. Finish treatment with EGF/DNA recovery concentrate □ RF Tightening Crème □ Sunscreen with Vitamin E if its summer or client will be going out in the sun. Rebook in 3-4 weeks.

ZESTY ORANGE ENZYME PROCEDURE

For All Skin Types. Great for mature, sun-damaged, dry, aged, dehydrated or cystic acne prone skins.

Procedure Time: 45 minutes

1. Before cleansing skin, apply a small amount of **Zesty Orange Exfoliating Scrub** onto dry skin with or without makeup before cleansing. With circular motion, massage into the skin and then rinse off with plenty of water. It can also be used under steam when treating very Sun-Damaged or excessively Dry skins.
2. Use **Rosaderm Foaming Cleanser** to remove final traces of environmental accumulation and make-up from the skin, rinsing thoroughly. Leave skin wet.
3. Apply Zesty Orange 10% or 20% Enzyme with a wet fan brush over the entire face and neck.

   If using 10% Enzyme,
   for the first visit leave on for:

   - 2 minutes: Only for Sensitive areas around eyes and cheek bones.
   - 5 minutes: Sensitive/Acne Skins
   - 10 minutes: Sun-damaged/Ageing Skins

   If using 20% Enzyme,
   for the first visit leave on for:

   - 2 minutes: Sensitive/Acne Skins
   - 5 minutes: Sun-damaged/Ageing Skins
4. After Recommended Time has elapsed, emulsify (using finger tips and liberal amounts of water to release the dead skin cells and enzyme peel) before gently removing with wet sponges or warm towels and pat dry.
5. Apply with a fan brush liberally onto areas treated with the **Zesty Orange Nutitional Solution** to stop the Enzymatic action. Pat lightly until completely penetrated to stop further tingling sensation.
6. Use **Zesty Cellular Repair Serum** after all the Nutritional solution has penetrated. This serum should be recommended for home-care to build upon and extend the results of your treatment.
7. **OPTIONAL:** If massage is included in your treatment, conduct massage at this stage of the treatment with Shea Butter Raspberry Massage Creme.
8. Apply the **Anti-Radical Masque** liberally. This creamy, soft and rich masque is non-drying. Leave on for 7-10 minutes with a damp towel or wet facial gauze over the masque if treating Dry skins to avoid the masque adhering to the dry skin surface. It may also be applied to the eye contour area if kept moist.
9. Finish with the **Zesty Orange Hydrating Crème** and preferably follow with Sunscreen.
10. Recommend a course of 6 treatments, 3-4 weeks apart, for best results.

Benefits:

- After a Zesty Orange Enzyme Peel, the skin is left moist and softened.
- This peel is an anti-oxidant and free-radical scavenger
- Contains anti-microbial, anti-inflammatory and analgesic properties
- Absorbs UVA and UVB radiation
- Contains Salicylic Acid which helps with Collagen Synthesis and Cellular regeneration assisting in the removal of fine lines and wrinkles when offered in a course or program of treatments.

Note: *By using steam during the treatment while the enzyme is on the skin the intensity of the treatment will be increased resulting in a deeper penetration of the enzyme.*

Important: When introducing this peel, please remember to gradually increase the enzyme application time from 2mins for the first visit to 5mins, then 8 and 10mins in each subsequent visit. Not all skins will be able to tolerate more than 5mins, so watch for over-exposure and stimulation at each visit.

CLIENT RETAIL PRODUCTS

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PRODUCT	SIZE	WSP EX. GST	RRP INC. GST	CODE	QTY
CLEANSERS					
Acne Skin Cleansing Bar	150g	45	90	CSR0008	
Clarifying Foaming Cleanser (Acne)	100ml	30	60	CSR3062	
Discolouration Cleansing Bar	150g	45	90	CSR0022	
Eye Make-Up Remover	100ml	10	20	CSR0060	
Sensitive Skin Cleansing Bar	150g	35	70	CSR0107	
Sensitive Skin Foaming Cleanser	100ml	30	60	CSR3061	
Rosaderm Foaming Cleanser (Rosacea)	50ml	25	50	CSR0091	
Rosaderm Foaming Cleanser (Rosacea)	30ml	15	30	CSR1654	
EXFOLIANTS					
Anti-Radical Scrub	100ml	50	100	CSR0121	
Anti-Radical Scrub	30ml	30	60	CSR1562	
Purifying Exfoliating Masque (All Skins)	50g	45	90	CSR0152	
Purifying Exfoliating Masque (All Skins)	30ml	30	60	CSR1593	
CRÈMES					
5% Glycolic Polymer Crème	50ml	45	90	CSR1340	
5% Glycolic Polymer Crème	30ml	30	60	CSR1531	
Acne Deep Pore Cleansing Crème	50ml	45	90	CSR1364	
Acne Deep Pore Cleansing Crème	30ml	30	60	CSR1548	
Anti-Radical Rejuvenation Crème	50ml	50	100	CSR1333	
Anti-Radical Rejuvenation Crème	30ml	35	70	CSR1555	
Lightening & Brightening Creme	50ml	45	90	CSR1623	
EGF-DNA Recovery Crème (All Skins)	50ml	55	110	CSR1302	
EGF-DNA Recovery Crème (All Skins)	30ml	35	70	CSR1579	
Glucana Hydrating Crème (Oily Skins)	50ml	45	90	CSR1456	
Glucana Hydrating Crème (Oily Skins)	30ml	30	60	CSR1586	
Rosaderm Repair Crème (Sensitive Skins)	50ml	50	100	CSR1326	
Rosaderm Repair Crème (Sensitive Skins)	30ml	35	70	CSR336	
Vitamin E Rose Petal Moisturising Crème	50ml	35	70	CSR0619	
Vitamin A Creme with PPE (Age Defence)	50ml	50	100	CSR1388	
Vitamin A Creme with PPE (Age Defence)	30ml	35	70	CSR1661	
Zesty Orange Hydrating Crème (dry skins)	50ml	50	100	CSR0893	
EYE CARE					
Anti-Radical Rejuvenation Eye Crème	15g	40	80	CSR0435	
Cobra Eye Serum (Puffy Eyes)	15ml	40	80	CSR0398	
Detoxyl Discolouration Eye Crème	15g	40	80	CSR1043	
SERUMS					
Clarifying Boost Serum (Acne Skins)	15ml	35	70	CSR0381	
EGF-DNA Recovery Serum (All Skins)	15ml	35	70	CSR0404	
EGF-DNA Recovery Serum (All Skins)	30ml	60	110	CSR0411	
Erase-A-Line Serum (Vitamin A + AHA)	30ml	45	90	CSR0145	
Firming & Tightening Serum (Anti-Ageing)	30ml	50	100	CSR0503	
Hydrolane Serum (Hyaluronic Acid & Vit-C)	30ml	60	100	CSR0534	
Rosaderm Soothing Serum (Rosacea)	30ml	45	90	CSR0428	
Vitamin A Advanced Repair Serum (Natural Retinaldehyde)	15ml	50	100	CSR1289	
Vitamin A Advanced Repair Serum (Natural Retinaldehyde)	30ml	70	130	CSR1500	
Zesty Cellular Repair Serum (Vit-C & Plant Stem Cells)	30ml	60	110	CSR3887	

Prices effective from **March 2021** and subject to review.

WSP is Exclusive of GST. RRP is inclusive of GST.

Minimum $300 per order for wholesale pricing.

PRODUCT	SIZE	WSP EX. GST	RRP INC. GST	CODE	QTY
TONERS					
Anti-Radical Toner	30ml	15	30	CSR0466	
Hydrating Mango Toner	30ml	15	30	CSR0510	
Phyto-Pumpkin Nourishing Toner	30ml	15	30	CSR0480	
MASQUES					
Collagen Face Masques	10/Box	35	70	CSR2682	
Rosaderm Soothing Masque	30ml	25	50	CSR1487	
SUN PROTECTION					
Antioxidant Sunshade **NEW**	50ml	25	50	CSR0961	
Antioxidant Sunshade **NEW**	100ml	40	80	CSR0862	
BODY PRODUCTS					
Anti-Ageing Hand & Body Moisturiser	250ml	15	30	CSR4013	
Balancing Body Lotion (Phyto-Estrogens)	250ml	25	50	CSR0701	
Skin Tightening Body Lotion **(Coming Soon)**	100ml	30	50	CSR0718	
MEN'S RANGE					
HE 5% Glycolic Polymer Crème	50ml	45	90	CSR1357	
HE EGF-DNA Recovery Crème	50ml	55	110	CSR1319	
HE Vitamin A Creme + PPE (Age Defence)	50ml	50	100	CSR1395	
MISCELLANEOUS					
Facial Brushes	S/L	7	14	CSR251	
PN Cell Hair Regrowth (For Hair Loss) **NEW**	30ml	100	150	PN-CELL	
Silky Smooth Foot Peel **NEW**	1 Pair	8	16	CSR0831	
Tangerine Moisturizing Hand Glove **NEW**	1 Pair	3	6	CSR2088	
RETAIL CLIENT KITS (save up to 20% when ordering retail kits)					
Clear Skin Treatment Kit	7 items	150	280	CSR2699	
Anti-Ageing Treatment Kit	7 items	150	280	CSR2729	
Skin Glow Treatment Kit	7 items	150	280	CSR2736	
De-Pigmentation Treatment Kit	7 items	150	280	CSR2705	
Rosacea & Sensitive Skins Treatment Kit	7 items	150	280	CSR2712	
CUPRON PRODUCTS					
Cupron Cosmetic Pillowcase	1 item	35	70	CU50011	
Cupron Cosmetic Eye Mask	1 item	15	30	CU50403	
Cupron Cosmetic Value Pack (1 Pillowcase & 1 Eye Mask)	2 items	45	90	CU50012	
Cupron Cosmetic Value Pack II (2 Pillowcases & 2 Eye Masks)	4 items	80	160	CU50014	

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PRODUCT	SIZE	WSP EX. GST	CODE	QTY
CLEANSERS				
Clarifying Foaming Cleanser (Acne)	500ml	110	CSP468	
Rosaderm Foaming Cleanser (Rosacea)	250ml	85	CSP623	
Sensitive Skin Foaming Cleanser (All Skins)	500ml	110	CSP467	
EXFOLIANTS				
Purifying Exfoliating Masque (All Skins)	100g	90	CSP410	
Cranberry Scrub (Acne Skin) **NEW**	100ml	70	CSP703	
Mango Scrub (Sensitive Skin) **NEW**	100ml	70	CSP704	
Zesty Orange Scrub (Heavy Duty)	100g	90	CSP705	
PEEL SOLUTIONS				
Glycolic Polymer 10% Peel Solution	50ml	90	CSP180	
Glycolic Polymer 20% Peel Solution	50ml	110	CSP190	
Cabernet Peel Solution	50ml	195	CSP418	
Discolouration Peel Solution	50ml	95	CSP416	
Modified Jessner Peel Solution	50ml	95	CSP417	
Lactic Acid 20% Peel Solution	50ml	95	CSP415	
Salicylic Acid 20% Peel Solution	50ml	110	CSP421	
SERUMS				
EGF-DNA Recovery Serum (All Skins)	100ml	160	CSP477	
Firming & Tightening Serum (Anti-Ageing)	100ml	140	CSP400	
Hydrolane Serum (Hyaluronic Acid & Vit-C)	100ml	140	CSP420	
Vitamin A Advanced Repair Serum (Natural Retinaldehyde)	100ml	170	CSP699	
Zesty Cellular Repair Serum (Vit-C & Stem Cells)	100ml	160	CSP716	
CREMES				
Lightening & Brightening Crème	250ml	160	CSP434	
Lightening & Brightening Crème	100ml	75	CSP433	
EGF-DNA Recovery Crème	100g	90	CSP230	
Glucana Hydrating Crème (Copper peptides)	100g	90	CSP812	
Restoraderm Crème (Post Laser Tx - Prevents Pigmentation)	100g	135	CSP465	
Rosaderm Crème (Rosacea)	100g	90	CSP625	
Vitamin E Rose Petal Moisturising Creme (Super Hydrating Creme with 25% Vitamin E)	100g	65	CSP789	
Vitamin A Creme with PPE (Phyto-Pumpkin Enzyme Moisturising Creme)	100g	90	CSP497	
Zesty Orange Hydrating Crème (Vitamin C)	100g	90	CSP706	
MASSAGE CREMES				
Shea Massage Creme (Mango | Pumpkin)	100g	60	CSP432	
Shea Massage Creme (Raspberry) **New Size**	380g	190	CSP432R	
BODY PRODUCTS				
Anti-Ageing Hand & Body Moisturiser	500ml	25	CSP588	
Skin Tightening Body Lotion **(Coming Soon)**	250ml	55	CSP585	
ENZYMES				
Cherry Berry 10% Enzyme (Vit-B + Vit-C)	100g	240	CSP396	
Cherry Berry 20% Enzyme (Vit-B + Vit-C)	100g	250	CSP397	
Cranberry Enzyme (Anti-Oxidant)	100g	240	CSP220	
Mango Enzyme (Vit-A & Vit-C)	100g	250	CSP532	
Papin Enzyme Activator (Pigmentation)	100ml	90	CSP392	
Papin Enzyme Powder (Pigmentation)	100g	90	CSP393	
Phyto-Pumpkin 10% Enzyme (Vit-A)	100g	240	CSP490	
Phyto-Pumpkin 20% Enzyme (Vit-A)	100g	250	CSP491	
Phyto-Pumpkin 35% Enzyme (Vit-A)	100g	260	CSP492	
Zesty Orange 10% Enzyme (Vit-C)	100g	240	CSP707	
Zesty Orange 20% Enzyme (Vit-C)	100g	250	CSP712	

PRODUCT	SIZE	WSP EX. GST	CODE	QTY
OXYGEN THERAPY				
Step 1 - Respiratory Solution	100ml	90	CSP192	
Step 2 - Hemo Oil	100ml	150	CSP193	
Step 3 - Oxygen Masque	100g	90	CSP194	
TONERS & SOLUTIONS				
Anti-Radical Toner (Allergy Prone Skin)	250ml	80	CSP230	
Cherry Berry Nutritional Solution (Oily Skin)	250ml	80	CSP398	
Cranberry Nutritional Solution (Acne Skin)	250ml	80	CSP210	
Mango Hydrating Toner (Ageing Skin)	250ml	80	CSP531	
Phyto-Pumpkin Nourishing Toner (All Skins)	250ml	80	CSP526	
Zesty Orange Nutritional Solution (Dry Skin)	250ml	80	CSP708	
AMPOULES & VIALS				
Bio-Collagen Ampoules	5ml x 10	90	CSP111	
Melatocin Essence Vials **NEW** (Use with needling to treat Melasma)	5ml x 10	150	MEL-AMP	
HP Cell Rejuvenation Serum Vials **NEW** (Use with needling to treat ageing skins)	3ml x 5	250	CSPDRN	
MASQUES				
Anti-Radical Masque (All Skins)	100g	85	CSP713	
Chiral A 10% Masque (Anti-Ageing)	100g	90	CSP698	
Clarifying Masque (Acne)	100g	80	CSP714	
Mineral Enzyme Masque (Pigmentation)	100g	85	CSP701	
Oxy-Gel Masque (All Skins)	100g	70	CSP715	
Revitalising Masque (Dull & Sun Damage)	100g	70	CSP463	
Rosaderm Soothing Masque (Reactive Skins)	100g	80	CSP620	
PROFESSIONAL CLINIC KITS (save up to 20% when ordering kits)				
Glycolic Polymer Treatment Kit	9 Items	485	CSP221	
Anti-Ageing Treatment Kit	7 Items	410	CSP725	
Cabernet Peel Treatment Kit	13 Items	670	CSP202	
Cherry Berry Enzyme Kit	8 Items	770	CSP395	
Cranberry Enzyme Kit	7 Items	410	CSP222	
De-Pigmentation Treatment Kit	10 Items	600	CSP191	
Mango Enzyme Kit	7 Items	590	CSP533	
Oxygen Treatment Kit	5 Items	340	CSP195	
Papin Enzyme Treatment Kit	7 Items	475	CSP394	
Phyto-Pumpkin Enzyme Kit	11 Items	985	CSP535	
Zesty Orange Enzyme Kit	9 Items	860	CSP710	
ENZYME TRIAL KITS				
Phyto-Pumpkin Enzyme Trial Kit **NEW**	7 Items	195	CSP535K	
Mango Enzyme Trial Kit **NEW**	7 Items	195	CSP533K	
Zesty Orange Enzyme Trial Kit **NEW**	7 Items	195	CSP710K	
MISCELLANEOUS				
Fan Brushes	S|M|L	20	CSP252	
Laser Peel Carbon Crème	300ml	175	S-PEEL	
Product & Treatment Manual	Each	150	MANUAL	
Sample Containers 3ml (Clear)	20/pk	10	CSP438	
Sample Skincare Pack	5 items	5	SAMPLEPK	
Skincare Retail Booklets	50/pk	35	MISC	
Clinical Skincare Retail Bags	20/pk	20	BG-SC	
Clinical Travel Bags	HE/SHE	10	BAGSHE	
TREATMENT GELS				
Ultrasound Gel (BULK)	5 Litre	140	GELBULK-US	
Ultrasound Gel	500ml	25	GEL500	
Aloe Vera Gel	1 Litre	45	GEL-AV1000	
Aloe Vera Gel	500ml	25	GEL-AV500	

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High-intensity focused ultrasound treatment for skin: *ex vivo* evaluation

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Background/Purpose: High-intensity focused ultrasound (HIFU) has been used for skin tightening. However, there is a rising concern of irreversible adverse effects. Our aim was to evaluate the depth of thermal injury zone after HIFU energy passes through different condition.

Materials and Methods: To analyze the consistency of the HIFU device, phantom tests were performed. Simulations were performed on *ex vivo* porcine tissues to estimate the area of the thermal coagulation point (TCP) according to the applied energy and skin condition. The experiment was designed in three orientations: normal direction (from epidermis to fascia), reverse direction (from fascia to epidermis), and normal direction without epidermis.

Results: The TCP was larger and wider depending on the applied fluence and handpieces (HPs). When we measured TCP in different directions, the measured area in the normal direction was more superficially located than that in the reverse direction. The depth of the TCP in the porcine skin without epidermis was detected at 130% deeper than in skin with an intact epidermis.

Conclusion: The affected area by HIFU is dependent on the skin condition and the characteristics of the HP and applied fluence. Considerations of these factors may be the key to minimize the unwanted adverse effects.

Key words: high-intensity focused ultrasound – treatment parameter – skin condition – porcine skin – *ex vivo* experiment

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ULTRASOUND (US) has been used for imaging in clinical diagnosis. However, the use of high-intensity focused US (HIFU) in medicine has taken center stage as a potential treatment modality. This energy source delivers direct and focused energy at preselected depths within soft tissue without damage to the surrounding tissue and no radiation hazard. Therefore, US has been used as a therapeutic modality in the medical fields of surgery, urology, obstetrics and gynecology, oncology, and dermatology (1–8). This system has been used to ablate benign and malignant tumors for the past few decades but is now an emerging star as a potential noninvasive therapeutic modality (2, 5, 7–9).

From a dermatologic point of view, HIFU is one of the optimized methods for nonablative skin resurfacing treatment to preserve the epidermis without downtime. It induces tissue destruction by heating due to absorption of acoustic energy. The histopathology of the damaged tissue is a sharply defined coagulative necrosis (6, 10, 11). HIFU has a target depth from the reticular dermis to the aponeurotic system (9, 12, 13). Therefore, tissue damage by HIFU for skin rejuvenation is expected to induce collagen shrinkage and stimulate neocollagenesis, leading to tightening and lifting of the skin while preserving the epidermis (9, 12–15). HIFU can also tighten aged fascia, resulting in a more 'lifted' look (14, 15). For the past few years, HIFU treatment has been proven safe and effective in tightening and lifting both facial and nonfacial skin (9, 12, 13, 15, 16).

However, there is a rising concern of unwanted loss of subcutaneous fat or skin burn after HIFU treatment in the clinical field. The

Ji-Hye Park and So Dug Lim contributed equally to this work.

characteristics such as depth and location of the thermal coagulation zone created by HIFU are the most important factors in determining adverse effects and achieving desirable clinical outcomes. For this reason, we investigated the area of the thermal injury zone with different preselected penetration depth of HIFU system and applied fluences. The influence of the skin condition through which energy passes was also evaluated.

Materials and Methods

Materials and devices

Fresh specimens of porcine muscle and skin were obtained according to the policies of the Institutional Animal Care and Use Committee (IACUC; CRONEX-IACUC201509-001). The porcine skin was obtained using a Zimmer Brown Electro Dermatome (Model 666; Zimmer, USA, Warsaw, IN, USA).

The HIFU device is designed to target and deliver focused US energy within tissue (Ultracel Inc., Jeisys, Seoul, Korea). This system has high-power transducers to create a coagulation zone with a temperature greater than 60°C along a straight line at a given depth. The target depth is defined by cartridges (transducers, HPs), which extend to depths of 3.0, 4.5, 6, or 8 mm. In other words, the depth of a single cartridge is equal to that of the thermal coagulation point (TCP) depth when the energy of the HIFU is applied from the epidermis to the fascia. In this study, HIFU power was measured by UPM-DT-1000PA (Ohmic, St Charles, MO, USA).

HIFU exposure on tissue-mimicking phantom

A phantom gel which is mainly made of an optically transparent polyacrylamide hydrogel was prepared according to a previous report (17). Addition of temperature-sensitive indicator such as bovine serum albumin can clearly visualize HIFU induced thermal lesions. The denaturation of protein induced by HIFU exposure is shown in the gel and its depth from the surface to the bottom of the TCP was measured. Application of HIFU parameter was 7 MHz, 30 W (watt), 500 ms (a total energy of 1.5 J) using different HPs (3.0, 4.5, 6.0 and 8.0 mm) which are initially designed to focus HIFU energy at respective depth below the transducer.

Ex vivo evaluation of what happened in the skin after HIFU exposure

Porcine tissue was used in this study because its tissue properties are well-known to be close to that of human skin (11). The porcine skin tissue was marked to create a grid before HIFU exposure. Its muscle was also used to evaluate the penetration depth of HIFU energy according to different HPs. After HIFU exposure to a porcine muscle, we identified and measured the white inverse-triangle regions of the coagulated zone which reflect TCP induced by HIFU.

Using a 4.5 mm HP, different parameters (2.7 J, 30 W-90 ms, 3.15 J, 35 W-90 ms) of HIFU were applied to the porcine skin to evaluate the influence of the applied energy.

Comparative study of the skin condition

Simulations were performed on *ex vivo* porcine skin (thickness of 2 mm) to estimate the depths of TCP according to the skin condition. It was designed in three orientations: from the epidermis to the fascia (normal direction), from the fascia to the epidermis (reverse direction), and from the dermis to the fascia (secondary to peeling off the epidermis). Exposures of HIFU were performed at the same power settings (35 W) and exposure times (90 ms) using two HPs (4.5 and 6.0 mm). Porcine tissues were examined using hematoxylin-eosin staining (H&E). We also observed coagulated tissue and measured the width, height, and depth of the TCP. A total of 10 shots of HIFU were delivered at 2 mm intervals for each condition.

Results

We determined the conformity of the HIFU device according to the experimental and porcine tissue test. First, we showed that the HIFU worked properly based on the phantom test (Fig. 1). The result of the phantom test showed the device created a TCP within regular intervals at given depths dependent upon the HP (Fig. 1). The practical depth was measured from the surface of the phantom gel to the bottom of the TCP. The margin of error did not deviate from the 15% of the theoretical depth given by the HP. At a TCP length from 1.4 to 1.9 mm, the error was not significant.

We analyzed the consistency and accuracy of the device using porcine muscle with

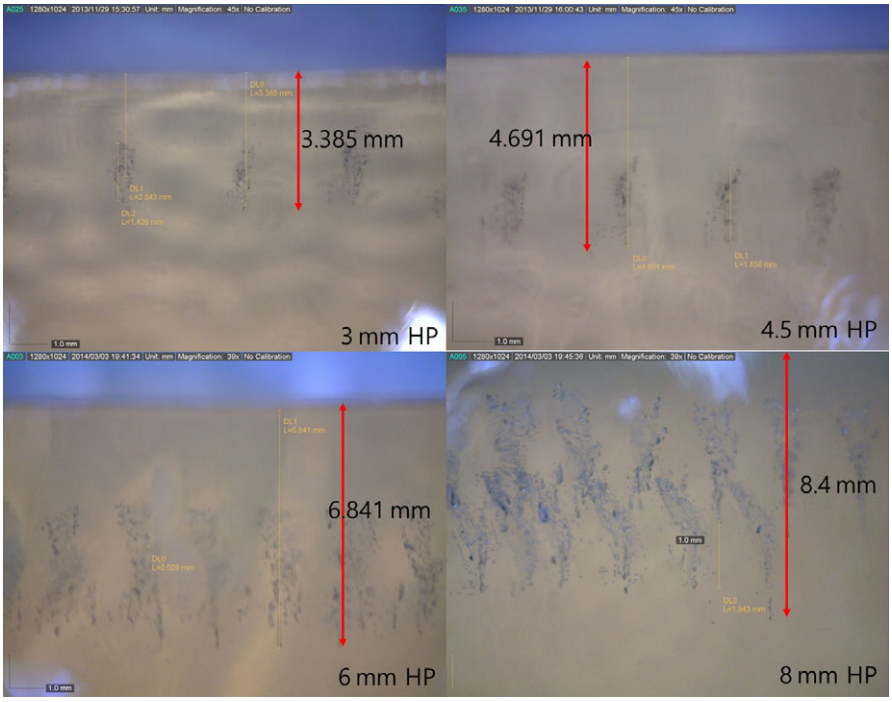

Fig. 1. At the same power (30 W-500 ms), the depth from the surface of the phantom gel to the bottom of the thermal coagulation point (TCP) was 3.385, 4.691, 6.841, and 8.4 mm using a 3.0, 4.5, 6.0, or 8.0 mm handpiece (HP), respectively (error margin = 12.8%, 4.24%, 14.01%, 5.0%).

homogenous composition and porcine skin, which is very similar to human skin. We observed gross muscle tissues irradiated using 3.0, 4.5, 6.0, or 8.0 mm HPs. We confirmed a TCP within regular intervals at the intrinsic depth of each cartridge. Using a 3.0 mm HP which is expected to induce the thermal injury at a depth of 3.0 mm, TCPs were noticed at 4.5 mm deep from the surface (Fig. 2). For 4.5 mm HP, 6.0 mm penetration depth was observed. The depth of TCP was 7.5 and 9.0 mm for 6.0 and 8.0 mm HP, respectively.

Histopathological examination also demonstrated regular spacing of the TCP at an average of 2 mm (3 mm HP, 30 W-90 ms) (1976 ± 101 μm; mean ± SD; minimum: 1807; maximum: 2077 μm; Fig. 3).

Higher fluence application resulted in larger and wider TCP areas (894.61 μm × 371.12 μm TCP in 2.7 J applied porcine skin [30 W-90 ms] vs. 1174.53 μm × 477.27 μm in the skin exposed to the fluence of 3.15 J [35 W-90 ms]; Fig. 4). Epidermal denaturation in the porcine skin exposed to higher fluence of HIFU was also detected.

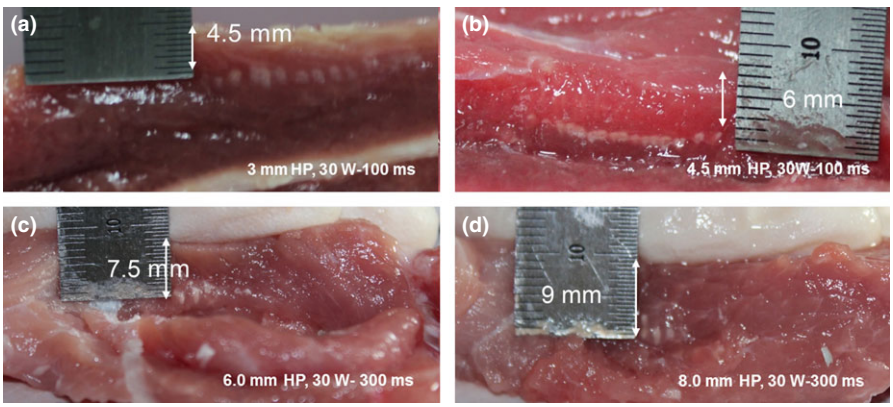

Fig. 2. TCP induced by HIFU in porcine muscle. In porcine muscle, TCP was measured at deeper area, compared with the preselected penetration depth of HIFU energy. Considering ultrasound attenuation in muscle is lower than that in skin, this experiment proved the excellent performances of HIFU device used in this study.

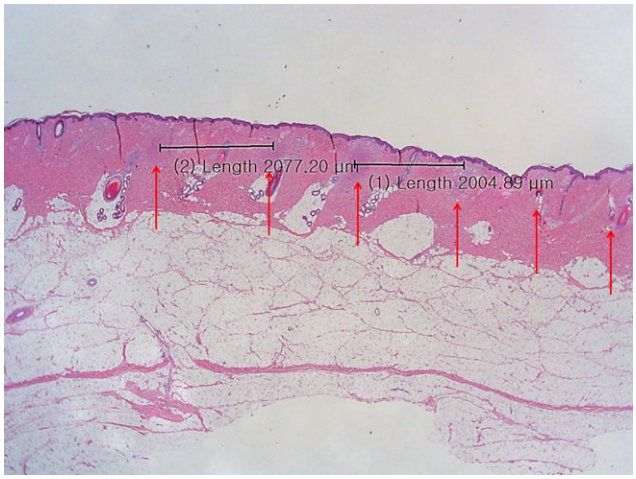

Fig. 3. The intervals between the TCPs were relatively regular from 1.8–2.0 mm with all HP. The basophilic degenerated points represent the TCPs (H&E, ×40). This figure showed formation of TCP at the regular interval using a 3 mm HP (30 W-90 ms). Noticeably, the TCP tended to be affected by hair follicles, which appear to act as a barrier to HIFU energy propagation.

When we applied two different HPs (a 4.5 mm and a 6.0 mm HP) with a total energy of 3.15 J (35 W-90 ms) on the porcine skin, measured average height of TCP was 882 μm using a 4.5 mm HP and 2268 μm with a 6 mm HP. Average width of TCP was 398 μm and 765 μm using a 4.5 mm HP and a 6 mm HP, respectively. The average depth from the surface to the bottom of the TCP was 2594 μm using a 4.5 mm HP and 4723 μm using a 6.0 mm HP. From the fascia to the epidermis at the same energy, the average depth was 6678 μm using a 4.5 mm HP and 8264 μm using a 6.0 mm HP. The depth of the TCP in the reverse direction was deeper than that in the normal direction: 160% using a 4.5 mm HP and 74% using a 6.0 mm HP (Table 1, Fig. 5). When the porcine skin was irradiated from the dermis to the fascia after peeling off the epidermis, the average depth from the surface to the bottom of the TCP was 6023 μm using a 4.5 mm HP. The depth of the TCP without the epidermis was detected at a level 130% deeper than that in the normal direction (Table 1, Fig. 5).

When the subcutaneous fat cell layer was involved within the TCP, adipose tissue was observed as a basophilic amorphous material. We also confirmed that the adipose tissue was vulnerable to thermal injury due to HIFU (Fig. 6). Compared with TCP induced by 4.5 mm HP, the thermally injured area in fat cell layer was approximately six times larger in the skin exposed to 6.0 mm HP even though the applied fluence was the same (35 W-90 ms, total energy of 3.15 J) (716.56 μm × 445.44 μm in 4.5 mm HP vs. 2267.12 μm × 829.31 μm in 6.0 mm HP).

Discussion

In 2009, a device delivering intense ultrasound energy (Ulthera; Ultera Inc., Mesa, AZ) received Food and Drug Administration clearance for use in a noninvasive brow lift and neck lift (18). Since then, HIFU has been the representative noninvasive method for skin rejuvenation. Various HIFU models have been introduced and are commonly used in the cosmetic field. Other than facial lift, HIFU has been used in a number of anatomic regions for body remodeling (19). This technique induces spatially defined heating and coagulation (TCP) within preselected depths using different transducers (HPs, cartridges) and initiates a wound healing process that stimulates new tissue formation and collagen remodeling. As a result, the skin is tightened, and the skin of the face and body are visibly lifted. A number of articles have reported the safety and efficacy of HIFU and

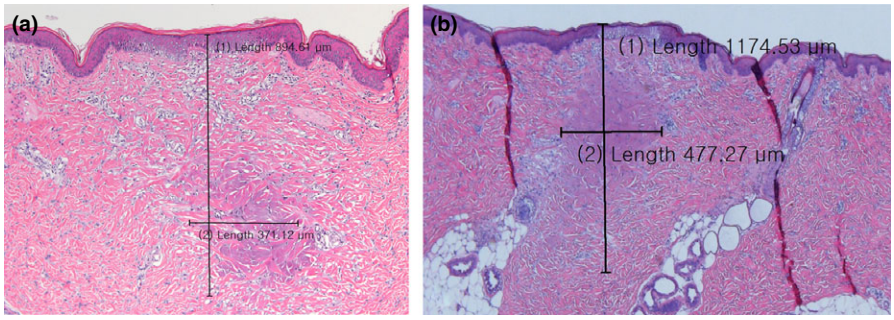

Fig. 4. The differences in TCP created by different applied energy levels (H&E, ×200): (a) 2.7 J of energy application on porcine skin using a 4.5 mm HP (30 W-90 ms), (b) 3.15 J of energy (4.5 mm HP, 35 W-90 ms).

TABLE 1. Comparative study of affected depth according to media. A total of 10 shots of HIFU were delivered at 2 mm intervals for each condition. The value was expressed in mean ± SD

	4.5 mm HP	6 mm HP
Average height of TCP	882 μm ± 56 μm	2268 μm ± 136 μm
Average width of TCP	398 μm ± 18 μm	765 μm ± 23 μm
Normal direction from epidermis to fascia	2594 μm ± 12 μm	4723 μm ± 81 μm
Reverse direction from fascia to epidermis	6678 μm ± 5 μm	8264 μm ± 4 μm
Normal direction without epidermis	6023 μm ± 8 μm	ND

ND, not determined; TCP, Thermal coagulation point.

the process has advantages compared with previous laser devices for rejuvenation (9, 13, 15–22). It thermally coagulates a target deep within the skin without affecting the intervening tissue, enabling noninvasive skin tightening (9, 11). The involved US energy is not absorbed by melanin, which means its energy is theoretically delivered independent of skin color and has minimal adverse effects such as postinflammatory hyperpigmentation in darker skinned patients (13, 16).

However, in practice, side effects such as unexpected fat loss and superficial nodules have been observed after the procedure. Burns arising underneath the skin are a side effect of HIFU (23). A possible reason for this is the variable thicknesses of the epidermis, dermis, and subcutaneous fat layer according to anatomical region and patient skin condition. The treatment parameter can influence the treatment outcomes and adverse effects. However, there have been no previous studies from this perspective of views.

Porcine skin was chosen for analysis in this study because it is similar to human skin in that it is composed of multiple layers. We evaluated the propriety and accuracy of the new HIFU device as well as the depth of thermal injury created by HIFU according to treatment and skin condition.

Through the phantom test and experiments using porcine muscle, we confirmed that the

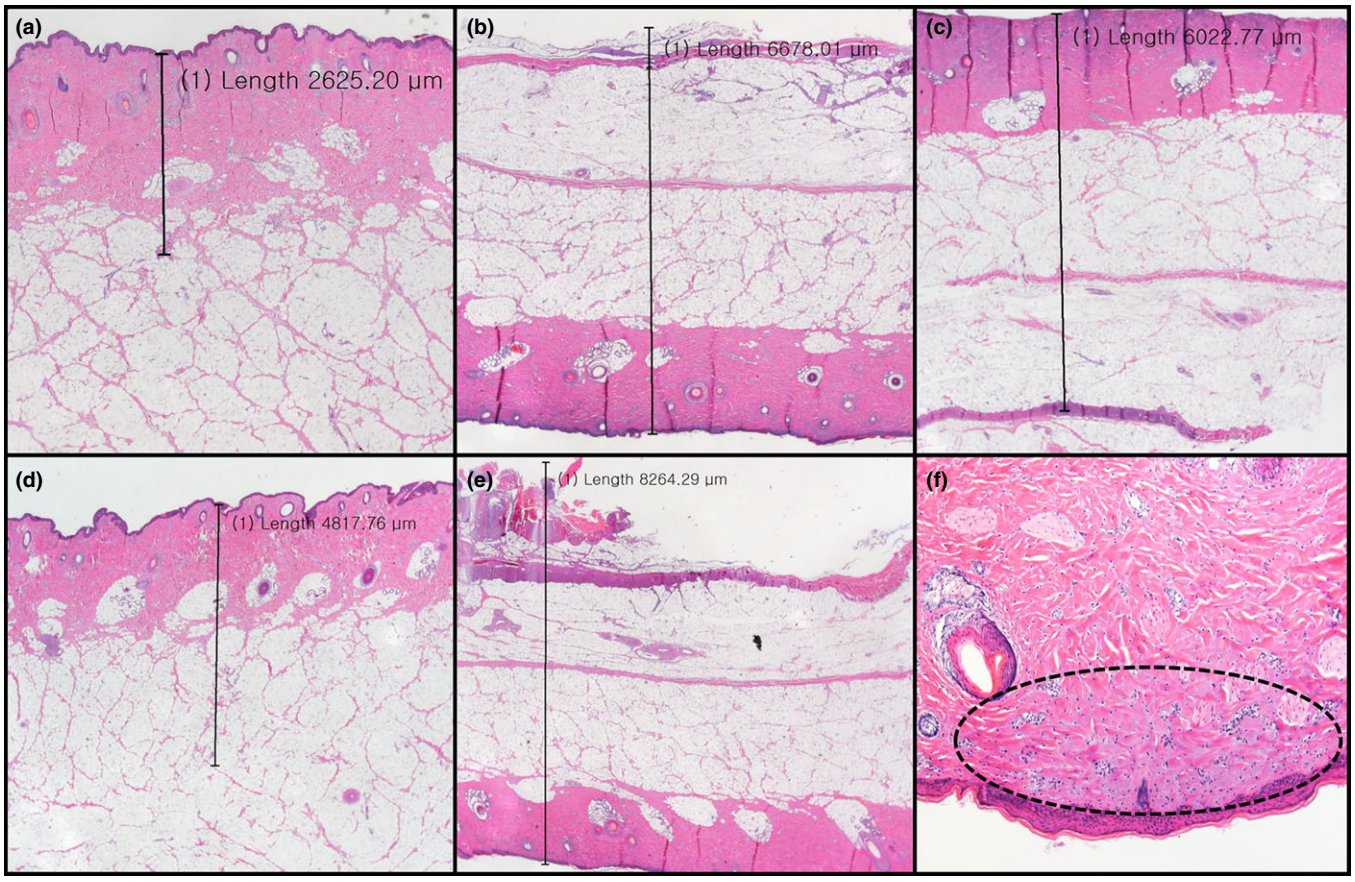

Fig. 5. The depth of TCP (from the surface to the bottom) was measured in each experiment (H&E). All experiments were performed at 35 W and 90 ms: (a) epidermis to fascia using a 4.5 mm HP (×40), (b) fascia to epidermis using a 4.5 mm HP (×40), (c) dermis to fascia after removing the epidermis and using a 4.5 mm HP (×40), (d) epidermis to fascia using a 6.0 mm HP (×40), (e) fascia to epidermis using a 6.0 mm HP (×40), (f) thermal coagulation point in the reverse direction (circle, ×100).

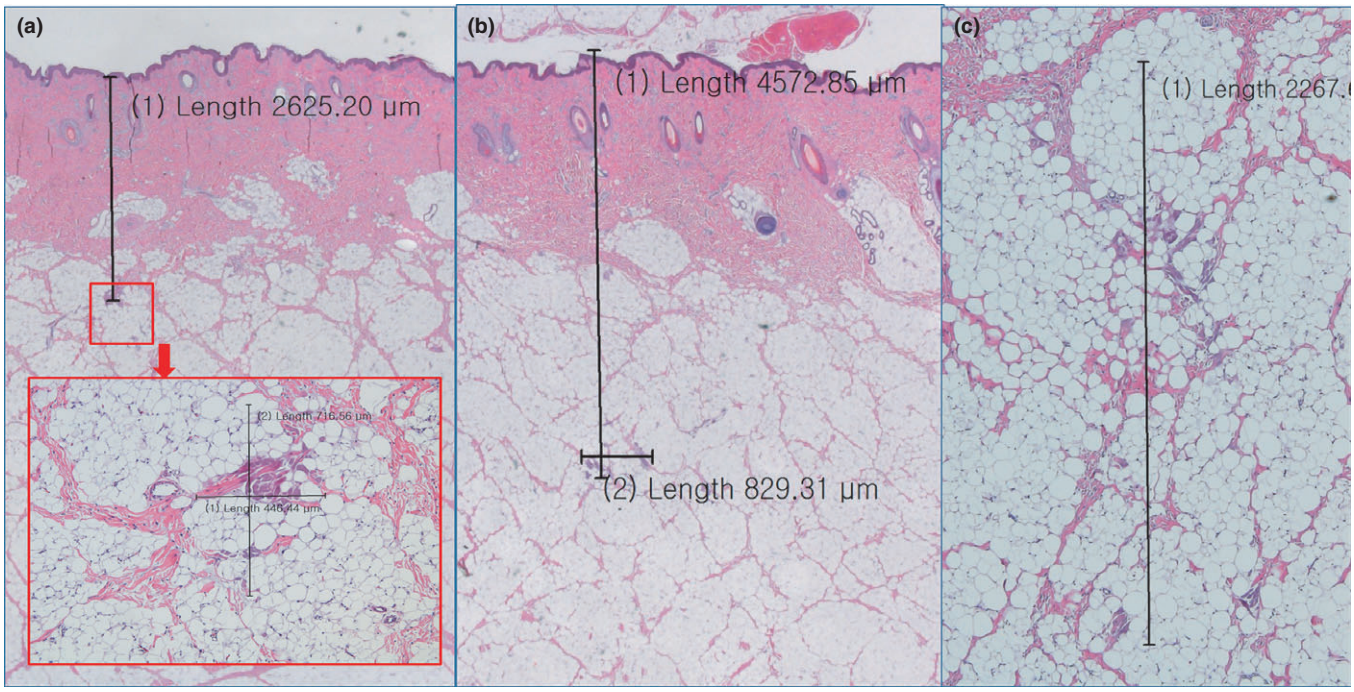

Fig. 6. When the subcutaneous fat cell layer was involved within TCP, it was also thermally damaged by HIFU energy. Compared with TCP induced by 4.5 mm HP, the thermally injured area in fat cell layer was larger in the skin exposed to a 6.0 mm HP. (a) A 4.5 mm HP (35 W-90 ms) was applied (H&E × 40). The inside small red box clarified the subcutaneous layer damage in this condition (H&E × 200). (b) A 6.0 mm HP (35 W-90 ms) was applied in the porcine skin (H&E × 40). (c) Denatured subcutaneous fat cell area was larger in the porcine skin treated with a 6.0 mm HP (35 W-90 ms) (H&E × 200).

device used in this study created a TCP at regular intervals and the expected depth using a preselected HP. The phantom test was designed such that the US line was visualized by HIFU exposure for the phantom gel (24). The result showed that the depth selected by the HP correlated with the affected depth with an error margin no greater than 15% of the preselected depth. The error margin was not significant compared to the height of the TCP (about 25% of the preselected depths). Figure 2 demonstrated that HIFU created TCPs at deeper area from the surface than the preselected penetration depth of HIFU system. Considering the attenuation coefficient of muscle (24%/cm) is lower than that of skin (39%/cm) (25), this result proved the accurate performance of HIFU device used in this study. These two screening tests also confirmed that the HP can control the degree of affect in the target tissue.

When comparing the effect of HIFU on the parameter, a higher fluence application was shown to result in a larger and wider TCP in the tissue. Figure 4b shows epidermal denaturation after HIFU exposure, which indicates that higher fluence of HIFU produces a skin burn. Burns like this are usually more severe than second degree because they start from deep within the skin and spread backward to the surface (23). Although there has been no report of this adverse effect after HIFU treatment for rejuvenation until now, there stands a possibility if proper care is not exerted during the procedure.

The influence of the skin condition through which HIFU passes was demonstrated in this study. All experiments were performed at the same parameters of 35 W and 90 ms (a total energy 3.15 J). We measured the width and height of the TCP and the depths from the surface to the bottom of the TCP. As summarized in Table 1, the height of TCP was more variable than the width of the TCP according to the HP, which implicates higher possibility of unwanted tissue damages above and below the target underneath the skin.

Exposure using a 3 mm HP in the normal direction showed regular TCPs in the dermis (Fig. 3). However, the TCP tended to be affected by hair follicles, which appear to act as a barrier to HIFU energy propagation. Treatment with the 8 mm HP in the normal direction

failed to be visualized by the H&E stain. For these reasons, we excluded the 3 and 8 mm HPs in the comparative study (data not shown here).

Figure 5 shows that the penetration depth in the reverse direction was deeper than that in the normal direction for both the 4.5 and 6.0 mm HPs. The TCP was deeper after removing the epidermis. These results indicate that the location of the TCP is dependent on the components and thickness of the media in which HIFU passes through. In theory, the absorption of energy in the skin is well-known to be dependent on the components of the skin. This is because each layer has inherent absorption coefficients (25). The thickness and condition of the epidermis influences the depth of the TCP. When the TCP included the fat layer instead of the targeted fascia, fat cells were damaged by the thermal energy of the HIFU, which is proved in Fig. 6. In other words, there is a risk that unintended fat tissue might be damaged and the affected depth might be different from the target depth. Therefore, patients and HPs must be chosen carefully with regard to the thickness of the skin and its composition.

Previous studies have shown that HIFU can reliably achieve discrete TCP values at various depths within tissue without surface disruption (11, 13). This study showed consistent results that changes in the TCP were observed as energy settings were varied. We demonstrated another worthy result that the media through which HIFU passes can also affect the depth and location of the TCP. This result indicates that skin thickness and patient condition should be considered during HIFU treatment. The thickness of skin varies among individuals and among regions on the same individual (26).

In conclusion, holistic consideration of anatomical location underneath the skin as well as skin surface condition should be taken into account for better treatment outcomes of HIFU and for minimization of unwanted adverse effects such as subcutaneous fat cell damage, dermal nodules, and serious skin burn.

Acknowledgements

All authors declare there have been no involvements that might raise the question of bias in the work reported or in the conclusions, implications, or opinions stated.

Conflicts of interest

None.

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ORIGINAL RESEARCH REPORT

Intense focused ultrasound for facial tightening: Histologic changes in 11 Patients

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Abstract
Introduction: Intense focused ultrasound (IFUS) is a novel modality for treating skin laxity that produces thermal effects at various depths while sparing the overlying tissue. This study assessed histologic changes and the safety and efficacy of intense focused ultrasound (Doublo™, HIRONIC Co., Sungnam, Korea) for tightening of facial skin in Asian patients. *Methods:* Eleven patients with facial laxity were treated with IFUS and evaluated before and after treatment. Mean age was 46 years (range, 35–64 years). Two available hand-pieces with different focal depths (3 mm and 4.5 mm) were used with three to five passes 1–2 mm apart. Outcome assessment included photographic evaluation by two blinded investigators, skin biopsies before and two months after treatment, and patient satisfaction. *Results:* Subjective and objective analyses showed 63.6% and 72.7% improvement at the two-month evaluation, respectively. Histologic evaluation by hematoxylin and eosin (H&E) and Masson's trichrome staining showed increased collagen fibers in the lower dermis and between fat layers. *Discussion and conclusions:* Intense focused ultrasound can be used as a non-invasive skin tightening technique in Asian patients. It induced collagen generation in the dermis and fat layers and was effective and safe in our study population.

Key Words: *tightening, ultrasound, laxity*

Introduction

As the average life expectancy increases, there are more people who wish to undergo cosmetic procedures for skin rejuvenation and tightening. Although ablative laser treatment is effective for rejuvenation, there is a long down time after the procedure. There are also risks of texture change, hypertrophic scarring, hyperpigmentation and hypopigmentation. An alternative treatment using a non-ablative rejuvenation (NAR) laser has become popular in aesthetic medicine. The NAR devices have been designed to induce thermal injury within the dermis while sparing the overlying epidermis. The problem with NAR devices, however, is that they are not effective as a conventional ablative treatment. Therefore, a non-ablative rejuvenation procedure with an efficacy comparable to that of ablative treatment is needed.

Ultrasound-based imaging systems have been used for clinical diagnoses for several decades. Intense focused ultrasound (IFUS) is an energy modality that can propagate through tissue up to several millimeters (1). IFUS has been used in the treatment of benign and malignant tumors for several years (2). By applying this technology, new devices have recently been developed for skin tightening. These devices are known to induce molecular vibration leading to the generation of thermal energy and formation of a thermal injury zone in the dermis and superficial musculo-aponeurotic system (SMAS) (1). This mechanism is different from that of other NAR devices in that the thermal lesion is made deeper in the tissue (1,3).

There are several reports describing a novel IFUS approach in human cadaveric facial tissue and porcine tissue. IFUS was reported to produce focused thermal collagen denaturation in the SMAS to induce shrinkage and tissue tightening. Alam et al. reported clinical results of ultrasound tightening of facial and

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neck skin (4). The present study was performed to demonstrate the safety and efficacy of intense focused ultrasound (Doublo^{TM}, HIRONIC Co., Sungnam, Korea) in Asian skin and to closely observe the histologic changes in the dermis after IFUS treatment.

Materials and methods

Eleven patients with facial laxity, diagnosed based on clinical findings, were enrolled in this study. All patients were treated with intense focused ultrasound. After having had the purpose and protocol of the study explained to them, all patients gave written informed consent to participate and for the use of their clinical photographs and biopsy specimens. The study protocol conformed to the guidelines set forth in the 1975 Declaration of Helsinki.

Topical anesthetic cream was applied for 40 mins before treatment. After gently removing the topical anesthetic cream, ultrasound gel was applied to the skin. The probe was then placed firmly on the skin surface with uniform pressure. The forehead, temples, and malar area, which is relatively thin, were treated with the 7 MHz, 3.0-mm probe at the following energy settings: forehead, 0.25–0.3 J; malar, 0.35 J; temple, 0.35 J. The cheeks and submentum were treated with the 4 MHz, 4.5-mm probe at an energy setting of 1.0 to 1.2 J followed immediately by treatment with the 7 MHz, 3.0-mm probe at an energy setting of 0.35 to 0.45 J. The spacing of pulses was set at 1.5–2.0 mm. On average, 100 treatment lines were delivered to the forehead, 30 to each temple, 200 lines to each cheek, and 40 lines to the submentum for a total of about 400 lines per face. After treatment, the ultrasound gel was wiped off and a cooling pack was applied.

Follow-up visits took place eight weeks after treatment. Digital photographic documentation under the same conditions (light source, room, and camera) was obtained before treatment and after eight weeks. Improvement was assessed from comparison of the before and after treatment clinical photographs by two blinded investigators. Subjective and objective scores were assigned as follows: 1, no improvement (0%); 2, mild improvement (1–25%); 3, moderate improvement (25–50%); 4, good improvement (50–75%); and 5, excellent improvement (>75%). The clinical data were gathered by two different observers, the principal investigator and the patient herself or himself. Side effects of the focused ultrasound treatment were documented after treatment and at the follow-up visit. Punch biopsies (2 mm) were taken from the lateral side of the cheek two months after treatment. All specimens were stained with hematoxylin and eosin (H&E), Masson's trichrome and Victoria blue.

Results

All eleven patients (one man and ten women) completed the study successfully. Their ages ranged from 35 to 64 years (mean 46.0). All patients were treated with IFUS. None dropped out of the study due to intolerable pain or side effects. During treatment, patients felt only minimal pain, with an average visual analogue score of 3. No patient reported severe pain requiring additional pain relief with analgesia or sedation. Patients had mild erythema that persisted for two to three days. There were no serious adverse events such as persistent erythema, swelling, bruising, or prolonged numbness. Patients were able to return to their usual activity immediately after treatment.

Compared to before treatment, 54.5% and 63.6% improvements in the subjective and objective scores were noted, respectively (Table I). After treatment, improvements in the appearance of fine wrinkles and dilated pores were prominent in seven patients (Figure 1).

Histopathologic results

Hematoxylin and eosin (H&E) staining of biopsy specimens taken at baseline showed non-specific findings (Figure 2 A1, B1, C1). Eight-week post-treatment biopsy specimens showed increased and thickened collagen in the reticular dermis (Figure 2 A2, B2, C2). Although there was no inflammation or fat necrosis, increased fibrosis was seen between fat layers. There were no significant changes in the epidermis in any of the cases. The increase in collagen in the reticular dermis and between fat layers was confirmed by Masson's trichrome staining (Figure 2 D1, D2).

Discussion

Various devices have been developed to treat skin laxity. Ablative skin resurfacing (ASR) rejuvenates skin by inducing sub-lethal thermal damage, leading to re-epithelialization and new collagen formation (5). Ablative carbon dioxide or erbium lasers are successful treatment devices in the ASR category (6). However, patients treated with ASR devices experience a prolonged recovery time, infection and post-inflammatory hyperpigmentation (7). To overcome these limitations, non-ablative skin resurfacing (NSR) devices including Nd:YAG, radiofrequency, infrared light and intensive focused ultrasound (IFUS) were developed (8).

Table I. Summary of treatment results in 11 patients.

Number	Sex/Age	Subjective satisfaction	Objective satisfaction
1	F/51	Moderate	Good
2	F/44	Moderate	Moderate
3	F/46	Excellent	Excellent
4	F/46	Excellent	Excellent
5	M/49	Moderate	Moderate
6	F/40	Good	Good
7	F/46	Good	Good
8	F/64	Good	Good
9	F/45	Excellent	Excellent
10	F/40	Mild	Mild
11	F/35	Mild	Mild

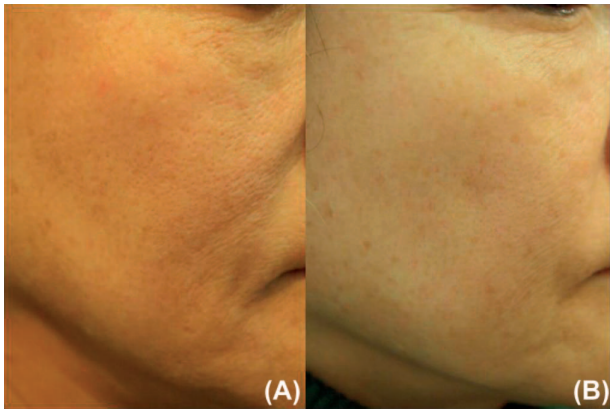

Figure 1. Baseline photograph showing the skin of a 64-year-old women with skin laxity (A). Improvement in fine wrinkles and laxity was seen two months after treatment with IFUS (B).

Intense focused ultrasound is a skin rejuvenation device that is intended to produce thermal effects in the dermis and superficial muscular aponeurotic system (SMAS). The system generates small controlled coagulation points at a certain depth by using short pulses of intense focused ultrasound in the millisecond domain. This technology plays an important role in ensuring both focus accuracy and minimal surrounding tissue damage.

High-intensity focal ultrasound was initially invented as a non-invasive device for the treatment of several benign and malignant tumors and mass reduction in prostate hyperplasia (9). Now it has also been applied for skin rejuvenation applying the concepts of the US-induced thermal treatment zone (9). Ultrasound penetrates the epidermis leading to friction between the cellular molecules. As a result, it generates heat greater than 60°C, which is sufficient for collagen denaturation in a given tissue (1,10). This heat generates a thermal coagulation zone in the target area, inducing a wedge-shaped thermal coagulation zone in the reticular dermis, without damaging the papillary dermis (1). Because melanin is not affected by ultrasound-induced thermal energy, IFUS can be used in a wide range of skin types (11). Furthermore, secondary scatter and absorption in the epidermis does not occur, thereby conferring reduced risk of inadvertent cutaneous injury.

Although previous studies mainly focused on the lifting effect of IFUS, the present study focused on the efficacy of IFUS with regard to collagen and elastic fiber formation in the dermis. We found increased and thickened collagen in the reticular dermis in eight cases after 8 weeks post-treatment. The increase in elastic fibers was not prominent, although some morphologic changes were noticeable, such as elongation. These findings are consistent with those of previous studies describing collagen formation and elastic fiber rearrangement after IFUS treatment (9). Recent studies have also shown that IFUS reduces pore size by inducing collagen formation and subsequent tightening around enlarged pores (12). We also observed improvement in the appearance of fine wrinkles and pores in seven patients. These histologic findings support the clinical finding that IFUS not only has a lifting effect, but also a rejuvenating effect. The lifting effect of IFUS can be explained by the coagulation points made in the SMAS layer. Since tissue only as low as the subcutaneous level is included in punch biopsies, the effect of IFUS on the SMAS layer could not be confirmed in this study. Punch biopsies were done in all cases; part of the fat layer was observed and there was microscopic fibrosis replacing part of the fat lobules after treatment with IFUS. Therefore, we presume that some of the coagulation points were made in the fat layer. Every human has a different dermis thickness, and depending on how much pressure the physician uses when performing IFUS, there can be some coagulation points made in the fat layer. The microscopic fibrosis in the fat layer may contribute to skin tightening. Although this process does not lead to lipoatrophy since the changes are microscopic, if the coagulation points are made repeatedly in the same spot, massive fat necrosis would be possible. However, despite concerns about lipoatrophy after treatment with IFUS, this phenomenon has not been reported in the literature so far. Liposonix®, another high intensity focused ultrasound(HIFU) device that was invented to lyse the fat layer, has a similar mechanism but a different frequency, pulse duration and intensities exceeding 1000 W (13). These parameters cause bulky heating that has a lipolysis effect. Therefore, although IFUS typically results in microscopic coagulation, treatment stacking will result in lipolysis as is seen with Liposonix®. Therefore, stacking should be avoided and repeat treatments with some time interval in between would be better in terms of safety than treatment with many lines at once.

Our results support the clinical effectiveness of IFUS in skin rejuvenation. In a previous clinical study performed by Lee et al., 80% of subjects were found to have clinical enhancement after treatment with IFUS device (Ulthera System, Ulthera, Inc., Mesa, AZ, USA). Our study revealed 63.6% and 72.7% of subjects with clinical improvement. The differences in effectiveness may be due to the fact that we used a different model (Doublo™) of IFUS for treatment.

Additional limitations include the fact that assignment of the subjective and objective scores based on the pre- and post-treatment photographs was not a quantitative evaluation of skin rejuvenation. More precise measurements should be utilized in future studies. Furthermore, if the depth is controlled by the physician and the skin level and structures are seen clearly with high quality ultrasound imaging, even better results can be expected.

To conclude, IFUS has many benefits for skin rejuvenation. It induces thermal damage in the deep dermis that leads to enhancement of collagen synthesis without disrupting the epidermis. We

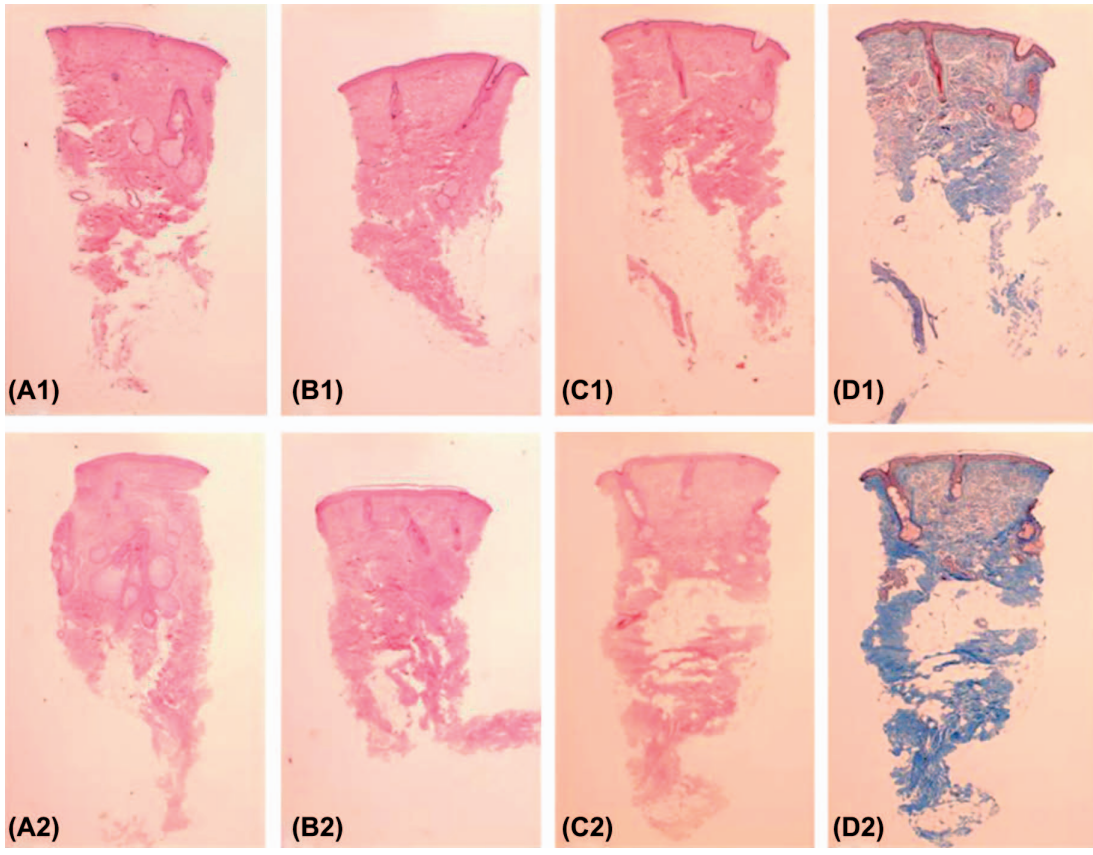

Figure 2. Skin histology of three different patients before treatment with IFUS (A1, B1, C1) and two months after treatment (A2, B2, C2). After treatment with IFUS, the lower layer of the dermis showed increased collagen density, and fibrosis was noted between fat layers. These findings were more evident on Masson's trichrome staining (D1, D2). (H&E × 20, Masson's trichrome × 20).

provide important data that HIFU treatment for skin rejuvenation might be a valuable procedure in Asian patients due to its safety and successful outcomes. Further studies are needed to achieve more effective strategies for skin rejuvenation with IFUS.

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Evaluation of a Microfocused Ultrasound System for Improving Skin Laxity and Tightening in the Lower Face

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Abstract

Background: The Ulthera System (Ulthera, Inc, Mesa, Arizona) employs microfocused ultrasound to cause discrete focal heating of the dermis and stimulate neocollagenesis and elastin remodeling.

Objectives: The authors investigated tightening and lifting of cheek tissue, improvement in jawline definition, and reduction in submental skin laxity in patients treated with the Ulthera System.

Methods: A total of 103 adults were enrolled in this prospective nonrandomized clinical trial. Three-dimensional photographs obtained at baseline and 3 months posttreatment were assessed qualitatively by 3 blinded reviewers and quantitatively with AutoCAD software (Informer Technologies, Redwood City, California). The relationship between outcomes and body mass index (BMI) was examined as well. Patients rated pain during the procedure and provided subjective assessment of their outcome at 90 days. Adverse events were documented.

Results: Ninety-three patients were evaluated. Blinded reviewers observed improvement in skin laxity in 58.1% of patients. During quantitative assessments, overall improvement in skin laxity was noted in 63.6% of evaluated patients. No change was detected in 54.5% of patients whose BMI exceeded 30 kg/m^2 or in 12.2% of patients whose BMI was ≤30 kg/m^2. At day 90, 65.6% of patients perceived improvement in the skin laxity of the lower half of their face/neck. The average procedural pain scores for the cheek, submental, and submandibular regions were 5.68, 6.09, and 6.53, respectively. Wheals, which resolved without intervention or long-term sequelae, were reported for 3 patients.

Conclusions: To the authors' knowledge, this is the largest clinical study of the effectiveness of the Ulthera System for rejuvenation of the lower face. At day 90, improvements were reported by two-thirds of patients and by nearly 60% of blinded reviewers. Outcomes were better in patients with BMI ≤30 kg/m^2.

Level of Evidence: 2

Keywords

microfocused ultrasound, nonsurgical skin rejuvenation, facial rejuvenation, Ulthera

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A face appears "aged" when it has undergone loss of volume, surface changes, reduced elasticity, and increased skin laxity. The goal of antiaging therapies is to create a more youthful, rejuvenated appearance through lifting, tightening, and excising redundant tissues in the face and neck. Therapies that address the lower half of the face, which bears the brunt of gravitational forces, can improve outcomes. Although rhytidectomy remains the gold standard for consistent long-term results in facial rejuvenation, many patients have sought alternatives to this procedure

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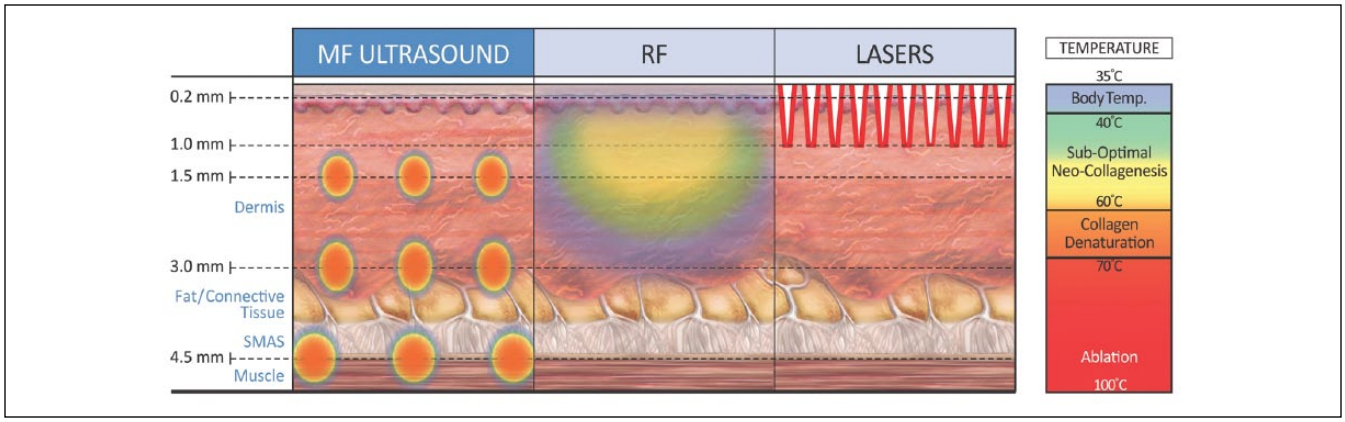

Figure 1. Comparison of microfocused ultrasound, radiofrequency, and laser technologies and their effects on skin and subcutaneous tissue. (Reprinted with permission from Ulthera, Inc, Mesa, Arizona.)

because of the associated recovery times, morbidity rates, financial implications, and/or concerns about surgery in general. Chemical peels, injectables, and light-based and laser (ablative and nonablative) therapies are the main nonsurgical options for facial rejuvenation; however, these treatments are not effective for lifting or tightening tissue. Moreover, their clinical outcomes are variable and their side effect profiles and have not proven superior to those of surgical facelifts.[1-4]

Another nonsurgical alternative for facial rejuvenation is high-intensity focused ultrasound (HIFU) therapy, a common treatment for solid malignant and benign tumors.[5,6] The HIFU devices heat tissue with acoustic energy in a focused, controlled manner. The thermal injury within the tissue leads to focal necrosis and cellular damage, initiating an inflammatory cascade that culminates in tissue remodeling, similar to changes that occur after ablative or nonablative laser treatments.[7-9] Ultrasonic energy not only penetrates deeper into the tissue, causing thermal coagulation, but also avoids the adverse posttreatment effects of more superficial treatments. These HIFU characteristics have piqued interest in its application for rejuvenating facial skin and deep tissue.

The Ulthera System (Ulthera, Inc, Mesa, Arizona) integrates microfocused ultrasound (MFU) therapy with high-resolution ultrasound imaging to deliver energy to precise depths (up to 5 mm) within dermal layers of the skin and superficial musculoaponeurotic system (SMAS), while sparing the epidermal layers (Figure 1). In previous clinical trials, the noninvasive system was shown to be a safe and effective method of improving skin laxity through subdermal tissue coagulation and tightening.[10,11] The Ulthera System works by potentiating thermally induced contraction of tissue and a "wound-healing" response that stimulates the formation of new tissue as well as collagen and elastin remodeling.[12] The heat is confined to small focal regions within the dermis, sparing the overlying epidermis and intervening tissue. The system is similar to a fractional ablative laser, in that thermally injured areas are bridged by undamaged skin.[13]

The goal of this study was to investigate the clinical effectiveness of the Ulthera System (an MFU device) for tightening and lifting cheek tissue, improving jawline definition, and reducing submental skin laxity. As part of this study, a mathematical method was applied to calculate neck and submental lift, which has been accepted by the US Food and Drug Administration (FDA, reference K121700).

METHODS

Institutional review board approval was granted by the University of Texas Southwestern (UTSW) Medical Center in accordance with regulations of the US Department of Health and Human Services (HHS) (45 CFR46) and the US FDA (21 CFR 50 and 21 CFR 56). Between July 6, 2010, and August 21, 2010, a total of 103 adults were enrolled in this single-site prospective, nonrandomized, clinical trial with masked evaluation. The inclusion and exclusion criteria are summarized in Table 1.

Before treatment, 3-dimensional baseline photographs were taken of each patient's face. For the efficacy analysis, additional 3-dimensional photographs were obtained immediately after the MFU procedure and during the 3-month follow-up visits.

Pretreatment Medication

All patients received some form of pretreatment medication to control pain. Oral medications (5-10 mg of diazepam and 5/325 mg of hydrocodone/acetaminophen [1 or 2

Table 1. Inclusion and Exclusion Criteria

Inclusion	Exclusion
Male or female	Pregnant or lactating
Aged 35-60 years	Presence of any active systemic or local skin disease that may alter wound healing
In good health	Severe solar elastosis
Desires lifted and tightened cheek tissue, and/or desires improved jawline definition, and/or desires reduction of submental skin laxity	Excessive subcutaneous fat on the cheeks
Willing and able to provide informed consent	Excessive skin laxity on the lower face and neck
Willing and able to attend follow-up visits	Significant scarring in areas to be treated
	Significant open facial wounds or lesions
	Severe or cystic facial acne
	Presence of a metal stent or implant in the facial area
	History of smoking in past 10 years
	Inability to understand the protocol or to give informed consent
	Mental illness
	History of cosmetic treatments in the facial area to be treated, including facial skin tightening procedure within the past year; injectable filler of any type within the past year; Botox in the lower face within the past 6 months; ablative or nonablative resurfacing/rejuvenating laser treatment or light treatment within the past 6 months; dermabrasion or deep facial peels within the past 6 months; facelift, blepharoplasty, or browlift (including contour threads) within the past 6 months
	Taking isotretinoin or other retinoids within the past 2 weeks; taking psychiatric drugs, warfarin, or heparin within the past 2 weeks

tablets]) were administered at least 30 minutes before treatment. Intramuscular medication (60 mg of ketorolac tromethamine) was given 60 minutes prior.

Treatment and Aftercare

During the procedure, ultrasound gel was applied to the patient's face, and the transducer was placed on the skin to obtain an ultrasonographic image of each section of the proposed treatment area and to ensure adequate coupling between the device and the skin. The physician placed multiple exposure lines 2 to 4 mm apart, each up to 25 mm long, in the selected area. The placement of each line took approximately 3 seconds. All facial regions were treated in this standardized pattern (Figure 2); approximately 295 exposure lines were placed on each patient's face and neck. Therapy was delivered by advancing the transducer 2 to 4 mm along each line in the matrix (17 individual ultrasound pulses per line). All treatment areas received 2 passes: the Ulthera DeepSee 4-4.5 transducer (deeper penetration) was employed for the first pass, followed by the DS 7-3.0 transducer (more superficial penetration) for the second pass. Upon completion of treatment, patients were advised to resume their normal skincare regimens.

Outcome Analyses

Patient Assessments

During treatment, the patient was asked to rate sensation on a scale of 0 to 10, with 0 denoting no sensation and 10 denoting the worst possible pain. At the 90-day follow-up visit, participants were asked to complete a patient satisfaction questionnaire, which entailed recording their perception of the clinical outcome and indicating whether they would be interested in receiving more such treatments in the future (see Appendix A available online at aestheticsurgeryjournal.com/supplemental).

Qualitative Masked Assessment

Most patient data were obtained from projected digital images: 5 pretreatment views and 5 posttreatment (day 90) views were examined for each patient. Each set comprised 1 frontal, two 45-degree (left and right), and 2 lateral (left and right) views, all prepared with Canfield Digital Software (Canfield Imaging Systems, Fairfield, New Jersey). Three physicians based in the plastic surgery department at UTSW but not involved in the recruitment, treatment, or postprocedure follow-up of the patients served as independent blinded reviewers. To permit direct comparisons, the 5 pretreatment images were grouped

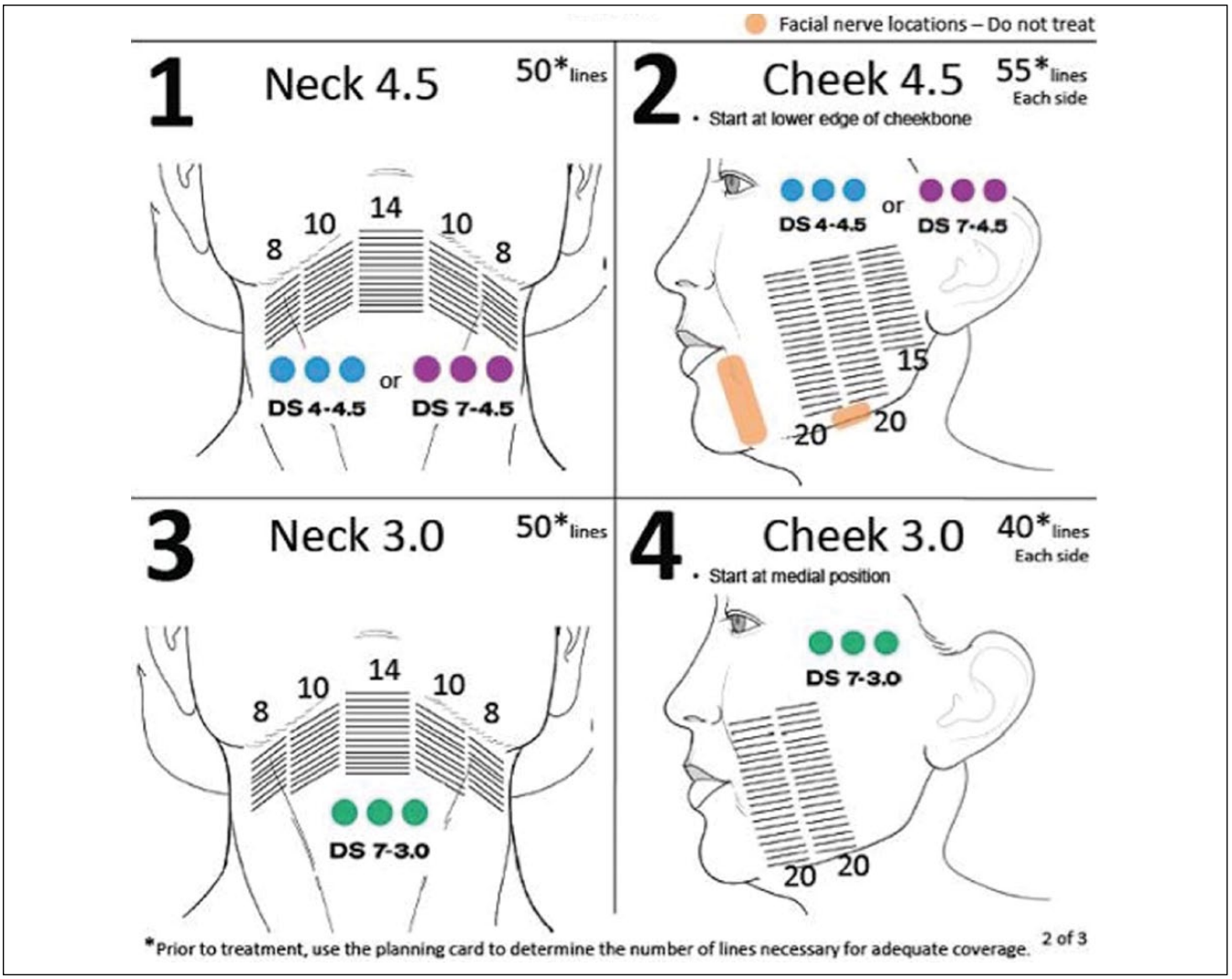

Figure 2. Ulthera System transducer selection and treatment exposure lines based on facial topograpy. (Reprinted with permission from Ulthera, Inc, Mesa, Arizona.)

together and presented alongside the 5 corresponding posttreatment images. However, the sides of placement varied so that reviewers would be unaware of which images were pretreatment and which were posttreatment. The reviewer also was provided with printed pre- and posttreatment photographs. In accordance with the validation protocol, only 1 viewing session of each patient's images was allowed.

Evaluation of 90-day results. Before viewing the images of evaluable patients, the 3 blinded reviewers had been informed that right/left positioning of the pre- and posttreatment images had been randomized. For each patient, they rated the images as "changed" or "not changed"; if change was observed, the reviewer was asked to identify the posttreatment image.

For all evaluable patients, the reviewers' assessments were recorded on a data sheet. Each reviewer's results were then compared with the reference key. If the correct posttreatment image was identified based on the reference key, the patient's result was considered improved. If the reviewer did not observe a change, the result was considered unchanged. If the reviewer identified the wrong photograph as the posttreatment image, the result was considered worsened. All results were then collated on a Microsoft Excel spreadsheet (Microsoft Corp, Redmond, Washington), and trends were analyzed.

Quantitative Assessment

For this assessment, the true lateral images obtained at baseline were compared with the corresponding 90-day images by measuring an area defined by fixed points. Both left and right lateral images were analyzed for each patient. The fixed points were the lateral canthus, the point where the nostril meets the columella, and the point where the

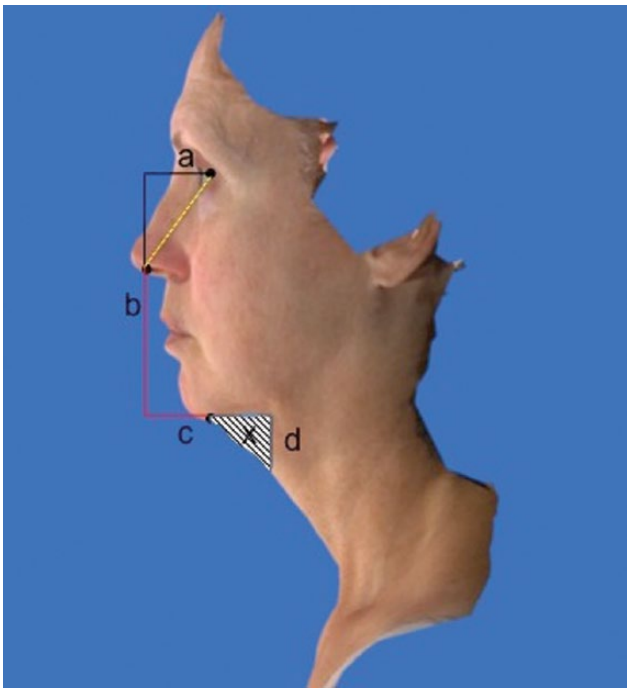

Figure 3. The objective assessment methodology developed for this study. Fixed points are the lateral canthus, the point where the nostril meets the columella, and the point where the chin meets the neck. Line a is drawn horizontally from the lateral canthus, and then a vertical line (b) is dropped down through the point where the columella meets the nostril. A second horizontal line (c) is drawn from line b to the point where the chin meets the neck and then extended an additional 35 mm. A second vertical line (d) is then drawn downward from this terminus. The resulting area (*x*) bounded by line c, line d, and the natural line of the neck is then calculated with AutoCAD software (Autodesk, Version 17.0, 2007; Informer Technologies, Redwood City, California).

chin meets the neck (Figure 3). For each lateral image, a line was first drawn horizontally from the lateral canthus (line a); a vertical line was then dropped down through the point where the columella meets the nostril (line b). An additional horizontal line was then drawn from line b to the point where the chin meets the neck; this line was then extended by 35 mm (line c). Finally, another vertical line was dropped from this point (line d). The area bounded by line c, line d, and the natural line of the neck (ie, area *x*) was then calculated with AutoCAD software (Autodesk, Version 17.0, 2007; Informer Technologies, Redwood City, California). A reduction in area *x* represented tissue lift. A reduction of >20 mm^2 denoted improvement. This proprietary company-developed measurement method (developed by Ulthera, Inc, Mesa, Arizona) has not been previously published but was accepted by the FDA (reference K121700) as supporting a clinical result consistent with neck and submental lift.

Table 2. Summary of Baseline Demographics of Enrollees (N = 103)

Characteristic	Value
Age, mean (range), y	49.2 (35-60)
Sex, No.	
Male	16
Female	87
Fitzpatrick skin type, No.	
I	12
II	66
III	15
IV	5
V	3
VI	2
Body mass index, mean (range), kg/m^2	25.6 (18.7-36.5)

Adverse Events

An unanticipated device-related adverse effect was defined as "any serious adverse effect on health or safety, or any life-threatening problem or death caused by, or associated with, a device; if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan, or application (including supplementary application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of patients." For example (and not limited to), events related directly to the device such as changes in skin pigmentation, erythema, swelling, or bruising were considered to be adverse events. Events not directly related to the device were also recorded, for example (and not limited to), unrelated admissions to the hospital or infections such as pneumonia.

RESULTS

Eighty-seven (84.5%) of the 103 enrollees were women. The mean patient age was 49.2 years (range, 35-60 years), and the mean body mass index (BMI) was 25.6 kg/m^2 (range, 18.7-36.5 kg/m^2). Most patients had Fitzpatrick skin type II. Patient demographics are summarized in Table 2.

Of the 103 enrollees, 93 completed the study and could be evaluated. Ten patients were excluded because of incomplete treatment (n = 1), self-withdrawal from the study (n = 3), or failure to attend the 90-day follow-up assessment (n = 6).

In the remaining 93 participants, skin surface remained intact, and there was no damage to the epidermis. Throughout the study, there were no reports of acute skin damage or long-term sequelae such as scarring, burns, hypopigmentation, hyperpigmentation, or ulceration.

Table 3. Patient-Assessed Pain Scores by Facial/Neck Region During Treatment With the Ulthera System (n = 93)

Score	Cheek	Submental Region	Submandibular Region
Average score	5.68	6.09	6.53
Maximum score	10	10	10
Minimum score	1	2	2

Sensory response was rated on a scale of 0 to 10: 0 = no sensation; 1 = series of pinpricks; 2 = pinpricks plus warmth; 3 = continuous prickly warmth; 4 = stinging heat; 5 = moderate pain; 6 = increasing discomfort; 7 = significant discomfort; 8 = severe discomfort; 9 = extreme discomfort; 10 = worst possible pain.

Patient Satisfaction

At the 90-day follow-up visit, 61 (65.6%) of the 93 evaluable patients reported improvement in the lower half of their face/neck; 32 patients (34.4%) felt there had been no improvement in this area. Of those who saw no improvement, 14 (43.8%) indicated they would undergo another treatment.

With respect to pain during the procedure, patients noted that the most comfortable treatment area was the cheek, followed by the submental region and then the submandibular area (Table 3). Average pain scores were 5.68 (range, 1-10) for the cheeks, 6.09 (range, 2-10) for the submental area, and 6.53 (range, 2-10) for the submandibular region.

Assessments by Masked Reviewers

According to assessments of masked reviewers, improvements in skin laxity of the lower two-thirds of the face and the neck occurred in 54 (58.1%) of the 93 patients. No change was observed for 16 patients (17.2%), and the result was worse for 23 patients (24.7%). Pre- and posttreatment images of several patients appear in Figures 4 to 6.

Effect of BMI

BMI exceeded 30 kg/m^2 for 11 of the 93 patients evaluated. According to clinical assessments, 3 (27.3%) of these patients had improvement, 6 (54.5%) remained unchanged, and 2 (18.2%) worsened. When these 11 patients were excluded from the overall analysis, the percentage of reviewer-assessed improvements increased to 62.2%, the percentage of patients with no change was reduced to 12.2%, and the number of patients with a worse result remained essentially the same.

Quantitative Assessments

Of the 103 enrollees, 78 satisfied the criteria for objective quantitative assessment. The 25 patients who were excluded had failed to complete treatment or follow-up (n = 10), or their photographs had lighting problems or other issues that rendered them inadequate for analysis (n = 15).

Correlation between the left and right lateral images was good (P = .522). The average amount of lift was 45.2 mm^2, reflecting improvement in skin laxity for 71.8% (56 of 78) of seventy-eight assessed patients. Of the patients who experienced a quantitative lift, 82.1% (46 of 56) were deemed improved according to the masked qualitative assessment, and 75.0% (42 of 56) noted improvement in their face and/or neck at day 90 (per the patient satisfaction survey).

Among patients with BMI >30 kg/m^2 (n = 8 [after exclusions]), the average amount of lift was 24.3 mm^2. This finding correlates with the improvement in skin laxity observed for 50% (4 of 8) of these patients.

Adverse Events

Seven adverse events were reported during the study (Table 4), 5 of which were deemed mild and 2 moderate. Four of these events were considered unrelated to the device or the procedure. All 3 device-related adverse events were wheals on the cheek or neck, all of which were rated as mild and resolved spontaneously with no sequelae. The adverse event profile with the Ulthera System compares favorably with that of traditional laser treatments. The duration of facial swelling did not exceed 7 to 10 days in any patient, and there were no reports of crusting, pigment changes, or persistent pain.

DISCUSSION

Rejuvenation of the neck and lower two-thirds of the face, particularly skin tightening and lifting, is a goal of many nonsurgical and surgical cosmetic procedures. Although surgical rejuvenation remains the gold standard for many patients and physicians, MFU devices have clear advantages. These devices provide dermal heating to induce collagen denaturation and subsequent synthesis. The epidermis is spared, and patient downtime is minimized.[14] When epidermal tissue is disrupted, crusting and peeling often occur for a lengthy period, and the protective barrier may be lost.

The epidermal-sparing properties of fractionated MFU devices such as the Ulthera System were demonstrated in a clinical study by Gliklich et al,[12] who also reported that the area damaged by thermal ablation from intense ultrasound exposure was approximately 1 mm^3. In a cadaveric study, White et al[15] found that ultrasonic energy deposited deep within the SMAS induces the most effective skin tightening.

Similar to other MFU devices, the Ulthera System is designed and configured to produce small (approximately

Figure 4. (A, C, E) Images of this 47-year-old white woman (Fitzpatrick skin type III; body mass index, 21 kg/m^2) before treatment to the cheeks, jawline, and neck with the Ulthera System (Ulthera, Inc, Mesa, Arizona). (B, D, F) Ninety days after treatment, her average lift was 60.6 mm^2.

1 mm^3) microthermal lesions in the mid to deep reticular dermis and subdermis, while sparing the overlying papillary dermis, the epidermis, and the intervening tissue between the lesions. Thermal damage to the dermis stimulates collagen neosynthesis, leading to clinically observed skin tightening. The device also enables visualization of the tissue, which permits its evaluation and ensures proper transducer contact. Four Ulthera transducers are available: the

Figure 5. (A, C, E) Images of this 52-year-old white woman (Fitzpatrick skin type I; body mass index, 26 kg/m^2) before treatment to the cheeks, jawline, and neck with the Ulthera System (Ulthera, Inc, Mesa, Arizona). Note the substantial laxity of the neck and submental area. (B, D, F) Ninety days after treatment, her average lift was 181.7 mm^2.

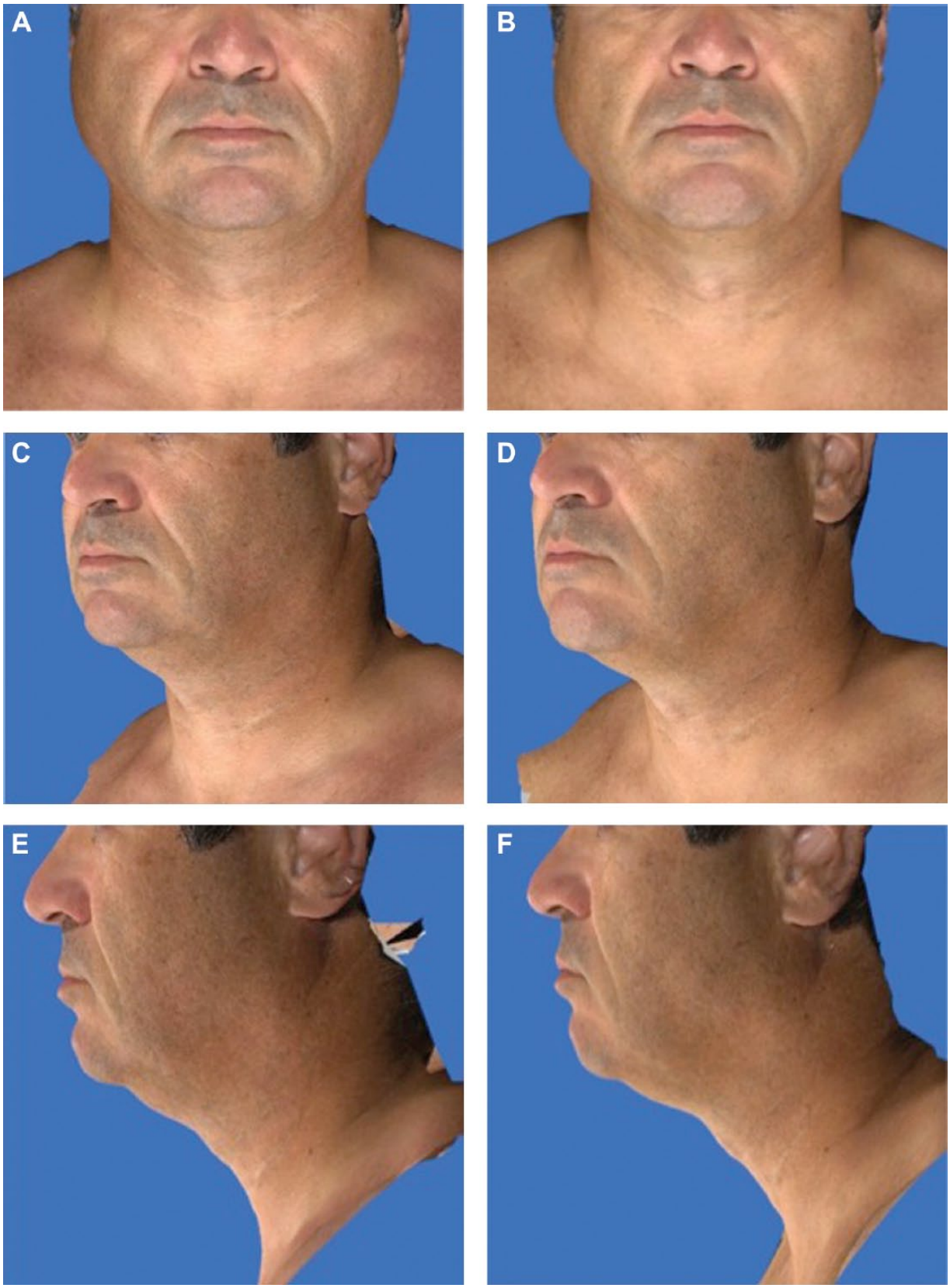

Figure 6. (A, C, E) Images of this 52-year-old white man (Fitzpatrick skin type II; body mass index, 27 kg/m^2) before treatment to the cheeks, jawline, and neck with the Ulthera System (Ulthera, Inc, Mesa, Arizona). (B, D, F) Ninety days after treatment, his average lift was 91.8 mm^2.

Table 4. Adverse Events and Relationship to Study Device (n = 7)

Patient No.	Days After Treatment	Adverse Event Description	Severity	Action Taken	Relationship to Investigational Device	Outcome
1	1	Wheals on right cheek and right side of neck	Mild	None	Possible	Resolved; no sequelae
2	1	Wheal on left cheek	Mild	None	Possible	Resolved; no sequelae
3	84	Common cold	Mild	Medication	Unrelated[a]	Resolved; no sequelae
4	78	Pneumonia	Moderate	Medication	Unrelated[a]	Resolved; no sequelae
5	78	Cracked rib	Moderate	Medication	Unrelated[a]	Resolved; no sequelae
6	1	Wheal on left side of neck	Mild	None	Probable	Resolved; no sequelae
7	79	Influenza	Mild	None	Unrelated[a]	Resolved; no sequelae

[a]Adverse event was not related to the study device.

DS 4-4.5 and DS 7-4.5 (which target subdermal tissues, including the SMAS), the DS 7-3.0 (which targets the dermis to a depth of ~3 mm), and the newer DS 10-1.5 (which targets the upper dermis).

Suh et al[16] obtained biopsy specimens from 11 patients who had undergone treatment with the Ulthera device 2 months earlier and reported a statistically significant increase in dermal thickness secondary to increased dermal collagen fibers. Moreover, they found no evidence of epidermal changes or inflammatory reactions. These results support previous findings of White et al,[15] who reported sparing of the epidermis and focused thermal microablative damage, characterized histologically in human cadaveric skin. In a pilot study, Gliklich et al[12] demonstrated that intense focused ultrasound had no effect on structures such as the facial nerve or its branches and produced discrete areas of coagulative damage. Furthermore, no thermal injury was apparent from histologic examination conducted 4 to 12 weeks posttreatment.

By contrast, traditional laser devices can induce epidermal injury that results in postprocedural morbidities such as prolonged erythema, scarring, pigmentary changes, and, rarely, infection or an unpredictable clinical result.[17] Monopolar and bipolar radiofrequency devices, which tighten the skin through volumetric heating, have shown variable efficacy over the past decade. Clinical results with these devices have been inconsistent and largely anecdotal.[1,18] For example, during a review of efficacy studies of nonablative radiofrequency devices, Atiyeh et al[19] noted low levels of evidence. Fractionated MFU differs from older radiofrequency devices in that it causes very little epidermal heating, with most of the energy deposited in the dermis (Figure 7).

To our knowledge, the present study is the largest to date of patients treated with an MFU device irrespective of anatomic region. Our results compare favorably with those of smaller published studies. Lee et al[11] examined the efficacy of Ulthera treatment and found that at 90 days, 80% of blinded assessors saw some clinical improvement in the 10 patients who completed the study, and 90% of patients noted improvement in skin laxity. The side effect profile was similar to that of our study, with all patients reporting slight erythema and edema but no lasting sequelae. In a recent publication, Suh et al[20] reported that all 15 of their patients treated by intense focused ultrasound had improvement in eyebrow lift, according to objective and subjective evaluation. In a blinded, prospective, cohort study, Alam et al[10] evaluated the outcome of Ulthera treatments to the forehead in 35 patients. All patients experienced erythema after treatment, which was transient and resolved within 7 days. Wheals on the neck

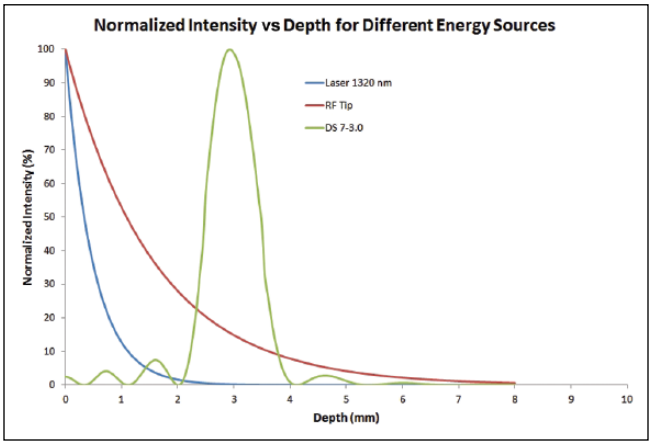

Figure 7. Depth of energy penetration with laser, radiofrequency, and Ulthera devices. The Ulthera transducer (DS 7-3.0) delivers peak energy at a depth of 2 to 4 mm, in contrast to traditional radiofrequency and laser energy sources, which delivers peak energy at the epidermis. (Reprinted with permission from Ulthera, Inc, Mesa, Arizona.)

developed in 2 patients and resolved within 7 days of topical steroid use. At the 90-day evaluation, 86% of patients were assessed as having statistically significant eyebrow lift, with a mean elevation of 1.7 mm.

Microfocused ultrasound compares favorably with lasers and radiofrequency devices. First, any evidence of edema produced by the Ulthera device subsided within 7 to 10 days—a result comparable to those of studies of radiofrequency devices such as Thermage (Solta Medical, Hayward, California).[18,21] The specific targeting of the dermis by MFU should help ensure consistent clinical results. Second, the Ulthera system allows direct visualization of the treatment area to ensure that energy is delivered to the targeted location/depth within the dermis and that proper contact is achieved between the transducer and the skin. Third, unlike many laser devices, ultrasound therapy does not target melanin and therefore is safe for all skin types. Chan et al[22] used this device for skin tightening in Asian patients (Fitzpatrick skin type III or IV) and found that only 2 (4%) of 49 patients experienced postinflammatory hyperpigmentation, which resolved fully within 9 months of treatment.

We quantitatively and qualitatively assessed the effect of Ulthera treatment on skin lifting, tightening, and laxity. On the basis of these assessments, nearly two-thirds of the patients had improvement in skin laxity. Improvement from baseline was noted by two-thirds of the patients at day 90. These findings compare favorably with results of other skin rejuvenation procedures that are maximized around the 3-month mark.[2,3,17,23,24] However, appropriate patient selection is essential for a successful outcome. In our study, patients whose BMI exceeded 30 kg/m^2 tended to have less perceptible improvement (clinically and quantitatively) than those with lower BMI. Most likely, this finding is due either to excess fat deposition within the face or to excess skin laxity, neither of which would improve substantially with this procedure. Brobst et al[25] also emphasized the importance of proper patient selection for maximizing aesthetic outcomes with an MFU device. Physicians should consider this finding when determining which patients are suitable for Ulthera treatment.

Patient Experience

In a study of focused intense ultrasound therapy in 36 patients, Alam et al[10] reported results similar to ours, with no adverse events other than erythema and edema that resolved within 7 days. Pain perception is very subjective, and the range of sensory responses to MFU treatments is broad. Patients who have undergone previous cosmetic procedures often have a higher pain threshold than treatment-naive individuals. In our study, patients experienced greater pain in the submental and submandibular regions than in the cheek. This is likely attributable to the bony prominences/dentition underlying these areas, and greater pain in the periorbital/brow region has been reported by other authors.[26] In our study, oral or intramuscular pain medication was administered to all patients before treatment. Local anesthesia such as nerve blocks or topical applications may improve the somatic experience during an MFU procedure.

Study Limitations, Future Directions, and Clinical Applications

This nonrandomized, noncomparative clinical study had several limitations. New technologies such as the Ulthera System also should be assessed in a randomized comparative manner, which will be implemented in future research. Because patients with excessive skin laxity and/or high BMI are not likely to benefit from this treatment, such characteristics should be incorporated into the exclusion criteria of future studies. Our objective method for assessing results with this device can now supplement subjective assessments, which remain useful but do not permit rigorous statistical scrutiny. Longer follow-up would enable evaluation of the long-term outcomes of Ulthera treatment.

Because MFU remains an emerging technology, few relevant clinical studies exist. When our study was designed, the number of treatment lines placed in the face and neck was somewhat arbitrary, and we erred on the side of caution. However, from subsequent studies we have learned that the treatment density applied in our study was only 40% of the currently recommended company guideline.[22,26] The next step is to examine the effect of a greater number of treatment lines on outcomes.

Investigations of the effects of local anesthesia on pain management and efficacy are needed to improve the patient experience. Future studies involving full-face rejuvenation, multiple treatments in responders and nonresponders, and targeted areas such as periorbital rhytides would be beneficial as well.

CONCLUSIONS

The thermal damage to tissue produced by MFU creates microcoagulative zones and stimulates collagen neosynthesis and subsequent skin tightening. Even though the treatment densities in our study were 40% lower than currently recommended values, promising results were achieved in the lower face and neck, equal to those of ablative or nonablative laser treatments, and side effects were minimal and transient. Additional studies are needed to assess the efficacy of Ulthera treatment for a broader range of clinical indications.

Disclosures

The authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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ORIGINAL ARTICLE

The efficacy and safety of intense focused ultrasound in the treatment of enlarged facial pores in Asian skin

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Abstract

Background: Intense focused ultrasound (IFUS) has been used successfully for skin tightening.
Objective: To investigate the efficacy of IFUS in treating enlarged pores and to evaluate changes in skin elasticity and sebum production following IFUS.
Materials and methods: Twenty-two subjects with enlarged pores were randomized to receive a single treatment with IFUS using 1.5-mm transducer on one side of the face, and 3.0-mm transducer on the other. Objective clinical assessments were made by blinded photographic evaluation. Subjective satisfaction and adverse effects were evaluated. Measurements of elasticity and sebum were performed at baseline, 3 and 6 weeks post-treatment.
Results: Physicians' evaluation showed clinical pore improvements in 86% and 91% of the IFUS-treated sites using 1.5-mm and 3.0-mm transducer, respectively. The mean improvement scores were 1.7 and 1.9 for 1.5-mm and 3.0-mm transducer, respectively, with no statistical differences. Cutometer measurement demonstrated a significant improvement in skin elasticity. Sebum level showed a reduction without statistical significance. There was a positive correlation between improvement in elasticity and pore improvement grades. All treatments were well tolerated without significant side effects.
Conclusion: IFUS using 1.5-mm or 3.0-mm transducer was safe and effective for reducing enlarged pores in Asian skin with an improvement in skin elasticity.

Keywords

Enlarged facial pores, intense focused ultrasound, skin elasticity

History

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Introduction

Enlarged facial pores are related to various factors including genetic predisposition, gender, age, sebum secretion, acne, sun exposure, and decreased skin elasticity (1,2).

Topical retinoic acid (3), chemical peeling (4), 1064-nm Nd:YAG laser (5–7), non-ablative fractional 1440-nm or 1550-nm laser (8,9), and radiofrequency (10) have been used to improve the appearance of enlarged pores with limited efficacy. The effect of lasers or radiofrequency on pores can be explained by the thermal damage-induced collagen remodeling adjacent to the pilosebaceous openings (9,11,12).

Recently, intense focused ultrasound (IFUS) has been introduced as a new treatment modality for skin tightening and rejuvenation. IFUS focuses ultrasound energy to produce confined focal zones of coagulation at the deeper tissue plane compared to non-ablative laser systems using transducers with different frequencies, resulting in collagen regeneration (13–19). To date, no clinical studies have evaluated the efficacy of IFUS on enlarged pores. Accordingly, we investigated the efficacy and safety of IFUS treatment in reducing enlarged pores as a prospective randomized clinical trial and evaluated the changes in skin elasticity and sebum production, the two major factors influencing pores, following IFUS.

Methods

Subjects

Twenty-two Korean subjects (3 men, 19 women; aged 22–51; Fitzpatrick Skin Types III–IV) with enlarged facial pores were enrolled in this study. The exclusion criteria included pregnancy, systemic or topical retinoid use, use of hormonal contraceptives, or skin resurfacing treatments within the preceding 6 months. The participants were not allowed to use systemic or topical retinoids and any skin resurfacing treatment during the study. This study was approved by the Institutional Review Board of CHA Bundang Medical Center, CHA University.

Device description and treatment

We used an IFUS device (UltheraTM system, Ulthera Inc, Mesa, AZ). 10-MHz, 1.5-mm and 7.0-MHz, 3.0-mm focal depth transducers were used in this study. Each subject's left and right side of the cheek was randomly assigned to IFUS treatment using 1.5-mm or 3.0-mm transducer. All subjects received one treatment session. One side of cheek was treated with IFUS using 1.5-mm transducer at 0.25 J per pulse and the other side with IFUS using 3.0-mm transducer at 0.63 J per pulse. Topical anesthetic ointment, eutectic mixture of 2.5% lidocaine hydrochloric acid and 2.5% prilocaine (AstraZeneca AB, Södertälje, Sweden), was

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applied to the cheeks under the occlusion for 40–50 min before the treatment. A total of 40 to 50 lines were delivered to each side of the cheek, adjusting to the size variations in each subject's face.

Objective and subjective evaluations

Photographs by digital camera (Nikon D90, Tokyo, Japan) of each subject were obtained by the same photographer, using identical settings, subject positioning, and room lighting at baseline, and at 3 and 6 weeks after treatment. Objective clinical assessments were performed by two blinded dermatologists. They compared the photos obtained at pretreatment and 6 weeks after treatment separately on each side of the face in a non-chronological order using a quartile grading scale scored as follows: grade 1, 0–25% = minimal to no improvement; grade 2, 26–50% = moderate improvement; grade 3, 51–75% = marked improvement; and grade 4, more than 75% = near total improvement. To evaluate subjective satisfaction, subjects were asked to complete a satisfaction questionnaire at each visit. Overall level of satisfaction was categorized as very satisfied, satisfied, slightly satisfied, or unsatisfied. At each follow-up visit, subjects were also asked to report the possible side effects including persistent erythema, edema, pain, post-inflammatory hyperpigmentation, or numbness.

Measurements of skin elasticity and sebum production

Skin elasticity and casual sebum levels of each side of the cheek were measured at baseline and at 3 and 6 weeks after treatment with a Cutometer® MPA 580 and a Sebumeter® SM815 (Courage & Khazaka, Cologne, Germany), respectively. All the measurements were taken from the same area of each central cheek three times and we calculated their average. Each measurement was performed under the constant temperature and humidity condition (25 °C room temperature and 50% humidity). Three different mechanical parameters of the Cutometer used in this study were: R2, the overall elasticity of the skin (Ua/Uf), R5, the net elasticity (Ur/Ue), and R7, the biological elasticity (Ur/Uf).

Table 1. Objectively assessed clinical improvement grades in pore appearance after a single session of intense focused ultrasound (IFUS) treatment using 1.5-mm and 3.0-mm focal depth transducers at 6 weeks after treatment.

Improvement grade assessed by physicians	1.5-mm focal depth transducer	3.0-mm focal depth transducer
Improvement	19 (86%)	20 (91%)
Mild improvement (1–25%)	10 (45%)	6 (27%)
Moderate improvement (26–50%)	5 (23%)	9 (41%)
Marked improvement (51–75%)	2 (9%)	3 (14%)
Very significant improvement (76–100%)	2 (9%)	2 (9%)
No improvement	3 (14%)	2 (9%)
Total	22 (100%)	22 (100%)

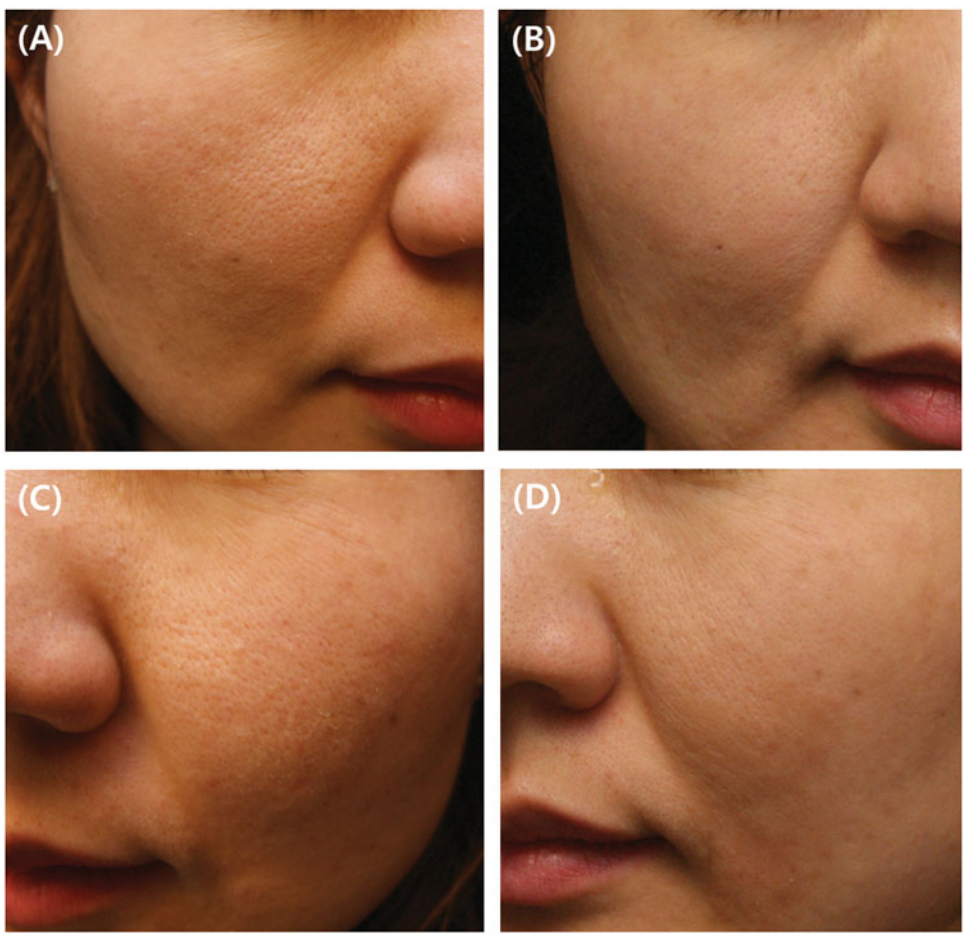

Figure 1. Thirty-nine-year-old woman with enlarged facial pores (A and C) before treatment and 6 weeks after one treatment session of IFUS (B and D). The total number of treatment lines was 50 in each side. The side treated with IFUS using 3.0-mm transducer (B) showed grade 4 improvement in pore size by objective evaluation along with a tightening of the nasolabial fold and marionette line. Subject's satisfaction score was very satisfied. The other side, treated with IFUS using 1.5-mm transducer (D), also showed grade 4 improvement in pore size by objective evaluation and subject's satisfaction score was very satisfied.

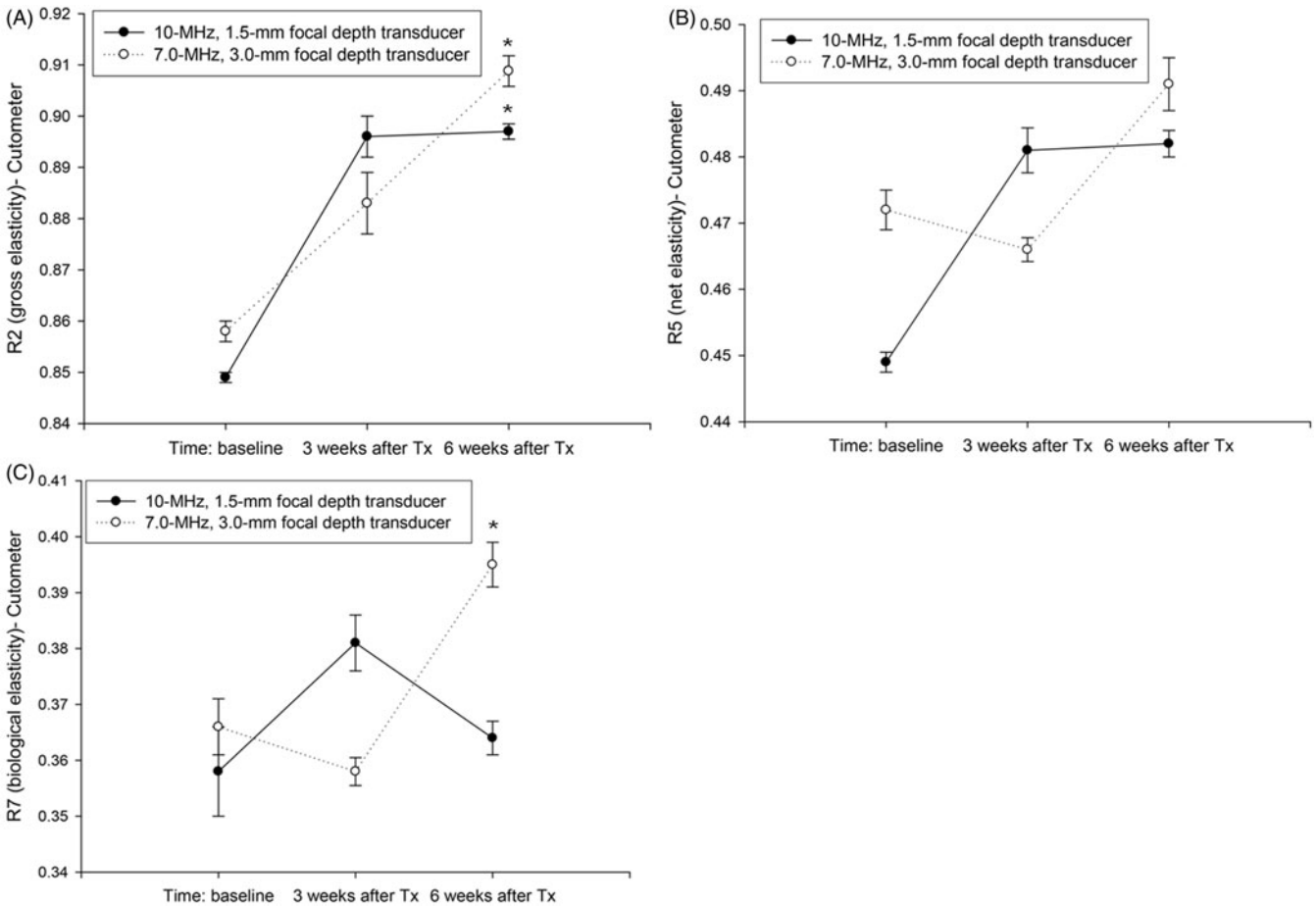

Figure 2. Changes in the skin elasticity as measured by Cutometer following a single session of IFUS treatment using 1.5-mm and 3.0-mm transducers at baseline and at 3 and 6 weeks post-treatment. Results represent mean ± standard deviation. Statistical significance as compared with baseline is indicated as $*p < 0.05$.

Statistical analysis

All statistical analyses were performed using SPSS software (version 12.0, SPSS Inc., Chicago, IL). To compare the post-treatment to baseline values in pore scores, skin elasticity, and sebum production, we used Student's paired *t*-test. Correlations between changes from baseline in elasticity parameters and the clinical improvement grades were tested by calculating the Spearman rank-order correlation coefficients. Statistical significance was defined as a p value of less than 0.05.

Results

At 6 weeks after IFUS treatment, randomized, blinded evaluation by two physicians using a quartile grading scale showed clinical improvements in the overall pore appearance in 19 of the 22 sites (86%) and 20 of the 22 sites (91%) treated with IFUS using 1.5-mm and 3.0-mm transducer, respectively. Four of the 22 sites (18%) and five of the 22 sites (23%) treated with IFUS using 1.5-mm and 3-mm transducer, respectively, demonstrated over 50% improvements (Table 1, Figure 1). The mean improvement scores by physicians were 1.7 ± 1.0 for 1.5-mm transducer and 1.9 ± 0.8 for 3.0-mm transducer, respectively ($p = 0.903$).

Cutometric measurement demonstrated significant improvements in skin elasticity following IFUS treatments. In the sides treated with 1.5-mm transducer, R2 values were significantly increased from 0.849 ± 0.01 at baseline to 0.897 ± 0.02 at 6 weeks after treatment ($p < 0.05$, Figure 2A). R5 and R7 values were also increased at 6 weeks, respectively, however, there was no statistical significance (Figure 2B and C). R2 and R7 values of the sides treated with 3.0-mm transducer were significantly increased from 0.858 ± 0.02, 0.366 ± 0.05 at baseline to 0.909 ± 0.03, 0.395 ± 0.04 at 6 weeks after treatment ($p < 0.05$, Figure 2A and C), indicating that IFUS using 3.0-mm transducer improves the two main parameters of skin elasticity. Furthermore, the clinical improvement grades assessed by physicians in all sites treated with IFUS using both transducers were significantly correlated to the % changes in R2 values (Spearman's $\rho = 0.402$, $p < 0.01$) (Figure 3).

Sebum levels decreased following one session of IFUS, from $44.23 \pm 5.03\,\mu g/cm^2$ and $41.68 \pm 15.26\,\mu g/cm^2$ at baseline to $35.78 \pm 6.04\,\mu g/cm^2$ and $34.52 \pm 14.22\,\mu g/cm^2$ at 6 weeks post treatment using 1.5-mm and 3.0-mm transducer (Figure 4), respectively, but these were not statistically significant.

Subjects' assessment of pore improvement showed that nearly half of the subjects (45.4% and 45.5% for 1.5-mm and 3.0-mm transducer, respectively) reported to be satisfied or very satisfied (Figure 5).

Most subjects experienced transient erythema or edema immediately after treatment. No severe pain but feeling of tightness that lasts about 1–2 weeks was reported in the 3.0-mm transducer-treated sites in six subjects. Edematous striations were noted in the 1.5-mm transducer-treated sites in four subjects, however, the swelling disappeared within 2 weeks. Other possible adverse events such as persistent erythema, bruising, post-inflammatory hyperpigmentation, or numbness were not observed.

Discussion

Loss of skin elasticity and enlarged pores are age-related changes, which can be treated with various skin rejuvenation treatments.

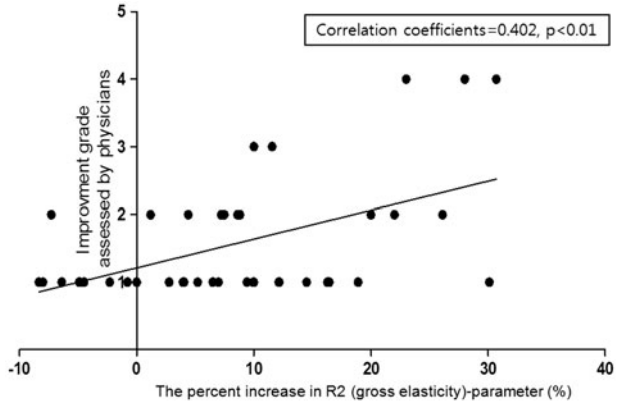

Figure 3. Correlation between the physician's global assessment scores on pore improvements and the percent increase in skin elasticity parameter following IFUS treatment at 6 weeks post-treatment. The association was tested by calculating Spearman's rank order correlation coefficient. A p value < 0.01 was considered to be statistically significant.

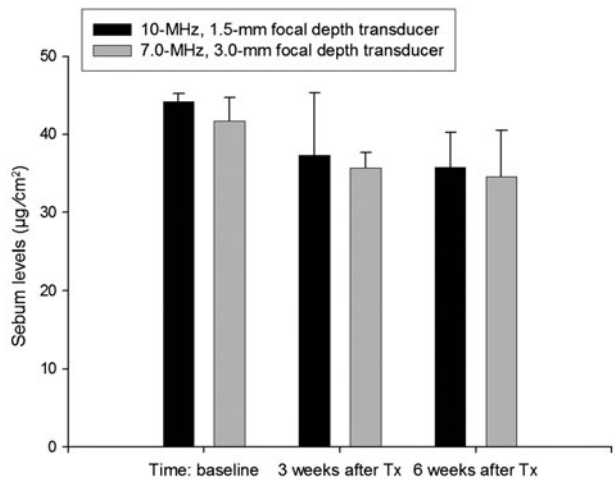

Figure 4. Changes in the sebum production as measured by Sebumeter following a single session of IFUS treatment using 1.5-mm and 3.0-mm transducers at baseline and at 3 and 6 weeks post-treatment. Results represent mean ± standard deviation. A p value < 0.05 was considered to be statistically significant.

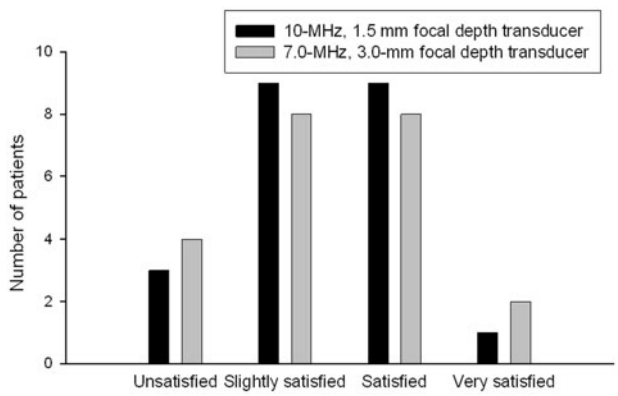

Figure 5. Subjective satisfaction rates after a single session of IFUS treatment using 1.5-mm and 3.0-mm transducers at 6 weeks after treatment.

Our study demonstrated that a single session of IFUS treatment using 1.5-mm or 3.0-mm focal depth transducer is effective for improving the appearance of enlarged pores.

Using the Cutometer, we also demonstrated that IFUS using 1.5-mm or 3.0-mm transducer caused a significant increase in skin elasticity over 6 weeks after treatment. In addition, a positive strong correlation between the clinical pore improvement scores and the post-treatment changes in R2 values suggests that IFUS-induced dermal regeneration and subsequent increases in skin elasticity are major mechanisms involving pore shrinkage and clinical improvement in pore appearance following IFUS.

Previously, Roh et al. (6) reported that five sessions of treatment with Q-switched or long-pulsed 1064 nm Nd:YAG laser were effective in reducing pores and sebum level, suggesting that reducing sebum production may be another possible mechanism of treating pores. We also postulated that IFUS-induced thermal damage may affect sebaceous glands, however, sebum production in both sides of the face showed a slight but statistically insignificant decrease at 6 weeks after treatment compared to baseline. From our results, we suggest that the effect of IFUS on enlarged pores may be attributed to the dermal remodeling at perifollicular area and increased skin elasticity rather than a decrease in sebum secretion. However, thermal injury-induced dermal remodeling may occur for up to 6 months, therefore, further studies are needed to determine the long-term effect of IFUS on the sebum production.

We would like to note that, in our study, a single session of IFUS treatment showed significant objective and subjective improvements in pores along with increased skin elasticity, whereas, in previous studies (5–9) using non-ablative laser resurfacing methods, three to five sessions of treatment were required to produce satisfactory clinical results. In addition, our subjects were all Asian with Fitzpatrick skin type III–IV, however, there were no noticeable adverse events such as post-treatment hyperpigmentation. Different from light-based laser devices, focused ultrasound energy is not selectively absorbed by chromophores such as melanin and hemoglobin (13), suggesting that IFUS may be relatively safe in treating darker skin types. Although our results showed that IFUS treatment improved the enlarged pores along with the increased skin elasticity at 6 weeks after the treatment, a long-term follow-up study is needed to determine the lasting effects of IFUS on reducing pores.

In conclusion, we suggest that IFUS treatment using 1.5-mm or 3.0-mm transducer is safe and effective for improving the appearance of enlarged facial pores with an improvement in skin elasticity in Asian skin.

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the article.

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