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HIFU, Laser and Micro HIFU Research and Reports in Focused Ultrasounds for Face Remodelling

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Abstract

High Intensity focused Ultrasounds (HIFU) is a novel therapeutic method for local hyperthermia and mechanical action on the tissue. The Ultrasonic waves emitted by a transducer propagate through the skin using a coupling gel to the desired target location. New HIFU transducers have been designed to increase flexibility, efficiency and precision of therapy. They can emits full long lines of 10 mm or more with no gap, but also be electronically steered by altering the phase of the different elements. Generally the extracorporeal therapeutic HIFU used frequencies in the range of 0.8 to 3.5 MHz; it depends of the target and the requirement of the penetration depth. Dermatology and Plastic surgery have innovated in using HIFU combined or not with cold laser to treat under the dermis a precise target the skin laxity or to rebalance the fat volume dispatch on ageing patients. Many studies show safety and efficiency in rejuvenation, skin lifting and fat contouring.

Keywords HIFU; Face lifting; Laser; Micro HIFU; Obesity

Introduction

Over the last decade the anti-ageing has gain greater interest to the mankind. The visual era of our modern society generates a rather large choice of methods from cosmeceutical creams to traditional surgery facelift. On a technological side the physicians have now several methods available from radio frequency, to laser therapy, to mesotherapy injection (Table 1). On the newest method remains the non-invasive HIFU (High focalized Ultrasounds) combined with low level laser 635 nm [1-4].

Definition, Method and Modified Forms of Ultrasounds

The ultrasonic waves are transmitted via a coupling gel into the tissue by propagation in real time. In using HIFU you can focus the ultrasound beam to epidermis, dermis or hypodermis [5,6].

The definition of an ultrasound can be expressed in an inaudible high frequency mechanical vibration created by a generator of electrical energy which is converted in acoustic energy from a piezo ceramic deformation located within a probe called transducer. The piezo ceramic can be of various metal components in long lasting high standard quality you can find gold, platinum or silver etc.	Definition
Power	Total amount of energy in an ultrasound beam (watts)
Acoustic impedance of a tissue	The product of the density of the tissue and the speed that ultrasound will travel through it
Attenuation	Progressive loss of energy during passage through tissue
Beam nonuniformity ratio (BNR)	The variability of the beam intensity: the ratio of the maximal intensity of the transducer to the average intensity across the transducer face
Coupling medium	Substance that prevents the reflection of ultrasound at the soft tissue/air interface
Duty cycle	The percentage of time that ultrasound is delivered over one on/off cycle
Standing wave (hot spot)	Created when reflected ultrasound meets further waves being transmitted, with potential adverse effects on tissue
Intensity (common examples): Spatial averaged intensity (SAI)	Intensity averaged over the area of the transducer. Calculated by dividing the power output by the effective radiating area of the transducer head
Spatial peak intensity (SPI)	The maximum intensity over time
Temporal peak intensity (or pulsed averaged intensity)	The peak intensity during the on period of pulsed ultrasound
Temporalaveraged intensity (TAI) (or pulsed averaged intensity)	The average power during the on and off periods of pulsed therapy
Temporalaveraged intensity (TAI)	The average power during the on and off periods of pulsed therapy
Spatial averaged temporal peak intensity (SATP)	The maximum intensity occurring during a single pulse

Table 1: Common terminology used in therapeutic ultrasound.

As a reminder, the epidermis is the top layer of the skin, the dermis middle layer of the human skin, and hypodermis known as the subcutaneous layer (Table 2). The gel prevents reflection of the waves away between emitter and patient skin. It is essential to exclude air between transducer and patient [7-9].

Type of effect	Results
Thermal	Increase in tissue extensibility Reduction of muscle spasm Mild inflammatory response Modulation of pain Increase in Blood flow Reduction in joint stiffness Reduction of muscle spasm
Nonthermal	In combination may result in stimulation of fibroblast activity, increase in protein synthesis, increased blood flow, tissue regeneration, bone healing Acoustic microstreaming

Table 2: Proposed effects of therapeutic ultrasound.

HIFU ultrasounds effects in the tissue. The physiological and biological effects of the HIFU can be described as "Non Thermal effects" and "Thermal effects". The Thermal effects of the ultrasounds includes increased in extensibility of collagen fibers, increased in the blood flow, elevation of temperature above 42°c may damage the tissue. The non-thermal effects of focal ultrasounds generates a realignment of fibroblast, acoustic micro streaming induced pressure changes in tissue fluids demonstrates in vitro the repair of the fibroblast and the collagen synthesis (Table 3). Acoustic micro streaming, the unidirectional movement of the fluids along cell membranes, occurs as a result of pressure changes in the target tissue. It results in a greater oxygenation of the tissue [10,11].

Ultrasound frequency
Wavelength
Intensity
Amplitude
Effective radiating area of transducer head
Beam nonuniformity ratio (BNR)
Continuous/pulsed therapy
Coupling medium
Tissue composition
Movement and angle of transducer
Frequency and duration of treatment sessions

Table 3: Some variables that may affect the dosage of ultrasound delivered to target tissue.

Preclinical studies and selection of patient

HIFU Therapeutic Ultrasounds combined with 635 nm Laser. For treating the skin : Two US emitters one Focal Ultrasounds HIFU in full linear delivery and one in dot mode and one Laser 635 nm in scanning mode. External ultrasonic energy is a high growth area, with several devices under development and other equipment already in use [12-15].

The most advanced technique are based upon the delivery of high-intensity ultrasound waves HIFU to a precise depth from 0.1 mm up to 5 mm under the skin. The device is non-invasively able to stimulate collagen regrowth, operates on SMAS, as well as it is able to disrupt and selectively reduce subcutaneous fatty tissue (in double chin area). Furthermore using a combined HIFU in Lines with micro hifu in dot physicians can lift eyebrow and remove crowfeet. These ultrasounds emitted in fractionate mode, in HIFU lines, dots or Micro focal are totally painless, make no scars, required no anesthesia neither recovery time.

It builds upon growing examination of ultrasound, which has long been considered primarily a diagnostic tool, in therapeutic use by physiotherapists. The great advantage of Ultrasounds is their penetration in real time at targeted areas in the dermis. In the last 20 years major advances in laser technology has revolutionized their use in the treatment of many skin conditions and congenital defects, including vascular and pigmented lesions, and the removal of tattoos, scars and wrinkles. Nowadays there is a wide spectrum of laser and light technologies available for skin resurfacing and rejuvenation

Laser devices with "low" output produce therapeutic effects by non-thermal absorption of photons by cells, such as the red laser 635 nm. These actions are in contrast to high-power lasers in surgery, where a focused laser beam produces intense heat to vaporize tissue. The absorption of photons by enzymes within the respiratory chain of mitochondria is the primary event by which the electromagnetic energy of a laser is transduced into electrochemical and electrophysical effects.

These actions initiate a cascade of secondary intracellular events that alter cell-specific functions, inducing tertiary physiological changes in tissues that cause therapeutic benefits, such as wound healing, pain relief and tissue repair. Clinicians have gained some understanding of the mechanisms for laser-induced wound healing after studying the effects of lasers on fibroblasts, macrophages and other cells critical to tissue repair. Studies of fibroblast cultures provide evidence that lasers absorbed by mitochondria stimulate ATP production to initiate intracellular events, such as increased mitosis and procollagen formation.

Patient's profiles: One hundred Caucasian types' patients have been treated from September 2015 to November 2015 in Clinic Prago Klinik Istanbul, Turkey.

The subject's where divided in 3 age's group

- From 18 to 35 years old
- From 36 to 45 years old
- Plus 46 years old

100 % of the patients were female gender. Group patient analysis. The group consisted in patient numbers as followed: Submental reduction -Jawlines definition: 46

- Skin laxity and skin tightening: 34
- Crow feet, Eye brow lifting smoothing wrinkles: 20

The protocol consists in Submental fat reduction (Double chin area) 3 treatments weekly applying first HIFU spatula for 5 minutes followed by 3 minutes of Laser. Skin Laxity and skin thightening (cheeks area) One treatment first applying HIFU spatula in orange mode level, then Laser immediately after. Crow feet, Eye brow lifting smoothing wrinkles (Figures 1 and 2). One treatment of Tri Focal micro HIFU in

the per orbital eye area, immediately followed by Laser for the patient of Wrinkle level 1, two protocols were performed at one week interval for the patient of level 2 and 3.

Results Assessment of the Method

To assess the results, patient's satisfaction, Caliper measuring and fix point distance measurements were used. Patient photos.

Figure 1: Crowfeet patient: 3 sessions one week apart.

Figure 2: Double chin patient: 2 sessions one week after last treatment.

Patient satisfaction

The results tabulated from the patient satisfaction questionnaires showed that overall, 67% and 55% of (Figure 3) subjects indicated their level of satisfaction to be "Satisfied" or "Very Satisfied" at 90 days and 180 days post-treatment, respectively. The results analyzed by groups are as follows

Group A: Crow feet and fine lines: Subjects' responses indicated that 62.5% and 41.9% of subjects were satisfied (either very satisfied or satisfied) with the study treatment at 90 days and 180 days post-treatment, respectively.

Group B: Jawlines definition and lifting: Subjects' responses indicated that 40% of subjects were satisfied (either very satisfied or satisfied) with the study treatment at both time points.

Group C: Double chin: Subjects' responses indicated that 75% of subjects were satisfied (either very satisfied or satisfied) with the study treatment at both time points.

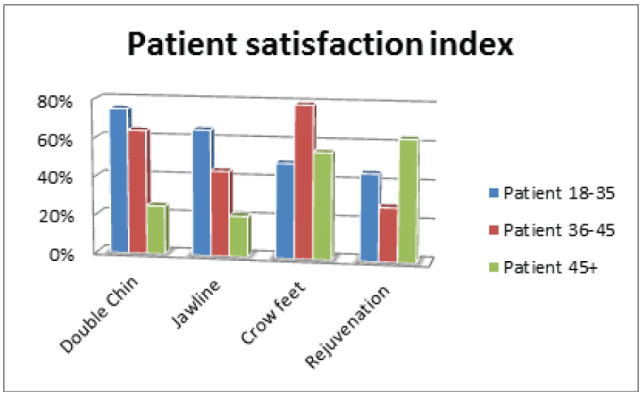

Figure 3: Patients measurements analysis (by Ultrasounds, Caliper and fix points).

Group A: Crow feet and fine lines

Total 20 patients: The Crow feet are wrinkles which initiate from corner of the eyes towards the ears. We have evaluated the deepness of the crow feet before the HIFU and Laser application by ultrasounds sonography (Table 4).

For wrinkles criteria we have define as follow:

- Wrinkles superior to 2 mm deepness: Grade 3
- Wrinkles from 1.5 to 2 mm: Grade 2
- Wrinkles from 1 to 1.5 mm: Grade 1
- Wrinkles from 0 to 1 mm: Grade 0

We have also counted the number of visible wrinkles in the area before and after.

Patient	Wrinkle grade before	Wrinkle grade After	Number of Wrinkle before	Number of Wrinkle after
1	3	1	16	7
2	1	0	5	0
3	3	2	10	6
4	3	1	18	6
5	2	1	4	1
6	3	2	25	12
7	1	0	3	0
8	1	0	4	0
9	3	1	14	5
10	3	1	16	6

11	3	1	19	8
12	2	1	7	3
13	3	1	14	3
14	3	1	21	5
15	3	2	22	9
16	3	1	16	6
17	3	1	17	6
18	2	0	6	0
19	3	1	15	7
20	2	1	8	2

Table 4: The Analysis of the Crow feet area before and after.

For patient of Grade 3 wrinkles, the number of wrinkles in the area varies from 22 to 14, the application of the protocol reduces by 50% the number of visible wrinkles. The major tendency shows that deepness of the wrinkles reduces from Grade 3 to Grade 1, so from 2 mm to 1 mm deepness.

Group B: Jawlines definition and lifting

Total 34 patients: In order to assess the effectiveness of the jaw lines contouring and lifting; we used fixed points on the patients mid face such as the corner of the mouth cheekbones, the nose, the ear and mandible bones (Table 5). The cheeks most prominent area level was measured before and after the treatment.

Patient	Lifting effect on the cheeks area after treatment in millimeters
1	0.4
2	0.5
3	0.4
4	0.6
5	0.7
6	0.4
7	0.5
8	0.6
9	0.4
10	0.5
11	0.6
12	0.6
13	0.8
14	0.2
15	0.4
16	0.8
17	0.7
18	0.5
19	0.4
20	0.6
21	0.5
22	0.3
23	0.4
24	0.6
25	0.4
26	0.5
27	0.4
28	0.5
29	0.6
30	0.7
31	0.4
32	0.5
33	0.4
34	0.6

Table 5: The Analysis of the Cheek lifting effect gives over 34 patients an average of 0.5 cm after 40 days of initial treatment.

The advantage of the HIFU lifting is that it is totally painless and requires no downtime neither anesthesia. It is an excellent alternative for patient who does not want any injection or surgery.

Group C: double chin (caliper)

Total 46 patients: The Analysis of the Double chin fat reduction based on 46 patients give an average of under chin fat thickness of 0.9 cm for a reduction of 0.45 cm reduction in final results 40 days after the first treatment (Table 6). This non-invasive method gives a valid alternative to surgery and lipo aspiration in this area. Patient benefits of a painless method with no incision neither injection of pharma product.

Patient	Before Treatments (Cm)	After Treatments (Cm)
1	0.8	0.4
2	1	0.6
3	0.8	0.4
4	0.5	0.3
5	1.2	0.5
6	0.9	0.4
7	1.1	0.4
8	0.8	0.6

9	1	0.3
10	0.9	0.5
11	1.3	0.4
12	1.1	0.3
13	0.7	0.4
14	1	0.5
15	0.8	0.4
16	0.8	0.3
17	0.7	0.3
18	1.4	0.6
19	0.9	0.3
20	0.8	0.5
21	0.9	0.6
22	1.2	0.5
23	0.9	0.4
24	1.3	0.7
25	1.6	1
26	1.2	0.7
27	0.8	0.4
28	0.9	0.5
29	1.2	0.6
30	0.9	0.8
31	1.1	0.4
32	0.9	0.3
33	1	0.3
34	1.5	0.9
35	1	0.4
36	1.3	0.8
37	1	0.6
38	0.9	0.5
39	1.1	0.9
40	1.2	0.7
41	1.4	0.6
42	0.8	0.3
43	0.9	0.5
44	1	0.4
45	1	0.7
46	1	0.4

Table 6: Double chin measurement is based on using a caliper before the protocol and after the protocol.

Conclusion

Sygmalift represents an alternative to more invasive method, without needle, no down time it is possible within 40 days to obtain effective lifting, double chin reduction, and crow feet smoothing. The highest response group being the group of 35 to 45 years old in term of rejuvenation. For the younger group we have achieved in the range of 18 to 30 excellent procedures of jawline redefinition and double chin fat reduction. Sygmalift HIFU in lines made the focal ultrasounds combined with laser unique in its kind on the Dermatology market.

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