

A PROSPECTIVE STUDY OF THE EFFICACY AND SAFETY OF A SINGLE SESSION OF MICROFUSED ULTRASOUND FOR THE NON-INVASIVE TREATMENT OF FACE AND NECK LAXITY AND PTOSIS.

Author: **Dr. Antonino Araco**

BACKGROUND

In recent years, there has been an increased demand for non invasive cosmetic procedures in order to prevent and treat face and neck aging, and in particular sagging skin, jaws, wrinkles and folds. Botulinum toxin, hyaluronic acid dermal fillers, lasers, and the most recently plasma related growth factors (prp techniques) have been used. Recent studies have shown that transcutaneous focused ultrasound can be effective for non-invasive skin tightening. We conducted the first independent prospective study on this new medical device that uses micro-focused ultrasound.

MATERIALS

We enrolled on the study in our cosmetic private practise in Milan, Italy, only patients of group 1 to 3 with soft to moderate skin laxity and ptosis of the face and neck, according to Araco's Ptosis Scale System (PAS), a 5-point quantitative scale (*Table 1*).

All of them were previously analyzed with digital macro-photographs. Exclusion criteria: any face or neck cosmetic or surgical procedure 6 months prior the treatment, age younger then 30 y.o or older then 65 y.o; group 4 and 5 according to Araco's Ptosis Scale System (PAS); the presence of face metallic implants or heart pacemaker or defibrillation devices; pregnancy; systemic or local illnesses that might affect wound healing; severe solar elastosis, scarring, active and severe inflammatory acne, a history of keloid formation or hypertrophic scar; use of anticoagulant or antiplatelet medications; history of autoimmune disease, chronic drug or alcohol abuse. Smokers patients were asked to stop completely at least 4 weeks before and 4 weeks after the treatment.

	1	2	3	4	5
Nasolabian folds	Absent	Minimal	Mild	Moderate	Severe
Cheek wrinkles	Absent	Minimal	Mild	Moderate	Severe
Jaw lines	Well defined	Minimal jowling	Mild jowling	Moderate jowling	Severe jowling
Neck	No wrinkles	Minimal wrinkles	Fine wrinkles	Deep wrinkles	Redundant skin
Indication for surgical face lifting	No	No	Borden Line	Yes	Yes
Indication for surgical neck lifting	No	No	No	Borden Line	Yes

METHODS

All patients were given 800 mg of ibuprofen 60 minutes before the treatment. Microfocused ultrasound were administered by using 3 different transducers (*Table 2*). All patient received the same protocol of treatment on face and upper neck with 400 lines for each transducer (1.200 lines in total). Also, they did not receive any other aesthetic or surgical procedures on the face and neck in association with the single session of microfocused ultrasound and for the following 3 months.

The primary end point of the study was the assessment of the aesthetic improvement in skin laxity and ptosis by two blinded independent doctors (F.A; M.A;) from standardised digital photographs according to the PAS 5-point scale system, before and 30 days after the single treatment session of microfocud ultrasound. Each doctor scored the photographs from 1 to 5 according to the PAS-scale system. The reduction of at least of 2 set points was considered a significant difference. The second end point was the patient's satisfaction assessed by a Patient Satisfaction Questionnaire (PSQ).

Transducer	Deep	Time	Lenth	Watt	Jouls
7 Mhz	1.5	100 ms	1 mm	4 to 6	v20
7 Mhz	3.0	100 ms	1 mm	5 to 6	20
4.5 Mhz	4.5	100 ms	1 mm	15 to 20	20

RESULTS

From November 2015 to January 2016, 20 white women with a mean age of $47,4 \pm 5,0$ years who fit the inclusion criteria, were enrolled for the study and completed the follow-up after 6 months. The majority of subjects were Fitzpatrick skin Types II (60.3.0%) and III (49.7%). No side effects were reported during the study. Before the treatment, skin laxity and ptosis of face scored 2.8 ± 0.2 according to the PAS 5-points scale system. At 3 months skin laxity and ptosis improved significantly (1.8 ± 0.3) ($p < 0.05$) (*Table 3*).



Three subjects (15.0%) have showed an improvement of 3 points, sixteen subjects (80.0%) have showed an improvement of 2 points and one subject (5.0%) have showed an improvement of 1 point according to the PAS 5-points scale system (*Table 4*).

The results showed that the majority of patients were very satisfied (70%) or satisfied (30%) at 180 days from the treatment (*Table 5*).

n. patient	20
Women	100%
Age (years)	$47,4 \pm 5,0$
Phototype	$2,5 \pm 0,3$

	No change	Improvement of 1 point	Improvement of 2 points	Improvement of 3 points	
n. patient	0	1	16	3	20
%	0%	5%	80%	15%	100%

	n. patient	%
Very Satisfied	14,0	70,0
Satisfied	6,0	30,0
Neither satisfied or dissatisfied	0,0	0,0
Dissatisfied	0,0	0,0
Very Dissatisfied	0,0	0,0
Total	20	100%

CONCLUSION

Our prospective study has been the first completely independent to test the efficacy and safety of a single session of microfocused ultrasound of Ultherapy® as sole treatment for face and neck in order to improve skin laxity and ptosis. The found results have been very encouraging from a clinical standpoint. The majority of patients showed aesthetic improvement on the face and neck as assessed by 2 independent doctors who have viewed the before and 60 days after photographs. Patients judged the clinical aesthetic result achieved very satisfied. We believe that further study assessing the histological difference on collagen quality and quantity should be done.