



**THE EFFECT OF THE LOCALIZED
ULTRASOUND APPLICATION ON THE
FAT CONSUMING SUBSEQUENT TO
AEROBIC EXERCISE**

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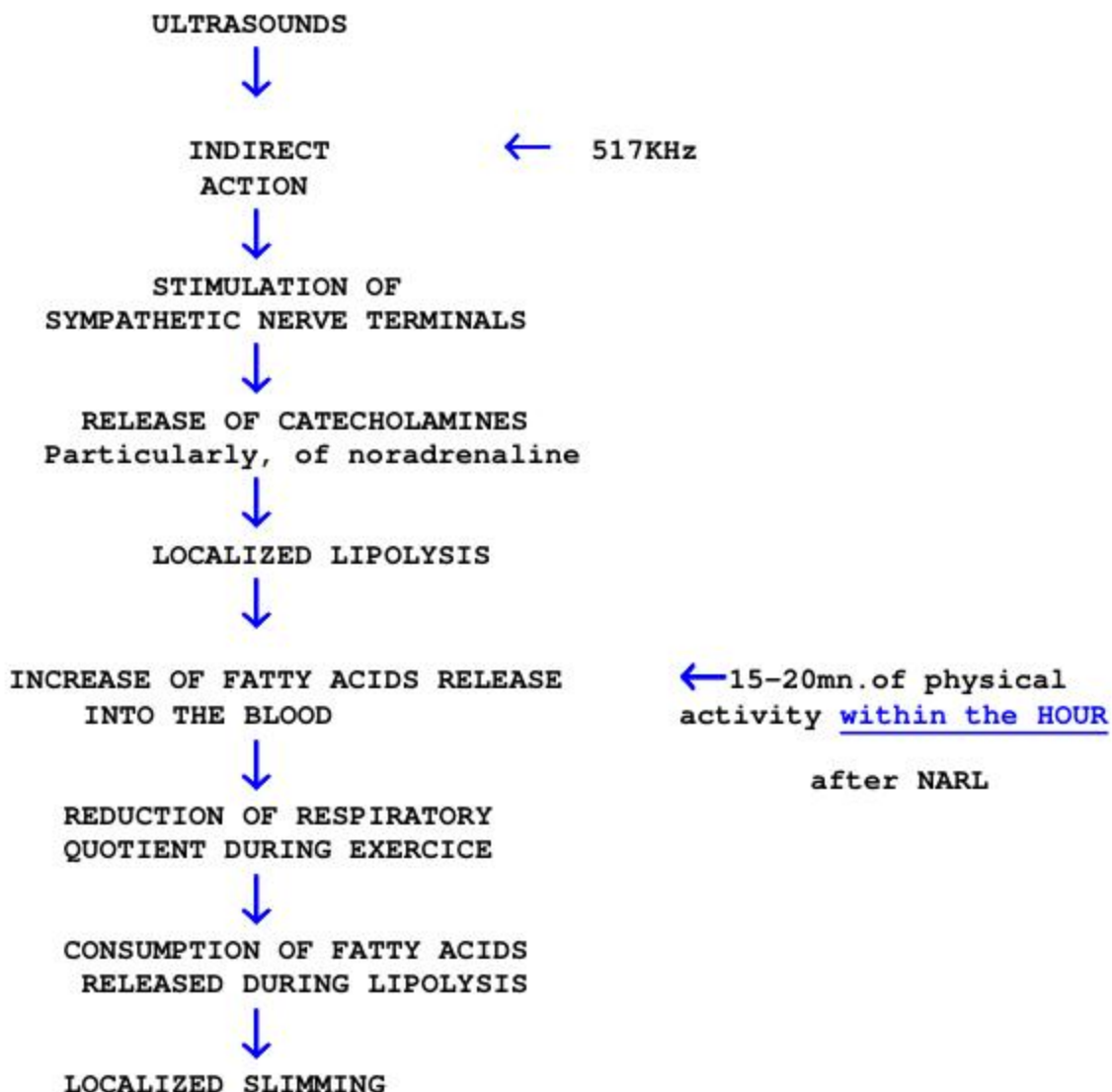
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INTRODUCTION

In order to find innovative and useful solution for the treatment of localized overweight, the ultrasound technology has been selected as potential method of high efficiency, significantly supported by a fundamental theory and confirmed by evidence based research. For this purpose, NARL, an ultrasound device emitting at a frequency of 517kHz has been used, determining specific and biological responses by the human body. It is a very simple working system, acting indirectly on the adipocytes and enabling the stimulation of the sympathetic nerve terminals which release then catecholamines. In particular, the noradrenaline shows a remarkable lipolysis effect.

Does an useful system, either than physical exercise for local slimming, exist? Excluding diet, the answer is, yes indeed.



An evidence based scientific research has shown the various steps of the working process as well as the safety specified by the FDA standards (USA).

<p>10 W/cm² 1 W/cm² 100 W/cm² 10 W/cm²</p> <p>20 kHz 30 100 200 300 1M 2M 3M 10MHz</p> <p>CAVITATION Breaks Tissue</p> <p>HEAT GENERATION Burns Tissue</p> <p>SAFE NATURAL LIPOLYSIS</p> <p>Hemolysis</p> <p>Through HIFU, SAFE NATURAL LIPOLYSIS</p> <p>NARL ULTRASOUND</p> <p>500 MHz below FDA, 200 MHz natural lipolysis, 100 MHz approved by US, Japan, China, Poland, etc.</p> <p>Dangerous: Hemolysis occurs FDA: 100 MHz by HIFU Breaks lipoproteins causes thrombosis Interfering or destroying organs are destroyed</p> <p>Dangerous: FDA: 100 MHz by HIFU No Lipolysis Resonance may cause flow induction Risk for infection</p> <p>Deep, Cheap! 100 MHz, 100 W/cm² 100 MHz, 100 W/cm²</p>	<p>SAFETY</p>	<p>FDA standards chart (USA)</p>
	<p>INDIRECT ACTION</p>	<p>Direct action upon adipocytes is technically impossible to get</p>
<p>Sympathetic Nerve Terminal</p> <p>NARL U.S.</p> <p>NORADRENALINE</p> <p>Adipocyte</p> <p>Sympathetic Nerve terminals in Fat Artery (by electron microscope)</p>	<p>VOLUME OF ACTION</p>	<p>Ultrasound wave outputs up to 10-12 cms deep (up to 35 cms max.)</p>
<p>Sympathetic Nerve terminals in Fat Artery (by electron microscope)</p>	<p>STIMULATION OF SYMPATHETIC NERVE TERMINAL</p>	<p>The ultrasound stimulates the sympathetic nerve terminals inducing the increase of hormonal activity (8,9)</p>
<p>Microlyse</p> <p>Essential Chromogranin A/B</p> <p>MA is inhibited during lipolysis</p> <p>Residual Flow</p> <p>1.0, 0.5, 0.1, 0.05, 0.01, 0.001</p> <p>1.0, 0.5, 0.1, 0.05, 0.01, 0.001</p> <p>1.0, 0.5, 0.1, 0.05, 0.01, 0.001</p>	<p>RELEASE OF CATECHOLAMINES</p>	<p>Free nerve terminals release the noradrenaline in particular (8,9)</p>
<p>SONICATED GROUP DATA</p> <p>517kHz</p> <p>Fig. 1: 100 Hz, 100 W/cm²</p> <p>Fig. 2: 100 Hz, 100 W/cm²</p> <p>Fig. 3: 100 Hz, 100 W/cm²</p> <p>Fig. 4: 100 Hz, 100 W/cm²</p> <p>Fig. 5: 100 Hz, 100 W/cm²</p> <p>Fig. 6: 100 Hz, 100 W/cm²</p> <p>Fig. 7: 100 Hz, 100 W/cm²</p> <p>Fig. 8: 100 Hz, 100 W/cm²</p>	<p>LOCAL LIPOLYSIS</p>	<p>The noradrenaline remarkably stimulates lipolysis, inducing a chemical break down of the triglycerides (fat deposit) into their basic components (fatty acids and glycerol) (8,9)</p>
	<p>INCREASE of FREE FATTY ACIDS in the BLOOD</p>	<p>Fat deposits break down into their basic components leading free fatty acids into the bloodstream, ready to be burnt by muscle activation (11)</p>

NARL 517 is provided with 4 pads made of soft non-allergic rubber with 21 transducers each.

Pads are put directly on the skin, using a specific conductive gel which ensures the emission of ultrasounds at a frequency of 517 KHz inducing the highest stimulation of sympathetic free nerve terminals which release catecholamines, by reaction. These induce a localized lipolysis, breaking down the stored triglycerides into their basic components (glycerol and fatty acids) into the blood, thus becoming available as a source of energy.

NARL 517 strictly complies with the safety index of the FDA standards (USA), as far as the thermal index (safety IT <2 ; NARL IT = 0.3) and the mechanical index (safety IM <0.3 and NARL IM =0.08), are concerned. Therefore, the use of ultrasounds is not recommended in the heart area, and in case of orthopaedics prosthesis, skin injury, pregnancy and pace-maker.

The increase of free fatty acids in the blood confirms that an adequate physical exercise after the NARL sessions is necessary, in order to burn that source of energy, thus preventing the return of those fatty acids into adipocytes.

RESEARCH PURPOSE

Focussing on the correct methods and timing of physical exercise to practise after the NARL sessions, it has evaluated that a concentrated free fatty acids increase in the blood could lead to a reduction of the respiratory quotient during the exercise.

The reduction of this respiratory quotient is the result of the increase of fatty acids consumption under the same training conditions, probably caused by a preferred switch of the bio-energetic system towards the most available fuel at that particular moment. If this hypothesis was demonstrated, we would have the possibility of doing physical exercise at a specific intensity and for a shorter time, thus obtaining the same quantity of burned fatty acids.

SUBJECTS

Thirty two subjects (16 males and 16 females) have participated in this program, able to perform physical exercise after certified medical check-up in order to measure their respective health conditions.

The selection of subjects has been carried out on individuals showing significant abdominal overweight which could justify the use of NARL. All subjects were medium over-weighted and all agreed to participate in this research study after being correctly informed on the method and the scope.




CASE STUDY GROUP (12 males and 12 females)

	MALES	FEMALES
Age	29.8 + 8.6	30 + 6.1
Weight	79.4 + 11	59.2 + 6.9
Height	175.6 + 7	164.5 + 3.4
Umbilical cutaneous skin fold	18.9 + 4.7	22.6 + 5
Waist measurement	89.2 + 10.1	75.3 + 5.7

CASE CONTROL GROUP (4 males and 4 females)

	MALES	FEMALES
Age	32.3 + 7.9	27 + 3.7
Weight	78.7 + 6.6	61.1 + 5.8
Height	176.3 + 6.9	166 + 1.2
Umbilical cutaneous skin fold	20.6 + 4.9	20.4 + 5.6
Waist measurement	90.7 + 4.6	76.9 + 3.7

MATERIALS

<p>NARI, the unique ultrasound machine available in the market which emits at a frequency of 517kHz, inducing an indirect lipolysis</p>	
<p>Metabolimetro K4b2 (Cosmed srl, Roma, Italia) for the sampling of both heart and lung parameters, breath by breath, in real time during exercise</p>	
<p>Heart Rate Monitors Polar S810 (Polar Electro - provided by Cosmed srl, Roma, Italia) for the integrated sampling of the heart rate</p>	
<p>Treadmill Nordirtrack 9600 (FreeMotion, Perugia, Italia), for the required training exercise</p>	
<p>Toshiba portable computer with a Notebook program for the analysis of data and statistics calculations</p>	

METHODS

A preliminary test has been scheduled to assess the aerobic power as well as maximum individual heart rate by means of an exhaustion triangular test on the treadmill (MUTT: Montreal University Track Test) (1). Such primary test is necessary to match the intensity of physical exercise to all subjects under examination.

A day of rest has followed the day of the primary test and was followed by the day of examination.

The research has been conducted under standard set of conditions as far as regular hours, environment conditions (air conditioned rooms) and nutrition are concerned, in order not to influence the results of physiological parameters sensitive to such variations.

This NARL research study has applied to the following protocol :

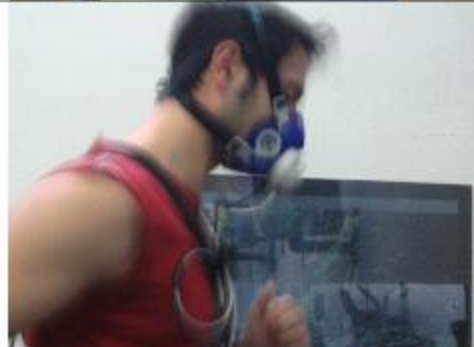
FISRT STEP: Running on the treadmill at 70% of the maximum aerobic power during 10 minutes, monitoring heart and lungs parameters by means of K4b2 metabolimeter as well as heart rate monitor.



SECOND STEP: Application of NARL517 De Luxe on the abdominal and back areas for 20 minutes, when the subject is lying down (clinostat condition).



THIRD STEP: Same as the first step in order to compare the results from heart and lungs activity before and after the ultrasound session.



The group of control has followed the same protocol except for the NARL device which was not in use (placebo effect).

The monitoring of heart and lungs parameters has led to calculate the Respiratory Quotient (RQ) before and after the ultrasounds emission; indeed before and after the release of lipolysis subject to the localized release of catecholamines.

The RQ has been assessed as average value of the last 2 minutes of each single test, indeed between the eighth and the tenth minute, in order to report the data in a possible metabolic steady-state.

The running speed selection at 70% of maximum aerobic power has been determined subject to the condition that such exercise intensity, generally speaking, is positioned in an intermediate consumption range of bioenergetics' substrates, leading to approx. 50% energy consumption from liquids and approx. 50% from glucids (2).

Once tests accomplished, all data has been collected and processed. The statistically significant result was measured by ANOVA and correlations have been reported among sensitive parameters.

RESULTS AND DATA PROCESSING

The following tables, show all data reported in the case study as well as in the control groups:

- PRE RQ : Respiratory quotient during the run before the application of NARL
 POST RQ : Respiratory quotient during the run after the application of NARL
 Δ RQ : Absolute differential of RQ between both tests, before and after NARL application
 Δ RQ% : Relative differential of RQ between both tests, before and after NARL application
 CORRELATIONS: correlation coefficient among sensitive parameters

Case Study Group - Results of male subjects

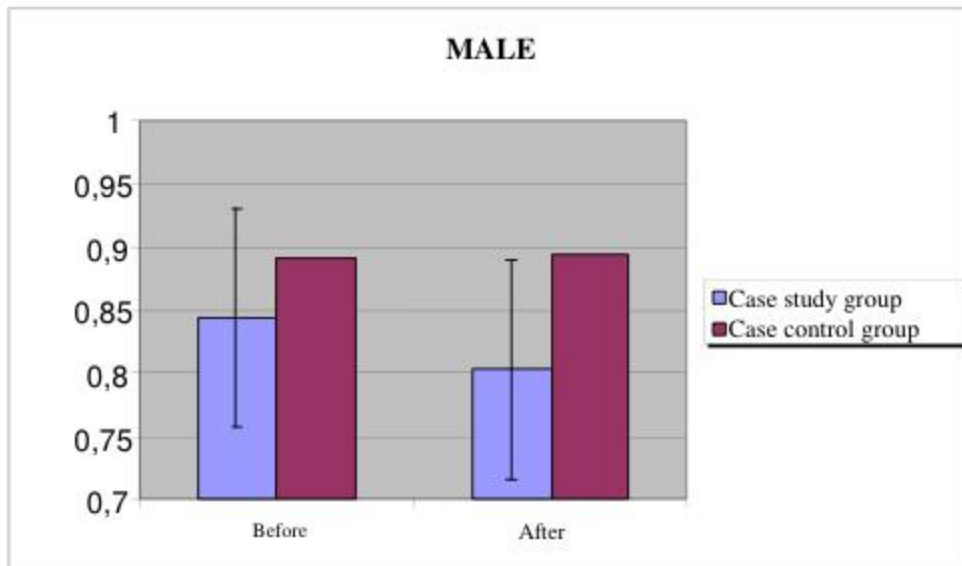
	PRE RQ	POST RQ	Δ RQ	Δ RQ %
Subject 1	0,840	0,801	-0,040	-4,733
Subject 2	0,887	0,807	-0,080	-9,060
Subject 3	0,829	0,801	-0,028	-3,363
Subject 4	0,826	0,791	-0,035	-4,241
Subject 5	0,891	0,849	-0,042	-4,716
Subject 6	0,907	0,879	-0,027	-3,033
Subject 7	0,837	0,809	-0,028	-3,324
Subject 8	0,882	0,838	-0,043	-4,904
Subject 9	0,824	0,780	-0,044	-5,361
Subject 10	0,633	0,592	-0,041	-6,439
Subject 11	0,932	0,889	-0,043	-4,565
Subject 12	0,932	0,990	-0,058	6,210
AVERAGE	0,844	0,803	-0,041	-4,885
	\pm 0,080	\pm 0,092		ns

CORRELATIONS	RQ1	RQ2	Δ RQ
Umbilical cutaneous skin fold	-0,01	-0,08	-0,22
Waist measurement	-0,04	-0,11	-0,21
Weight	-0,14	-0,26	-0,35

Case control group - results of male subjects (1/3 of the case study group)

	PRE RQ	POST RQ	Δ RQ	Δ RQ %
Subject 1	0,914	0,918	-0,004	-0,429
Subject 2	0,906	0,912	-0,006	-0,712
Subject 3	0,909	0,900	-0,010	-1,083
Subject 4	0,832	0,847	-0,015	-1,773
AVERAGE	0,890	0,894	-0,004	-0,485
				ns

RESPIRATORY QUOTIENT



Case study group - results of female subjects

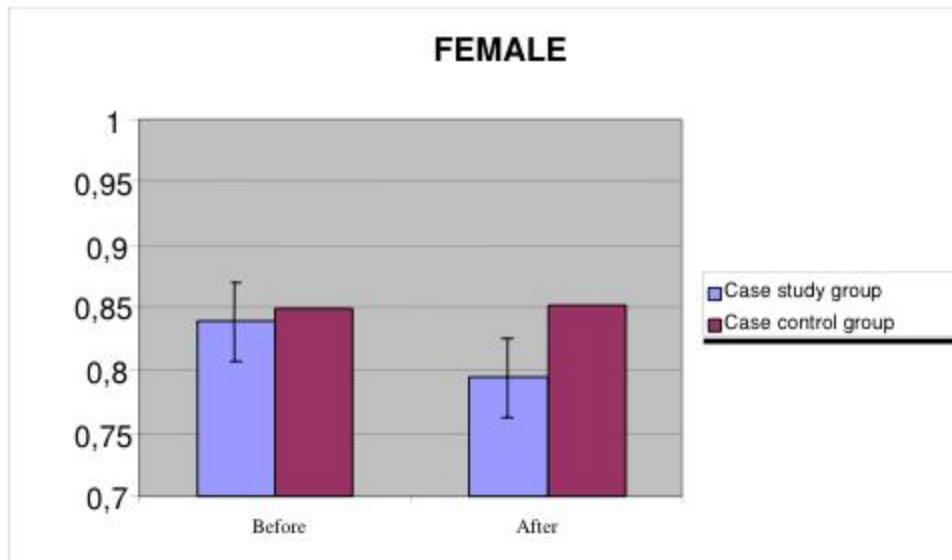
	PRE BQ	POST BQ	Δ BQ	Δ BQ %
Subject 1	0,855	0,818	-0,037	-4,357
Subject 2	0,881	0,827	-0,054	-6,150
Subject 3	0,795	0,745	-0,050	-6,275
Subject 4	0,826	0,785	-0,041	-4,974
Subject 5	0,780	0,752	-0,028	-3,608
Subject 6	0,888	0,839	-0,049	-5,502
Subject 7	0,843	0,808	-0,035	-4,104
Subject 8	0,866	0,821	-0,045	-5,144
Subject 9	0,825	0,790	-0,034	-4,144
Subject 10	0,850	0,802	-0,048	-5,695
Subject 11	0,833	0,770	-0,063	-7,546
Subject 12	0,824	0,769	-0,055	-6,695
AVERAGE	0,839	0,794	-0,045	-5,349
	$\pm 0,032$	$\pm 0,030$		
				$p < 0,05$

CORRELATIONS	RQ1	RQ2	Δ RQ
Umbilical cutaneous skin fold	-0,17	-0,09	-0,41
Waist measurement	-0,35	-0,11	-0,35
Weight	-0,23	-0,03	-0,41

Case control group - results of female subjects
(1/3 of the case study group)

	PRE RQ	POST RQ	Δ RQ	Δ RQ %
Subject 1	0,885	0,899	-0,014	-1,615
Subject 2	0,875	0,869	-0,006	-0,655
Subject 3	0,834	0,823	-0,011	-1,299
Subject 4	0,801	0,812	-0,011	-1,323
AVERAGE	0,849	0,851	-0,002	-0,246
				ns

RESPIRATORY QUOTIENT



DISCUSSION

As far as male subjects are concerned, the reported data show a significant RQ reduction by 4.88% after NARL sessions documenting the bio-energetic switch towards the fat metabolism as expected through this research study.

The Case Control group strengthens this result by showing an irrelevant increase of 0.46%.

The lack of statistically significant results, mainly due to the low homogeneous pattern leaves, however, open ground to positive considerations subject to the high RQ percentage switch.

Concerning female subjects instead, the data shows a clear RQ reduction by 5.35% after NARL sessions confirming the clear bio-energetic switch towards the fat metabolism as expected through the research function. The Case Control group strengthens this result showing an irrelevant increase by 0.25%.

The statistically significant results obtained strongly strengthen this result outlying a high response from the female subjects as a result of the ultrasound treatment.

It is definitively curious to note that as there is no significant correlation among the sensitive variables. Indeed, some correlation were expected to be found between the umbilical skin fold or/and the waist measurement and the reduction of RQ caused by a significant release of fatty acids. This evidence can be explained by the fact that regardless of the quantity of adipose tissues (as long as significant), a somehow individual biological barrier of the subjects was remarked as a result of the impossibility to release catecholamines beyond a certain threshold with a quantitatively proportional lipolysis effect.

It is to be noted that this research pattern has required the selection of moderate overweight subjects moderately trained in order to secure the feasibility of the research tests. A research study with similar characteristics can't be suggested to sedentary and heavy overweight subjects as the same biological response is to be assumed.

CONCLUSION

In summary, we may confirm that the ultrasound treatment is able to produce a significant metabolic change towards the lipids as a major source of energy used during aerobic exercise practiced immediately after.

An average RQ decrease by 0,043 is able to unbalance the energetic metabolism by 16% approx. towards fats creating a 32% variance between fats and glucids (2).

RQ RESULTS IN RELATION TO SUBSTRATES USED BY THE ENERGETIC METABOLISM			
RQ	FATS %	GLUCIDS %	Kcal/LtO2
0,70	100	0	4,60
0,80	67	33	4,80
0,85	50	50	4,86
0,90	33	67	4,92
1,00	0	100	5,05

It comes out that, if the aim is 'to get rid' of the blood fatty acids resulting from the locally treated adipocytes with NARL, some aerobic exercise is required to be performed within 60 minutes after the ultrasound treatment.

For the same physiological reasons, it is recommended, alternatively, to perform anaerobic physical exercise (resistance training or mechanical vibrations) in such an extent to be able to produce a reasonable increase of post-exercise metabolism (EPOC).

The suggested average treatment is 15 minutes at an intensity of 70% of the maximum heart rate (higher intensity up to a maximum of 80% of the H_{rmax} is acceptable).

Certainly, the suggestion of performing exercise of mixed-type (aerobic/anaerobic) is the most valuable. In this case, it is recommended to have the NARL application followed by anaerobic exercise first (use of resistance training or mechanical vibrations) immediately followed by no more than 10 minutes of aerobic exercise (3, 4, 5, 6, 7).

In the light of the research results and due to individual biological constraints of the human body, it comes out that NARL treatment shows no increased benefits if applied in the same body

area for more than 20 minutes. This confirms the Manufacturer indications to use NARL for 10-20 minutes, timeframe only.

NARL 10/20min



15 min. aerobic exercise at 70% Hrmax

NARL 10/20min



15/20 min. anaerobic exercise weights, mechanical vibrations)?

NARL 10/20min



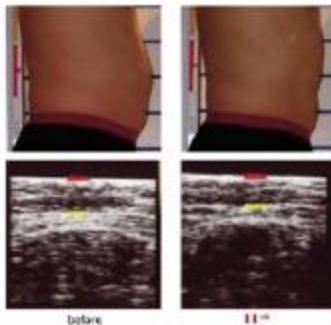
10/15 min. anaerobic exercise (weights, mechanical vibrations)?



EPOC



AEROBIC EXERCISE



International scientific research, in addition to acute effects, shows real effects on the reduction of localized fat subject to NARL application cycles (12, 13, 14). These study findings confirm these indications and place the ultrasound treatment at a frequency of 517kHz as a valuable tool in treatment of localized fat in the aesthetic field as well as visceral adiposity prevention in order to prevent fat correlated diseases such as cardiovascular diseases and diabetes.

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