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RANDOMISED CLINICAL TRIAL ON PATIENTS COMPLIANCE AND THE ERGONOMICS OF TWO DEVICES FOR MECHANIZED MASSAGE

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Abstract

Massage is an ancient technique used to improve the look of the skin and the subcutaneous layer. It is also used to treat musculoskeletal disorders, local lymphedema, as a support for athletes and for cosmetic and beauty-related reasons.

Various different new tools are currently used in the cosmetic sectors. In this trial, we have compared two of these modern devices: a technology using motorised rollers (T.R:M.) and ICOONE®. These are devices used for massage, equipped with double motorized rollers that automatically 'roll up' and 'unroll' the skin folds in all directions, applying negative pressure. In the technology with motorized rollers, the negative pressure is applied by means of a central treatment chamber positioned between the two rollers, whilst in the ICOONE® appliance, the negative pressure can be applied either by means of the treatment chamber alone, or alternatively by the combined action of the chamber and the two rollers.

This monocentric trial aims to compare the use of the T.R.M. and ICOONE® in order to obtain subjective effects on skin and subcutaneous quality, as well as on a systemic and psychological level with the attainment of a general condition of wellbeing and pleasure. The appliance ergonomics have been evaluated by physiotherapists and patients, by means of questionnaires.

10 female patients were enrolled and treated twice a week for 5 weeks and a total of 10 treatments, with randomised application sessions (5 T.R.M. and 5 ICOONE®).

The patients reported enjoying both treatments and found an improvement in skin quality on a local level, in systemic effects and psychological state. T.R.M. was held to be most efficient on the musculoskeletal apparatus, whilst ICOONE® had greatest effect on the skin and superficial tissues.

Introduction

Massage is an ancient technique used to improve the look of the skin and the subcutaneous layer. It is also used to treat musculoskeletal disorders, local lymphedema, as well as for cosmetic and beauty-related reasons, and as therapy for athletes. Massage can be performed manually or by means of medical appliances, sometimes together with creams, balsamic preparations, aromatherapy and music.

Various different new tools are currently used in the cosmetics sector. In this trial, we have compared two of these modern appliances: a technology using motorised rollers (T.R:M.) and ICOONE®. These are both appliances used for massage, equipped with double motorised rollers that automatically 'wind up' and 'unwind' the skin folds in all directions, applying negative pressure. In the technology with motorised rollers, the negative pressure is applied by means of a central treatment chamber positioned between the two rollers, whilst in the ICOONE® appliance, the negative pressure can be applied either by means of the treatment chamber alone, or alternatively by the combined action of the chamber and the two rollers. In the ICOONE® appliance, the treatment head rollers, called 'Robosolo' are fitted with pierced surface micro-alveoli through which suction is applied. With the ROBOSOLO rollers, the skin receives 1,180 micro-stimulations per square decimetre with every stroke. Both technologies therefore simultaneously move tissue, intercellular matrix and intravacuolar liquid, but ICOONE® can stimulate the skin surface in a punctiform and extended manner.

It is now commonly accepted that mechanical, non-surgical, non-invasive cosmetic massage helps reduce cellulite and improves skin tone and quality. The problem of

unsightly cellulite is fairly common in women, and particularly affects the lower limbs, buttocks, abdomen and arms. Also known as edematous fibrosclerotic panniculopathy, cellulite is caused by the presence of fat cells trapped within bands of connective fibres that can lead to the blockage of vascular and lymphatic drainage. These connective fibre bands create deep skin adherences, giving the skin the characteristic orange peel appearance. Mechanical massage acts deep-down, improving local circulation, relaxing tired connective fibres and thereby releasing tension in the adipose layers. Apart from the local effects on the skin and subcutaneous layer, this type of massage also generates systemic effects for greater psychophysical wellbeing.

This monocentric trial aims to compare the use of the technology with motorised rollers, with that of ICOONE®, in order to improve the quality of the skin and subcutaneous layer on a local level, to obtain effects on a systemic and psychological level, and to reach a general condition of wellbeing and pleasure. The appliance ergonomics have been evaluated by physiotherapists and patients.

Materials and methods

Between September and December 2007, a perspective trial was carried out on 10 female patients aged between 25 and 61 years old and in good health. Trial exclusion criteria was as follows: ulcers or infections in the areas to be treated, coagulopathies or thromboembolic pathologies, use of FANS during treatment, simultaneous treatment of area involved with other methods, tendency towards ecchymosis and capillary fragility.

All patients were treated twice a week for 5 weeks (and a total of 100 treatments). The following areas of the body were treated: thighs, buttocks, arms, back and abdomen. Each treatment with Technology with motorised rollers and ICOONE® lasted for 35 minutes.

T.R.M. was set to the 'cellulite and silhouette' programme, at a power of: 4-6, 14 Hz; speed of first roller: 80; speed of second roller: 60; roller rotation direction: roll-up rotation. Treatment duration in minutes was divided up on the basis of the gynoid shape (tab. 1) using a preset diagram for the machine.

ICOONE® was set to the cell draining base programme; power: 10, frequency parameter 8; high speed for the two rollers; micro-alveolar and central chamber suction. Treatment duration in minutes was divided up on the basis of the gynoid shape (tab. 1) using a direct and lateral palm-top diagram.

Sessions were always held by the same physiotherapist. Each patient completed 5 treatments with the T.R.M. and 5 with ICOONE® according to a randomised treatment sequence.

	T.R.M.	ICOONE®
Arms	4	2
Abdomen	4	5
Thighs	12	8
Buttocks + outer thighs	6 + 6	7 + 7
Back	3	5

Table 1: *Massage application time in minutes in the various areas, using the T.R.M. and ICOONE®*

At the start of treatment, weight, stature and stage of cellulite was recorded for each patient according to the Nürnberger-Müller scale (tab. 2).

At the end of treatment, the patients were immediately asked to fill in a questionnaire about the effects obtained (tab. 3). Evaluation was made in consideration of local and systemic effects, psychological conditions, state of health and physical form, and ergonomics. The same questionnaire was given to patients 48-72 hours later, before the subsequent treatment, in order to evaluate both immediate sensations and those after a period of time had elapsed. Points from 1 to 5 were awarded for each parameter, where 1 equated to worsening, 2 no improvement, 3 slight improvement, 4 significant improvement, 5 optimal improvement.

The physiotherapist was also asked to give an opinion on the appliance ergonomics and the efficiency of the treatments (tab. 4).

Nürnberg-Müller scale
Stage 0: No dimpling when the subject is standing or lying. The pinch test reveals ‘folds and furrows’, but there is not ‘mattress-like’ appearance.
Stage 1: No dimpling when the subject is standing or lying, but the pinch test reveals the ‘mattress-like’ appearance.
Stage 2: Dimpling appears spontaneously when standing but not when lying down.
Stage 3: Dimpling appears spontaneously when standing and lying down.

Table 2: Nürnberg-Müller scale

Data analysis

Parameter were evaluated by combining the absolute values obtained for the individual treatment. To give greater statistical meaning to the negative responses (value 1 assigned by the patient) a value of -1 was assigned, where no improvement was reported (value 2 assigned by the patient) a value of 0 was assigned, whereas where slight improvement was reported, the value 3 was maintained, significant improvement remained as 5, and optimal improvement 5.

Effects on the skin	Smooth	1-2-3-4-5
	Compact	1-2-3-4-5
	Smoothed out dimpling	1-2-3-4-5
Subcutaneous effects	Tone	1-2-3-4-5
	Oedema	1-2-3-4-5
Vascular effects	Generation of heat	Yes No
	Colour change	1-2-3-4-5
Psychological effects	Pleasant	Yes No
	Relaxing	Yes No
	Regenerating	Yes No
	Caused a sensation of general wellbeing	Yes No
Good health - physical shape	Modelling effect	1-2-3-4-5
	Drainage effect (stimulation to diuresis)	1-2-3-4-5
	Constipation	1-2-3-4-5
	Effects on musculoskeletal apparatus	1-2-3-4-5
Patient / machine	Head/skin contact	Pleasant/Irritating/Painful
	Noise	Average/Scarce/High

Table 3: Evaluation table distributed to all patients after treatment session. 6 parameters were evaluated. Each was assigned a value according to the following. (1 = worsening, 2 = no improvement, 3 = slight improvement, 4 = significant improvement, 5 = optimal improvement).

		Technology with motorised rollers	Appliance B
Ergonomics	Ease of handling	Zero, little, very	Zero, little, very
	Contact with skin	Regular, Irregular	Regular, Irregular
Appliance characteristics	Fixed unit	Cumbersome, Compact Easy to control, Difficult to control	Cumbersome, Compact Easy to control Difficult to control
	Volume	Low, medium, high	Low, medium, high
	Noise	Pleasant, none, irritating	Pleasant, none, irritating
Physical effort	Force necessary	Minimal, average, high	Minimal, average, high
	Adjustment	Difficult, average, easy	Difficult, average, easy

Table 4: Questionnaire for the physiotherapist

Results

Average patient age was 41.6 years old (range: 25-61 years). 45% of patients showed second stage cellulite, 35% third stage and 10% fourth stage. At the end of the treatment, none of the patients had experienced weight change.

In our study, we considered the same parameters both immediately after treatment and some time later.

With regards to the sensation of smoother skin (considering only the values of 4 - significant improvement, and 5 - optimal improvement) an immediate positive response was reported in 52% of cases where ICOONE® was used, as compared with 32% of cases where T.R.M. was used. After some time had elapsed, the values were respectively 62% and 32% (tab. 5).

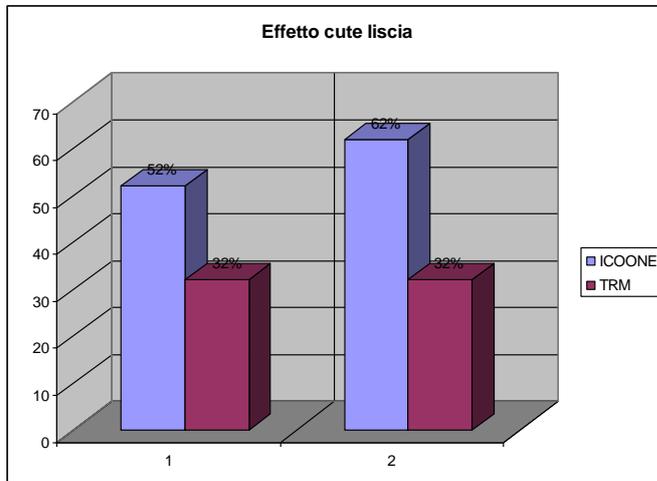


Table 5: Percentage of patients reporting an increased sensation of smooth skin after treatment (graph 1) and a few days later (graph 2).

As concerns the level of skin tone, considering only the cases where patients reported significant or optimal improvement (values 4 and 5 in the evaluation scale), immediately after treatment 72% of patients treated with ICOONE® and 50% of those treated with T.R.M. made a positive assignment. After some time had elapsed, the percentages were respectively 48% and 50% (tab. 6).

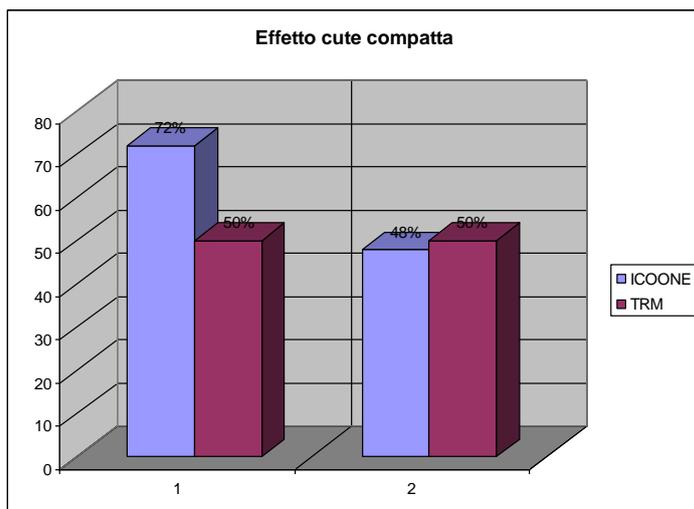


Table 6: Percentage of patients reporting an increased sensation of compact skin after treatment (graph 1) and a few days later (graph 2).

With regards to dimpling, considering only the cases where improvement was found (values 3, 4 and 5 of the evaluation scale), immediately after treatment we have a 36% positive response from patients treated with ICOONE® and 40% from those treated with T.R.M.. A few days later, the percentages were respectively 52% and 44% (tab. 7).

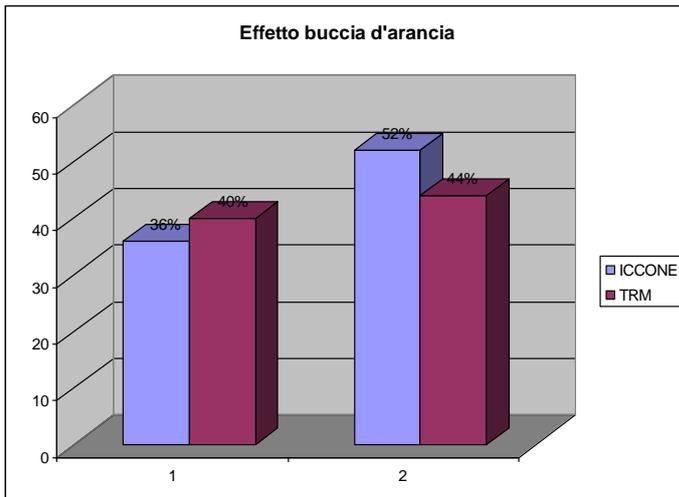


Table 7: Percentage of patients reporting an improvement in dimpling after treatment (graph 1) and a few days later (graph 2).

Subcutaneous oedema and tone was considered. The patients treated with ICOONE® reported an improvement in tone in 70% of cases, and in oedema in 76% of cases in immediate evaluation, and respectively 76% and 76% after some time had elapsed. The patients treated with T.R.M. showed an improvement in tone in 68% of cases, and in oedema in 78% of cases in immediate evaluation, and respectively 74% and 76% after some time had elapsed. For these parameters, the differences between the two machines in the immediate term and after a short time had elapsed, are minimal (tab. 8).

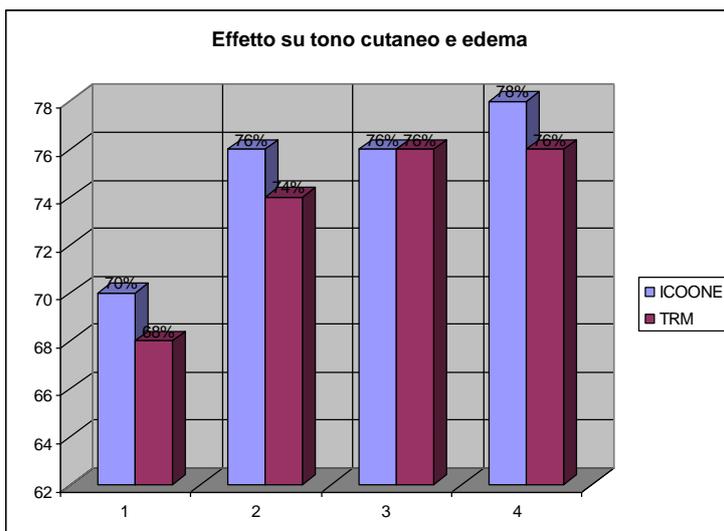


Table 8: Percentage of patients reporting an improvement in subcutaneous tone and oedema. Series 1 compares the improvement in tone immediately, series 2 after a short time. Series 3 compares the improvement in oedema immediately, series 4 after a short time.

All patients reported an improvement in their silhouette, with values, after time, of 80% with ICOONE® and 72% with T.R.M..

The head/skin contact was stated as irritating in 26.8% of treatments with T.R.M. as compared with a percentage of just 2.6% for ICOONE®. In any case, patients only complained of this during the first 2-3 treatments.

As shown by the data reported, for all parameters considered, both machines almost always obtained positive responses. If we compare the values assigned by the patients (value -1 where worsening is reported, value 0 where there is no improvement, values of 3, 4 and 5 respectively assigned to slight, significant and optimal improvement), we can see some important differences (tab. 8).

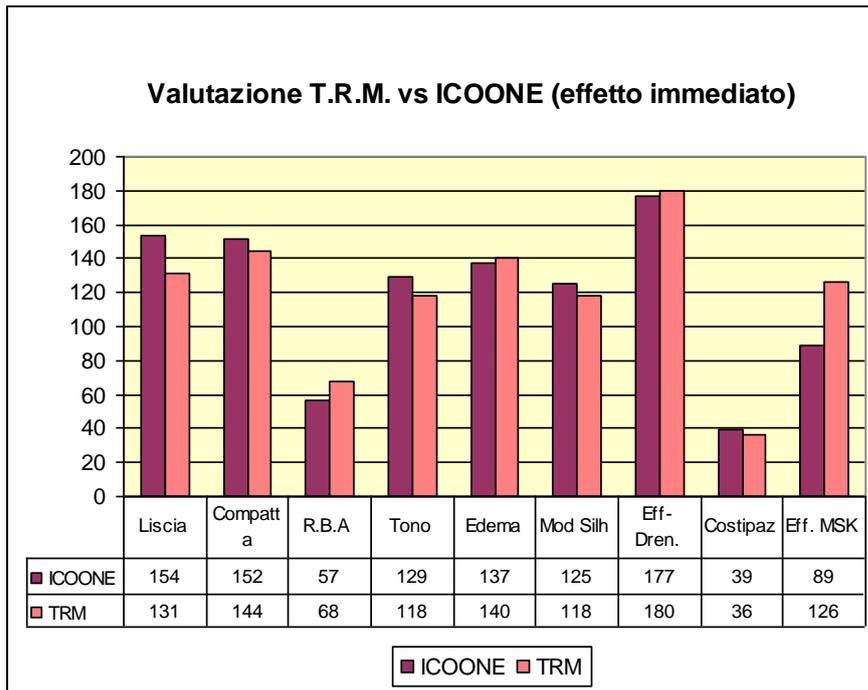


Table 8: The difference parameters are considered both for ICOONE® and for T.R.M., immediately after treatment (smooth skin; compact skin; dimpling effect; subcutaneous tone, subcutaneous oedema, modelling effect; drainage effect; constipation; effect on the musculoskeletal apparatus).

In the immediate term, the patients mainly observed an increased effect of smooth and compact skin with ICOONE® as compared with T.R.M.. The values are comparable with regards to the treatment of dimpling, subcutaneous oedema and tone, modelling effect, drainage and constipation. The values instead invert when considering the effect on the musculoskeletal apparatus, where T.R.M. is assigned greater efficiency.

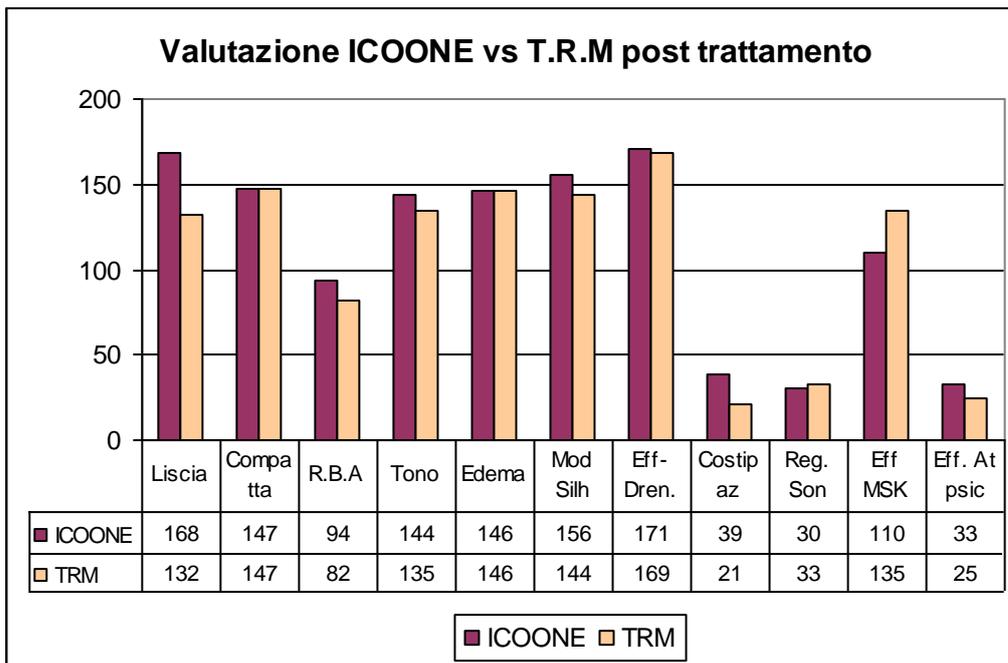


Table 8: The various parameters are considered both for ICOONE® and for T.R.M. after a short time has elapsed.

If we evaluate the same parameters after some time has elapsed, we can see that the results obtained with the two different machines basically level out, with the exception of skin smoothness and the effects on the musculoskeletal system, where respectively ICOONE® and T.R.M. prevail.

Overall, patients judged both treatments as efficient and pleasant both in the immediate term and a few days later (tab. 9, 10).

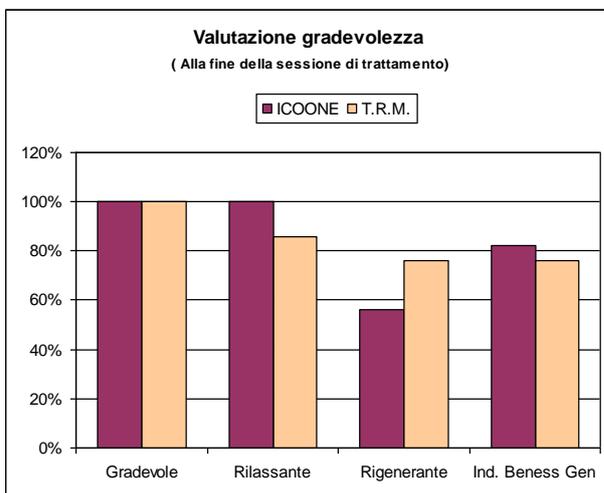


Table 9: Immediate evaluation of the psychological effect.

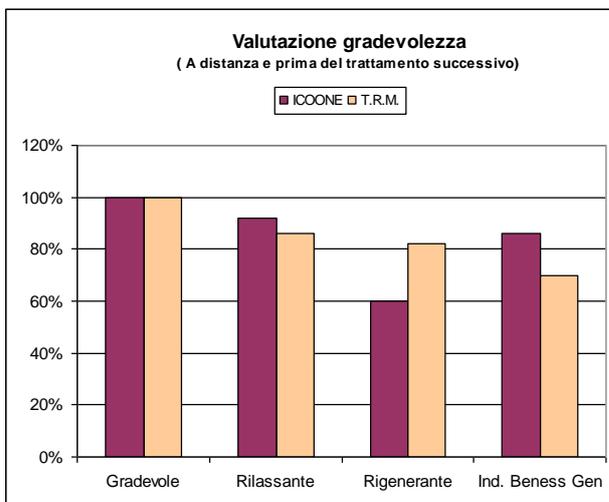


Table 10: Evaluation of psychological effect of treatment after a short time.

With regards to machine-skin interaction, 100% of patients treated with ICOONE® judged this as pleasant, and just 68% of those treated with T.R.M., with 32% reporting it as unpleasant. ICOONE® was defined as silent by 94% of patients and quiet by 6%. T.R.M. was defined as silent by 28% of patients, quiet by 58% and very noisy by 14%.

The physiotherapist judged the ergonomics of both appliances positively with regards to the shape, monitor, volume and noise, but in their opinion, manoeuvres were easier with ICOONE®, whilst the appliance head was more easily controlled in the T.R.M. (both hands are needed to handle the ICOONE® head). Menu selection in ICOONE® takes place by means of a touch screen, whilst with the Technology with motorised rollers, there are buttons to the side of the screen.

Discussion

Recent years have seen a progressive increase in the design and manufacture of medical devices for massage. The aim is to obtain tools that are increasingly efficient and pleasant for patients.

The technology with motorized rollers has been widely used since 1980, ICOONE® is a new device that uses the same motorized roller technology, with a central treatment chamber, but applies negative pressure also through the roller micro-alveoli. These devices allow for the treatment of skin layers deep down, improve blood circulation, separate loose connective fibres and reduce pressure on adipose accumulations.

Both treatment with the Technology with motorized rollers and with ICOONE® were reported as pleasant and showed an improvement in skin quality.

As these tools fall under the scope of medical devices where the therapeutic effect blends with cosmetics and psychological effects, we observed less disturbance in terms of irritation concerning contact and noise or ICOONE® as compared with the T.R.M.. ICOONE® was evaluated as more relaxing and more able to cause a sensation of general wellbeing, whilst T.R.M. was more regenerative. The head/skin contact of ICOONE® was also reported as more pleasant than that of T.R.M..

Another important difference was the smoothing and compacting effect obtained by ICOONE®. If we compare the sensations, the ICOONE® appliance was more efficient at producing the sensation of smoother skin to the touch, whilst T.R.M. was more efficient on the musculoskeletal apparatus. The greater smoothing effect obtained with ICOONE® can be explained by the more uniform distribution of pressure obtained thanks to the roller micro-alveoli. The multi-micro-alveolar suction was designed by

exploiting the idea of the skin and sub-skin as a three-dimensional system comprising a fibrillar structure encompassing cell elements and interstitial and intra-cell liquid. This device allows for a massage that is uniformly distributed on the superficial vascular bed, and a delicate friction on the superficial skin layer. This leads to the sensation of smoother skin and greater drainage, reducing irritation and pain to a minimum.

In T.R.M., on the other hand, pressure is only applied by the central chamber, and it is therefore more efficient in deeper layers, because it is concentrated on a single point, thereby leading to more in-depth penetration. The fact of acting on the more in-depth layers stresses the lesser delicacy of this treatment, which discharges all the machine's force in a single point, as compared with ICOONE® that, instead, distributes its suction power over a more extended area, resulting in a massage that the patient enjoys more. This may explain the sensation of a greater effect on the musculoskeletal apparatus and the regenerative sensation, but as the pressure is not so finely modulated, it does lead to an irritating sensation and, at times painful even, during massage.

In ICOONE® technology, we can, in any case, obtain greater in-depth effects by adjusting some of the parameters. This means that the ICOONE® technology allows for a more flexible use that can, if required, yield results comparable to those of T.R.M..

Conclusions

Massage with medical appliances, exploiting the combined technology of suction with motorised rollers, is extremely efficient in helping drainage, whether applied with T.R.M. or ICOONE®. Both treatments report improvement of between 50.8% and 100% of all parameters considered. We can therefore confirm that ICOONE® and Technology with motorized rollers are two aesthetic non-surgical and non-invasive massage techniques that improve skin quality and the overall psycho-physical state of wellbeing in a pleasant manner for patients but ICOONE® is considered an evolution of TRM technologies, and it is more efficient in different parameters examined.

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Table 5: Smooth skin effect

Table 6: Compact skin effect

Table 7: Dimpling effect

Table 8: Effect on cutaneous tone and effect

Table 8: Evaluation T.R.M. vs. ICOONE® (immediate effect)

Smooth - Compact - Dimpling - Tone - Oedema - Silhouette shaping - Drainage - Constipation
- MSk effect

Table 8: Evaluation T.R.M. vs. ICOONE® (post-treatment)

Smooth - Compact - Dimpling - Tone - Oedema - Silhouette shaping - Drainage - Constipation
- Sound adjustment - MSk effect - Psych. effect

Table 9: Evaluation of enjoyment (after treatment session)

Pleasant - Relaxing - Regenerative - Index of general wellbeing

Table 9: Evaluation of enjoyment (a few days later and before next treatment)

Pleasant - Relaxing - Regenerative - Index of general wellbeing