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EFFECTS OF LPG SYSTEMS® TECHNIQUE ON MOTOR PERFORMANCE IN HIGH LEVEL FOOTBALL PLAYERS

ENGLISH VERSION

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INTRODUCTION

The practice of modern competitive football induces a fairly high physical workload (cumulated competition and training). The recovery of the different muscular functions needs to be optimised and, in particular, muscular power as well as the ability to produce intense efforts that appear to be essential performance factors (Tumilty, 1993; Bangsbo, 1994). Muscular fatigue (Bosco et al, 1986 ; Komi et al, 1992) and the stiffness induced upon intensive exercise (Kyröläinen et al, 1998, Horita et al, 1999) play a significant role in the reduction of musculoskeletal efficiency and the ability to produce intense efforts. This stiffness seems to generate neuromuscular dysfunctions (Saxton et al, 1995) and, in addition, the muscular fatigue induced by physical exercise over a long period of time, hypoxic conditions and the formation of free radicals tend to produce stiffness as the result of increased lysosome activity (Appell et al, 1992).

Optimising performance often involves increasing the training workload but also improving the training tolerance that is a key factor in sports-related successes. Football is no exception to this rule. Medical and paramedical assistance significantly helps facilitate recovery between matches and training sessions. Physiotherapy techniques are extensively used although their objectives have not been clearly defined (Cafarelli and Flint, 1992 ; Rodenburg



et al, 1994; Weber et al, 1994 ; Tiidus and Shoemaker, 1995; Gullick et al, 1995 ; Tiidus, 1997). Recently, positive results were obtained regarding the fatigue and stiffness induced by intense physical exercise (Portero et al, 1996 and 1999) with a new technique designed by LPG Systems® generating movement of cutaneous and subcutaneous tissues.

This technique was included in the paramedical follow-up study of a team composed of professional football trainees. The purpose of this study was to determine with simple functional tests the effects this technique would have on strength and muscular power as well as the production of intense efforts and muscular fatigue.

MATERIAL AND METHODS

Population

Two groups including twelve (12) professional football trainees each

volunteered in the study. Players were distributed randomly in both groups. The objective of those players as they complete their training is to improve their performance and become active professionals. The population under study is presented in Table 1.

The first group (control group) received a conventional treatment (physiotherapy, stretching etc.) and the second one was treated with the LPG® technique in addition to conventional training every Monday, Tuesday, Wednesday and Thursday. Treatment was suspended on Friday and Saturday, the weekly match day.

The players trained from 12 to 15 hours every week during the study. One football match was played every week.

Material

→ The isokinetic dynamometer was of the Cybex Norm type : This dynamometer helped measure the force torques developed by the musculo-

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	Age	Weight	Stature
Control group	19.25 ± 0.4	72.6 ± 5.5	178.3 ± 5.5
LPG® treated group	20.25 ± 0.6	73.4 ± 4.7	176.9 ± 2.3

Table 1 : Characteristics of the population under study.

skeletal system and the readings were expressed in Newton x meter (N.m)

➤ **The Bosco treadmill (Power-timer)** includes a contact treadmill, photoelectric cells and a reaction time measuring element. This system allows calculating the mechanical parameters involved in jumping and, of particular interest in this study, the vertical jumping height.

➤ **The equipment used in the study was an LPG Systems® S6 model** : This model was designed to specifically mobilise muscular tissues and fascia. Tissues are exercised regularly or sequentially between motorised rollers operating in a variable volume chamber. A tissue 'wave' is thus folded and unfolded according to the therapeutic objectives of the study. The data are continuously displayed on a liquid crystal monitor operated with the main S6 module and parameters can be modified in real time.

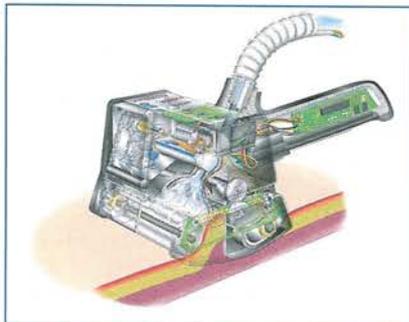


Figure 1 : LPG Systems® Model S6 main module

Protocol

The study lasted 3 weeks. Measurements were made before and after those 3 weeks. The LPG Systems® treatment was given 4 days a week.

➤ **LPG Systems® treatment** : A physiotherapist trained in the technique beforehand applied the treatment to the lower limbs for twenty (20) minutes.

The treatment was given before training sessions for scheduling reasons. Since training took place on Mondays, Tuesdays, Wednesdays and Thursdays, the players were not treated the day before weekly matches.

The S6 model was used continuously with power intensity 4.

➤ **Measured parameters** : The measurement chronology in this experimental protocol was 10 minutes warm-up on a stationary bicycle – isokinetic tests – 10 minutes rest – relaxation tests on the Bosco treadmill.

➤ **Maximum quadriceps strength** (3 extension–flexion movements of the knee at 60°.s⁻¹ angular speed) and maximum quadriceps power (5 extension–flexion movements of the knee at 180°.s⁻¹ angular speed). The speeds were selected for their functional representation. Slow angular speeds (e.g. 60°.s⁻¹) and fast angular speeds (e.g. 180°.s⁻¹) respectively are the reflection of strength and muscular power (Ivy et al, 1981). The best results were taken into account during those dynamometric tests.

➤ **Muscular fatigue** evaluated during an isokinetic test including a maximum of 25 extension–flexion movements of the knee at 180°.s⁻¹ angular speed. A fatigue index was determined from the values measured and their progressive reduction. This index was expressed as a percentage of the initial value measured at the beginning of the test.

➤ **The vertical jump test** was divided into two tests including a counter-movement jump and a squat jump respectively. Measurements were made with a Bosco treadmill according to the method described by Komi and Bosco (1978). The subjects were allowed three tries for each test. The best results were taken into account in the study.

A 5-minute rest period was allowed between each series of tests throughout the protocol and increased to 10 minutes after the isokinetic fatigue test.

➤ **Statistics** : Individual group results were compared with a Student's t test in paired series and inter-group results were compared with a single Student's t test. The significant threshold was set to P = 0.05.

RESULTS

Results are given as averages (± SEM) for 12 subjects in each group.

➤ **Muscular strength and power** : The force torques are expressed in N.m and representative either of muscular strength at 60°.s⁻¹ or muscular power at 180°.s⁻¹.

➤ **Maximum torque at 60°.s⁻¹ in N.m** (Fig. 2) : The torque values in the LPG Systems® treated group increased from 159.1 ± 17.9 to 167.7 ± 20.1 i.e. a significant 5.44% strength increase (P = 0.03).

In the control group, the torque values increased from 159.8 ± 31.3 to 164.9 ± 28 i.e. a non-significant 3.16% strength increase.

➤ **Maximum torque at 180°.s⁻¹ in N.m** (Fig. 3) : The torque values in the LPG Systems® treated group increased from 123.2 ± 15.1 to 132.8 ± 16.4 i.e. a significant 7.76% power increase (P = 0.001).

In the control group, the torque values increased from 119.8 ± 24.1 to 126.9 ± 12.6 i.e. a non-significant 5.96% power increase.

➤ **Fatigue** : The calculated fatigue indices evidenced no significant difference either between groups or from a time standpoint.

- LPG® treated group (before versus after measurements) : 68.4 ± 10.8 versus 63.2 ± 3.5

- Control group (before versus after measurements) : 63.8 ± 5.4 versus 65.9 ± 5.3.

➤ **Vertical jump test (in centimetres measured on Bosco treadmill)**

➤ **Squat jump** : There was a significant increase before and after measurements in both groups but this significance was higher in the LPG® treated group (40.9 ± 5.1 versus 43.0 ± 3.2 – P = 0.008) than the control group (40.5 ± 4.9 versus 41.5 ± 4.3 – P = 0.05).

➤ **Counter-movement jump** (Fig. 4) : An indicative increase (P = 0.09) was noted for performance in the LPG® treated group (43.8 ± 5.7 versus 45.5 ± 3.7) whereas there was no significant variation in the control group (43.9 ± 5.5 versus 43.7 ± 5.3).

➤ **Squat jump / Counter-movement jump difference** :

- LPG® treated group before and after measurements : 2.9 cm versus 2.5 cm

- Control group before and after measurements : 3.4 cm versus 2.2 cm.

A decrease in difference is noted in both cases but it is low and non-significant in the LPG® treated group, therefore enhancing its performance whereas performance

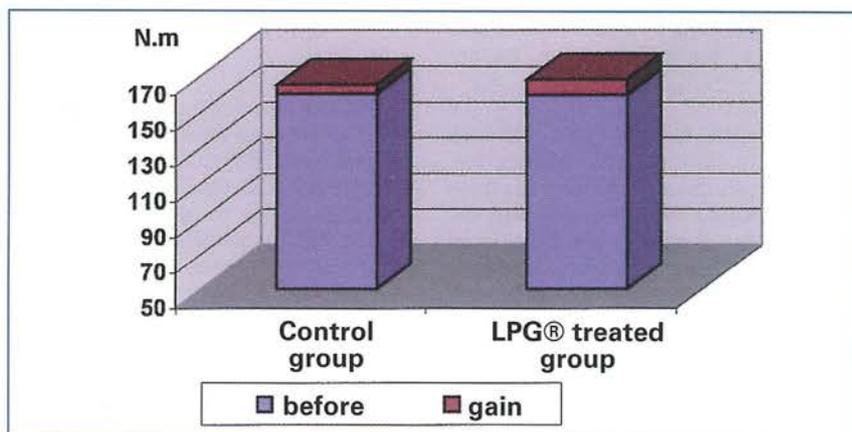


Figure 2 : Evolution of quadriceps force torques at 60°·s⁻¹ angular speed

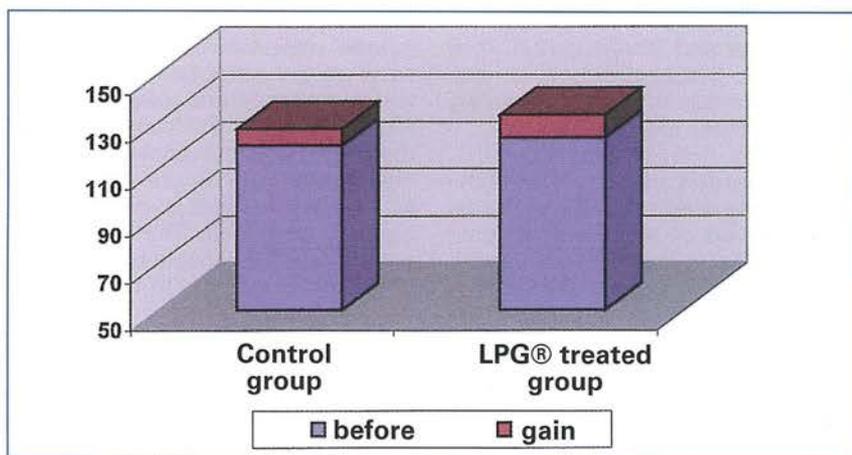


Figure 3 : Evolution of quadriceps force torques at 180°·s⁻¹ angular speed

remains unchanged in the control group.

DISCUSSION

The intensive practice of a competitive sport like football induces a fairly high workload for the body as a whole. The multiplication of competitive events associated with training makes it difficult for the players to recover between training sessions, between training sessions and matches and after matches. Facilitating recovery means improving training tolerance and, consequently, optimising the players' response in those background and technical phases. Medical and paramedical assistance was considerably developed within professional structures to meet those requirements. Every

available therapy is used while physiotherapy and re-adaptation to training, in particular, are used to counter the effects of fatigue and limit, if possible, stiffness and the dysfunctions it is causing. Numerous techniques are applied although their effectiveness and the mechanisms involved have not been clearly demonstrated. A number of studies attempted to evaluate the effects of the techniques applied to facilitate recovery from fatigue and stiffness that are the main factors contributing to the reduction in musculoskeletal efficiency. The results of those studies were at best inconsistent and contradictory, particularly as regards manual massage (Lightfoot et al, 1997; Gulick et al, 1996).

Functional overload in high level football players as well as other

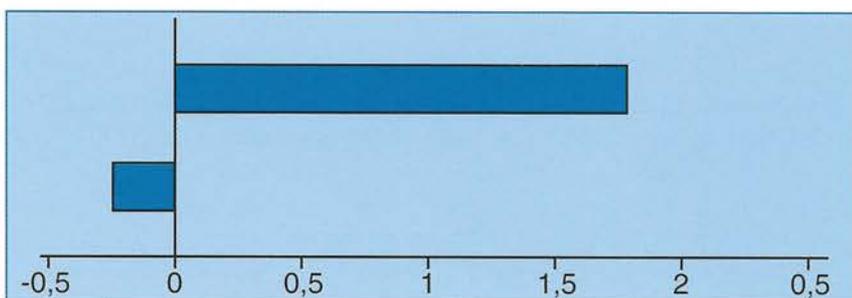


Figure 4 : Performance gained during counter-movement jumps

sportsmen induces a muscular fatigue and stiffness that reduce the ability to produce intense efforts (Bosco et al, 1986; Komi et al, 1992; Kyröläinen et al, 1998, Horita et al, 1999). Yet, this ability is essential in football players (Tumilty, 1993).

Overall, the results evidenced an improvement of the musculoskeletal functions in the LPG® treated group.

Motor control is analysed with isokinetic and vertical jump tests that help evaluate both muscular power (squat jump) and the ability to stock and spend elastic energy (counter-movement jump). As regards the initial values of isokinetic and relaxation tests, the isokinetic torques reported match the values published in previous studies (Rochcongar et al, 1998). Those authors measured torques averaging 124 N.m in 17-year old football players and 145 N.m in 24-year old football players versus 119.8 and 132.8 N.m in our study. As regards squat jump, the values in our study (40.9 to 43 cm) are lower than those (generally higher than 55 cm) published in the literature (Tumilty, 1993; Wisløff et al, 1998). These differences may be related to age or the measuring protocol used since no details were given regarding methodology in the studies involved. However, when our values are compared with those obtained during counter-movement jumps, they are found to be much lower than the values quoted above. It would thus appear that the ability to produce intense efforts was limited in the population included in our study. This was confirmed with the analysis of the difference between both types of jump that is comprised between 2.2 and 3.4 cm in our study whereas Bosco and Komi (1992) are suggesting a 6 cm average (although this was for the national Italian football team). The difference in the ability to produce intense efforts must therefore be considered as an intrinsic difference (age, motor skills, playing level etc.)

As regards the effects of LPG® treatment on those motor parameters, we noted that the isokinetic performance of the LPG® treated group was significantly improved as regards both strength (+5.44%) and power (+7.76%) whereas the increase of those criteria was not significant in the control group.

Thus, it may seem probable that this strength and power increase is partly related to a learning curve in between before and after measurements but more likely to the LPG® treatment effects.

CONCLUSION

The same findings apply for the vertical jump test and performance was significantly improved in the LPG[®] treated group. Motor performance improvement (strength, power, intense efforts) is consequently a highly significant point in professional football trainees because it was obtained during a difficult part of the season when their workload was quite heavy. In the light of the Kyröläinen et al, (1998) and Komi et al (1992) studies, one might think that the LPG[®] treatment may have had positive effects on some of the muscular fatigue and stiffness factors to explain those results, all the more since the effects of this technique on motor performance improvement, recovery from fatigue, in particular, and stiffness were demonstrated (Portero et al, 1996 and 1999). Insofar as cumulated fatigue and stiffness is a major factor interfering with the ability to stock and spend some elastic energy during stretching-contraction cycles, we can assume that the LPG[®] technique simultaneously facilitated fatigue recovery and limited stiffness. This dual effect was also perceived and expressed as easier movement during matches by the players whereas they were describing a tone reduc-

tion immediately after treatment while the technique was being applied.

The muscular fatigue tests did not show any significant difference within individual groups or between groups. This is explained by the fact that if metabolic fatigue is considered from a purely acidosis viewpoint, massage is efficient immediately after effort production (Portero et al, 1996) and, even without treatment, metabolic recovery and the return to a normal pH level takes approximately ten minutes (Allsop et al, 1990). However, since muscular fatigue is very much a multi-factor phenomenon (Enoka and Stuart, 1992), it is likely that the application of the LPG[®] technique could also have an effect on other mechanisms.

The integration of the LPG[®] technique in the medical and paramedical follow-up of professional football trainees helped improve some motor functions that are highly significant for players' performance, and this despite the fact that the study was initiated at a time in the season when sportsmen are using their full potential. Training tolerance improvement probably played a significant role too.

This study demonstrated the efficiency of LPG[®] treatment associated to conventional paramedical follow-up for high-level football players. Power and the ability to produce intense efforts, both significant performance criteria in this sport, were improved despite the physiological overload the players were being subjected to and the fact that the time in the season was not favourable to recovery. The limits of this study are the limitations inherent to high-level sport e.g. limited availability of the players on the one hand, preventing multiplying experiments or using heavier experimental equipment and field conditions on the other hand, where evidencing phenomena specifically related to fatigue, stiffness or other disorders is difficult contrarily to studies undertaken in the laboratory. Multiplying tests is a delicate problem in this case. The therapeutic strategy could probably be refined as treatment is adapted to training and the application of other techniques. Yet, despite the limitations inherent to high-level sport, this study demonstrated advantages to be directly gained from this technique as regards football players' recovery and performance.



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LPG SYSTEME ET DERMATOLOGIE

en particulier CICATRICES

Le LPG Système est un appareil de massage associant à la technique du masser-rouler, une aspiration modulable et mobile.

LA TECHNIQUE

Cette technique est brevetée mondialement. Elle provoque les actions physiologiques suivantes :

1) Hypervascularisation et hyperoxygénation

Le massage relance la vascularisation cutanée permettant de recréer les échanges et favoriser la nutrition cellulaire. L'effet se propage et retentit à distance sur divers systèmes musculaires et viscéraux par exemple. Lorsque le sens du massage se calque sur celui de la circulation de retour, l'élimination des déchets est accélérée permettant une décongestion des tissus.

2) Défibrossage et assouplissement tissulaire

La relance de la vascularisation cutanée permet la restructuration du tissu conjonctif. L'élimination accrue des déchets toxiques ainsi que l'apport d'enzymes et d'éléments nutritifs agissent sur la matrice extra-cellulaire du tissu conjonctif.

3) Drainage tissulaire et lymphatique

Les actions précédemment décrites de l'hypervascularisation, de défibrossage et d'assouplissement tissulaire vont permettre aux liquides (sang, lymphe, liquides interstitiels) de mieux véhiculer les apports et de drainer les toxines. Le réglage et l'intensité de l'aspiration associés au choix de la chronologie du sens des manoeuvres vont permettre de drainer les espaces tissulaires. La traction légère imprimée aux tissus, permettra l'ouverture des parois lymphatiques, facilitant ainsi la mobilisation de la lymphe.

4) Tonification

La stimulation des fibres d'élastine, associée à la décongestion des tissus, permettront de redonner à la peau une véritable tonicité.

5) Décollement

L'aspiration permet un décollement du plan cutané dermo-épidermique par rapport au plan musculaire.

LE MATERIEL

L'appareil Cellu M6 est constitué :

- d'un corps permettant l'aspiration,
- d'une «tête» de soins principale autotractée reliée au pupitre par un tuyau flexible,
- un jeu de 4 têtes amovibles.

La tête principale est constituée d'un corps contenant la chambre de massage et d'une poignée munie d'un interrupteur à 2 positions instables commandant l'aspiration et le sens de déplacement de la «tête».

La chambre de massage se compose de rouleaux motorisés permettant la mise en forme du pli cutané, puis l'entraînement de la «tête» et du pli, l'étanchéité étant assurée par 4 clapets latéraux et 2 clapets longitudinaux mobiles

APPLICATION DE LA METHODE DANS LE TRAITEMENT DES CICATRICES

Le praticien est quotidiennement confronté au problème causé par les cicatrices.

En traumatologie et dans les suites de brûlures graves, les cicatrices gênent la rééducation parce qu'elles provoquent un blocage circulatoire, cause de rétention et d'oedème, ou un blocage mécanique, cause de limitation articulaire ou de raideur.

D'un point de vue esthétique et psychologique, la cicatrice n'est pas toujours acceptée car elle est souvent disgracieuse, et particulièrement lorsqu'elle est visible en dehors de zones cachées par les vêtements.

Enfin, la cicatrice par l'emprisonnement de corpuscules sensitifs dans la fibre conjonctive est souvent douloureuse à la palpation.

Elle peut, à l'inverse, représenter une zone d'anesthésie, en raison de la lésion iatrogène des filets nerveux du territoire concerné. Cette zone est alors ressentie comme cartonnée, morte ce qui est source de perturbations corporelles supplémentaires.

La réparation cutanée apparaît comme l'oeuvre essentielle du tissu conjonctif et en particulier du collagène. En effet, celui-ci grâce aux fibres qu'il élabore va constituer la cicatrice. L'hémorragie locale permet la formation d'un caillot qui assure très vite une liaison entre les berges d'autant plus facilement qu'une suture chirurgicale a été effectuée, mettant ainsi les berges en contact intime.

Cette trame fibreuse grâce à un envahissement cellulaire secondaire (entre autre par des fibroblastes) se transforme progressivement, réalisant un véritable bourgeonnement du collagène.

L'épidermisation, réalisée dans un second temps, finira la cicatrisation.

Cependant, le tissu cicatriciel ainsi formé présentera souvent des particularités ayant des conséquences à des degrés divers pour le praticien :

- fibrose excessive,
- chéloïde lorsque l'hypertrophie persiste après une année d'évolution,
- adhérence sur les plans profonds tendant vers l'hypertrophie.

Il est donc nécessaire de mobiliser la cicatrice très rapidement sur les plans profonds, afin de limiter les adhérences, de drainer les alentours, afin que la stase laisse place à une vascularisation correcte permettant les échanges et la trophicité tissulaire.

Cependant, en fonction des régions du corps où elle se situe la cicatrice sera difficile à mobiliser et douloureuse au massage et l'oedème perturbera souvent la circulation locale accentuant la difficulté.

Il convient d'agir à distance tant que les fils ou les agrafes sont en place, puis sur la cicatrice quand elle est libre de toute contention.

Lorsqu'une plaque de compression est indiquée, le travail circulatoire aux alentours de la plaque dans le sens du drainage tissulaire, permet la résorption, facteur de meilleure cicatrisation.

Cette technique permet de venir à bout des cicatrices les plus délicates et les plus anciennes grâce :

- aux différentes têtes de traitement rendant accessibles les moindres parties du corps ;
- à l'aspiration applicable sur la cicatrice assurant ainsi une parfaite mobilisation des tissus par rapport aux plans sous-jacents évitant ainsi l'aspect hypertrophique réalisant un barrage ;
- au palper-rouler, associant l'effet de vascularisation à l'effet défibrossant, qui permettra la libération des corpuscules emprisonnés.

En cas de cicatrices hypertrophiques ou chéloïdes, lorsque les plaques de compression sont indiquées, l'effet drainant de la technique permettra, grâce à un travail périphérique de drainage et de dispersion, de redonner aux tissus lésés une trophicité nécessaire à la bonne circulation.

Si les plaques n'ont pas été prescrites, les manoeuvres seront réalisées en étoile autour de la cicatrice, et viseront à drainer la stase.

CONCLUSION

La technique du palper-rouler est un partenaire efficace de la dermatologie dans de nombreuses applications autres que les cicatrices particulièrement développées dans ce chapitre.

Grâce au réglage de l'intensité du traitement, au choix précis des manoeuvres, le drainage du visage et des différentes régions opérées est possible ; la variété des têtes de traitement permet de s'adapter à toutes les surfaces à traiter, si infimes soient-elles, le drainage des hématomes et des oedèmes devient rapide et simple.

Les cicatrices bénéficient largement de cette technique, en particulier celles difficilement accessibles à la main du fait de leur localisation ou de leur sensibilité au pincement : l'aspiration permet de les mobiliser sans douleur avec prudence et efficacité.

BRIEF REPORT

Use of a Mechanical Massage Technique in the Treatment of Fibromyalgia: A Preliminary Study

Chrisanne Gordon, MD, Clélia Emiliozzi, PhD, Marie Zartarian, MD

ABSTRACT. Gordon C, Emiliozzi C, Zartarian M. Use of a mechanical massage technique in the treatment of fibromyalgia: a preliminary study. *Arch Phys Med Rehabil* 2006;87:145-7.

Objective: To investigate how a mechanical massage technique (LPG technique) could contribute to the treatment of fibromyalgia.

Design: Feasibility study.

Setting: A single center.

Participants: Ten women having a preexisting diagnosis of fibromyalgia based on American College of Rheumatology criteria were enrolled.

Intervention: Subjects received a total of 15 sessions of mechanical massage administered by a physical therapist once a week.

Main Outcome Measures: The Fibromyalgia Impact Questionnaire and a physical examination scoring tender points (number, pain intensity). Evaluations were conducted at the screening visit, after 7 sessions (V7), and after completion of 15 sessions (V15).

Results: Most of the parameters (pain intensity, physical function, number of tender points) showed a significant improvement at V15 compared with screening.

Conclusions: The findings suggest the possibility that the studied intervention might be associated with positive outcomes in women with fibromyalgia, and support the need for a controlled clinical trial to determine its efficacy.

Key Words: Connective tissue; Fibromyalgia; Physiotherapy; Questionnaires; Rehabilitation.

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FIBROMYALGIA IS AN ENIGMATIC syndrome characterized by chronic, widespread pain along with tender points, fatigue, sleep disturbances, abnormal stress response, and tension headaches. One of the most difficult aspects of fibromyalgia is the lack of radiologic, biologic, or genetic signs. Clinical criteria for diagnosis of fibromyalgia have been

developed by the American College of Rheumatology (ACR).¹ Although the pathophysiologic mechanisms of fibromyalgia are not clear, treatments of fibromyalgia must target disease consequences and also break the vicious circle of pain, anxiety, sleep disturbances, and muscular exhaustion. Multidisciplinary treatments combining different approaches, including drug therapy, acupuncture, and connective tissue massage,²⁻⁵ may have the best overall effectiveness.

The LPG technique is an original noninvasive technique, consisting of a delicate and reproducible mechanical massage³ with claims such as relief of minor muscle aches and pains, relaxation of muscle spasms, relief of delayed-onset muscle soreness, and increase in blood flow.⁶ A single-center feasibility study was carried out to investigate whether this mechanical massage technique could be helpful in treating fibromyalgia.

METHODS

Population and Treatment

At inclusion, eligibility criteria required, according to ACR, a minimum of 11 positive trigger points out of 18 areas and a normal thyroid-stimulating hormone level (bloodwork, <12mo). Ten female patients were enrolled, with an average age of 46.8±9.5 years (range, 28–62y) and a mean weight of 69.1±15.6kg (range, 49.9–104.3kg). The mean duration of fibromyalgia from the time of initial diagnosis was 8.11±3.2 years (range, 3–13y). Patients taking medication were not excluded from the study, and participants recorded their use of medication over the course of treatment.

Each patient signed an informed consent form and received a total of 15 sessions of mechanical massage once a week (35min/session). The mechanical massage technique consisted of a deep tissue mobilization provided by a medical device (Cellu M6).³ This device is composed of a treatment chamber in which an aspiration system draws a skinfold between 2 motorized rollers that roll and unroll this fold.⁶ The treatment was administered on the full body with particular focus on the tender point areas.

Evaluations

The principal outcome measure was the Fibromyalgia Impact Questionnaire (FIQ), a validated disease-specific instrument.⁷ The first 10 FIQ items are scored to create the physical functioning score (PFS) and focus primarily on the patient's ability to perform activities of daily living, such as walking and driving, and are scored from 0 (always able) to 3 (never able to do). The next 2 FIQ items ask the patient to circle the number of days in the past week when they felt good and the number of days where they missed work. The last 7 items—ability to do job (work difficulty), pain, fatigue, morning tiredness, stiffness, anxiety, and depression—are measured by 100-mm, anchored horizontal visual analog scales (VASs).

The second outcome was a physical examination performed by the investigator trained to evaluate fibromyalgia tender points. Each point was scored 0 to 4 (0, no pain; 1, mild; 2, moderate; 3, severe; 4, unbearable) and then summed to give a

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Table 1: Mean FIQ VAS Scores (0–10) From Screening to V7 and V15

Items (13–19)	Screening (N=10)	V7 (n=9)	P	V15 (n=9)	P
Pain	6.1±2.7	3.8±2.5	.036	3.1±1.8	.007
Work difficulty	5.2±2.8	3.8±2.6	.089	2.8±1.8	.013
Fatigue	7.5±2.3	5.4±2.4	.014	3.9±2.1	<.001
Morning tiredness	7.8±2.2	5.4±2.9	.029	4.2±2.1	.008
Stiffness	6.9±2.5	5.4±2.0	.057	3.7±2.1	.004
Anxiety	5.9±2.9	4.1±2.1	.144	2.7±1.7	.01
Depression	4.3±3.0	3.0±1.7	<.003	1.9±0.9	<.034

total tender pain score, which ranged from 0 to 72. The number of painful tender points was defined as the number of points with pain intensity greater than 0.

Both evaluations were performed at screening, midpoint of treatment (V7), and after completion of treatment (V15). At V15, patients were asked if the mechanical massage technique was helpful (no, not much, yes enough, a lot) and if they wanted to continue (evaluation of satisfaction).

Data Analysis

The statistical significance of the change in each parametric measure from baseline to 7 weeks and baseline to 15 weeks was examined using matched-pairs *t* tests. Change in medication use and satisfaction with treatment are described qualitatively.

RESULTS

Nine patients completed the 15 sessions; 1 patient dropped out after the fourth session due to poor compliance. The sample size for analyses was 10 at screening, 9 at V7, and 9 at V15.

Fibromyalgia Impact Questionnaire

The mean PFS was 1.0 ± 0.7 at screening, 0.7 ± 0.5 at V7, and improved significantly ($P < .009$) to 0.4 ± 0.4 at V15 (improvement from screening, 60%). The mean number of days when patients felt good during the past week (0–7) was 3.1 ± 2.3 at screening and increased significantly to 5.9 ± 0.9 at V15 ($P = .003$). The mean number of days patients missed work (0–7) was 0.9 ± 1.2 at screening, 0.2 ± 0.4 at V7 ($P = .089$), and 0.1 ± 0.3 at V15 ($P = .169$). The FIQ VAS showed significant improvement after 15 sessions of mechanical massage, by 50% for all items (table 1).

Physical Examination

The mean pain score was 26.7 ± 9.1 at screening; it reduced significantly to 14.8 ± 10.4 at V7 ($P < .001$) and reduced again significantly to 10.22 ± 8.6 at V15 ($P < .001$) (improvement from screening, 50% and 60%, respectively). The mean number of painful tender points was 15.5 ± 2.1 at screening, decreased significantly to 10.0 ± 5.0 at V7 ($P = .002$), and to 7.6 ± 6.3 at V15 ($P = .005$) (improvement from screening, 36% and 50%, respectively).

Acceptability

Exactly 88.9% of the patients considered the treatment as “very” or “enough” helpful and wanted to continue.

Medications

Recorded medications were only nonsteroidal anti-inflammatory drugs (NSAIDs) and amitriptyline. At V15, 2 of the 6 patients using NSAIDs daily had reduced to sporadic evening usage; no change was observed in the use of amitriptyline.

DISCUSSION

The primary outcome measure of this study was the FIQ, which is the only disability instrument designed and extensively validated for persons with fibromyalgia.⁸ All the parameters of FIQ, except for the number of days when patients missed work, significantly improved after 15 sessions of mechanical massage compared with screening; both the PFS and VAS changed in the range of 50%. In addition, the pain score and number of painful tender points decreased significantly from screening to V15 by 60% and 50%, respectively.

The literature on the effect of massage or behavioral-based therapy on fibromyalgia reports different fragmentary improvements with a lower magnitude.^{3,9,10} Massage is thought to affect outcome by both physiologic and psychologic mechanisms. Physiologic effects can be either mechanical or reflexive in nature.⁸

This pilot study had a number of significant methodologic weaknesses that should be kept in mind when interpreting the results. They include a small sample size (which can reduce the reliability of the findings), a lack of control for therapist attention, expectancy, and time effects (which can work to reduce pain report on their own), and a lack of control for the specific effects for the mechanical massage system used versus other massage strategies.

CONCLUSIONS

In this study, after 15 sessions of mechanical massage, we found a 50% improvement in the FIQ PFS, FIQ VAS, and pain scores. The findings suggest the possibility that the studied intervention might be associated with positive outcomes in women with fibromyalgia, and support the need for a controlled clinical trial on a larger population to determine its efficacy.

Acknowledgment: We thank H el ene Pace-Soler of Axonal, Nanterre, France, for performing statistical analysis.

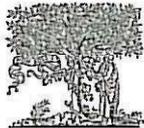
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ELSEVIER

ARTICLE ORIGINAL

La maladie de Mondor : une complication de la chirurgie mammaire

Mondor's disease: a complication after breast surgery

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MOTS CLÉS

Maladie de Mondor ;
Seins

Résumé La maladie de Mondor est une complication relativement rare en chirurgie plastique mammaire. Elle est souvent décrite comme une thrombophlébite des veines sous-cutanées au niveau du mur thoracoabdominal antérolatéral. La symptomatologie la plus fréquente consiste en l'apparition d'une corde douloureuse sous-cutanée accompagnée d'une tension et d'une rétraction de la peau. Cette symptomatologie apparaît aux niveaux sous-mammaire et axillaire. Fondé sur l'étude de huit patientes ayant présenté la maladie de Mondor après chirurgie mammaire, nous avançons une hypothèse étiologique basée sur une atteinte fasciale. Toutes ces patientes ont bénéficié d'un traitement LPG et myofascial. Une guérison complète a été observée dans les dix jours.

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KEYWORDS

Mondor's disease;
Breast

Abstract Mondor's disease is a rare but not uncommon complication of breast surgery. This problem is commonly described as the thrombophlebitis of the superficial thoracoabdominal veins. Symptoms combine painful contracture occurring in the sub-mammary region and/or in the axillary region, rising during arm abduction. The contracture located in the axillary region usually join the epitrochlea. Based on a serie of 8 patients, the fascial hypothesis is developed. All the patients were treated by LPG and myo-fascial techniques with a complete relief of pain in 10 days.

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Introduction

La chirurgie plastique mammaire regroupe les interventions les plus pratiquées en chirurgie plasti-

que. Il s'agit des réductions ou augmentations mammaires, des mastopexies ou des reconstructions après tumorectomies, mastectomies ou pour malformations congénitales. Même si les résultats sont généralement excellents, des complications spécifiques existent. Les plus fréquentes sont les infections (0,6 à 35 %), les hématomes (1 à 6 %), les

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contractures capsulaires (0,5 à 20 %), les séromes (0,1 à 4 %), les nécroses cutanées (0,1 à 1,8 %), les déhiscences de plaies (0,4 à 5,6 %), les replis au niveau prothétique (20 %) et les ruptures d'implants (0,3 à 23,9 %) [1-6]. La plupart d'entre elles possèdent des facteurs favorisants et sont spécifiques de certaines interventions. Outre ces complications classiques, la maladie de Mondor mérite également d'être citée sans qu'elle possède de nette spécificité pour un type d'intervention chirurgicale. Cependant, il s'agit d'une complication relativement rare, souvent décrite comme une thrombophlébite des veines sous-cutanées au niveau du mur thoracoabdominal antérolatéral [6-12]. Cependant, son étiopathogénie n'est pas encore clairement établie, pas plus que sa réelle incidence.

Se fondant sur une pratique générale de chirurgie mammaire, nous étudierons son incidence et exposerons notre attitude thérapeutique. Une hypothèse étiopathogénique ainsi qu'un traitement spécifique seront également avancés.

Matériel et méthode

Nous avons étudié 504 patientes ayant bénéficié d'une intervention chirurgicale mammaire entre le 1^{er} janvier 2001 et le 30 décembre 2003. Les augmentations, réductions, reconstructions et pexies mammaires représentent respectivement 21, 40, 28 et 11 % des cas. La totalité des dossiers a été revue afin de mettre en évidence la survenue de complications. Le mode de développement, le délai d'apparition, le traitement seront étudiés. Le diagnostic de maladie de Mondor est envisagé lorsqu'un cordon induré, douloureux et saillant est présent dans la région sous-mammaire, perpendiculairement au pli sous-mammaire ou au niveau du creux axillaire, dans un sens transversal se prolongeant sur la face interne du bras vers le coude.

Dès la pose du diagnostic, les patientes sont prises en charge par un kinésithérapeute appliquant un protocole de traitement incluant deux techniques. La technique LPG[®] traite le tissu conjonctif par un mécanisme d'aspiration du pli cutané entre deux rouleaux déplacés sur la zone à traiter. Les effets principaux à long terme sont : la stimulation des fibroblastes et restructuration de la trame conjonctive entraînant une meilleure vascularisation et un meilleur drainage régional [13]. Dans les cas traités, l'effet immédiat produit est une décongestion tissulaire réduisant la réaction inflammatoire et le spasme musculaire local, améliorant la symptomatologie.

Les techniques myofasciales, appliquées en ostéopathie, traitent le tissu musculoligamentofas-

cial. Par des techniques manuelles (allant du creux axillaire à la main, dans ce cas), le thérapeute agit aussi bien sur les muscles (grand pectoral, grand dorsal, muscles du bras et de l'avant-bras) que sur le tissu fascial (fascia superficiel et profond) entraînant : un relâchement des muscles spasmodés, un meilleur drainage veineux et lymphatique, concourant ainsi à la décongestion de la zone inflammatoire et à une stimulation des muscles hypotoniques par le réflexe d'allongement [14].

Les deux techniques, qui ont montré leur efficacité, peuvent être utilisées en alternance mais si le thérapeute décide de n'en utiliser qu'une, le traitement manuel myofascial devra être préféré en raison de son action plus globale et plus complète. L'amélioration de la symptomatologie sous le traitement prescrit sera quantifié au cours du temps.

Résultats

Huit patientes présentaient les caractéristiques cliniques compatibles avec le diagnostic de la maladie de Mondor. La symptomatologie observée incluait l'apparition d'une corde douloureuse, sous-tension, au niveau mammaire, accompagnée de façon plus ou moins importante d'une corde similaire au niveau du creux axillaire homolatéral, se prolongeant jusqu'au pli du coude (Fig. 1). La tension et la douleur, évoquées comme une brûlure, au niveau de ces cordes augmentent lors de la mise en abduction du membre supérieur. Il existe une réduction concomitante de la fonction de l'épaule. Quatre patientes présentaient la symptomatologie complète alors qu'une ne présentait qu'une corde sous-mammaire et trois autres des cordes prédominant au niveau axillaire, se prolongeant vers le pli du coude. Toutes ces patientes ont présenté cette symptomatologie entre le 10^e et le 15^e jour postopératoire. L'âge de ces patientes se situe entre 43 et 45 ans.

Les interventions chirurgicales réalisées sont deux réductions mammaires bilatérales (symptomatologie complète), une pexie mammaire bilatérale (symptomatologie complète), deux augmentations mammaires (une symptomatologie mammaire et une symptomatologie complète), une reconstruction mammaire par prothèse sans évidemment axillaire, une reconstruction mammaire par lambeau de grand dorsal et prothèse et une reconstruction mammaire par DIEP sans évidemment axillaire préalable (symptomatologies axillobrachiales).

Toutes ces patientes ont bénéficié d'un traitement LPG[®] et d'étirements myofasciaux. Nous avons observé une guérison complète dans les dix jours dans tous les cas observés.

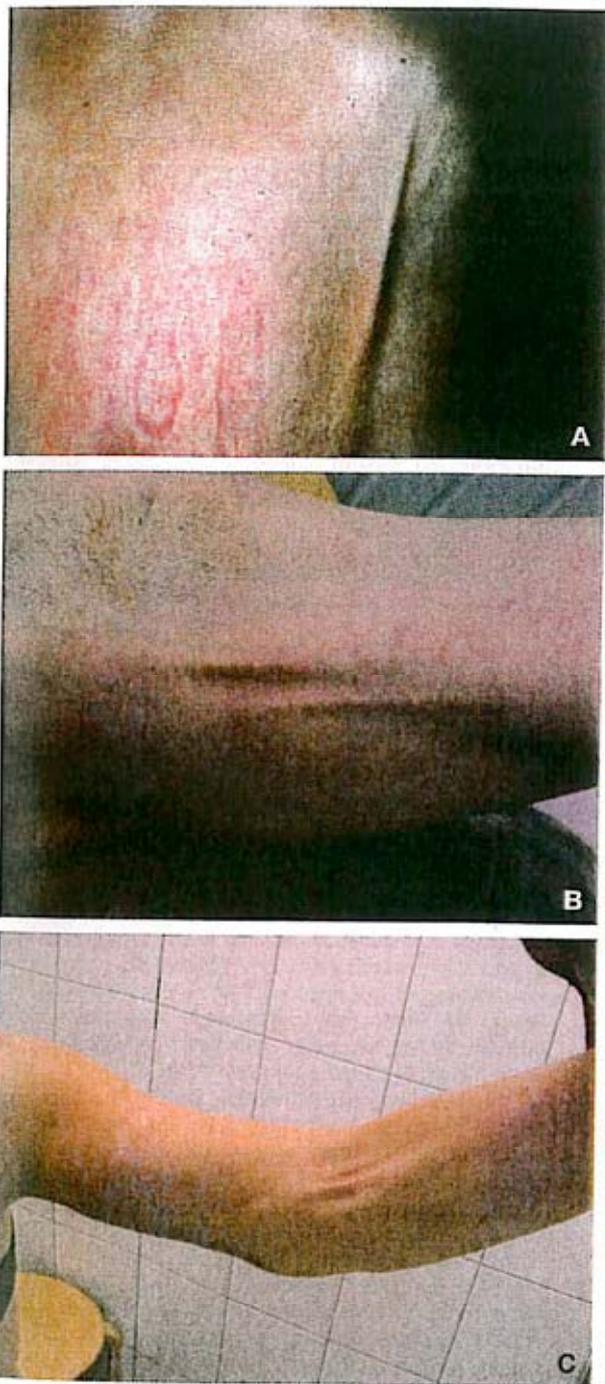


Figure 1 Brides localisées en région sous-mammaire (A), au niveau axillaire (B), se prolongeant vers le pli du coude (C).

Discussion

La maladie de Mondor est généralement considérée comme une complication rare de la chirurgie mammaire, caractérisée, dans la littérature, par une thrombophlébite des veines sous-cutanées au niveau du mur thoracoabdominal antérolatéral. Les veines les plus souvent citées sont les veines thoracoépigastriques, thoraciques latérales et épigastriques supérieures. Parfois, on retrouve une atteinte

des veines drainant la partie supéromédiane du sein [7,8,10]. Même si nous mettons en doute la réalité de ces thromboses veineuses, en tant que cause, la topographie lésionnelle est en effet similaire.

L'origine de la maladie de Mondor n'est actuellement pas définie et aucune cause étayée n'est mise en évidence. Le développement de cette pathologie est rapporté après une activité physique intense, une grossesse, un traumatisme, une intervention chirurgicale (augmentation mammaire, réduction mammaire, reconstruction mammaire et biopsie mammaire) et diverses maladies (néoplasies, infection mammaire, processus inflammatoire tels que l'arthrite rhumatoïde) [7-12,15,16]. La diversité des facteurs favorisants et les contextes d'apparition contribuent également à l'incompréhension de l'étiopathogénie.

La symptomatologie la plus fréquente consiste en l'apparition d'une corde douloureuse sous-cutanée accompagnée d'une tension. Parfois cette corde est accompagnée d'érythème, d'un hématome, d'un aspect perlé ainsi qu'une fièvre [7,8]. Ces symptômes persistent pendant deux semaines à six mois et disparaissent après un traitement conservateur symptomatique tel qu'un repos associé à l'application de chaleur et à la prise d'AINS [7,8].

Certains auteurs pensent qu'il s'agit d'un traumatisme direct au niveau des veines thoraciques [17]. Les prélèvements histologiques, réalisés dans quelques cas rapportés dans la littérature, démontrent que la maladie de Mondor peut entreprendre les veines mais également les artères et les vaisseaux lymphatiques [7]. En revanche, Marsch et al. avancent une origine lymphovasculaire plutôt qu'une phlébite [5]. En effet, un examen au microscope électronique réalisé chez un patient présentant ce type de lésion révèle des modifications au niveau lymphatique plutôt que veineux. Les huit cas cliniques que nous avons décrits ont été observés au cours de la période postopératoire immédiate. L'incidence de 1,5 %, dans notre série, rend ces cas, non exceptionnels, pourtant cette pathologie est peu décrite dans le cadre des différentes complications observées après chirurgie mammaire.

Dans tous les cas rapportés, en l'absence d'évidement axillaire, nous avons noté une association plus ou moins importante entre la corde douloureuse située au niveau mammaire et une corde au niveau axillobrachial homolatéral. Ce type de tableau clinique a également été décrit par Eastcott après mastectomie radicale [18]. Catania décrit également des cordes transverses similaires [8]. Ces auteurs pensent que ces cordes seraient dues à un épaississement de la paroi veineuse ou à une

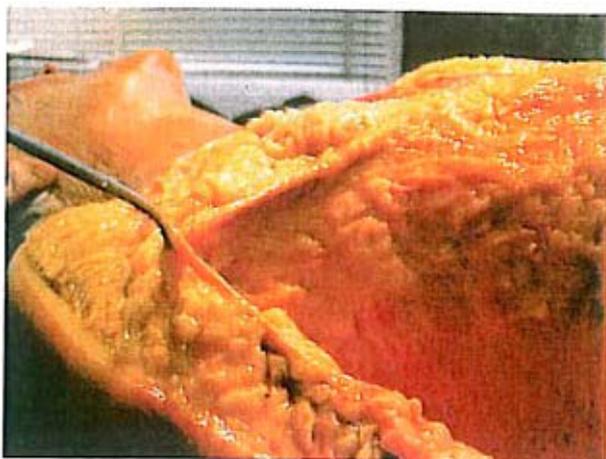


Figure 2 Fascias superficiales.
Mise en évidence sur cadavre frais.

thrombose des veines sous-cutanées se drainant vers le creux axillaire où un ralentissement du flux sanguin peut apparaître. Malheureusement, d'un point de vue anatomique, il n'existe pas de connexion veineuse directe, de continuité, entre la région sous-mammaire et la région du pli du coude. De plus, la mise en abduction du membre supérieur homolatéral amplifie la tension au niveau des cordes mammaire, axillaire et brachiale. Ce faisceau d'indices nous pousse à mettre en doute l'origine thrombotique de la maladie. En effet, une continuité entre la région sous-mammaire, axillaire et brachiale existe physiquement par le biais du fascia superficialis thoracique (Fig. 2) se continuant par le fascia clavipectoral lié au fascia superficialis du bras [19]. De plus, la mise en tension d'une partie de la corde accentue la visibilité des autres parties atteintes, reproduisant les douleurs à ce niveau. La palpation de la corde en région sous-mammaire, non adhérente au plan profond et à la peau corrobore cette possibilité. Enfin, le succès des traitements LPG® et myofasciaux, dans les dix jours, renforce plutôt cette hypothèse. Il pourrait donc s'agir d'une contracture du fascia superficialis. Ceci serait aisément expliqué par les différentes manipulations techniques appliquées au tissu mammaire et donc au niveau du fascia superficialis thoracique lors des différentes interventions mammaires. Lors des augmentations mammaires par voies sous-mammaires, le fascia superficialis est incisé puis resuturé lors de la fermeture. L'excision glandulaire réalisée lors des réductions mammaires, suivie du remodelage de la glande pourrait aboutir sans aucun doute à la genèse de ce type de traction pouvant se répercuter par continuité directe du fascia jusqu'en région axillaire.

Même si cette hypothèse étiopathogénique, fondée sur la clinique, semble s'opposer aux données histologiques, rien n'infirme la possibilité de

thrombose vasculaire au sein d'une contracture fasciale. En effet, plusieurs études ont démontré la présence d'occlusions microvasculaires au sein de contractures tissulaires observées dans la maladie de Dupuytren [20] ou dans des cicatrices hypertrophiques ou chéloïdes [21-23].

Conclusion

La maladie de Mondor n'est pas une complication rare en chirurgie mammaire. Bien qu'une thrombose des veines thoraciques superficielles ait été invoquée comme étiologie, une contracture post-traumatique du fascia superficialis nous semble plus probable. Cette pathologie, pouvant invalider la fonction de l'épaule, une fois correctement diagnostiquée, elle peut être efficacement et rapidement traitée par le LPG® et les techniques myofasciales.

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ORIGINAL ARTICLES (TRANSLATION)

CURRENT EVENTS
EPIDEMIOLOGIE

LPG AND THE CUTANEOUS SOFTENING OF BURNS

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INTRODUCTION

Massage has been used for many years to improve the physical properties of scar tissue resulting from burns. Hypertrophic fibrous zones can be softened by direct and gentle movements. The tissue, whose physical properties (slide, elasticity) and look (color, texture) have been altered, can be modified one to two years after healing through specific technique. Manual techniques are designed to lift the skin off its base using tangential pressure leading to the creation of a cutaneous fold.

The LPG device is designed to achieve a skin lift through suction without putting too much strain on the new epidermis. Our study focused on the effects of this machine on:

- skin elasticity,
- skin lift,
- inflammation
- the articular state,

which were quantified in clinical studies. They were then paired with an echographic study.

We compared the results of these different parameters obtained through:

- Continuous LPG technique
- Rhythmic LPG technique
- Traditional manual massage

Results show that the LPG techniques are more efficient than manual massage. Indeed, this method seems more successful than manual massage at mobilizing collagen without harming the surface epithelium.

ACTIVE FOLD ROLLS (or P.R.A.)

These are carried out on great surfaces of skin. The dorsal part of the trunk is the point of predilection. This operation is carried out is for an advanced stage of the scarring.

Indeed, several factors contribute to adopting this action:

- 1 °/ The mechanized head, that which has the largest opening, will have the most power of suction. It is necessary to be particularly vigilant during its use.
- 2 °/ Volume and the mechanization of the rollers allow for a closer monitoring of the skin. (with difficulty monitoring brought closer to the skin after the passage of the head.)
- 3 °/ The association of the suction and the movement of rollers succeeded has a very intense mobilization of the skin.

The POSE/RETIRE (or P.R. – *Touch-Withdraw*)

As soon as that is possible it is the operation that we generally employ and that brings us the best results. It is carried out by application of the head on the surface burned, suction, traction of the skin and withdraw of the head without displacement on the cutaneous level.

Indications:

- 1 °/ The PRP east indicates in the event of adherent skin. One uses a head of average size which one moves in parallel, perpendicularly or star shape with suction of average intensity (of 3 A 8).
- 2 °/ the P.R.A. east indicates in the event of mobile skin but hypertrophic with a depression between 3 and 6. Displacement is multidirectional.
- 3 °/ the P.R. east indicates in the event of very adherent skin: one carries out simply a cutaneous suction. The depression is maximum (7-9) remains function of the solidity of the skin.

CLINICAL ASSESSMENT

These methods of massage will be indicated only after one precise and rigorous appreciation of quality of the skin.

It will be done by test simple comparative and reproducible:

- the test of vitropression (V.P.)
- the test of cutaneous stretching
- the test of cutaneous sliding
- a measurement of articular amplitudes

These assessments could be possibly supplemented by an echographic study allowing the mist in obviousness important modifications of the scar structure.

1- VITROPRESSURE TEST

Clinical test assesses cutaneous inflammation.

It is a comparative referential test.

EQUIPMENT AND METHOD

I-POPULATION

We compared 606 patients:

- 202 subjects who had been treated before 1992 with manual massage on 250 zones
- 404 subjects who, after 1992, represented 500 burn zones treated with two LPG techniques:
 - 250 zones of continuous pulsated suction
 - 250 zones of intermittent pulsated suction

These patients benefited in all other respects from the same treatment: hydration, Pressure garment therapy, active and passive mobilization of the cutaneous fold, equipment, and filiform high-pressure showers. We made no assumptions as to the treatment or etiology of the burn.

II-EQUIPMENT

There are two types of apparatuses of massages. They have in common: a vacuum pump connected by a flexible device to a choice of several interchangeable heads, with different suction levels. All the heads, except the punctiforme one, move on the skin by 2 parallel and symmetrical mobile rollers.

These machines are adjustable in their intensity to allow essential safety. The depression of 650 millibars causes suction of the cutaneous plan, the two rollers allow a displacement of the cutaneous fold by decreasing the friction.

The depression of 650 millibars causes suction of the cutaneous plan, the two rollers allow a displacement of the cutaneous fold by decreasing the friction.

The other machines, M50 and S70, have moreover, one adjustable intermittent rhythmic suction in intensity and time.

Possible adjustments:

- 1°/ standard heads (small, medium, large, punctiforme),
- 2°/ free rolling head or mechanically driven (big head): passive rolled fold (P.R.P.), active rolled fold (P.R.A.),
- 3°/ suction intensity: 1 to 9
- 4°/ programmable working time
- 5°/ rhythmic frequency, from 1 to 99
 - 1 correspondent with a beat every 12.2 seconds
 - 99 correspondent with 12.5 beats per second
- 6°/ The ratio of the cycle: is equal to the duration of the suction time compared to the duration of rest: the two times corresponds to one beat; it goes from 1 to 9. the resting period is equal to the working time accounting for 5.
- 7°/ The various parameters for each patient can be memorized in a program. This makes it possible to find those of the preceding session and to simplify manipulations.

PASSIVE FOLD ROLLS (or P.R.P):

It is used in the beginning of the treatment. The first operations are performed on the circumference of the scar. They are centrifugal in order to drain from the periphery a maximum of the haematic collection. As soon as the skin offers a more important solidity and the test of vitropression increases, we start on the scar, longitudinal, transverse and "star shape" maneuvers.

The measuring apparatus is composed of a cutaneous temperature gauge, a stop watch to the 1/10 of second with a transparent surface in the center and a concave protuberance of 15mm of diameter.

The application of the pallet on the zone to be treated will allow:

- 1° / to test the temperature
- 2° / to carry out a cutaneous bleaching

Normal recoloration timing is 3 seconds. The shorter the interval, the more inflammatory the skin is.

2- CUTANEOUS STRETCH TEST

The clinical test assesses

- cutaneous expandability
- adhesion to deep layers

-This is a test conducted with a tape measure:

One chooses:

Separate from 1 to 5 cm, according to topography. One then measures the difference in length between the position of maximum stretching and the position of cutaneous relaxation. This test is also carried out in a healthy zone in order to compare the elasticity of the skin.

3- CUTANEOUS SLIDING TEST:

It is possible to assess the mobility of the skin in relation to the deep layer as well as skin thickness: a rating from 0 to 5 is available, ranging from maximum adhesion (rating 0) to the possibility of an appreciable cutaneous fold displacement between the thumb and the index finger (rating 5).

Test can be carried out with 2 fingers or hands flat:

- 0 Impossibility of lifting the skin
- 1 Slight lift of the skin
- 2 Complete lifting of the skin

Measure between the inch and the index or with a adipometer

- 3 Possibility of pinching of the fold
- 4 Measurement of the easily gripped fold
- 5 Rolled fold

4- ARTICULAR RECOVERY:

This is controlled by weekly assessments. Measurement machines include:

- goniometer,
- tape measure

The amplitudes of the majority of the articulations are taken in degree.

For the hand, there is:

TPM Total Passive Movement
Analytical, comparative, referential

<u>DPPPD</u>	Distance finger pad / palmar distal fold for long fingers
<u>KAPANDJI Index</u>	Mobility of thumb column
Rachis	Mobility sought for: Schober Test Thoracic Expansion

5- CUTANEOUS STRENGTH

Cutaneous solidity is appreciated visually by a concerted examination (Doctor / Nurse / Physical Therapist): aspect, coloring, detail of scarring.

PROTOCOL:

Tests were performed on 606 patients in 750 zones (3 x 250). A vitropressure test (V.P.) was done three times a week after scarring, at Day 15 and Day 30. The test examiner was always the same for various assessments. The therapist and the test examiner were different in order to preserve a certain objectivity for the study.

TYPICAL SESSION:

a-Patient set up:

Bone segments are laid out so that the cutaneous coating is fully relaxed to facilitate the LPG-generated suction.

b-Technique options:

- Dimensions of the head (treatment zone functions)
- Suction intensity
- Frequency
- Cycle choice
- Techniques used

This choice is made according to the feelings perceived by the patient, before all indolence, then the cutaneous reactions. Parameters are readjusted as needed.

c-After the session:

- Make the patient aware of cutaneous inflammation (Color of the Skin)
- Monitor closely the changes of the inflammation.

TECHNIQUE SELECTION BASED ON SKIN TYPE

1/ ADHERING SKIN

- The operation of predilection remains the P.R. (touch / withdraw)
- Time on the scar tissue is a function of the inflammatory state and cutaneous solidity. On a small zone that goes from 10 to 20 suctions for 3 or 4 minutes.
- The choice of the head is a function also of cutaneous solidity. In reality, the larger the surface of the head, the more important the suction.

In ascending order, one starts with the punctiforme, then the small head and finally the average head.

In the event of maneuvers on stiff fingers, we start with suction on the lateral side strips of the I.P.P. in order to release as much adherence as possible.

2- SKIN WITH LITTLE ADHERENCE

From the start we adopt a head of average surface. It uses the technique of the P.R.P. with suction parameters of about 50% of the maximum power.

Indeed this displacement of the head by the intermediary rollers causes a skin fold rolling which at the time of the first session is painful.

In time, the painful feelings decreasing, the suction power is increased and the head is changed for a larger one.

- At the end of the treatment, we use the main head of the <<ES 2>>. This head performs the P.R.A.
- the monitoring of the state of the skin is important, because of the power of the suction of this head. We seldom exceed 50% of the maximum of intensity.

3- LOOSE BUT HYPERTROPHIC SKIN

As in the preceding chapter, we start with an average head.

- the course of the sessions will be identical with a faster progression in the rise in power of the suction.
- the most important head will be used according to the extent of burned surface.
- In all the cases, a very strict monitoring of the cutaneous state and inflammatory state will be observed.
- Motion techniques should be slow and head should be moved around without losing skin contact.

SPECIAL CASES

We have utilized LPG technique on the eyelids. In all of these cases:

- low pressure is applied
- the smallest head is used
- in the beginning of the technique, P.R. is used and with time multidirectional P.R.P. technique is used.

Here one must listen to of the reactions of the patients.

RESULTS:

They more take account of the progression of the same patient and the evaluations for each test.

1-VITROPRESSURE TEST

It must be carried out less than one half an hour after the end of the treatment.

Two elements appear:

- a) After 30 days of massages, LPG rhythmic technique appears definitely less aggressive than LPG continuous technique. Traditional massage comes in third place. (Table 1)
- b) Earlier increase in the time of the test with LPG rhythmic technique sign a faster regression of the inflammatory state.

We begin the treatment by the LPG rhythmic technique in order to avoid:

- painful phenomena
- the hyper-vascularization
- cutaneous aggravations.

We begin 2 months approximately after the scarring of a burn. The next step is the technique known touch-withdraw which is adapted and more effective on less inflammatory skin.

2- SKIN FOLDING TEST

It is difficult to quantify the effects of the massage on this test for the delay of day 30 is too short.

This test is improved more quickly with the continuous LPG technique, then the LPG rhythmic technique, and finally the traditional massage.

We have tests relatively homogeneous being in the choice of the patients and it is necessary to take account of the variation of the times of assumption of responsibility after the burn. Broadly, we deal with two types of patients:

- either in an important proportion, those whose burn (or condition) is recent and who test results are between 0 and 1.
- or those who return for maintenance treatments whose skin folding test results are between 3 and 4 (Table 2).

3- STRETCHING TEST

The progression is faster with the LPG continuous, then LPG rhythmic then the manual massage. The mathematical assessment could not be carried out taking into account too great differences in scar surfaces.

However, the opinion of the 6 physical therapists and occupational therapists is unanimous: the continuous technique touch- withdraw is most effective and the most used then the rhythmic technique, the choice comes being guide by the inflammatory evolution of the skin.

4- ARTICULAR ASSESSMENT

It is difficult, in the current state of this study, to quantify the profits obtained. However, it would be necessary to defer the effectiveness of the method has the topography of the burn. In a general way, the continuous LPG affects articular recovery in 2/3 of the cases. Then the rate/rhythmic comes which largely exceeds the effects of the manual massage. This effectiveness is all the more remarkable since the zones are difficult to access such as the face or the hands.

CONCLUSION

Results of LPG technique used on burns are very encouraging, especially in treating sub-cutaneous adhesions. In our opinion, the combination of suction, garment therapy massage is a perfect example of effective mechanical treatment of collagen scar tissue.

The four years of use currently enable us to adapt in very precise manner the intensity of the treatment has the inflammatory changes of the scar.

The LPG technique is important for range of mechanical proposals: frequency, suction, rhythmicity, diversity of morphology and surface of the suction heads seems perfectly adapted has the chronology of the scar changes.

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Table 1
Results of Day 30

	Improved	Same	Worsened
Manual Massage	62 (T+8/10 sec)	187	1
LPG Rhythmic Technique	103 (T+8/10 sec)	145	2
LPG Continuous Technique	105 (T+8/10 sec)	141	4

Table 2

	LPG Continuous		LPG Rhythmic		Manual Massage	
	D0	D30	D0	D30	D0	D30
0	172	52	161	59	166	104
1	44	119	49	111	47	86
2	24	35	29	36	27	26
3	7	18	8	17	7	14
4	2	19	3	21	3	13
5	1	7	0	6	0	7

Physiological tissue changes after administration of micronized Diosmin/Hesperidin, individually or in association with Endermologie®

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Abstract (1)

Introduction

Despite the individual use of Endermologie and Diosmin/Hesperidin producing active physiological changes in the cutaneous microcirculation, the possibility of using individual treatments in association has never been taken into consideration. In the cutis treated with Endermologie, microcirculatory changes concern the increase of the blood and lymphatic flow; this effect is no doubt linked to the mechanical stimulation of the cutis and of the subcutis through the contemporary action of positive pressure, suction and the mechanical massage operated by rollers.

Materials and methods

The study was carried out with Optical Probe Videocapillaroscopy (OPVC), Laser Doppler Flow measurements and transcutaneous Oxymetry on 34 subjects, 20 females and 14 males, after having informed them and obtained their consent; their ages ranged from 18 to 42 (average of 30). The phlebotonical drug used is a phlebotropic and venoprotective drug whose active ingredients are micronized. Diosmin/Hesperidin.

Results

Molecular activities on microcirculation are conducted through various mechanisms that go from reduction of blood viscosity and capillary permeability to an increase in tcpO2 and the capillary blood flow with reduction of stasis and of anti-inflammatory activity. The data we obtained after Videocapillaroscopic measurements indicate that capillary blood flow rate values and an increase in capillary density virtually overlap both after Endermologie and after intake of 4 tablets of the phlebotonical drug as compared to initial values. After associating the two therapeutic methods, values appear to be almost doubled.

Conclusion

To conclude, the data that we found unquestionably reveals greater combined treatment efficacy in terms of an increase in microcirculatory parameters; the mechanical action of Endermologie, which in our opinion must also be studied neurologically, is more efficacious with the intake of micronized Diosmin/Hesperidin.

Abstract (2)

Introduzione

L'Endermologie è una tecnica non invasiva di massaggio meccanico associato a suzione della cute, che viene sottoposta all'azione fisica di due rulli rotanti. Alcuni autori hanno trovato un incremento della perfusione cutanea e del flusso linfatico, altri un incremento della componente fibrillare collagenica nello strato profondo del derma. Partendo da questo presupposto, abbiamo pensato di valutare gli effetti della terapia fisica Endermologie in associazione con un principio attivo farmacologico che ne potesse potenziare il meccanismo d'azione e quindi l'effetto terapeutico.

Materiali e metodi

Lo studio è stato effettuato dopo ottenimento del consenso informato su 34 soggetti, 20 di sesso femminile, 14 di sesso maschile; l'età era compresa fra 18 e 42 anni (media di 30).

Avendo la necessità di un principio attivo ad azione rapida e in unica somministrazione, abbiamo usato la Diosmina/Esperidina in forma micronizzata. Il protocollo da noi studiato prevedeva la Valutazione strumentale con Videocapillaroscopia a Sonda Ottica (VCSO), Laser Doppler Flussimetria (LDF), Ossimetria Transcutanea (tcpO2) dopo trattamenti, in singolo o in associazione del flebotonico con la terapia endermologica.

Risultati

I dati da noi ottenuti indicano che i valori della velocità del flusso ematico capillare e l'incremento della densità capillare, sono pressoché sovrapponibili sia dopo Endermologie sia dopo assunzione del flebotonico. Pressoché raddoppiati appaiono i valori dopo associazione delle due metodiche terapeutiche. Anche i valori di perfusione (PU) all'LDF e della tcpO2 seguono lo stesso andamento dei precedenti, eccetto un incremento della perfusione di circa 10 volte dopo Endermologie rispetto alla somministrazione del farmaco.

Conclusione

I dati da noi rilevati, dimostrano inequivocabilmente una superiore efficacia della terapia combinata in termini di incremento dei parametri microcircolatori; l'azione meccanica dell'Endermologie, che a nostro parere deve essere studiata anche dal versante neurologico, si potenzia efficacemente con l'assunzione di Diosmina/Esperidina micronizzate.

Introduction

Endermologie is a noninvasive mechanical treatment of tissues associated with suction of the cutis, which undergoes the physical action of two rotating rollers. The technique came into being in France and developed in Europe. Initially it was used in the treatment of traumatic and burn scars (1). It was then used to relieve exhaustion after muscular fatigue (2). Lastly it was successfully introduced in the treatment of the localized Adiposity. Since then a great deal of work has been done to clarify what mechanism triggers off the Endermologie effect on tissue: some authors found an increase in cutaneous perfusion and lymphatic flow (3), others an increase in the collagenic fibrillary component in pigs' endepidermis after a complete therapeutic cycle (4) others an recovering of interstitial matrix and the collagenic component associated with secondary venolymphatic actions (5). To date this method has been successfully used in "single-treatment" in the field of Aesthetic Medicine and Surgery; these results are sustained by an increase in microcirculatory perfusion induced by the physical action of Endermologie on the dermis. The best results are borning after the utilisation in the integrated protocol of treatment named BIM.ED (6).

Based on this assumption, we thought of assessing the effects of physical Endermologie treatment in association with a pharmacological active ingredient that could strengthen its action mechanism and, therefore, its therapeutic effect in the venolymphatic system.

As a fast-acting single-dose active ingredient was required, we used Diosmin/Hesperidin in micronized form (Arvenum 500 Stroder / Daflon 500 Servier). It is a venotonic and venoprotective drug whose purified flavonic fractions are 90% Diosmin and 10% Hesperidin. Drug micronization enables quick, efficacious intestinal absorption. The drug reduces blood viscosity (7), increases tcpO2 (8), reduces capillary permeability (9), and increases flow speed and stasis reduction (10 -11-12-13-14-15).

Materials and methods

The study was carried out with Optical Probe Videocapillaroscopy (OPVC), Laser Doppler Flow measurements and transcutaneous Oxymetry on 34 subjects, 20 females and 14 males, after having informed them and obtained their consent; their ages ranged from 18 to 42 (average of 30). All subjects were clinically studied to exclude vascular and/or internist pathologies that could affect the assessment outcome of the study proposed (macro and/or microvascular disorders, liver/kidney pathologies). All subjects were non-smokers and had not taken drugs for at least four months.

The study protocol included the following points:

- a) Instrumental measurements with Optical Probe Videocapillaroscopy (OPVC), Laser Doppler Flow Measurements (LDF), transcutaneous Oxymetry (tcpO2). (15 -16)
- b) Individual Endermologie session, administration of four tablets of Diosmin/Hesperidin in a single bolus, Endermologie and Diosmin/Hesperidin in association.

The pattern followed was as follows:

Day 0 = OPVC, LDF, tcpO2, basal;

day 4 = Endermologie treatment;

day 8 = Diosmin/Hesperidin 4 tablets;

day 12 = Endermologie + Diosmin/Hesperidin 4 tablets;

"Dynamic" instrumental measurements were taken 30 minutes after treatment; the intake of Diosmin/Hesperidin took place 30 minutes before treatment individually and/or in association.

An individual operator trained to use the machine performed Endermologie (LPG - System's) on a limb for 20 minutes. (17-18).

All instrumental measurements were taken in standard conditions (21°C) and absence of machine noise, and after the subject had rested in a supine position). The OPVC (Moritex, Alfa Strumenti) equipped with optical fibres and a microtelecamera was conducted enlarged 100x and 200x in order to obtain detailed morphological information; the areas examined (lower limbs) were marked with a demographic pencil; the cutaneous surface examined was dampened beforehand with cedar oil to avoid light from reflecting on the horny layer.

Parameters taken into consideration with the OPVC were:

- a) Red globule flow rate in the most significant observation field
- b) Modification of capillary density

To quantize the red globule flow rate, 200x optics were used and the following score was adopted:

- 0 = blood stasis;
- 1 = to and fro movement;
- 2 = rectilinear movement;
- 3 = quick rectilinear movement.

As for capillary density, 100x optics were used and the following score was adopted:

- 0 = no increase;
- 1 = slight increase (20%);
- 2 = good increase (60%);
- 3 = excellent increase (> 80%).

Laser Doppler Flow Measurements and transcutaneous Oxymetry (tcpO₂) were conducted with a Perimed PF 5040 (Swedish) instrument. (19-20)

Oxymetry setting parameters were calibrated at 21degrees, 156 mmHg of atmospheric O₂. The detector electrode was preheated to 44°C and positioned on the subject's cutis.

The Laser Doppler followed the same parameters; the probe was fixed to the cutis in the vicinity of the electrode for tcpO₂. Quantization of values obtained was expressed in Perfusion Units (PU) for the Laser Doppler, and in mmHg for the tcpO₂.

Results

Optical Probe Videocapillaroscopy (OPVC) (Tab. 1)

* Average values scored in basal conditions

BASAL FLOW = 1.75

CAPILLARY DENSITY = 0.75

* Average values found after Endermologie

FLOW = 2.50 (+0.75)

CAPILLARY DENSITY = 2.25 (+1.50)

* Average values found after Diosmin/Hesperidin

FLOW = 2.00 (+0.25)

CAPILLARY DENSITY = 2.25 (+1.50)

* Average values found after Endermologie + Diosmin/Hesperidin

FLOW = 2.75 (+1.00)

CAPILLARY DENSITY = 3.00 (+2.25)

Laser Doppler Flow Measurements and transcutaneous Oxymetry (Tab.2)

* Perfusion and basal tcpO₂ values

PU= 9.63

TcpO₂ = 60.69

* Values after Endermologie

PU = 27.90 (+18.27)

TcpO₂ = 75.74 (+15.05)

* Values after Diosmin/Hesperidin

PU = 17.98 (+8.35)

TcpO₂ = 88.68 (+17.99)

* Values after Endermologie + Diosmin/Hesperidin

PU = 31.79 (+22.16)

TcpO₂ = 104.5 (+43.81)

Discussion and conclusions

Some years ago new noninvasive instrumental methods were developed and perfected enabling the entire cutaneous microcirculation to be studied both clinically (microangiopathies and focused treatment) and purely investigatively (microcirculatory changes in response to various pharmacological, physical, etc. stimuli). Laser Doppler Flow Measurements and transcutaneous Oxymetry enable us to quantify, through perfusion analysis of metabolic activity, microcirculatory changes in response to various stimuli; Visuocapillaroscopy instead provides a direct morphological pattern of microcirculation enabling us to appreciate the finest capillary damage. These instruments are the most avant-garde in the complete study of microcirculation. As they are highly sensitive to the outside environment, it is indispensable to observe certain environmental and patient parameters for correct data interpretation.

Despite the individual use of Endermologie and Diosmin/Hesperidin producing active physiological changes in the cutaneous microcirculation, the possibility of using individual treatments in association has never been taken into consideration: the former with physical-mechanical action and the latter with purely pharmacological action. In the cutis treated with Endermologie, microcirculatory changes concern the increase of the blood and lymphatic flow; this effect is no doubt linked to the mechanical stimulation of the cutis and of the subcutis through the contemporary action of positive pressure, suction and the mechanical massage operated by rollers. Our experience has taught us that these effects are protracted for approximately two hours after individual stimulation. (21-22-23-24). It is quite a long time considering that stimulus is physical-mechanical: we think that an autonomic indirect neuromechanism maintaining this effect could come into play.

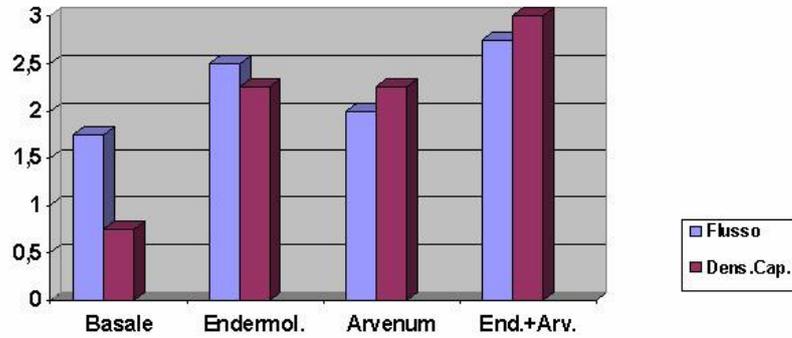
The phlebotonic drug used is a phlebotropic and venoprotective drug whose active ingredients are micronized. Diosmin/Hesperidin. Molecular activities on microcirculation are conducted through various mechanisms that go from reduction of blood viscosity and capillary permeability to an increase in tcpO₂ and the capillary blood flow with reduction of stasis and of anti-inflammatory activity. The data we obtained after Videocapillaroscopic measurements indicate that capillary blood flow rate values and an increase in capillary density virtually overlap both after Endermologie and after intake of 4 tablets of the phlebotonic drug as compared to initial values. After associating the two therapeutic methods, values appear to be almost doubled.

LDF and tcpO₂ perfusion values (PU) follow the same trend, except for an approximately tenfold perfusion increase after Endermologie as compared to drug administration. An increase in tcpO₂, which peaks after associating the two therapeutic methods, reflects a marked increase in the blood flow rate and capillary density; in turn, the latter is linked to the opening of shunts and consequential "virtual" capillary perfusion.

To conclude, the data that we found unquestionably reveals greater combined treatment efficacy in terms of an increase in microcirculatory parameters; the mechanical action of Endermologie, which in our opinion must also be studied neurologically, is more efficacious with the intake of micronized Diosmin/Hesperidin.

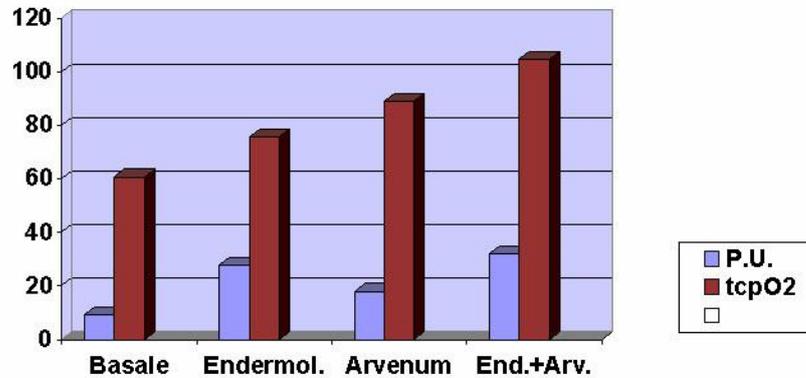
This means that, in our opinion, even though the study is based on the investigation of physiological changes after individual treatment, the association of these two methods can form a therapeutic protocol in pathologies for which Endermologie and the Diosmine micronised Esperidine are proposed, certainly enhancing their efficacy and reducing treatment time. Moreover, there are no demonstrated side effects, making these treatments far more popular with patients. The best results with Endermologie are possible only if the methodology is used with precise and good methodology. Badly used the Endermologie cause the alteration of the connective structure with the slackening of the tissues.

Optical Probe Videocapillariscopy (Tab.1)



Average values in individual and associated basal conditions

Laser Doppler Flow Measurement and Transcutaneous Oxymetry (Tab.2)



Average values in individual and associated basal conditions

* N.B. The phlebotonical drug used in this study is named " ARVENUM 500" .

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COMPARISON OF THE EFFECTIVENESS OF MLD AND LPG TECHNIQUE[®]

Amanda Moseley, Neil Piller, Jan Douglass, Mari lle Esplin

Abstract

Background: This study compares Endermologie[®] — a new treatment for lymphoedema which involves mechanised massage — with manual lymphatic drainage (MLD). **Methods:** A single-blinded, randomised study compared the two techniques combined with compression bandaging to treat secondary arm lymphoedema post breast cancer treatment. The MLD group (n=20) and the Endermologie group (n=10) received treatment four times a week for four weeks. Measurements of arm and truncal fluid volumes, overall limb tissue volumes and subjective symptoms were taken at baseline, directly after the first treatment, at 24 hours, at the beginning and end of weeks 1, 2, 3 and 4 and at the one-month follow up. **Results:** Both groups had similar and significant reductions in whole arm volume, arm fluid and truncal fluid. There were also significant improvements in subjective heaviness, tightness, tissue hardness, limb size and range of movement at trial end compared with the baseline. Statistically significant softening occurred in the posterior thorax region. Both groups had a non-significant deterioration in all parameters at one-month follow-up, but none returned to baseline level. **Conclusions:** MLD and Endermologie are both beneficial for secondary arm lymphoedema. **Declaration of interest:** This trial was funded by LPG France and administered through Flinders Consulting Group. LPG had no influence except in the initial stages by advising on treatment protocols.

Key words

Randomised trial
Arm lymphoedema
Treatment comparison
Objective measurement

Breast cancer is a significant cancer in women and it has a number of treatment-related side-effects. Perhaps one of the most significant side-effects is lymphoedema of the breast, trunk or arm. A recent review has indicated that an average of 30% of women who undergo breast cancer treatment will develop secondary arm lymphoedema (SAL) (Williams et al, 2005). However, this rate varies between 3% to more than

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44% according to a range of factors including the staging of the axilla, the amount of breast tissue removed, tumour location, radiotherapy and body mass index (BMI). A review of breast and trunk oedema also showed significant problems, with some studies indicating that 23% of patients experienced swelling even following

Although techniques for cancer treatment are improving — especially regarding sentinel lymph node biopsy — and the use of radiotherapy is being reduced and targeted more efficiently, there will remain a cohort of women who will need to manage this distressing condition.

sentinel node biopsy and almost 50% in patients who had node positive axillary clearance (Williams, 2005).

Although techniques for cancer treatment are improving — especially

regarding sentinel lymph node biopsy — and the use of radiotherapy is being reduced and targeted more efficiently, there will remain a cohort of women who will need to manage this distressing condition. There have been a number of therapies that have been established to help treat SAL and it is crucial that clinicians have a clear understanding of both established techniques and emerging therapies.

One new therapy is LPG technique[®] (Endermologie[®]) which was originally developed in France and is currently available in the private sector. This system delivers mechanical massage to the limb via two motorised, cylindrical skin rollers which pick up and massage the skin inside its treatment head. Pilot studies of this equipment have shown that it improves superficial lymphatic drainage (Bartolo and Allegra, 2001) and lymphatic transport capacity (Leduc et al, 1995), decreases fibrotic induration (Campisi et al, 2001) and functional discomfort (Guillot, 2001).

This study investigates the effects of this system compared with manual

lymphatic drainage (MLD), which is an established treatment for SAL and has been demonstrated to reduce micro-lymphatic hypertension (Franzeck et al, 1997), limb volume (Kriederman et al, 2002; Korpon et al, 2003) and pain (Johansson et al, 1998). It has also been shown to soften limb tissues (Piller and Harris, 2001; Williams et al, 2002) and improve emotional well-being (Williams et al, 2002).

Methods

The study was given ethical approval by the Flinders Medical Centre Clinical Research Ethics Committee, Adelaide, Australia and informed consent was obtained from each participant. Participants were recruited from the Flinders Medical Centre Lymphedema Assessment Clinic. Participants were required to have had clinically established lymphoedema for more than one year and have significant fibrotic induration in the lymphatic territories of the arm, related to previous breast cancer treatment (surgery ± radiotherapy ± chemotherapy) and a volume difference ≥ 200 ml between the affected and unaffected arm as determined by perometry. Those who had underlying primary lymphoedema, recurrent cancer, current or recent cellulitis, or who had received active treatment in the past month were excluded from the trial.

Upon entry into the trial, each participant was randomised into one of two groups. The first group received MLD by a therapist trained in the Vodder method, while the second group received LPG therapy applied by an occupational therapist trained in the technique. The treatment time and protocol for each group is represented in *Table 1*. Both groups received the treatment four days a week for four weeks (16 treatment sessions in total).

Compression bandaging consisting of a gauze sleeve, high density foam rubber and 2–3 layers of short-stretch bandaging (similar to that recommended in the Best Practice guidelines [Lymphoedema Framework,

Table 1

Treatment time and protocol for manual lymphatic drainage compared with Endermologie

	MLD	LPG technique®
Treatment time	45 minutes	30 minutes
Total time	720 minutes	480 minutes
Treatment protocol	Bilateral neck, contralateral torso, ipsilateral torso, posterior thorax, upper arm, forearm, hand (if involved) and then reversed. Ipsilateral torso and clearance of the posterior thorax at the end of treatment. Firmer massage used for fibrotic induration where required	Ipsilateral to contralateral axilla, posterior thorax and lateral side, upper arm, forearm, hand (if involved) and then reversed. Clearance of the posterior thorax at the end of treatment. A slightly bigger treatment head was used on the thorax and upper arm, resulting in a greater surface area being massaged

Best Practice for the Management of Lymphoedema. International consensus, 2006]) was applied to the affected arm immediately after each treatment session. Participants were asked to wear the compression bandaging overnight and to fill in a log book, which recorded when the bandages were removed so that compliance could be monitored.

Compression bandaging was not worn over the three days of non-treatment, as many of the participants lived alone and wearing bandaging would have severely restricted their ability to shower and undertake activities of daily living. At the end of four weeks of treatment each woman was encouraged to purchase a new compression garment for the affected arm, as this would fit the reduced arm and thus help to maintain the improvement, and to continue their usual self-maintenance techniques (skin care and self-massage) over the following month.

Measurement

Objective and reliable measurement of the limb parameters is crucial if treatment effect is to be accurately tested and validated (Piller, 2007). Measurements in this trial were taken using previously validated equipment, including multifrequency (5–500Hz) bioimpedance (Ward et al, 1997;

Moseley and Piller, 2005) to measure arm and truncal fluid; opto-electronic perometry to measure arm volume (Leduc et al, 1992; Stanton et al, 1997) with the percentage change in actual oedema calculated according to Swedborg (1984); and tonometry (Clodius et al, 1976; Casley-Smith et al, 1993) to measure fibrotic induration in the lymphatic territories of the fore and upper arm and the posterior and anterior thorax. In all cases the contralateral arm was used as the control. A 10-point Likert scale (Lee et al, 2002) was used to rate participants' subjective reports of pain, heaviness, tightness, tissue hardness, range of movement and limb size.

Measurements were taken by an investigator who was blinded to the participants' treatment allocation. Measurements were undertaken at baseline, directly after the first treatment session, 24 hours after the first treatment session, at the beginning and end of each treatment week and at one-month post treatment.

Analysis

All data were analysed using SPSS (version 12.0). Both groups were evenly distributed in terms of arm volume at baseline, therefore the paired sample student T-test was used

Table 2
Characteristics of the MLD and Endermologie treatment groups

	MLD group (n=20)	Endermologie (n=10)	Significance of difference between groups
Age	46–79 years (62.3 ± 10 years)	45–72 years (60.3 ± 7.6 years)	not significant (n.s.)
Surgery type			
Total mastectomy	5 (25%)	8 (80%)	n.s.
Partial mastectomy	15 (75%)	2 (20%)	0.586
Radiotherapy	14 (70%)	9(90%)	0.007
Co-morbidities			
Hypertension	11 (55%)	5 (50%)	n.s.
Type II diabetes	5 (25%)	2 (20%)	n.s.
Thyroid dysfunction	3 (15%)	1 (10%)	n.s.
Arthritis (in affected arm)	9 (45%)	2 (20%)	0.005
Lymphoedema			
Onset	35.5 months (+ 48.1 months)	24.2 months (+ 21.2 months)	n.s.
Worse in evening	12 (60%)	6 (60%)	n.s.
Worse in heat	13 (65%)	8 (80%)	n.s.

to analyse within group variables and the independent sample T-test was used to analyse between group variables, where $p < 0.05$ is significant.

Results

Twenty women aged 46–79 years (62.3 ± 10 years) participated in the MLD group. Five (25%) of these women had undergone a total mastectomy, while 15 (75%) had undergone a partial mastectomy. Overall, 14 (70%) of the women received adjunct radiotherapy, with the average time to onset of lymphoedema being 35.5 months (± 48.1 months) after treatment cessation (Table 2). Ten women aged 45–72 years (60.3 ± 7.6 years) were treated with LPG technique. Eight (80%) of these women had undergone a total mastectomy, while two (20%) had undergone a partial mastectomy. The majority (90%) of the participants had received radiotherapy, with the onset of lymphoedema occurring 24.2 months (± 21.2 months) after

treatment cessation (Table 2). The two groups were similar in terms of characteristics, except for the number of participants that had received radiotherapy — 70% of the MLD group compared with 90% of the LPG technique group ($p = 0.007$) — and the number of participants who had self-reported arthritis in the affected arm — 45% of the MLD group compared with 20% of the LPG technique group ($p = 0.005$) (Table 2).

Arm volume (measured by perometry)

Against a baseline measurement of 3145mls, in the MLD group a mean amount of 22ml (6%; $p = \text{not significant [n.s.]}$) reduction in whole arm volume was seen directly after the first treatment, 41ml (8%) reduction at 24 hours ($p = 0.039$) and 80ml (9%) at the end of one week ($p = 0.000$). Steady volume reductions occurred over weeks two and three, with an overall reduction at the end of the trial of 140ml (21%; $p = 0.000$), (Figure 1). At the one-month follow-

up there had been a slight volume increase of 34ml (8%; $p = \text{n.s.}$), but there was still a 106ml (15%; $p = 0.023$) volume reduction compared with the baseline. The majority of the volume reduction was demonstrated to occur in the forearm, with an overall reduction at the end of trial of 129ml (19%; $p = 0.000$). This area also increased in volume at the one-month follow-up, but did not return to the baseline level.

In the Endermologie group there was also a slight reduction in whole arm volume of a mean amount of 17.5ml (1.8%; $p = \text{n.s.}$) after the first treatment. This group also experienced statistically significant volume reductions after 24 hours (60ml; 6%; $p = 0.018$), the end of week one (124ml; 13%; $p = 0.003$), and over weeks two and three. The overall reduction at trial end was 186ml (22%; $p = 0.002$), with a slight increase in volume of 44ml (4.4%; $p = \text{n.s.}$) at the one-month follow-up (Figure 1), with the overall reduction at this time (142ml; 17.5%) being statistically significant ($p = 0.002$).

This group also experienced the majority of the volume reduction in the forearm, with a reduction of 138ml (14%; $p = 0.003$) at the end of the trial. This area also increased slightly (60ml; 6%; $p = \text{n.s.}$) at the one-month follow-up.

Both treatment groups experienced similar reductions in whole arm volume over the trial duration and a slight volume increase at one-month follow-up. Although the whole arm volume and arm fluid reduction was greater in the LPG technique group (186ml compared with 129ml), the difference between the two groups was not statistically significant. A larger trial group may be needed to determine statistical significance.

Arm and truncal fluid (measured by bioimpedance)

There was also a reduction in arm fluid volume in the MLD group. At 24 hours this equated to a mean value

of 35ml (6%; $p=n.s.$), 120ml at one week (18%; $p=0.005$) and 165ml at the end of the trial (25%; $p=0.003$). At the one-month follow-up there was an increase of 30ml (3%; $p=n.s.$) (Figure 2), with an overall volume reduction at this point of 135ml (18%, $p=0.042$). Interestingly, there was a slight increase in fluid in the truncal region directly after treatment and at 24 hours of a mean value of 5ml and 32ml ($p=n.s.$) respectively. After this time there were steady decreases in truncal fluid, with an overall reduction of 285ml ($p=0.015$) at trial end (Figure 3). There was a slight increase in truncal fluid at one-month follow-up of 20ml ($p=n.s.$), with the overall reduction being 265ml ($p=0.042$).

The LPG technique treatment group experienced an arm fluid reduction of 60ml (6%; $p=n.s.$) at 24 hours and of 116ml (12%; $p=0.027$) at the end of the first week. Steady reductions occurred over weeks two and three, with an overall statistically significant fluid reduction of 216ml (23%; $p=0.014$) at the end of the trial (Table 2). A fluid increase of 98ml (10%) occurred in the affected arm at the one-month follow-up. There was a slight, non-significant reduction in the truncal region initially at 24 hours and the end of the first week (20ml and 40ml respectively; $p=n.s.$). At trial end there was an overall reduction in truncal fluid of 290ml ($p=n.s.$), with a slight increase in this region of 78ml at one-month follow-up and overall truncal fluid reduction of 212ml.

The arm fluid reduction (along with the total arm volume reduction measured by perometry) was greater in the LPG technique group compared with the MLD group (216ml compared with 165ml at trial end), however, there was not a statistically significant difference between the two groups. Although there was a slight initial increase in fluid in the truncal region in the MLD group, the overall fluid loss was greater in this group and may indicate the greater time spent clearing the thorax region during the

Table 3

Changes in subjective parameters over trial duration in the MLD and LPG technique® groups

	MLD (p)	Endermologie (p)	B/W groups
Pain			
After first treatment	-1.0 (0.039)	-1.3 (n.s.)	Not significant at any time
After 24 hours	-1.2 (0.020)	-1.2 (n.s.)	
End of trial	-1.4 (0.023)	-1.7 (n.s.)	
One-month follow-up	+0.1 (n.s.)	+1.0 (n.s.)	
Heaviness			
After first treatment	-0.9 (0.033)	-1.4 (0.025)	Not significant at any time
After 24 hours	-0.4 (n.s.)	-1.6 (0.011)	
End of trial	-1.7 (0.009)	-3.2 (0.007)	
One-month follow-up	+0.3 (n.s.)	+1.1 (n.s.)	
Tightness			
After first treatment	-1.2 (0.015)	-1.9 (0.004)	Not significant at any time
After 24 hours	-1.1 (0.004)	-2.1 (0.016)	
End of trial	-2.2 (0.004)	-3.0 (0.001)	
One-month follow-up	+0.9 (n.s.)	+0.8 (n.s.)	
Tissue hardness			
After first treatment	-1.6 (0.001)	-1.1 (0.032)	Not significant at any time
After 24 hours	-1.6 (0.020)	-1.3 (0.028)	
End of trial	-2.6 (0.002)	-2.4 (0.011)	
One-month follow-up	+0.6 (n.s.)	+0.7 (n.s.)	
Arm temperature			
After first treatment	-1.0 (n.s.)	0.0 (n.s.)	0.002
After 24 hours	-0.6 (n.s.)	-0.4 (n.s.)	n.s.
End of trial	-1.2 (0.004)	-0.8 (n.s.)	n.s.
One-month follow-up	+0.6 (n.s.)	-0.1 (n.s.)	n.s.
Arm size			
After first treatment	-0.5 (0.029)	-0.4 (n.s.)	Not significant at any time
After 24 hours	-0.7 (n.s.)	-0.7 (0.025)	
End of trial	-3.4 (0.000)	-2.4 (0.003)	
One-month follow-up	+1.2 (0.001)	+0.3 (n.s.)	
Arm range of movement			
After first treatment	-0.1 (n.s.)	0.0 (n.s.)	0.020
After 24 hours	-0.8 (0.046)	-0.1 (n.s.)	0.007
End of trial	-1.8 (0.006)	-2.2 (0.013)	n.s.
One-month follow-up	+0.4 (n.s.)	+0.9 (n.s.)	n.s.

(-) represent a reduction in the parameter (hence an improvement); (=) represent an increase in the parameter (hence a worsening)

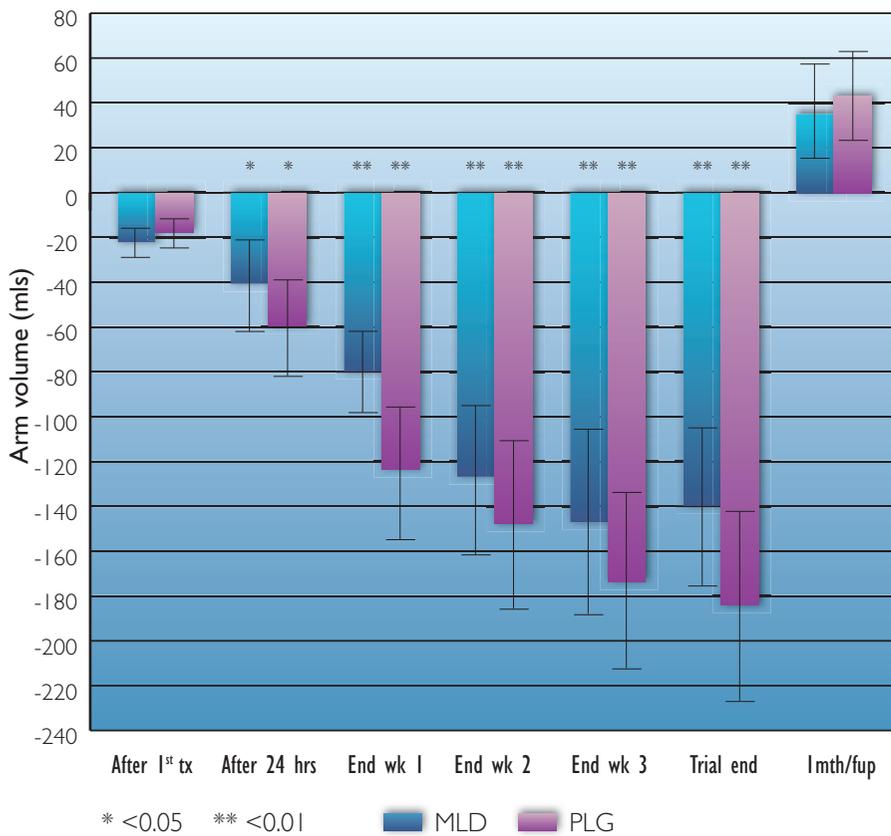


Figure 1. Whole arm volume change (as measured by perometry) after the first treatment, 24 hours, each treatment week, at trial end and at one-month follow-up (mean + standard error of the mean [SEM]).

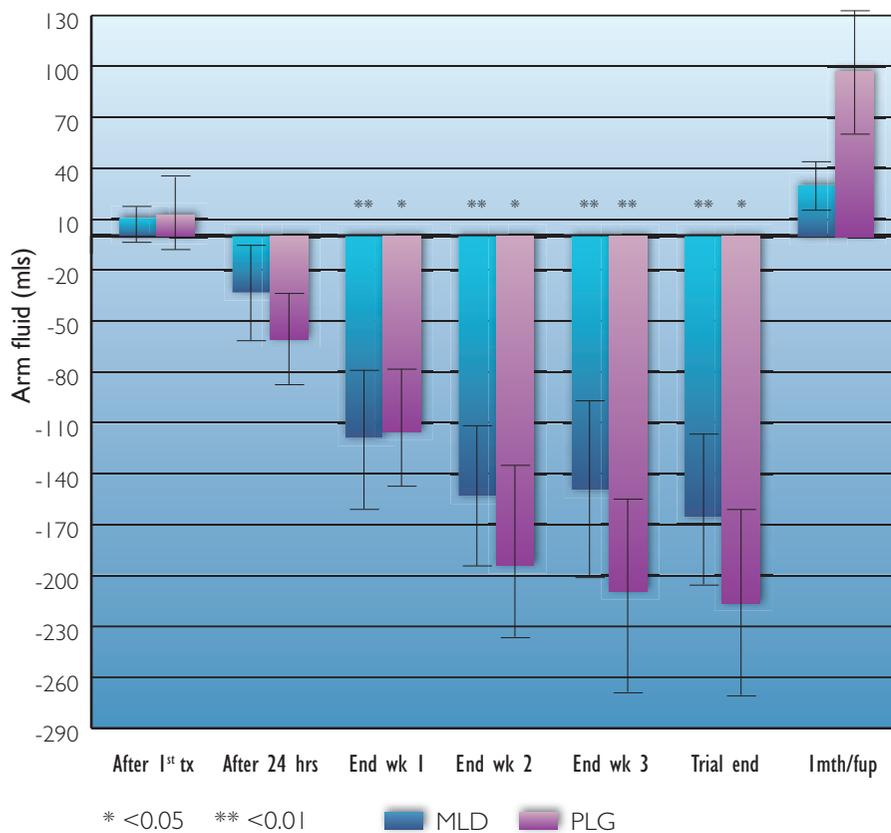


Figure 2. Arm fluid change (as measured by bioimpedance) after the first treatment, 24 hours, each treatment week, at trial end and at one-month follow-up (mean + SEM).

MLD protocol. It would appear that the reductions obtained by the MLD programme were better sustained at the one-month follow-up, with the LPG technique group experiencing a greater increase in whole arm volume, arm and truncal fluid over this time. Why this is the case is uncertain. Possibly a follow-up treatment at the two-week period during the intervening four-week period may have remedied this and the effect of this would be worth investigation.

Fibrotic induration (as measured by tonometry)

In the MLD group there was a tendency to soften but there was no statistically significant change in the forearm, upper arm or anterior thorax lymphatic territories. However, there was an improvement in the posterior thorax which was statistically significant ($p=0.041$) at the end of the trial compared with the baseline.

In the LPG technique group there was a tendency to soften in the forearm, anterior and posterior thorax territories, with the softening in the forearm territory being statistically significant ($p=0.020$) at trial end compared with the baseline. In both treatment groups, the tonometry of all the lymphatic territories showed a tendency to harden at the one-month follow-up, but this was not statistically significant.

The treatment groups experienced significant softening in different areas of the affected arm, with the MLD group experiencing it in the posterior thorax (with this improvement being statistically significant in comparison with the LPG technique group; $p=0.020$), and the LPG technique group experiencing a mean improvement in softening in the forearm region.

Subjective symptoms

The participants in the MLD group showed a perceived reduction in pain ($p=0.039$), heaviness ($p=0.033$), tightness ($p=0.015$) and tissue hardness ($p=0.001$) even after the

first treatment. These, along with limb temperature, perceived limb size and arm range of movement continued to improve during the trial, with all improvements being statistically significant at trial end ($p=0.05$; Table 3). The participants in the LPG technique group also reported statistically significant perceived reduction in heaviness ($p=0.025$), tightness ($p=0.016$) and tissue hardness ($p=0.032$) directly after treatment and had significant improvements ($p<0.05$) in both these and reported limb size and range of movement at trial end (Table 3).

Both groups rated other subjective parameters such as limb cramps and pins and needles low on the 10-point Likert scale and these underwent little change over the trial duration. There were recorded increases in the majority of subjective parameters at one-month follow-up, but no parameter returned to baseline level. In comparing the groups, the MLD group reported significant initial improvements in range of movement after the first treatment and at 24 hours compared with the LPG technique group ($p=0.020$ and 0.007 respectively). The MLD group also had significant improvements in limb temperature after the first treatment in comparison with the LPG technique group ($p=0.002$). After this time, both groups experienced similar reductions in the reported subjective parameters.

Compliance and adverse effects

Overall, 55% of the participants in both groups were completely compliant with wearing the compression bandaging, while 45% were slightly to moderately compliant (the bandaging was taken off early, i.e. not worn over the whole course of the day and evening). Both groups also experienced tiredness, increased urination and thirst after massage treatment (predominantly in the first week of treatment). Most complaints during treatment were related to the compression bandaging, with the majority of participants (90%) stating that it was uncomfortable and 20% stating it caused itchiness.

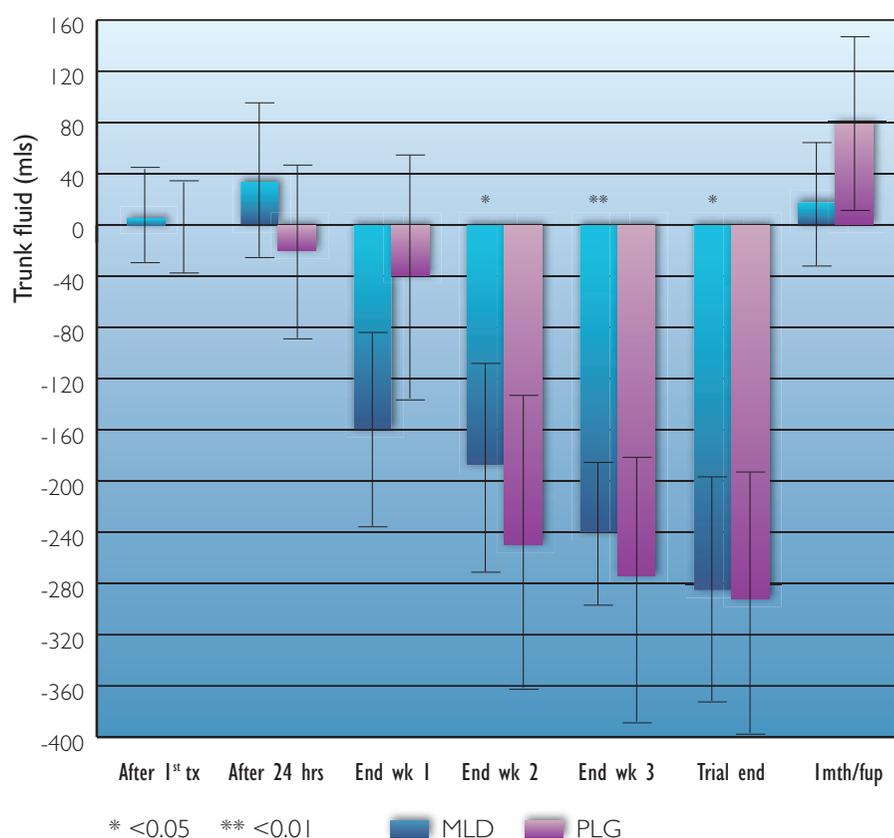


Figure 3. Trunk fluid change (as measured by bioimpedance) after the first treatment, 24 hours, each treatment week, at trial end and at one-month follow-up (mean + SEM).

Conclusion and recommendations

The gold standard treatment of MLD and the newer LPG technique treatment when combined with compression bandaging both resulted in a reduction in whole arm volume, arm and truncal fluid, a softening in specific lymphatic territories and improvements in subjective symptoms. The limb volume reduction in both groups is similar to those seen in other intensive massage and compression studies where both treatments were applied over two weeks (Piller et al, 1994) and four weeks (McNeeley et al, 2004). The majority of arm volume and fluid reduction occurred in the LPG technique group in the first two weeks of treatment, suggesting (along with established literature) that this would be the minimum treatment time.

It is interesting to note that the MLD group experienced greater (although not significant) decreases in truncal fluid over the trial and that

this group had lesser increases at the one-month follow-up. This may be reflective of the different treatment protocol employed in the MLD group or of the larger sample size. An increased sample size in the LPG technique group would provide an answer to this question, but this was not possible in this initial study of the new technique.

For those clinicians looking to advise patients, the following recommendations may be useful:

- ▶▶ Both MLD and LPG technique plus compression bandaging applied over a minimum of two weeks (but preferably four weeks) are beneficial for the treatment of secondary arm lymphoedema
- ▶▶ The treatment time for LPG technique is shorter and will achieve a similar result in most objective and subjective parameters
- ▶▶ Some deterioration in this improvement is to be expected

over a one-month period, but self-massage and wearing a compression garment may minimise this deterioration

- ▶ Additional treatment(s) during the month after the intensive treatment period may reduce or eliminate the rebound effect and allow continuing improvement (although this does require further investigation)
- ▶ The education of the patient in terms of the importance of self-massage and compression therapy and an open dialogue between the therapist and patient plays an integral role in the overall treatment plan
- ▶ Both forms of massage (MLD and LPG technique), as well as the compression bandaging, must be applied by a trained therapist who has a good understanding of the pathophysiology of lymphoedema and who can monitor the response to treatment
- ▶ Using LPG technique to treat lymphoedema represents a new and effective option which can be used in place of, or alongside MLD, which is the current gold standard of treatment options of secondary arm lymphoedema. JL

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Key points

- ▶ Both MLD and Endermologie plus compression bandaging applied over a minimum of two weeks (but preferably four weeks) are beneficial for the treatment of secondary arm lymphoedema.
- ▶ Endermologie has a 33% shorter treatment time than MLD.
- ▶ Bandaging is important to maintain good outcomes.
- ▶ Treatment effects can last for up to one month but some patient management is required to maintain gains of treatment.
- ▶ The education of the patient in terms of the importance of self-massage and compression therapy and an open dialogue between the therapist and patient plays an integral role in the overall treatment plan.

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ENDERMOLOGIE® (WITH AND WITHOUT COMPRESSION BANDAGING) – A NEW TREATMENT OPTION FOR SECONDARY ARM LYMPHEDEMA

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ABSTRACT

Two treatment protocols are presented using the LPG® Endermologie® system in combination with compression bandaging as a new treatment option for secondary arm lymphedema. Both protocols were applied 4 days a week for 4 weeks but differed in Trial I in time spent clearing the regions of the trunk adjacent to the swollen limb and the addition of a larger treatment head so that a greater area could be covered more quickly. The first protocol involved 24 women and the second involved 10 women. At the end of the treatment period, both protocols demonstrated overall reductions in limb volume (134mls; 18.3% $p = 0.000$ and 185mls; 28%, $p = 0.002$), limb fluid (182mls; 28%, $p = 0.000$ and 216mls; 33%. $p = 0.014$), truncal fluid (342mls; $p = 0.002$ and 290mls; $p = 0.066$), improvements in fibrotic induration in some lymphatic territories, and significant improvements in subject reporting of heaviness, tightness, tissue hardness and limb size. Trial II demonstrated additional benefits in terms of reduction in whole arm volume at 24 hours, improved fluid and arm volume reductions, and a significant improvement in subject reported arm range of movement. The additional time spent clearing the regions adjacent to the swollen limb in the second protocol appears to produce an increase in limb volume

and limb fluid loss compared to the original treatment protocol.

Keywords: Lymphedema, mechanical massage, objective outcomes

Secondary arm lymphedema still remains a problem for those who have undergone surgery and/or radiotherapy for breast cancer, with a recent review stating that in excess of 30% (1) of women who have undergone such treatment will go on to develop lymphedema. It is known that secondary lymphedema is chronic in nature (2) and therefore there is a continual focus on establishing therapies which will not only reduce the limb swelling but also the detrimental tissue changes and the accompanying subjective symptoms. One therapy is practitioner applied massage (manual lymphatic drainage, MLD), which has been shown to vary total tissue pressure, increase lymphatic transport and soften fibrotic induration (3,4). Given that MLD practitioners are not always available, the focus of this trial was to test the effect of mechanical massage delivered to the limb via the LPG® Endermologie® system. This system involves two motorized, cylindrically shaped skin rollers which are applied to the limb by an appropriately trained therapist and which picks up and massages the skin inside the

TABLE 1
Treatment Time and Protocol

	Trial I	Trial II
Treatment Time	25 minutes	30 minutes
Treatment	Ipsilateral posterior thorax and lateral side, upper arm, forearm, hand (if involved) and then reversed.	Ipsilateral to contralateral axilla, posterior thorax and lateral side, upper arm, forearm, hand (if involved) and then reversed. Extra time spent clearing posterior thorax at end of treatment. Slightly bigger treatment head used on thorax and upper arm resulting in a greater surface area being massaged.

treatment head. Pilot studies of this equipment have shown that it improves superficial lymphatic drainage and lymphatic transport capacity (5), decreases fibrotic induration (6) and functional discomfort (7). Therefore it was postulated that this type of massage would result in arm fluid and volume reductions and improvements in fibrotic induration and reported subjective symptoms.

METHODS

Before trial commencement the study was given ethics approval by the Flinders Medical Centre Clinical Research Ethics Committee, Adelaide, Australia and informed consent was obtained from each participant.

Two trials were undertaken using the same LPG® Endermologie® system applied over the same duration (4 weeks) and using the same measurement schedule. Participants in both groups were recruited through the Flinders Medical Centre Lymphedema Assessment Clinic (Adelaide, Australia). Inclusion criteria included the presence of established fibrotic induration (>1 yr) of the major arm lymphatic territories (detected by tonometry), unilateral secondary arm lymphedema related to previous breast cancer treatment (surgery + radiotherapy +

chemotherapy) and a volume difference of >200mls (determined by perometry). Those who had underlying primary lymphedema, recurrent cancer, cellulitis or had received treatment in the last month were excluded from the trial.

Both trial groups had the LPG® Endermologie® system applied to the affected arm and adjacent areas by a trained Occupational Therapist four days a week for four weeks (resulting in 16 treatment sessions in total). Immediately after each treatment session, compression bandaging consisting of a gauze sleeve, high density foam rubber and 2-3 layers of short stretch bandaging was applied to the arm. Participants were asked to wear the compression bandaging over night (if tolerated) and to fill in a log book so compliance could be monitored. Compression bandaging was considered to be important in order to gain the greatest reduction and importantly to maintain LPG treatment associated reduction. However, compression bandaging was not worn over the 3 days of non-treatment, which generally encompassed the weekend. This gave participants time to undertake activities which were restricted while wearing the bandaging and gave the skin the opportunity to be uncovered. At the end of 4 weeks of treatment each woman was

TABLE 2
Participant Characteristics

	Trial I	Trial II	p
Number	24	10	0.005
Age (yrs)	63.3 ± 10.7 (38 - 84yrs)	60.3 ± 7.6 (45 - 72yrs)	0.818
Surgery (%)			
Partial Mastectomy + Axillary Clearance	37.5	20.0	0.027
Total Mastectomy + Axillary Clearance	62.5	80.0	
Received Radiotherapy (%)	83.3	90.0	0.313
Time since onset of LO (mos)	30.6 ± 43.2 (2-192 mos)	24.2 ± 24.1 (2-60 mos)	0.523
Arm Fluid volume at baseline (Mean (± S.D.))	2,207 ml (± 434)	2,438 ml (± 399)	0.982

encouraged to purchase a new compression garment for the affected arm and to continue self-maintenance techniques (predominantly skin care and self massage) over the next 1 month period. Measurements were taken at baseline, directly after the first treatment session, 24 hours after the first treatment session, at the beginning and end of each treatment week and at 1 month post treatment.

The two trials differed slightly in the duration of the treatment given at each session and the treatment technique (summarized in *Table 1*). At the end of the first trial (n=24) it was found that although the treatment technique did result in significant overall volume reductions, there was a transient increase (not significant) in the upper arm volume after the first massage and at 24 hours follow up (as measured by perometry, see results section). This indicated that perhaps fluid was not adequately draining through this area and based upon this, a second pilot study (n=10) was under-

taken with a slightly different treatment technique emphasizing clearance of the root of the limb and its adjacent trunk, to try and negate these increases.

Measurement

Measurements were made using validated techniques and equipment including multi-frequency (5-500Hz) bio-impedance (8,9) to measure arm and truncal fluid, Opto-electronic Perometry (10,11) to measure arm volume, and Tonometry (12) to measure fibrotic induration in the lymphatic territories of the forearm, upper arm, posterior and anterior thorax. The contralateral arm was measured as a control comparison with these three methods of measurement. A 10 point Likert scale (13) was used to rate participants' subjective complaints such as: pain, heaviness, tightness, tissue hardness, range of movement and limb size.

Analysis

TABLE 3
Forearm, Upper Arm and Whole Arm Volume (mls) Serially over Trial Duration
(Measured by Perometry)

	1st tx	24hrs	Wk 1	Wk 2	Wk 3	Wk 4	1 mo f/up
Trial I							
Forearm							
Change (mls)	-7	-34	-61	-78	-82	-102	+22
SD	(±39.5)	(±56.7)	(±60.4)	(±60.3)	(±67.9)	(±66.8)	(±54.1)
p=	0.410	0.011	0.000	0.000	0.000	0.000	0.122
Upper arm							
Change (mls)	+7	+10	-5	-27	-26	-32	+7
SD	(±18.8)	(±37.2)	(±33.8)	(±32.5)	(±42.3)	(±30.1)	(±40.4)
p =	0.089	0.240	0.417	0.000	0.004	0.000	0.134
Whole arm							
Change (mls)	0	-24	-66	-105	-108	-134	+29
SD	(±43.3)	(±84.9)	(±77.2)	(±81.5)	(±96.5)	(±87.6)	(±102.0)
p =	0.811	0.184	0.000	0.000	0.000	0.000	0.066
Trial II							
Forearm							
Change (mls)	-13	-64	-107	-128	-135	-138	+30
SD	(±28.9)	(±54.0)	(±66.2)	(±93.4)	(±97.5)	(±110.0)	(±105.5)
p=	0.185	0.005	0.001	0.002	0.001	0.003	0.349
Upper arm							
Change (mls)	-6	+3	-16	-21	-37	-47	+3
SD	(±10.2)	(±28.9)	(±36.8)	(±35.9)	(±31.3)	(±34.7)	(±37.5)
p =	0.106	0.580	0.184	0.015	0.003	0.002	0.857
Whole arm							
Change (mls)	-19	-61	-123	-149	-172	-185	+33
SD	(±26.4)	(±64.9)	(±95.0)	(±118.2)	(±118.6)	(±139.8)	(±147.8)
p =	0.063	0.018	0.003	0.003	0.001	0.002	0.370

All data were analyzed using SPSS (version 12.0). Both groups were evenly distributed in terms of arm volume at baseline, therefore paired sample student T-test analysis was used and $p < 0.05$ was considered significant. The percentage change in actual edema was calculated according to Swedborg (14).

RESULTS

Twenty four women aged 63.3 ± 10.7 (mean \pm SD) yrs participated in the first trial,

and 10 women aged 60.3 ± 7.6 yrs participated in the second trial (Table 2). In the first trial it was observed that there were reductions in the forearm volume but a transient increase (not significant) in the upper arm volume (as measured via perometry) directly after the first massage (+ 7mls; 3.1% actual edema) and 24 hours post massage (+ 10mls; 4.3% actual edema; Table 3). After this time, there were steady reductions in whole arm volume (forearm + upper arm) culminating in a loss of 134mls (18.3% actual edema; $p = 0.000$). The major loss occurred in the forearm region

TABLE 4
Arm and Truncal Fluid (mls) over Trial Duration (Measured by Bioimpedance)

	1st tx	24hrs	Wk 1	Wk 2	Wk 3	Wk 4	1 mo f/up
Trial I							
Trunk Fluid							
Change (mls)	-24	-96	- 150	- 187	- 248	- 342	+100
SD	(±218.0)	(±432.9)	(±404.0)	(±489.1)	(±421)	(±487.1)	(±459.7)
p =	0.586	0.289	0.082	0.073	0.008	0.002	0.298
Arm Fluid							
Change (mls)	-17	-62	-96	- 137	- 133	- 182	+51
SD	(±46.9)	(±138.7)	(±136.7)	(±148.7)	(±157.4)	(±169.6)	(±125.4)
p =	0.088	0.038	0.002	0.000	0.000	0.000	0.060
Trial II							
Trunk Fluid							
Change (mls)	0	-20	-40	- 270	- 270	- 290	+78
SD	(±141.1)	(±225.1)	(±306.2)	(±405.6)	(±392.3)	(±438.3)	(±345.6)
p =	1.000	0.785	0.689	0.065	0.075	0.066	0.519
Arm Fluid							
Change (mls)	-13	-60	-116	-194	-211	-216	+97
SD	(±80.6)	(±92.5)	(±139.5)	(±194.1)	(±203.1)	(±223.1)	(±190.9)
p =	0.622	0.070	0.027	0.012	0.009	0.014	0.163

(102mls; 17.9% actual edema; $p = 0.000$) with a smaller reduction in the upper arm region (32mls; 5.8% actual edema; $p = 0.00$). Arm fluid (as measured by bioimpedance) was reduced at the end of 4 weeks of treatment (182mls, 28% actual edema; $p = 0.000$), as was truncal fluid (342mls, $p = 0.002$; *Table 4*). Tonometry demonstrated trends towards improvement in the forearm and posterior thorax lymphatic territories, with a significant softening in the anterior thorax region ($p = 0.006$). Measurements taken on the contralateral arm were not significantly changed (data not shown). Reported subjective parameters such as pain, heaviness, tightness, tissue hardness and arm size were all significantly reduced at trial end (*Table 5*). All subjective measurements non-significantly increased at 1 month follow up, but did not return to pre-treatment levels (although not significantly different).

The second trial demonstrated that the transient increase in the upper arm volume could be modulated with a decrease of 6mls (6.8% actual edema; $p = n.s.$) after the first massage and a very small increase of 3mls (2.9% actual edema; $p = n.s.$; *Table 3*) at 24 hours. Similar losses to the first trial were seen after this time, with a decrease of 138mls in the forearm (24% actual edema; $p = 0.003$), 47mls in the upper arm (8.6% actual edema; $p = 0.002$) and 185mls in the whole arm (23% actual edema; $p = 0.002$; *Table 3*) after 4 weeks of treatment. Arm and truncal fluid also decreased (216mls; $p = 0.014$ and 290mls; $p = 0.066$, respectively; *Table 4*). Measurements taken on the contralateral arm and tonometry assessments were not significantly changed. The same subjective parameters were also significantly reduced, with the addition of range of movement ($p = 0.013$; *Table 5*), which was not observed in the first

TABLE 5
Subjective Parameters at Baseline, End of 4 Weeks of Treatment,
and at 1 Month Follow Up

	Trial I	Trial II
Pain		
Baseline	1.8 (\pm 1.5)	2.7 (\pm 2.7)
Week 4	1.0 (\pm 0.1)*	1.0 (\pm 0.0)
1 month f/up	1.0 (\pm 0.0)	2.0 (\pm 1.5)
Heaviness		
Baseline	3.3 (\pm 2.5)	4.7 (\pm 3.1)
Week 4	1.2 (\pm 0.5)**	1.5 (\pm 1.3)**
1 month f/up	1.9 (\pm 1.5)	2.6 (\pm 1.9)
Tightness		
Baseline	2.8 (\pm 2.3)	4.8 (\pm 2.6)
Week 4	1.1 (\pm 0.3)**	1.8 (\pm 1.3)**
1 month f/up	1.9 (\pm 1.9)	2.6 (\pm 2.2)
Tissue Hardness		
Baseline	3.3 (\pm 2.5)	4.4 (\pm 2.9)
Week 4	1.2 (\pm 0.5)**	2.0 (\pm 1.6)*
1 month f/up	1.9 (\pm 1.5)	2.7 (\pm 2.3)
Arm Size		
Baseline	5.7 (\pm 2.1)	6.3 (\pm 2.3)
Week 4	3.2 (\pm 2.1)**	3.9 (\pm 2.2)**
1 month f/up	3.9 (\pm 2.1)	4.2 (\pm 2.0)
Range of Movement		
Baseline	1.8 (\pm 1.9)	3.6 (\pm 2.5)
Week 4	1.2 (\pm 0.6)	1.4 (\pm 0.9)*
1 month f/up	1.6 (\pm 1.2)	2.3 (\pm 1.8)
*p<0.05; **p<0.01		

trial. At 1 month follow up the subjective measurements increased, but again these had not returned to pre-treatment levels (although not significantly different).

Compliance and Adverse Effects

In the first trial, 87.5% of participants were compliant with the compression bandaging, 4.2% could not tolerate the bandaging and wore a compression garment as an alternative and 8.3% could not tolerate any form of compression. In the second trial

90% of participants were compliant with the bandaging and 10% wore a compression garment. It was deemed clinically appropriate to offer participants the alternative of wearing a compression garment when the bandaging could not be tolerated, as this ensured that the participant still received the benefits of some form of compression and helped to maintain compliance. In trial I, the subjects reported compliance with compression as: not at all (16.7%), slightly (12.5%), moderately (33.3%), and completely (37.5%). In trial II, 10% were slightly

TABLE 6
Comparison of Changes in Arm Volume and Subjective Symptoms as a Result of
LPG® Plus Compression and MLD plus Compression

Treatment Protocols	Arm Vol. Change	Subjective Change	Reference
Trial I: 25mins of LPG® + compression bandaging over 16 sessions (n = 24)	Trial I: ↓ 134mls (18.3%) p=0.000	Trial I & II: ↓ heaviness p < 0.01 ↓ tightness p < 0.01 ↓ tissue hardness p < 0.05 ↓ arm size p < 0.01 Trial I only: ↓ pain p < 0.05 Trial II: ↓ range of movement p < 0.05	present study
Trial II: 30mins of LPG® + compression bandaging over 16 sessions (n = 10)	Trial II: ↓ 185mls (23%) p = 0.002		
MLD + Compression (n = 17)	↓ 156mls (23%) p < 0.01	↓ heaviness p = 0.03 ↓ tension p = 0.01 ↓ pain p = 0.00	Korpon et al (2003) (17)
Compression bandaging for 3 wks followed by 45mins of MLD for 5 days (n = 18)	↓ 47mls (11%) p < 0.001	↓ tension p < 0.001 ↓ heaviness p < 0.001 ↓ pain p < 0.03	Johansson et al (1999) (16)
2 weeks of wearing a compression sleeve (30-40 mmHg) followed by 45mins of MLD + sleeve over 10 sessions (n = 12)	↓ 75mls (15%) p < 0.001	↓ tension p = 0.01 ↓ heaviness p = 0.008	Johansson et al (1998) (15)

compliant, 20% moderately compliant and 70% were completely compliant all by self-report. The main complaint after the first week of treatment in both trials was increased urination and thirst (10% in the first trial, 35 % in the second trial), this was possibly related to the fluid mobilization. Apart from this, the massage delivered by the LPG® Endermologie® system was very well tolerated. Some participants, however, found that the bandaging disrupted their sleep as it was itchy and uncomfortable.

DISCUSSION

While the two treatment protocols produced similar results, the second protocol conferred additional benefits in terms of

reducing arm volume at 24 hours, an improved trend in arm fluid and volume reductions, and a significant improvement in reported arm range of movement. These improvements may be related to clearing the pathway to the contralateral axilla, the extra time spent clearing the posterior thorax region and the use of the larger, mechanized treatment head which more efficiently mobilized the tissues over a larger area.

As new techniques of treating secondary lymphedema emerge on to the market, clinicians need to know the benefits of such techniques so that patients can be adequately informed. The LPG system reduces arm fluid and volume, with the reductions being comparable to similarly designed studies using massage plus compression (15-17,

Table 6). Additional benefits of this treatment regime include reductions in truncal fluid, softening of fibrotic induration and improvements in subjective parameters. It is noted that the sample sizes are small for these two trials, which was largely due to the commitment required for the treatment regime and the fact that some participants did not wish to undergo compression bandaging. The latter fact made adding a compression only comparison group unattainable, however, Trial 1 does show (with Trial II close to significance) a reduction in truncal fluid which may be difficult to explain with only compression of the arm. Despite the small trial sizes and large standard deviations, significance was reached in many of the measured parameters. Future studies with more subjects and a longer follow-up period for confirmation are warranted.

It should be emphasized that the LPG system and compression bandaging should be administered by a trained health professional who understands the underlying pathophysiology of lymphedema and who can continually assess the patient's response to treatment. The fact that subjective measurements increased at 1 month follow up (not returning to baseline) emphasizes the importance of continuing self-maintenance regimes such as performing self-massage and wearing a compression garment. It is of significance that the parameters had not returned to baseline, as long term data collected by Casley-Smith and Casley-Smith (18) and studies involving placebo groups (19-21) demonstrates that the lymphedematous arm will progressively worsen without some form of therapy. This shows that the self massage and compression instigated by the participants in this study did help to arrest some of this worsening and that all patients should be encouraged to undertake self-maintenance activities in between health professional visits to maintain the benefits gained from intensive treatment.

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ŒDÈME ET TECHNIQUES LPG®

Jocelyne ROLLAND¹

MOTS CLÉS

Œdème
Techniques LPG®

“ Cette technique sera appliquée en complément des bandages de compression et s'adaptera au sein de l'arsenal thérapeutique mis en place, au résultat clinique obtenu progressivement chez chaque patient ”

La technique LPG® s'intéresse depuis de nombreuses années au traitement des œdèmes [1-3], en particulier dans le contexte du lymphœdème après chirurgie du cancer du sein.

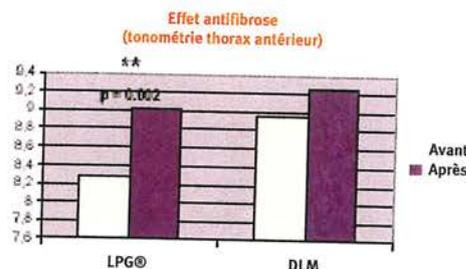
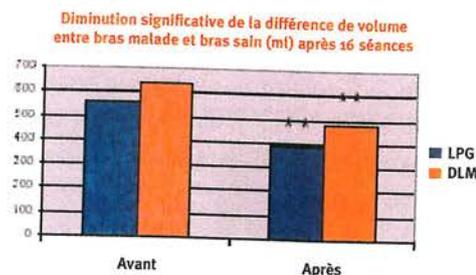
Le Cellu M6 et l'utilisation des têtes auxiliaires ont fait la preuve de leur efficacité dans une étude menée en Australie en 2005, conduite par le Pr Neil Piller (Flinders University, Adelaïde - Australia). Cette étude visait à comparer les effets de 45 minutes de drainage lymphatique manuel (groupe de 21 patientes) contre 25 minutes de technique LPG® (groupe de 24 patientes) [4].

Les résultats de cette étude ont fait l'objet d'une conférence lors des 37^e Journées de

l'INK et d'une conférence au 20^e Congrès international de lymphologie [5]. Les principaux résultats sont rappelés sur les schémas 1 et 2.

Cette étude ayant néanmoins montré une réduction incomplète de l'œdème dans la partie proximale du bras, il a été décidé de réaliser une seconde étude sur 10 patientes avec la tête Keymodule 150 du Cellu M6, Keymodule motorisée sous la direction du Pr Piller.

Le même protocole a été utilisé (4 séances, 4 fois par semaine, en association avec des bandages de compression) ; les évaluations ont porté sur les mesures de volume (volumétrie opto-électronique = pérométrie) et de fluides corporels (impédancemétrie) avant traitement,



▲ Schémas 1 et 2

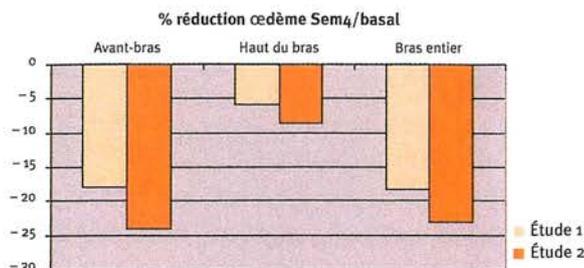
Autres résultats :

- diminution significative des symptômes associés (lourdeur, sensation d'être enserré, douleur) ;
- bonne persistance des effets à un mois de l'arrêt du traitement (différence significative $p < 0,0001$) ;
- meilleure compliance pour les résultats LPG obtenus avec 25 minutes de traitement contre 45 avec le DLM.

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Directrice du Département Formation-Évaluation-Recherche LPG Systems®



39^e Journées de l'INK



▲ Schéma 3

à 24 h, à chaque semaine, en fin traitement (après 16 séances) et à un mois de l'arrêt du traitement (follow-up 1 mois) ainsi que sur les paramètres subjectifs (questionnaire qualité de vie) avant et en fin de traitement. Les résultats ont été comparés avec ceux obtenus dans le groupe LPG® de la première étude.

Les principaux résultats sont les suivants (schéma 3) :

- réduction supplémentaire des volumes et fluides (meilleur drainage de l'œdème) ;
- amélioration significative de l'amplitude articulaire, en particulier au niveau du coude ;
- persistance des effets à un mois.

Cette étude a permis d'affiner le protocole technique réalisé aujourd'hui avec les têtes motorisées du Cellu M6 Keymodule ; la rotation privilégiée est le roll-up majeur (différentiel de vitesse des rouleaux ; rouleaux "avant" plus rapide que rouleau "arrière" avec même sens de rotation) permettant une mécanisation accrue des tissus fibrosés.

La puissance est "séquentielle" pour préparer (étape 1) et drainer (étapes 3 et 4) ou "continue" pour mobiliser (étape 2). Tous les déplacements sont réalisés en trace directe, selon des tracés transversaux ou longitudinaux, disto-proximaux dans une progression proximo-distale, puis disto-proximale (fig. 1). La séance complète dure 30 minutes.

La technique LPG® dans la prise en charge du lymphœdème après chirurgie pour cancer du sein a montré son efficacité, en particulier lorsque les tissus fibrosés rendent le drainage manuel moins efficace. Cette technique sera appliquée en complément des bandages de compression et s'adaptera au sein de l'arsenal thérapeutique [6] mis en place, au résultat clinique obtenu progressivement chez chaque patient. ■

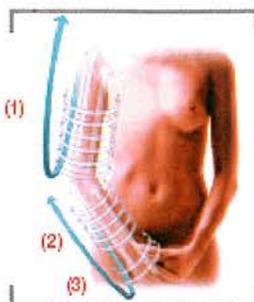
Mots clés Internet :
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Technologie

Bibliographie

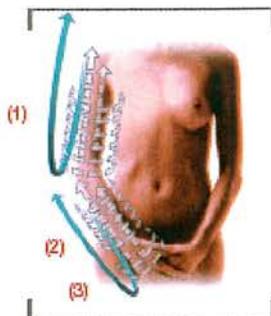
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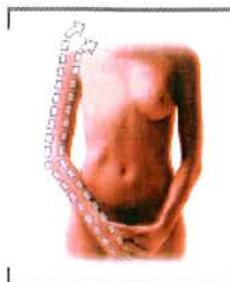
Étape 1 : préparer



Étape 2 : mobiliser



Étape 3 : drainer
(longitudinal, puis transversal)



Étape 4 : drainer
(longitudinal)

Figure 1

Physiological Effects of Endermologie®: A Preliminary Report

James Watson, MD^a; Peter Bela Fodor, MD^b; Brian Cutcliffe, BA^a; David Sayah, MD^a; and William Shaw, MD^a

Background: Endermologie® is a noninvasive, suction-assisted massage technique that has been advocated for body contouring and cellulite treatment. Theories with regard to the mechanism of action remain unproven.

Objective: This investigation was designed to elucidate the mechanism of action by observing the physiological effects of Endermologie® based on both animal and human studies.

Methods: In the SUS scorfa pig model, Endermologie® was studied by use of subcutaneous endoscopy (original magnification × 80), photography, gross tissue examination, and histologic examination. In human volunteers, Endermologie® was studied with lymphoscintigraphy, venous color-flow Doppler ultrasonography, and laser Doppler blood flow analysis of skin perfusion.

Results: Endoscopic and gross analysis of treated fat failed to conclusively demonstrate that Endermologie® can actually redistribute fat *in vivo*, but we were able to demonstrate that Endermologie® can redistribute free, autologous fat after autologous fat injections. Laser Doppler measurements showed a 4-fold increase in cutaneous blood flow. This increase in skin perfusion peaked approximately 10 minutes after treatment and lasted for more than 6 hours. Color-flow Doppler measurements showed increases in the flow velocities of the subcutaneous veins within the adipose tissue and a concomitant decrease in flow velocities of the deep muscular veins. These effects were also noted to be prolonged, lasting for at least 6 hours after the Endermologie® treatment was completed. Lymphoscintigraphy studies revealed a 3-fold increase in lymphatic flow in the treated limb, as compared with the untreated limb. This increase in lymphatic flow was prolonged, lasting at least 3 hours after the treatment was completed.

Conclusions: We conclude that Endermologie® has a profound physiological effect that can be easily measured, but its anatomic effects are more difficult to identify. This suggests that Endermologie® may exert its effects by altering the physiological and metabolic activity of fat. Whether Endermologie® has a measurable anatomic effect of redistributing fat cells is yet to be proven.

Endermologie® (LPG Endermologie USA, Fort Lauderdale, FL) is a noninvasive, suction-assisted massage technique that was initially developed in the late 1970s by the French inventor Louis Paul Guitay to standardize scar massage therapy.¹ This mechanical device consists of two moving rollers that travel across the skin with a suction-generated vacuum between the rollers (Figure 1). The rollers exert a positive

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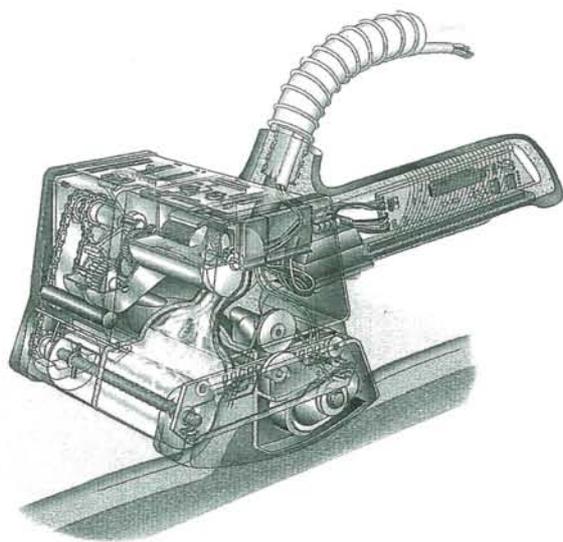


Figure 1. Mechanical drawing of the Endermologie® handpiece. Courtesy LPG Endermologie USA.

force on the skin and subcutaneous tissues, and the suction draws a fold of skin and fat into the vacuum space (Figure 2). With roller motion, this produces a “moving fat roll,” massaging the tissues much more effectively than manual massage.

This device was initially used in Europe for burn and traumatic scars; many users noted the additional improvement in the appearance of cellulite and an appar-

Table. Theories regarding the mechanism of action of Endermologie®

- Vertical stretching of connective tissue (retinaculae cuti)
- Increased metabolism of fat cells
- Stimulation of lymphatic flow
- Increased skin tone and elasticity
- Stimulation of subcutaneous collagen production

ent alteration in fat distribution. As a consequence, Endermologie® has been used in Europe, Japan, and South America for cosmetic purposes for more than a decade. Recently it was approved by the Food and Drug Administration for use in the United States.² In spite of the widespread use of this device, the mechanism of action is still unclear. Many theories have been advocated but remain unproven (Table).

Purpose

This investigation was designed to elucidate the mechanism of action by observing the physiological and anatomic effects of Endermologie®. Two separate experimental studies were carried out in laboratory animals and human volunteers. The animal study was performed by use of SUS scorfa swine with Institutional Review Board (IRB) approval by the Animal Research Committee

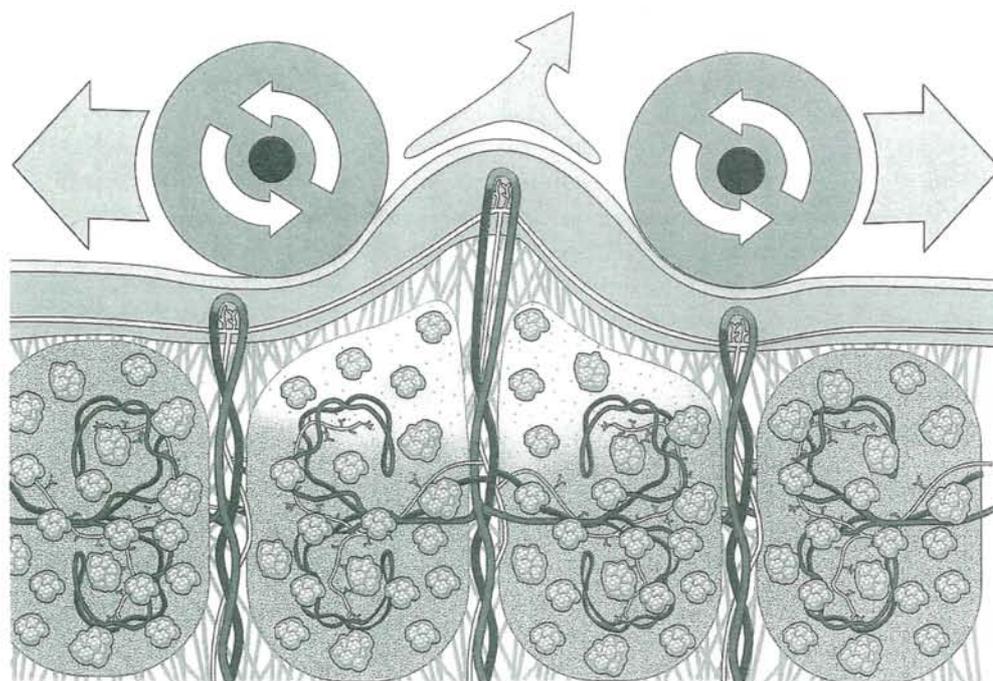


Figure 2. Stylized illustration of the effect of the mechanical rollers and suction on the skin, retinaculae cuti, and adipose tissue.

at the University of California at Los Angeles (UCLA). Animals were housed in the UCLA animal care facility in accordance with National Institutes of Health guidelines for the care of experimental animals. The human study was performed with the approval of the Human Subject Protection Committee.

Animal Study

Rationale

To elucidate the exact mechanism of action of Endermologie® in subcutaneous tissue, we believed that real time visualization of the tissues during the treatment sessions would be necessary. For this reason, a model was developed that would give us near-microscopic, in vivo pictures of the blood vessels, lymphatics, adipocytes, and retinaculæ cuti during Endermologie®. Animal studies are also required to obtain tissue samples for gross and microscopic analysis. For this reason, we developed the following protocol.

Methods

Four female SUS scorfa swine weighing 100 kg were used in the laboratory study of Endermologie®. With the pigs under general anesthesia, matching rectangular test sites measuring 5 × 9 cm were marked out on each swine's back, with contralateral sites serving as the controls. Each test site was photographically documented before and after treatments. Test sites were divided into three groups to evaluate the following: group 1, Endermologie® versus no Endermologie® on normal, undisturbed subcutaneous tissue; group 2, Endermologie® versus no Endermologie® in test spots that had been treated with liposuction just before treatment; and group 3, Endermologie® versus no Endermologie® in test spots where autologous fat had been injected just before Endermologie®.

Group 1: Endermologie® versus no Endermologie®. This portion of the experiment was designed to determine whether fat redistribution could be documented by endoscopy, autopsy, or light microscopy with Endermologie® treatments. In matching test spots, Endermologie® was performed on one side of the pig's back and no Endermologie® was performed on the opposite side. Endermologie® treatments were performed with the standard handpiece by use of suction settings of 6 to 7. Standard Endermologie® techniques were used, with "smoothing," "bouncing," and "figure-eight" motions for 20 minutes per test site. To ensure quality control, the treatments were monitored by an experienced Endermologie® instructor from LPG to ensure that the technique was

properly performed. During the Endermologie® treatment, real-time endoscopic visualization of subcutaneous tissue was achieved by use of a high-powered endoscope, an image intensifier, and a three-chip CCD camera (Karl Storz GmbH & Co., Tuttlingen, Germany). Video recordings of these endoscopic findings were taken, and 35 mm photographic slides were taken of the test sites before and after treatments. After the experiment was completed, the pig was euthanized. The skin and fat of each test site were harvested "en bloc," photographed, and sent for microscopic analysis.

Group 2: Endermologie® versus no Endermologie® with suction-assisted lipoplasty. This portion of the experiment was designed to determine whether Endermologie® could redistribute fat in areas treated by suction-assisted lipoplasty (SAL). Contour defects were deliberately created to determine whether Endermologie® could correct these depressions. Traditional SAL was performed with the "super-wet technique" of subcutaneous infusion.³ SAL was performed in the deep layer of the pig's subcutaneous fat, with a 3-mm, single-hole cannula.* Within this treatment area, a large 5-mm cannula was used in a 3 × 3 cm area to create an "iatrogenic" contour deformity. Matching contour defects were created on each side in this group of test sites (group 2). Photographs were taken of these contour defects before and after the Endermologie® treatments were performed. Endermologie® was performed with the same parameters used in group 1 test sites, except that the "smoothing" technique was primarily used to "redistribute" the fat into the contour deformity that had been created with the 5-mm SAL cannula. High-powered endoscopy was also used to catch real-time images of the SAL being performed, as well as the "intraoperative" Endermologie®. Postmortem gross and microscopic examinations of these test spots were performed just as they were in group 1.

Group 3: Endermologie® versus no Endermologie® in autologous fat transfers. This portion of the experiment was designed to determine whether Endermologie® could redistribute autologous fat that had been transferred by use of standard fat grafting techniques. Autologous fat was harvested by use of the syringe technique with a mercedes-tipped 2-mm cannula. The

*SUS scorfa pigs have a dense superficial layer of fat that does not resemble any fat seen in human beings. Below this layer, there is a thin, superficial fascial layer similar to Scarpa's fascia in human beings, and below that, there is a loose layer of subcutaneous fat that closely resembles the density of fat seen in human beings. That is why we chose this layer for the experimental model.



Figure 3. Endoscopic view of skin roll between the rollers within the Endermologie® handpiece.

harvested fat was allowed to settle, and the infranatant fluid was decanted. The remaining fat was then rinsed with saline solution decanted three times. The remaining fat was then stained with methylene blue and reinjected into the contour defects in the group 3 test sites. Ten minutes of Endermologie® was then performed on the experimental side; no Endermologie® was performed on the opposite control side. These two test sites were then harvested immediately after the pig was euthanized. The methylene blue-stained autologous fat was then evaluated by gross examination and photographically documented.

Results

In group 1, high-powered endoscopy, gross examination, and histologic examination were performed to compare areas treated with Endermologie® with those not treated (Figure 3). With high-powered subcutaneous endoscopy (original magnification $\times 80$), we were able to demonstrate actual blood flow in transilluminated small blood vessels (<1 mm) within the fat. The blood flow was documented by use of videotape recording before, during, and after Endermologie® treatments. During Endermologie® treatments, a significant increase in subcutaneous blood flow was noted. This seemed to be a direct mechanical effect (massaging) to the treated area, because we did not see increases in blood flow in the contralateral (untreated) area. With endoscopy, we were unable to demonstrate any fat “redistribution.” The animals were sacrificed immediately after the treatment session, so no long-term follow-up was done in this preliminary study, which was designed primarily to examine the immediate physiological effects of Endermologie®. Direct examina-

tion and histologic examination of the treatment sites and control sites showed no gross or histologic differences between specimens.

In group 2, high-powered endoscopy, gross examination, and histologic examination were also performed to compare Endermologie®-treated sides with those not treated in areas on which SAL had been performed. One significant finding in this portion of the study was the effect of the wetting solution on subcutaneous blood flow. After infusion of a super-wet solution before performing SAL, blood flow nearly ceased in the small subcutaneous vessels (this had been well visualized in group 1). Sludging of blood within the small venules occurred, and extreme vasoconstriction of the small arteries was observed. As a consequence of the sludging and vasoconstriction, no changes in blood flow with Endermologie® treatments could be videographically documented. In the iatrogenically produced contour deformities, we were able to demonstrate smoothing of these contours with Endermologie® by use of still photography. Endoscopic and autopsy findings failed to show actual fat redistribution into the contour deformities, however. Instead, they showed evidence of fluid mobilization (wetting solution and edema) into these depressions. The animals were sacrificed immediately after the treatment session, so no long-term follow-up was done in this preliminary study to determine whether these contour deformities improved with time.

In group 3, only gross examination at autopsy was done to examine the effects of Endermologie® on autologous fat grafting. The methylene blue-stained fat that had been reinjected into the test sites could be easily visualized on gross examination to determine whether any fat redistribution occurred. When Endermologie® test sites were compared with untreated autologous fat transfer sites, we noted a significant fat redistribution into a larger area. This seemed to be a direct mechanical effect (massage) that had spread the autologous fat transfer over a larger area in the subcutaneous space.

Human Study

Rationale

Because the animal study portion of this research was primarily qualitative in nature, the primary purpose of the human portion of the study was to obtain some quantitative information about the physiological effects of Endermologie®. The study was designed to be a noninvasive study with proven diagnostic modalities currently

used clinically to evaluate the effect of Endermologie® on lymphatic flow, skin perfusion, and venous flow in both muscles and subcutaneous tissue. With proven techniques used to measure these effects, the data obtained would better substantiate the clinical significance of the animal study.

Methods

Five human volunteers with no lymphedema, surgical incisions, or previous liposuction were recruited to participate in this IRB-approved human study. Skin perfusion was measured on the ipsilateral thigh, before and after Endermologie® treatments with a laser Doppler flowmeter (Transonics, Ithaca, NY). Venous return was measured by color-flow ultrasound Doppler imaging of the greater saphenous vein, superficial femoral vein, and the deep femoral vein. Lymphatic flow was measured by lymphoscintigraphy, with a technetium-labeled dextran clearance from a first web space injection. Exact methods used for each limb of the study are described as follows.

Skin perfusion. Baseline cutaneous blood flow was established by placing the laser Doppler flow probe over the skin of the volunteer's left anterior thigh. Contralateral blood flow measurements of the exact same spot on the right thigh were also obtained for control subjects. Twenty minutes of Endermologie® treatments were performed by a trained Endermologie® technician, using smoothing, kneading, bouncing, and figure-eight motions. Immediately on completion of the treatment session, skin perfusion was remeasured every 30 seconds for the next 30 minutes.

Venous return. Baseline venous return was measured by use of color-flow Doppler imaging in the vicinity of the femoral triangle. Velocity measurements (cm/sec) could be accurately and reproducibly obtained from the greater saphenous vein, the superficial femoral vein, and the deep femoral vein at their confluence in the groin. Measurements were made by a trained, certified ultrasound technologist with the standard techniques used for clinical, diagnostic use. Contralateral simultaneous flow velocities of the untreated extremity could not be done (because of the lack of two separate color-flow Doppler machines to measure simultaneous flow velocities).

Lymphoscintigraphy. In selected patients who were undergoing lymphoscintigraphy for diagnostic purposes, Endermologie® was performed while the lymphoscintigraphy nuclear medicine scan was carried out. Technetium-labeled dextran was injected into the first

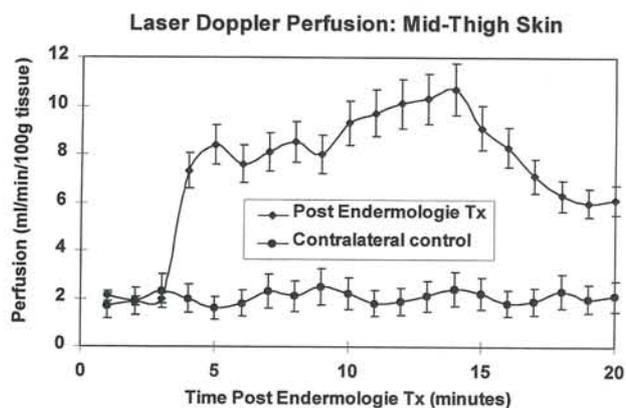


Figure 4. Laser Doppler skin perfusion of right thigh skin after 20 minutes of Endermologie® (patient 2).

web space of both lower extremities, and a gamma camera was used to collect images over a 5-hour time period. Endermologie® was performed twice on one lower extremity for a total of 20 minutes. The scanning continued for 3 hours after the completion of the last Endermologie® session. The lymphoscintigraphy test was performed by a licensed nuclear medicine technologist under the supervision of a radiologist. The interpretation of the results was made by a radiologist who did not know which extremity had been treated with Endermologie®.

Results

Laser Doppler skin perfusion showed a dramatic increase in perfusion after the completion of Endermologie® (Figure 4). Skin perfusion increased 4- to 5-fold over baseline measurements, with the peak perfusion occurring 6 to 10 minutes after the Endermologie® treatment. Although this peak was transient, the perfusion remained elevated for more than 6 hours after the completion of the treatment session. This effect was reproducible in all of the treatment sessions performed on different patients and in subsequent treatment sessions in the same patient. Venous flow velocity in the lower extremity veins showed a 2- to 3-fold increase in flow in the veins within the fat (Figure 5). Flow velocities increased 2- to 3-fold over baseline, with the peak flow occurring 8 to 10 minutes after the completion of the Endermologie® treatment. In contrast, the venous flow in the deeper muscular veins (deep femoral, superficial femoral, and common femoral vein proximal to the confluence of the saphenous vein) showed a decrease in flow velocity (Figure 6). This decrease peaked at 10 to 14 minutes after the Endermologie® treatment was completed. These effects were also noted to be prolonged and did not

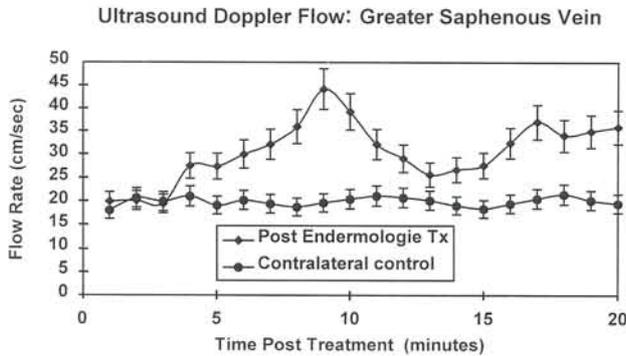


Figure 5. Color-flow ultrasound Doppler velocity of greater saphenous vein after 20 minutes of Endermologie® (patient 3).

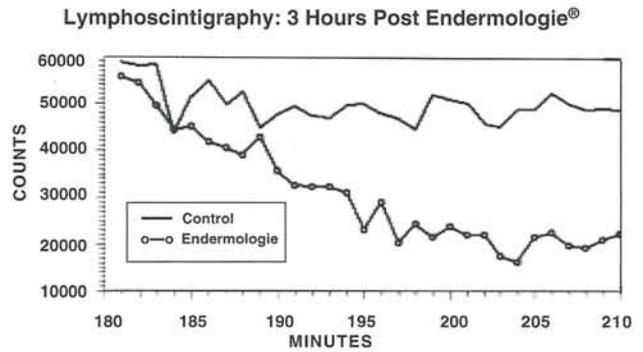


Figure 7. Lymphoscintigraphy quantitative counts of technetium-labeled dextran 3 hours after Endermologie® treatment, with untreated control (opposite lower extremity).

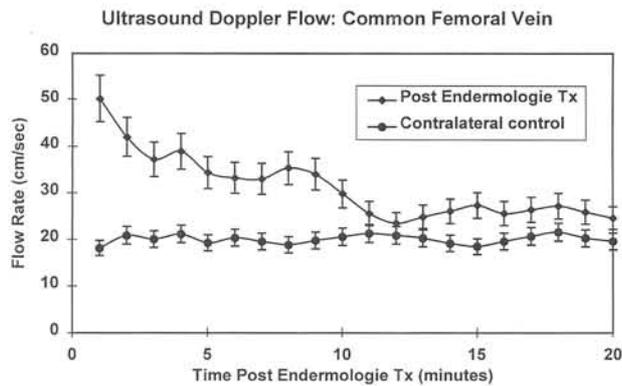


Figure 6. Color-flow ultrasound Doppler velocity of right common femoral vein proximal to confluence of the saphenous vein (patient 2).

return to baseline throughout the 6-hour period of observation. Lymphoscintigraphy measurements in treated and untreated lower extremities showed a dramatic increase in lymphatic flow. When compared with the opposite, untreated extremity, there was a 3-fold increase in lymphatic flow (Figure 7). Although this effect was observed as early as 30 minutes after the Endermologie® treatment session, the most dramatic change in lymphatic flow occurred more than 3 hours after Endermologie® treatment. This effect was reproducible in all of the patients who were studied. With laser Doppler, ultrasound Doppler, and lymphoscintigraphy, we were unable to document any systemic effect of Endermologie®, however.

Conclusions

On the basis of our animal studies, we conclude that Endermologie® can produce physiological alterations in cutaneous blood flow. This effect seemed to be local, rather than a systemic effect. Although we attempted to document actual fat mobilization in normal subcutaneous

tissue and fat mobilization into contour defects, we failed to show any fat translocation on gross and microscopic analysis. The fact that we were able to demonstrate that free autologous fat could be mobilized comes as no surprise, because this can be done with manual massage as well. However, because this study was designed to examine the immediate effects of Endermologie®, we cannot conclude that Endermologie® does not produce any long-term anatomic effects. This is an ongoing study, and we hope to ultimately answer this question.

On the basis of our human study, we conclude that Endermologie® produces a profound physiological alteration in cutaneous perfusion, subcutaneous perfusion, and lymphatic flow. This effect seems to be delayed and prolonged, lasting for hours after the completion of the treatment. Of interest is the observation that Endermologie® increased blood flow in the subcutaneous tissue (greater saphenous vein flow) and skin (laser Doppler flow), but decreased blood flow in the deep veins within the muscles (superficial femoral vein, deep femoral veins). In our human studies, we looked for changes in the untreated areas (controls) to determine whether we could document a systemic physiological effect.

Discussion

It must be emphasized that this study is a preliminary report that was designed to examine the immediate—not the long-term—effects of Endermologie®. Because any long-term study of Endermologie® would have to account for changes in diet and exercise, it may be difficult to prove conclusively that Endermologie® alters fat metabolism. Nevertheless, we believe that this study leaves little doubt that Endermologie® has a measurable

physiological effect on local skin and subcutaneous tissue. Some may argue that these effects can be reproduced with exercise. We are currently duplicating this study to answer this question; however, on the basis of our observations to date, the physiological effects of exercise seem to be targeted toward muscle, not fat or skin. There also seems to be a significant systemic effect of exercise, whereas the only measurable effects of Endermologie® seem to be confined to the treated area. In this aspect,

Endermologie® may prove to be a simple method of targeting physiologic changes to a localized area, rather than affecting total body fat metabolism. ■

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Vibroassisted Liposuction and Endermologie for LipoLymphedema

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INTRODUCTION

The dream of the aesthetic surgeon has always been the body improvement, since he is not able to act against the aging. But each of his efforts has to deal with the scars, the unavoidable traces of the knife.

Adipose tissue, as well as from its various composition as from its distribution, represents the main structure for the silhouette definition and the body harmony. But the attempt to reduce or to remove fat in excess or badly located, has always been limited by scars.

On September 1976 has been published the first and revolutionnary operation allowing removal of fat tissue while limiting trauma and scars^{1,2}: liposuction was born.

This methodology had various evolutions^{3,4,5,6} since getting the possibility to use it either in different pathologies^{7,8,9} or in unaesthetic affections as lymphedema, lipoedema or lipolymphedema^{10,11}.

CELLULITE

The silhouette is characterized by the particular localization of the subcutaneous adipose tissue over the osteomuscular structure. We know that human body is characterized by the presence of rigid fasciae, and especially deep muscular fasciae which, starting from the cranium base and without any solution of continuity, to the ankles and metatarsus promoting various physiological functions: vascular, neurophysiological and orthopedic.

Cellulite is a classically degenerative and evolutive affection of the subcutaneous tissue which grows on a constitutional substrate itself linked to a whole series of predisposed and releasing factors. According to the authors who have described cellulite from an histomorphologically point of view, defining it as a P.E.F.S.: "oedematofibrosclerotic dermo-ipodermical pathology"^{12,13}.

Cellulite is considered as a series of events characterized by interstitial edema, secondary connective fibrosis and consequent sclerotic evolution. Recent clinical observations demonstrated that if P.E.F.S. is a true part of cellulite it does not represent all the various clinical aspects of cellulite.

In fact there are often particular forms of connective and interstitial damage or diffuse syndroms characterized by a lipoedema associated with a lymphedema and/or lipodistrophy. Such pathologies are mainly observed on gluteal muscle and on lower limbs of female gender.

LIPOEDEMA AND LIPOLYMPHEDEMA

Lymphedema is described¹⁴ as a pathology characterized by a tumescent state of soft tissues, -usually superficially-, and related to the accumulation of lymph highly containing proteins by stasis in the interstitial space. It is determined by primary and/or secondary damage of the transport vessels.

On the contrary, lipoedema is a particular syndrom, which etiology is not well known nowadays, and characterized by fat and water deposition in the subcutaneous tissue (particularly in lower limbs and gluteal muscle) associated to lymphedema and/or lipodistrophy.

Lipoedema was described for the first time as an accumulation of subcutaneous fat with hard leg edema avoiding the feet. In the various next descriptions¹⁵ the following observation has always been underlined, that is to say a foot hypothermy with a localized gradient of temperature. During the last years, this syndrome has been well described with 4 major criteria mandatory for its diagnostic.

Such a pathology, often superficially defined as a lymphedema, a venous insufficiency or cellulite, is observed in more than 65% of female gender between the age of 14 and 35 years, becoming a lipodistrophic lipolymphedema after the age of 40.

The common characteristics of a lipolymphedema are the

incisions. Cannula are not connected to a suction device, it is only the movement of the cannula which induces the cellular disruption and channel formation.

The adipocyte disruption is not induced by suction but essentially by the backward-forward motion of the cannula. The created channels will help, in the healing phase, the adhesion of subcutaneous tissue to skin and also the angiogenesis.

The adipocyte contains collagen. Then, its disruption leads to a collagen exposure into the extracellular matrix, very useful in the post operative healing phase.

With the introduction of ultrasound assisted liposculpture and so, with the patented vibroassisted method Microaire, the possibilities have been multiplied^{17,18,19}.

The benefits obtained from the reduction of the interstitial pressure due to the adipocyte decrease are characterized by the microcirculation (arterial and lymphovenular) and tissue metabolism improvement.

The reduction in adipocytes number and size prevents the hormone action and thus the evolution of the adipose and lipodystrophic pathology.

A consequence in the adipocytes reduction is the systemic slimming and the improvement of systemic metabolism related to improvement of insulin peripheral metabolism.

All this is now intensified by the use of Endermologie in the rehabilitation post surgery phase.

An important application for liposuction is also the treatment of lymphedema and particularly, lipolymphedema.

Lipolymphosuction allows the reduction of all the previous selected lymphedema, which can be treated as ankle, knee, calf.

THE VIBRO-ASSISTED METHOD

The Vibratory Pneumoassisted Liposculpture by Bacci (1997) or the Reciprocal Automatic Liposculpture by Scuderi, (1999), according to the US patented Microaire method, is a methodology which consists in a 300g device linked in a part to the compressed air from the surgery room or to a nitrogen bottle, and in another part to a 2-3 mm, little and light cannula connected to a little vacuum device.

The system, defined in this version PAD100-MicroAire, allows vibrations of the cannula top, 2mm transversely and 4 mm vertically, inducing the rupture and homogenization of the fat tissue, simultaneously aspirated (Tab. 4)

Heat production and venolymphatic tissue trauma are avoided because the important backward - forward motions are not necessary, as in traditional liposuction; a little movement is sufficient as a violin bow does. Such a methodology, with 1,8 - 2,4 mm cannula, is now well used in the treatment of lymphedema and lipolymphedema, particularly at level of the ankle, calf or arm.

Such a methodology due to its easy use and its rare side effects, even for not skilled users, is an extremely useful remedy²⁰.

ENDERMOLOGIE AND TECHNIQUE LPG

Endermologie^{21, 22, 23, 24, 25} designs a non invasive technique for the mechanical treatment of skin, subcutaneous and connective tissues. This technique is realized by the way of the medical device "Cellu-M6" conceived and produced by the French company LPG Systems. This mechanical device is constituted of two motorized rollers included in a treatment room, which

mobilize the skin by folding and unfolding it, previously grasped by the vacuum power generated between the rollers. The technique LPG, born in France and developed both in Europe and USA, has initially been used to soften burn and traumatic scars (Tab. 5).

Numerous studies have been performed in order to explore the mechanism of action of Endermologie and its effects on tissues, showing a dramatic increase of skin blood perfusion, venous return and lymphatic flow, the creation of thick, longitudinal bands of collagen in the deep subdermal layer, moreover both changes in interstitial structure and tissue vascularization.

Then the results have become exponential with the use of this technique in a protocol validated and improved by us from 1997 to 2000. (BIM.ED protocol)^{25, 26, 27}.

CLINICAL STUDY

Despite of the clinical results confirming the usefulness of the methodology in the conservative treatment of lipolymphedema and lymphedema of the lower limbs, but also the quick recovery or the rare occurrence of complications, we underwent a clinical trial in order to underline the side effects and to evaluate the benefits in an experimental way.

MATERIALS AND METHODS

Objective evaluations have been carried out by videocapillaroscopy with optical probe (VCOP), laser Doppler flowmetry (LDF), transcutaneous oxymetry (tcpO2), lymphoscintigraphy^{28, 29, 30, 31} and measurement of body perimeters.

The subjects were 7 female patients, 18 -28 years old (mean 20.7), who underwent surgery for malleolar and calf lipolymphedema.

The patients were enrolled after signing a consent form. All the subjects have been studied clinically for excluding vascular and/or systemical pathologies which could have an incidence on the objective evaluations (macro and/or micro vascular troubles, renal/hepatic pathologies). All the subjects were non smokers and did not take estroprogestogens.

The protocol included:

- a) experimental evaluations before and 30 days after surgery: VCOP, LDF, tcpO2.
- 8 Endermologie Sessions (LPG Systems), twice a week in the postoperative period when the patient wear elastic garment during the day (Solidea 14mmHg).
- Lymphoscintigraphy 30 days after surgery.

The followed design was:

- Day 0 = VCOP, LDF, tcpO2, body perimeter Surgery
- Day 30 = VCOP, LDF, tcpO2, body perimeter Lymphoscintigraphy

VCOP was performed at magnification 100x and 200x. VCOP parameters were:

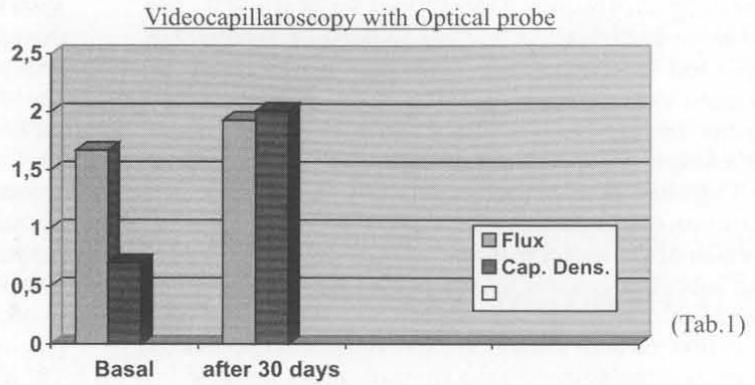
- a) Red blood cell velocity (chosen in the most significative field)
- b) Capillar density changes

RESULTS

VIDEOCAPILLAROSCOPY WITH OPTICAL PROBE (TAB.1)

Average values in basal conditions
 basal flux = 1.67
 capillar density= 0.70

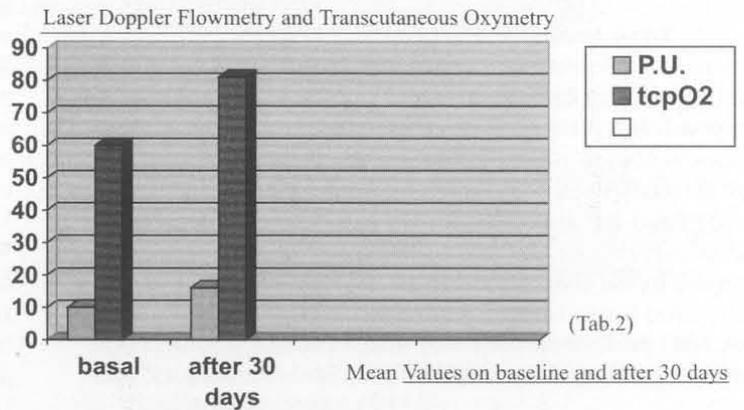
Average values after 30 days
 flux = 1,93 (+0.26)
 capillar density= 2,01 (+1.31)



LASER DOPPLER FLUXIMETRY AND TRANSCUTANEOUS OXYMETRY (TAB.2)

Perfusion and tcpO2 basal values
 PU= 10,04
 TCPo2 = 60.02

Values after 30 days
 PU = 16,12 (+6,08)
 TcpO2 = 81,09 (+21,07)



CIRCUMFERENCES (TAB.3)

Circonfereces have been measured with a tape misure before surgery and 60 days after at the malleolar level, superior area of the thigh, Boyd's and solear perforating.

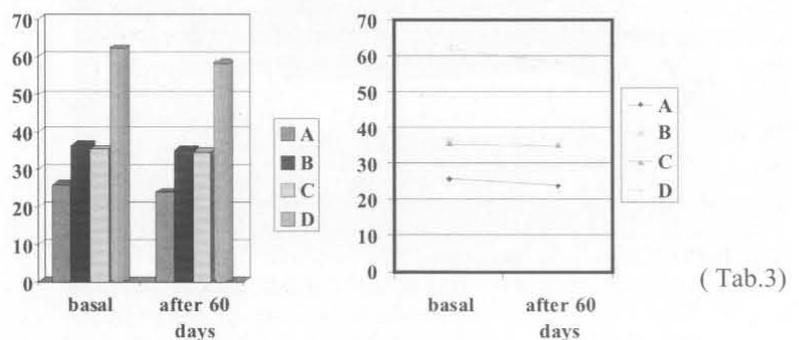
Average basal values

- Malleolar level: 25,8 cm
- Solear perforating: 36,4 cm
- Boyd's perforating: 35,3
- Thigh: 62,1 cm

Average values at 60 days

- A) Malleolar level: 23,9 cm
- Solear perforating: 35,1 cm
- Boyd's perforating: 34,9
- Thigh: 58,1 cm

Circumference values (after 60 days)



All the values made at the end of this study show a sensitive decrease of the circumferences showing the decreased thickness of the lymphoadipose tissue and the improved lymphovenous deflux. Infact, in case of the lymphatic vessel lesions, we'd had a progressive increase of the circumferences and, at the end, we could have a worst situation. Certainly, the lipolymphedema is a cronical pathology, so, it requires an integrated medical and physiotherapeutical treatment, in association to elastic stocking therapy, to mantein long time this results.

LYMPHOSCINTIGRAPHY

The lymphoscintigraphy has been made before and after the treatment in 8 cases of leg's lipolymphedema treated by vibroassisted liposculpture MicroAire System. All the examinations has been made in Nuclear Medecine Center by the radioisotopic test Tc-99m with quantity less 0,5 cc using the traditional methodology. Each study has been repeated after 60 days from the surgery and we never notice lymphatic vessel lesions in the surgical treated areas. More over, a reduction of the time Foot- Thigh has been shown.

This examination shows that the vibroassisted surgery provides us a real reduction of the complications about the lymphatic vessel system and subcutaneous tissue. We can notice, sometime, an improvement of the lymphatic stasis, a reduction of the ipodermocal fibrosis and, finally, a real reduction of the speed's evolution of this pathology.

The evolution until the ipodermocal fibrosis and hard lipolymphedema is a common complication of the lymphatic stasis.

DISCUSSION AND CONCLUSION

In this clinical study, an important and significant increase of the measured values has been observed showing the improvement of the microcirculation of the cutaneous oxygenation and of the interstitial metabolism.

This underlined the improvement we can obtain by decreasing the interstitial pressure and tension caused by the presence of fat and lympe in the tissue. This result is always detectable also clinically after lower limbs liposculpture or lipolymphosuction surgery, well performed with very small cannula and in a non traumatic way using MicroAire Method. Such a metabolic and

microcirculatory improvement has already been observed in other clinical trials using the LPG Systems patented device and the Technique LPG specific way.

Off course every liposculpture or lipolymphosuction surgery must be completed by physiotherapeutic sessions making an unique therapeutic period between the surgery act and the sessions of Endermologie.

Conclusion must always been referred to this complete treatment, the both therapeutic sessions could not be separated.

The circumference decrease also showed how the proposed physio- surgery therapeutic protocol gave good results by decreasing edema and adipose tissue, thus leading to a clinical, functional and aesthetic improvement.

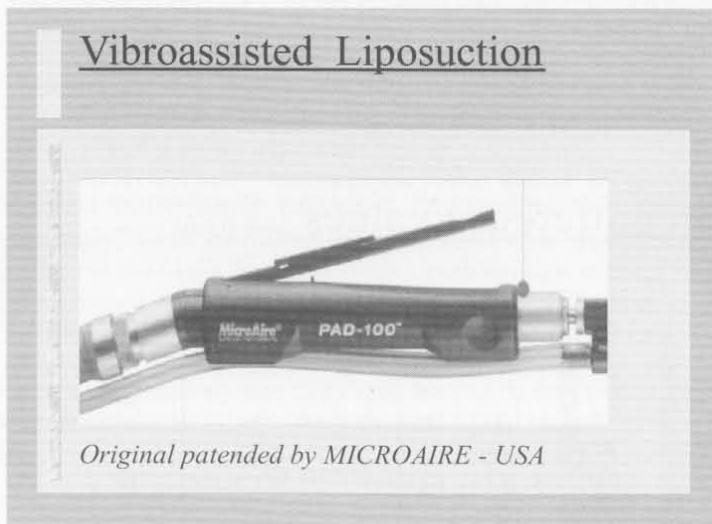
The improvement can also be valuable by the delay of the typical evolution of these pathologies towards fibrosis and phlebolympartrosis with articular rigidity.

The lymphoscintigraphy, performed after 60 days, demonstrated, beside the MicroAire surgical technique validity, the absence of lymphatic damage.

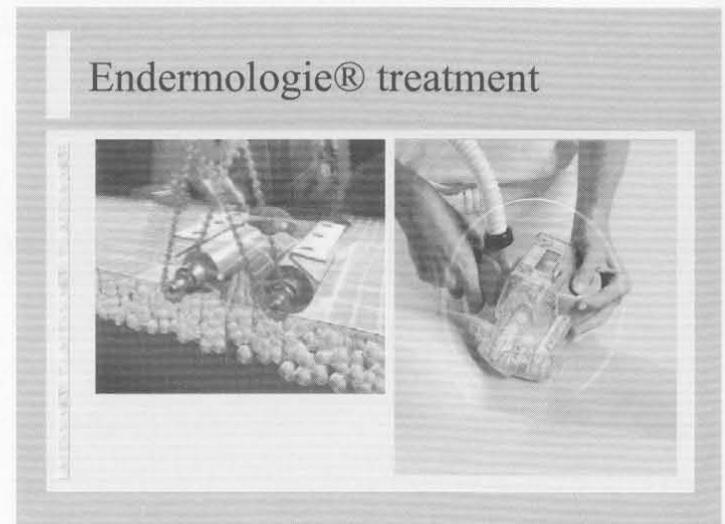
Such observations confirm clinical observations such as the slight surgery traumatism and the synergy with Endermologie achievement in the treatment of lower limbs lipolymphedema and lymphedema.

This treatment is conservative and will be always associated with elastocompressive treatment and physiotherapeutic maintenance. Sometime, a new surgery will be necessary if the pathology is evolutive. Such an evolutivity must always tend to evaluate the eventual indication of other surgical solutions of lymphatic correction.

When clinical evaluations are not able to guarantee a real success and a long-term effect, by the way of the traditional surgical solutions, we believe that such a protocol of conservative surgery by both a vibro-assisted lipolymphosuction and Endermologie is justified.



(Tab. 4) The Vibroassisted liposuction



(Tab. 5) The Endermologie – LPG System

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LPG[®] Technique in the Treatment of Peripheral Lymphedema: Clinical Preliminary Results and Perspectives

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INTRODUCTION

Lymphedema is a chronic worsening disease with progressive appearance of fibrosis in the interstitial tissue involving dermal and hypodermal layers.

LPG technique supplies a sort of standardized massage procedure by means of two moving rollers, shifting over the skin. This method creates a kind of traction on the tissue together with an aspiration effect, that can be continuous or intermittent. The mechanical action on the skin represents a stimulation on the most superficial layers allowing to soften fibrosis.

We tried to use LPG technique to reduce fibrosis in lymphedemas at advanced stages, from the 3rd to 5th, after treating them by combining complex decongestive physical therapies and microsurgical operation.

MATERIALS AND METHODS

We performed a prospective study in twenty patients affected from secondary lymphedema of arms (12) and legs (8) treated by combining physical therapies and microsurgical operations. After a period variable from 1 to 3 months from microsurgery, patients underwent a standardized protocol of therapy by LPG technique to cure the remaining less responsive fibrosis. We used Cell M6-IP device.

The protocol of therapy by LPG consisted in a treatment of 25 minutes, 3 times a week, for 5 weeks.

The results were assessed by photographs, volumetric measurements, US, lymphoscintigraphy, MR and Laser-Doppler.

RESULTS

By comparing photographs before and after LPG treatment, we could notice an evident improvement in terms of reduction in size of the treated part of the limb.

Volumetric measurements showed a decrease of excess volume from 5% to 10% after LPG therapy.

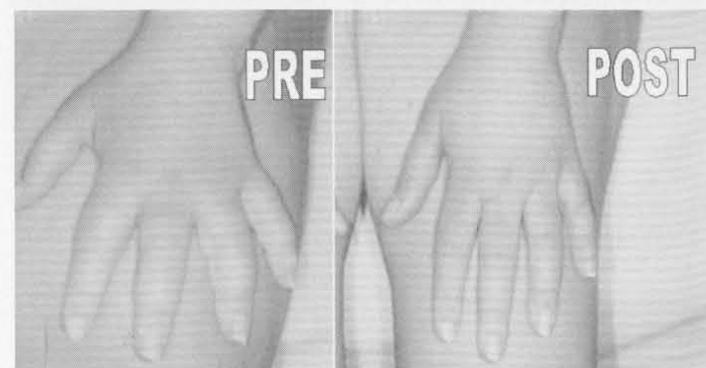
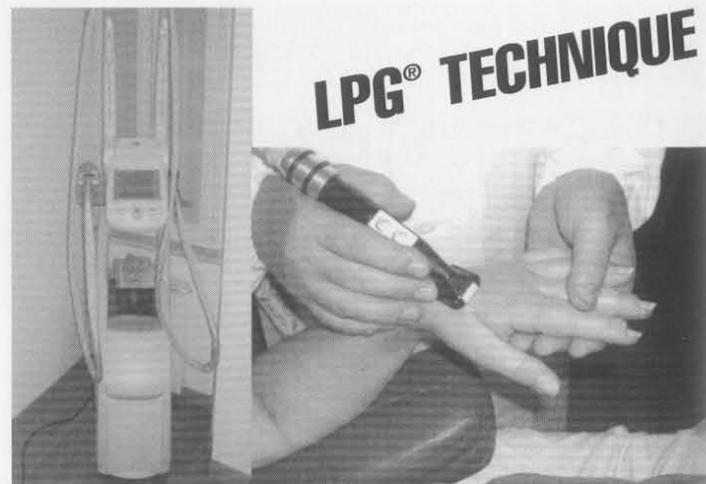
Ultrasounds allowed to obtain a better assessment of fibrosis of tissues and follow results obtained by LPG treatment. Echo-

scanning performed by the same operator demonstrated a significant reduction of fibrosis together with a consequent decrease of the thickness of superficial layers after LPG therapy.

Lymphoscintigraphy showed a reduction of dermal back flow at the site of fibrosis after treating the area by LPG technique.

MR proved to be useful to assess the reduction of fibrosis but is too expensive to be performed routinely.

Laser-Doppler evaluated perfusion of blood microcirculation of superficial tissues and showed a significant improvement of perfusion after LPG treatment of fibrosis.



DISCUSSION AND CONCLUSIONS

Lymphedema is assumed to increase in amount and stage with time. These increases together with that of fibrosis were caused mostly by duration rather than by patient aging¹.

Due to pathophysiological changes that occur in chronic extremity lymphedema, fibrosis progressively appear, resulting also from overexpressions of relevant genes like TGF-beta in the dermal and subcutaneous tissue fibroblasts and subsequent extracellular matrixes syntheses and deposition.

Thus, patients should be persuaded to undergo treatment early, starting with complex physical therapies for 2 intensive weeks of treatment. If after 3-6 months there is the relapse or worsening of lymphedema, notwithstanding proper elastic support (stockings, sleeves, etc.) another cycle of therapy of other 2 weeks is performed. If after 3-6 months after this second treatment lymphedema relapse or increases it is recommended to refer to microsurgical operations, in order to create new pathways of drainage of lymph. This way, the appearance of fibrosis is prevented or at least reduced at the utmost². For those cases addressed to this kind of combined treatment physical and microsurgical late, at the most advanced stages, with a lot of fibrosis already present, LPG technique proved to be extremely useful to greatly reduce and soften fibrosis.

Lymphedema is characterized by complications consisting of infections followed by fibrosis and occlusion of the collecting lymphatic vessels. Lymphedema is worsened by fibrosis.

Manual lymph drainage, through a constant change in pressure, moves fluid in the skin, increases lymphomotricity and softens fibrosis³. But, often fibrosis is not enough responsive to this kind of physical therapy, also if associated with compression, and

requires some other method of treatment.

Microsurgery offers valid solutions in allowing the drainage of the obstructed lymph flow by carrying out lymphatic-venous shunts⁴ or by reconstructing lymphatic-pathways where obstructed by means of autologous venous grafts interposed between lymphatic collectors above and below the obstacle to lymph circulation⁵. This drainage, if applied precociously, can prevent the formation of fibrosis and the progressive evolution of extremity lymphedemas. Unfortunately, several patients are addressed to microsurgical solutions lately when fibrosis is present at a certain amount.

In these cases, LPG technique helped us in reducing fibrotic tissural component, allowing to softening skin and superficial tissues, further improving lymphatic drainage of the affected limb.

As concerns the objective assessment of fibrosis, among different clinical and instrumental criteria, we think that ultrasounds can show better the amount of reduction of fibrosis in lymphedematous tissues from the morphological point of view. Lymphoscintigraphy is useful to evaluate the functional improvement of the drainage of lymph at the areas of fibrosis (reduction of dermal back flow)⁶. Laser-Doppler gives precise information on the benefit effects of the therapy on blood microcirculation and thus is considered an indirect sign of decrease of fibrotic component of tissues.

In conclusion, in our preliminary clinical experience, LPG technique showed to be a valid method to reduce and soften fibrosis in chronic extremity lymphedemas after reducing edema volume by physical therapies associated to microsurgery.

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