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 muscluar 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.

ndermologie[®] (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. 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

From the Division of Plastic and Reconstructive Surgery, a UCLA School of Medicine, Los Angeles, CA, and a private plastic surgery practice in Los Angeles, CAb.

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Reprint requests: James P. Watson, MD, UCLA School of Medicine, Division of Plastic and Reconstructive Surgery, 200 UCLA Medical Plaza, Suite 465, Box 956960, Los Angeles, CA 90095-

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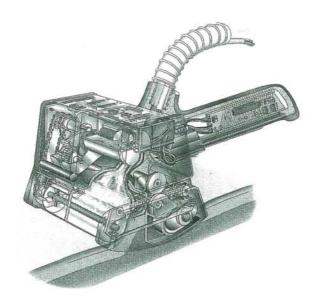


Figure 1. Mechanical drawing of the Endermologie® handpiece. Courtesy LPG Endermologie USA.

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

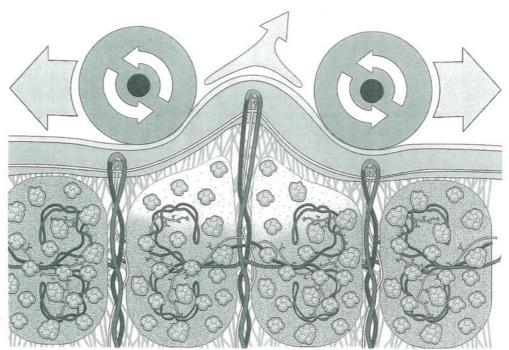


Figure 2. Stylized illustration of the effect of the mechanical rollers and suction on the skin, retinaculae cuti, and adipose tissue.

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 retinaculae 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 × 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 examination 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

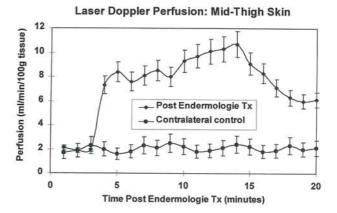


Figure 4. Laser Doppler skin perfusion of right thigh skin after 20 minutes of Endermologie® (patient 2).

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

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Ultrasound Doppler Flow: Greater Saphenous Vein

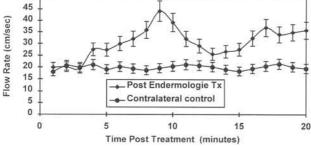


Figure 5. Color-flow ultrasound Doppler velocity of greater saphenous vein after 20 minutes of Endermologie® (patient 3).

Ultrasound Doppler Flow: Common Femoral Vein 60 50 Post Endermologie Tx Contralateral control Flow Rate (cm/sec) 40 30 20 10 0 20 0 10 15 Time Post Endermologie Tx (minutes)

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

Lymphoscintigraphy: 3 Hours Post Endermologie®

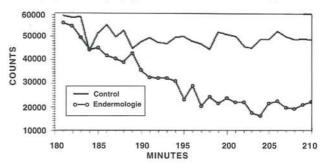


Figure 7. Lymphoscintigraphy quantitative counts of technetiumlabeled dextran 3 hours after Endermologie® treatment, with untreated control (opposite lower extremity).

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 longterm 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

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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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