

The "Lymphapress" - A New Pneumatic Device for the Treatment of Lymphedema: Clinical Trial and Results

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SUMMARY

The "Lymphapress" - A New Pneumatic Device for the Treatment of Lymphedema: Clinical Trial and Results

The "Lymphapress" is a new intermittent pneumatic machine which in our experience has more physiological effect than the conventional machines. In a series of 25 women with post-mastectomy lymphedema, reduction of edema between 36% to 70% by using volume and circumference measurements was found in 80% of the patients. The almost complete absence of side effects as well as the satisfactory results obtained recommend the use of this machine as an effective device for the treatment of lymphedema.

ZUSAMMENFASSUNG

„Lymphapress“ - Ein neues pneumatisches Gerät für die Therapie des Lymphödems

Das Gerät „Lymphapress“ ist ein neuer, pneumatisch gekammerter Apparat, welcher - nach unserer Erfahrung - einen durchgreifenderen und physiologischeren Erfolg hat, als die konventionellen Geräte.

In einer Serie von 25 Frauen mit post-mastektomiertem Lymphödem wurde eine Verminderung des Ödems von zwischen 36 bis 70% in Volumen- und Umfangmaßen festgestellt.

Das fast vollständige Fehlen von Nebenerscheinungen, wie auch die befriedigenden Therapieerfolge, lassen den Gebrauch dieses Gerätes als eines zweckmäßigen Instrumentes in der Behandlung des Lymphödems empfehlenswert erscheinen.

RESUME

Le Lymphapress un nouveau appareil pneumatique pour le traitement des Lymphoedems: experience clinique et resultats

Le Lymphapress est un nouvel appareil pneumatique séquentiel qui selon notre expérience, a un effet plus physiologique que les appareils conventionnels. Sur 25 femmes souffrant d'un lymphoedème après mastectomie, 80% d'entre elles ont eu leur oedème réduit de 36 à 70%, mensurations prises après l'application.

L'absence totale de complications ainsi que les résultats satisfaisants obtenus recommandent l'utilisation de cet appareil qui représente un moyen efficace de traitement des lymphoedèmes.

Introduction

Carcinoma of the breast is the most common cancer among women, six percent of whom, all over the world, will develop the disease (1). Almost three-quarters of these patients undergo surgery by one of the accepted procedures: either radical or modified mastectomy or simple removal of the breast, followed by radiation treatment and/or chemotherapy in a considerable number of cases. Lymphedema of the arm occurs frequently as a complication of the surgery itself or of radiation treatment. According to the literature its incidence varies between 20% to 70% (2-7). This complication makes daily life difficult because of the functional disability of the limb; it presents an obvious cosmetic problem and constitutes a convenient target for local infection (erysipelas) which exacerbates the lymphedema by the destruction of the remaining lymph vessels. Another complication to be mentioned although rare, is malignancy of the skin (pseudo-kaposhi) following longstanding lymphedema (8).

The treatment of lymphedema has always presented a challenging problem; in fact, to date, there has been no treatment able to solve it radically. The conventional

conservative treatment such as arm lifting, diuretics, massages and bandaging of the arm are of limited effectiveness (9, 10, 11). The results of the various surgical procedures published up to date leave much to be desired (12). About twenty five years ago, treatment of lymphedema by pneumatic compression was introduced. These pneumatic machines worked on the principle of a sleeve wrapped around the swollen arm, emptying and refilling intermittently at relatively low pressures (60-90 mmHg). Results of the published reports indicate that these machines reduce only approximately 30 per cent of the swelling (9).

Since pneumatic compression appeared to us a very logical treatment we were surprised by the relatively poor results obtained. We realized that: a) by compressing air into a single-compartment sleeve, compression is applied equally to all the points and in all directions according to Pascal's law so that only a part of the flowing lymph is directed proximally via the remaining lymphatic pathways of the shoulder and the arm. The result is that a good part of the great pressure entering the sleeve is wasted thus diminishing its effectiveness; b) the moving pressure cycle in the sleeve is of too long duration causing great discomfort to the patient thereby

preventing the advantages which could be gained by the use of high pressure.

With this in mind we develop a new instrument — "The lymphapress" with the purpose of improving results of the pneumatic treatment.

Technical Details

The lymphapress is constructed of a carpet adapted into a tight sleeve which is fitted to the arm and contains 9 to 12 cells according to the length of the arm. In order to avoid any gaps between the functioning cells during their inflation we constructed them so that they overlap one another, the overlapping comprising one third of each cell providing a smooth outflow. The cells are inflated starting from the first distal cell, then the second, the third and so on, successively. When

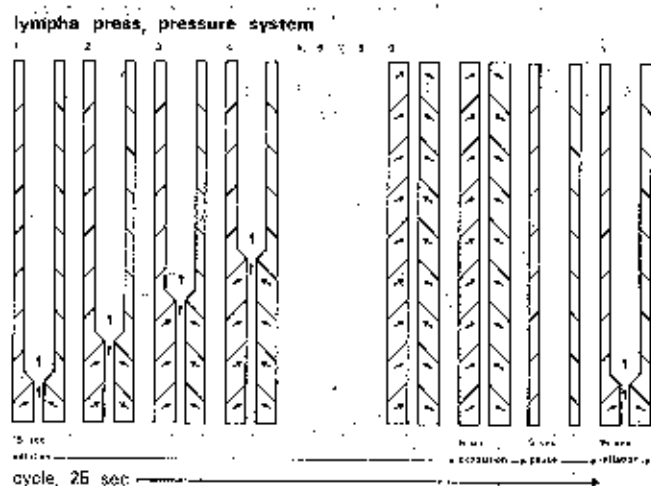


Figure 1:
The cycle of the lymphapress. Note the overlapping of the cells. Inflation time 15 sec., exposition 5 sec., pause 5 sec., Total cycle 25 sec.



Figure 2:
The lymphapress during treatment

the whole sleeve is filled with air all the cells empty themselves automatically and simultaneously. The duration of the cycle including the intermission is twenty-five seconds of which the compression period is twenty seconds (Figure 1). Due to the short duration of the cycle it is possible to use much higher pressures than usual up to 120–160 mmHg, without causing discomfort to the patient. The source of pressure is derived from a compressor and a distributor which feeds each cell separately. In this way successive inflation generates a sort of milking mechanism (Figure 2).

Clinical Assessment

In order to assess this instrument we hospitalised (Department of Surgery) 25 patients who suffered from lymphedema of the arm, 20 of whom had been treated for many years with the conventional pneumatic machines. The main purposes of this trial were as follows:

- To assess the reduction of lymphedema by measuring the volume and the circumference of the arm;
- To check the drainage of the lymph following the treatment with the help of radioactive albumin;
- To check the influence on the arterial tree during treatment with the help of photoelectric plethysmography;
- To assess influence of the treatment on the muscles by examining the serum enzymes: lactic dehydrogenase, transaminase, creatinin phosphokinase and aldolase.

Material and Anamnestic Data

We examined 25 patients, among whom 17 (68%) were between 40–50 years of age, 72% had undergone radical mastectomy and 28% underwent modified mastectomy. 14 women (56%) were up to 5 years after surgery and 11 women (44%) from 5 to 20 years. In 4 women (16%) axilla was negative, in 18 positive (72%) and in 3 women no results were known. All these patients received radiation therapy after surgery. 18 patients experienced recurrent erysipels on the swollen arm.

Lymphedema appeared immediately following surgery in 11 women (44%) whereas in 14 women (56%) it appeared after the first year.

The patients chosen for our trial were hospitalized for three days during which they received compression therapy.

Physical findings

• The consistency of the oedema which was found to be hard in 22 patients (88%); in only 3 women (12%) was the consistency found to be somewhat softer.

• The circumference of the limb was measured at three points: wrist, mid-forearm and mid-arm. The differences between the swollen limb and the healthy one varied from 3 cm to 22 cm, the average difference in the entire group being 9 cm.

- The volume of the arm was measured by the method of water displacement. The differences between the affected limb and the health one varied between 150 cc to 3100 cc within average difference of 1282 cc.

- Phlebography was performed in order to rule out venous occlusion in 15 patients.

- All patients underwent blood tests before and after treatment in order to evaluate serum transaminase, lactic dehydrogenase, aldolase and creatinine phosphokinase.

- Digital plethysmography was performed during the treatment of 15 patients in order to assess the influence of the pressure on the arterial flow of the limb.

- Two millicuries of serum radioactive albumine was injected into the dorsum of both palms of 10 patients and the radioactivity measured after injection, 24 hours later, and two hours after the pneumatic treatment.

Treatment

During their three-day hospitalization, all the patients were subjected to three compression sessions a day of 2-3 hours each, with sleeve pressure of 100 to 150 mmHg.

Following this intensive treatment the patients were kept on a maintenance schedule of one to four sessions per week of two hours each. At the end of a six-month period the results were studied.

Results

Oedema was determined by the differences in circumference or volume between the swollen and the healthy arm.

$$\text{Reduction of oedema} = \frac{\text{Reduction of oedema after treatment} \times 100}{\text{Oedema before treatment}}$$

The following tables demonstrate the results achieved after three days of intensive treatment. Those results remained constant after six month with the weekly treatment.

Table 1:
Reduction of oedema as represented by decrease of circumference of arm

% of Decrease of oedema	No. of Patients	% of Patients
Less than 35%	3	12
36-50	9	36
51-70	13	52

Table 2:
Reduction of oedema as represented by decrease of volume

% of Decrease of oedema	No. of Patients	% of Patients
Less than 35	7	28
36-50	7	28
51-70	11	44

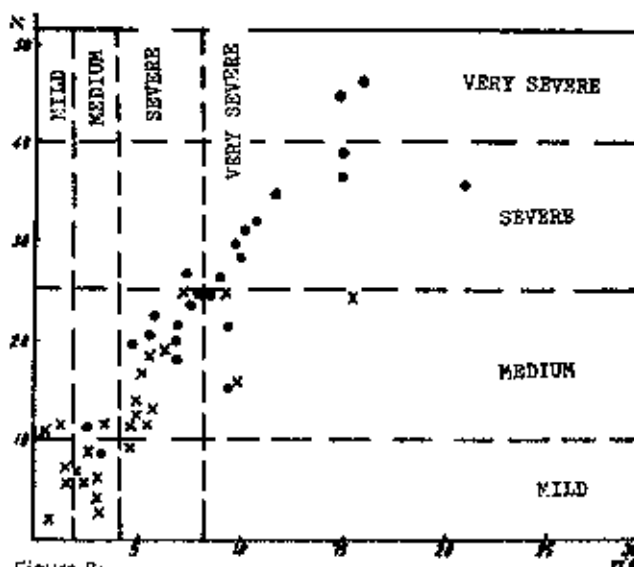


Figure 3:
Circumference parameter
Black dots = patients before treatment
x's = patients after treatment

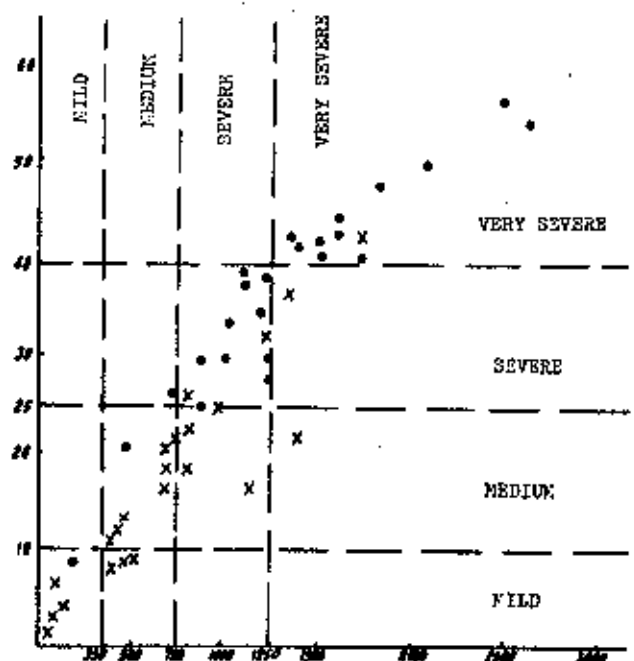


Figure 4:
Volume parameter
Black dots = patients before treatment
x's = patients after treatment

Table 1 shows favorable response to treatment according to parameter of circumference; in 88% of the patients (22 women) reduction between 36 to 70% was achieved. Figure 3 illustrates the patient's group before and after treatment.

Table 2 shows the results after treatment according to parameter of volume. In 72% of the patients (18 women) a reduction of volume of lymphedema between 36 to 70% was achieved. Figure 4 illustrates those results.

The mean results according to those two parameters of circumference and of volume shows a reduction of 36% to 70% of lymphedema in 80% of the patients.

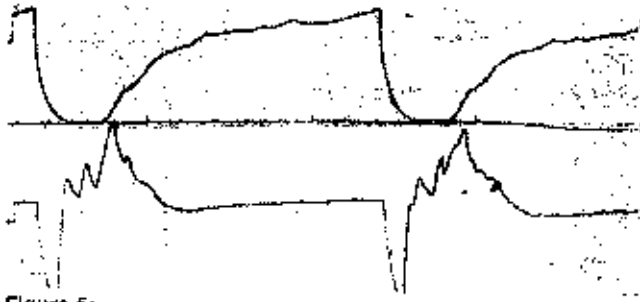


Figure 5:
Digital plethysmography during treatment
The upper curve represents the rising pressure of the air cells on the arm (120 mm Hg in this case)
The lower curve shows the plethysmography appearing during the pause. This, together with one short 25 sec. cycle, may explain the absence of pain during lymphapress treatment using relatively high pressure

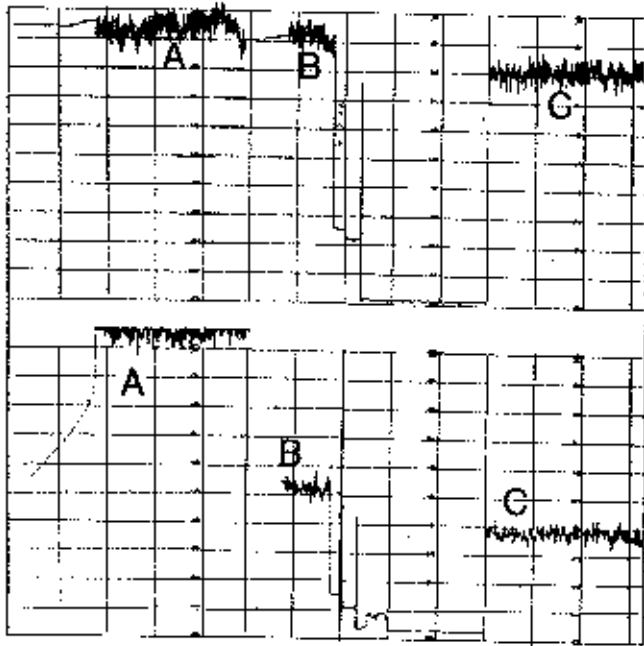


Figure 8:
Radioactive albumin clearance of both arms: The upper part of the photograph shows lymphedematotic arm; the lower part, the unaffected arm
A: CPM immediately after injection of 2 millicurie of radioactive albumin
B: CPM after 24 hours
C: CPM two hours after pneumatic treatment with the lymphapress
After 24 hours there is almost no change in CPM in the affected limb. Note the marked reduction after 2 hours of treatment which corresponds to the physiological reduction in the normal limb

The consistency which had been firm in 88% of the patients remained so in only 8% after treatment.

Phlebography performed in 15 patients showed them to be normal.

Serum enzymes: there was no elevation in transaminase and in lactic dehydrogenase. Creatinine phosphokinase values showed a 100% increase in 68% of the patients immediately following treatment.

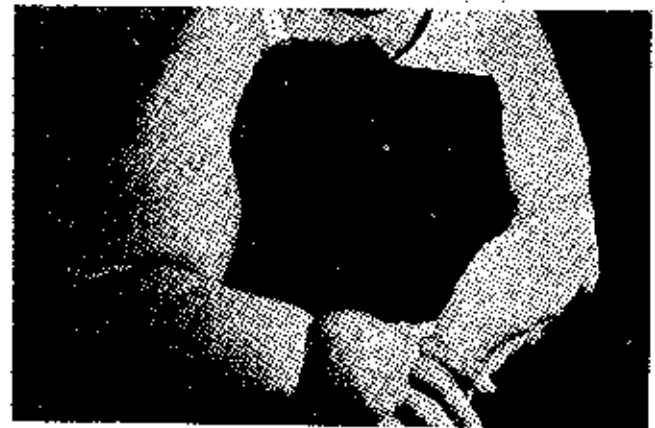
In 88% of the patients aldolase was found increased by over 100% after treatment. This increase may be due to the relative hypoxia and also to the direct pres-

sure on the muscle, with the resultant release of enzymes into the blood stream.

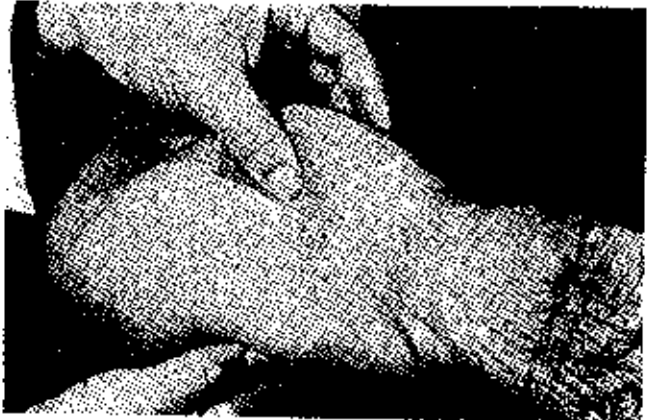
Three days after treatment the count of elevated serum enzymes returned to normal in all the patients.

Digital plethysmography was used in order to assess arterial circulation to the limb during the treatment (Figure 5). The short duration of the cycle may explain the fact that the patient had no discomfort during the treatment. This may be explained by the free flow of the arterial blood during the intermission phase which relieves the pain associated with the relative ischemia of the limb during the inflation phase.

Figure 7:
a) Post-mastectomy lymphedema 16 years after radical mastectomy



b) + c) The arm and the hand after six hours of treatment (one day)



The radioactive albumin clearance showed that the milking effect of the "lymphapress" on the affected limb (during treatment) produces almost the same quantity of lymphatic drainage as in the healthy limb (Figure 6).

Figures 7 a, b, c show post mastectomy lymphedema before (Figure 7 a) and after treatment (Figures 7 b and c) with the lymphapress.

Side effects

Six patients complained of pain in the arm shortly after the treatment was started; in four patients the pain subsided spontaneously without changing the pressure of the sleeve. A reduction of the pressure by 30 mmHg relieved the pain felt by the remaining two patients. Three patients complained of a sensation of heat all over the body although this was not accompanied by any rise in the body temperature. The sensation subsided spontaneously after a short period of time. Marked polyuria was noted in all the patients during the first three days of the treatment.

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