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BRIEF COMMUNICATION

DEVELOPMENT AND EVALUATION OF A NEW APPARATUS FOR LYMPH DRAINAGE: PRELIMINARY RESULTS

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ABSTRACT

Due to the lack of a specific treatment apparatus that enhances lymph flow, we developed a simple, easy-to-use, portable device for patients presenting with lower extremity lymphedema. The aims of the present study were to demonstrate the design and operation of the equipment and to test its efficacy. The new apparatus encourages articulation of the ankle and contraction of the muscles of the calves and feet. Eight patients with clinically diagnosed primary or secondary lymphedema were imaged by lymphscintigraphy before and after one week of using the apparatus. The images were evaluated by two experienced nuclear medicine physicians blinded to the other's results. An improvement in the lymphscintigram images was seen in all patients evaluated. This preliminary study suggests that the new apparatus was easily tolerated, enhanced lymph flow as assessed by lymphscintigraphy, and may have benefits as an adjunctive treatment. Further clinical studies are necessary to fully evaluate its use.

Lymphedema is caused by failure of the lymphatic system to remove interstitial liquids and substances (1). It can be a chronic disease without ideal clinical treatment options, although treatment can limit and control its evolution. The principal therapies to reduce the effect of lymphedema include drugs, manual lymph drainage, compressive bandaging and garments, pneumatic pumps, and lymphatic-directed exercises and care for day-to-day life (1-8). The use of equipment which promotes lymph drainage could help the patient control the lymphedema both in and outside the home. However, few devices which fulfil these characteristics are marketed at this time making this option difficult. Further studies in this area are needed, and we undertook this study to evaluate by lymphscintigraphy a new apparatus to enhance lymph flow.

Eight patients (3 male, 5 female; age range 19-56, mean=49) were entered into the study. The patients voluntarily agreed to participate in the study. However, the Research Ethics Committee at our institution was not yet in existence prior to the study and accordingly official consent forms were not obtained. Patients presented with either primary or secondary (grade I and II) lymphedema as diagnosed by clinical and lymphscintigraphic evaluation. Lymphscintigraphy was obtained by the intradermal administration of 500 mCi (20 Mbq) of 99mTc antimony sulphate colloid in the second interdigital space of each foot. Scintigraphy was performed 50 minutes after the administration of the colloid using a

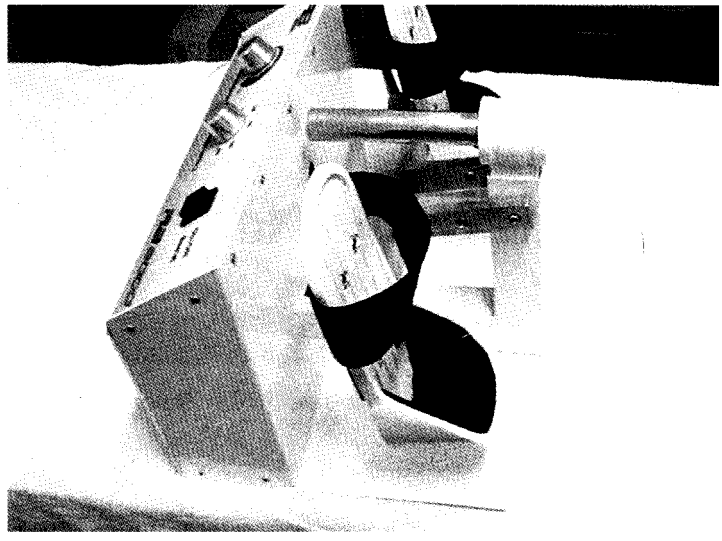

Fig. 1. Photograph of the new apparatus of passive exercise for the lower limbs used by subjects in this study.

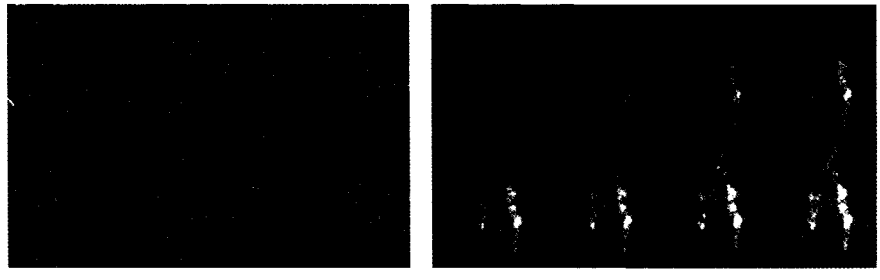

Fig. 2. Pelvic lymphscintigrapic images of one patient before (left) and after (right) one week of use of the new apparatus. Note tracer transport into pelvic lymphatics and nodes after but not before treatment.

computerized gamma camera (Elscint SP 4, Haifa). Following the initial lymphscintigram, each patient used the apparatus (*Fig. 1*) for a period of one week (3 hours per day) with no other treatments. The apparatus is designed to encourage articulation of the ankle and contraction of the muscles of the calves and feet and is used at 25 to 30 cycles per minute. A follow-up lymphscintigram was obtained after this treatment period. Two experienced nuclear medicine physicians, blinded to each other, evaluated the images for improvements in lymph flow.

The apparatus was well tolerated by all patients who felt relaxed with its use and reported no problems. Volumetric evaluation of the lymphedematous limbs demonstrated significant reduction at one week compared to controls (138.3 ml vs. 26.6 ml, p=0.029) (9). In all patients a subjective improvement (data not shown) was seen in the dynamic lymph flow as demonstrated by lymphscintigraphy compared with the initial (control) image (*Fig. 2*). In three patients with bilateral lymphedema and one leg demonstrating limited lymph flow on the initial image,

improvement in flow was also seen in this leg (data not shown).

The apparatus functions by passively reproducing the physiological movements of the contractions of the musculature of the calves and feet. The musculature of the calf is considered to be a "pseudo" venous heart, and it could represent a "pseudo" lymphatic heart as a possible mechanism of action for external contraction. Another possible mechanism is the intrinsic stimulation, which give the lymphangions the capacity of a "mini lymphatic heart." During walking exercises, the contraction of the calf muscles can impose a pressure of between 200 and 300 mmHg on the vessels which are inside the muscle and between 100 and 150 mmHg on the vessels between the muscles (10). In addition, the decubitus position reduces the gravitational pressure imposed on the lower limbs and may also facilitate the return of the veno-lymphatic system. In future trials, a non-elastic garment may be incorporated with this technique to increase the pressure in the subcutaneous compartment and possibly increase the enhancement of the lymph flow.

This preliminary study has shown that the apparatus was well tolerated by patients and subjective, qualitative improvements in lymph flow assessed by lymphscintigraphy and mild reduction in lymphedema volume were seen in patients with lymphedema of the lower limbs. Further clinical testing and carefully controlled trials will be needed to confirm and expand these results.

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