The effectiveness of three external pneumatic compression (EPC)devices was examined in a clinical setting, within the context of the non-surgical management of lymphedema in a paediatric population. Volumes of the lower leg and circumferences at the upper calf were measured in nine patients with lymphedema involving one of the lower extremities. Values were recorded before and after pump-down on an inpatient basis in eight children and on an outpatient basis in nine children for a maximum period of 24 months. Before-and-after volumetric measurements were taken by recording water displacements, and circumference values were based on girth measurements. Although the trends indicated improvement for all three EPC devices, the Lympha-Press and Wright Linear Pump were more effective in reducing the edema over time. The Hemaflo 2 was inadequate and mechanically unreliable. The Lympha-Press was easier to use and teach to families. The addition of an EPC device to a non-surgical management program helped improve the quality of life in paediatric patients with lymphedema.

KEY WORDS: Congenital lymphedema, intermittent external pneumatic compression, volumetry

L'efficacité de trois dispositifs de compression pneumatique externe (EPC) a été examinée en milieu clinique, dans le cadre du traitement non chirurgical du lymphoedème en pédiatrie. On a mesuré le volume de la jambe inférieure et la circonférence de la partie supérieure du mollet chez neuf patients atteints de lymphoedème de l'une des extrémités inférieures. On en a enregistré les valeurs avant et après la pressothérapie, chez huit enfants hospitalisés et chez neuf enfants en service externe pendant une période maximale de 24 mois. On a pris les mesures volumétriques avant et après l'intervention, en inscrivant les déplacements hydriques, et les mesures étaient basées sur les mesures de la circonférence. Même si les tendances ont indiqué une amélioration des trois dispositifs EPC, la Lympha-Press et la pompe linéaire Wright étaient les plus efficaces pour réduire l'oedème au cours d'un certain temps. L'Hemaflo 2 était inadéquat et mécaniquement non fiable. La Lympha-Press était plus facile d'emploi et il était plus facile d'enseigner aux familles de s'en servir. L'addition d'un dispositif EPC à un programme de gestion non chirurgicale a aidé à améliorer la qualité de vie des enfants atteints de lymphoedème.

A CLINICAL REPORT ON THE USE OF THREE EXTERNAL PNEUMATIC COMPRESSION DEVICES IN THE MANAGEMENT OF LYMPHEDEMA IN A PAEDIATRIC POPULATION

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Lymphedema, chronic swelling of an extremity, can have serious complications, including skin lesions, fibrosis and an increased risk of infections owing to the accumulation of protein-rich fluid in the interstitial spaces.[1,2] In the paediatric population, primary lymphedema resulting from abnormal development of the lymphatic system is the most common form. Cases of secondary lymphedema due to obstruction of the lymph vessels and nodes by malignancy are also encountered. Non-surgical management of lymphedema has been well documented.[2-9,11]

The physiotherapist working with patients with lymphedema is involved in making decisions about treatment. This report investigates the management of lymphedema as described in the literature, discusses our clinical experience at The Hospital for Sick Children, and examines the suitability of three external pneumatic compression (EPC) devices: the Lympha-Press, the Wright Linear Pump and the Hemaflo 2.

BACKGROUND

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Review of the literature on non-surgical management of lymphedema indicates consensus that the best treatment is elevation of the affected limb (where possible), compression, massage, specific activity to promote the muscle pump action, and the use of EPC devices.[6,12] Although the literature has focused almost exclusively on the adult population, one case report by Alexander et al[7] describes the non-surgical management of congenital lymphedema in a nine year old girl. In the clinical experience of The Hospital for Sick Children, the outcome of such conservative management of infants and children presenting with lymphedema has been encouraging. Early intervention helps control accumulation of lymph fluid, thus limiting or preventing secondary changes associated with this condition. Both our clinical experience and the literature[6] suggest that lymph flow and drainage are not completely blocked and that treatment to increase interstitial and intraluminal pressures produce enough centripetal force to enhance lymph flow.

Although there are various EPC devices on the market,[7-10] the literature offers little to educate physiotherapists or other health professionals about selection criteria in recommending an effective device for patients with lymphedema.[4,8] Comparison of various EPC devices is limited to a study by Zanolla et al, [11] whose evaluation of treatment methods for post-mastectomy lymphedema included two types of EPCs. However, results obtained in that study cannot be extrapolated to lymphedema of the lower extremity.

**MECO AFEK, Haifa, Israel*
+Wright Linear Pump, Pittsburg, PA, 15205
***Model 7055 CAMP International Inc., Jackson, MI, 49204.*

Moreover, in the post-mastectomy population the lymphatic vessels were functioning normally before surgery, whereas in congenital lymphedema the lymphatics may be aplastic, hypoplastic or hypertrophied with incompetency.

To examine the EPC device that may be most appropriate for use in the non-surgical management of lymphedema in children, we undertook a clinical trial of the three multicompartment EPC devices referred to earlier. Percentage changes in volumetric and circumferential measurements were used to reflect the patients' responses over time.

METHOD

SUBJECTS

The clinical trial was carried out on nine children (seven female, two male) with lymphedema of one lower extremity. Eight of the selected patients had congenital lymphedema and one had lymphedema secondary to excision of Hodgkin's lymphoma followed by radiation to the area. Six patients had the right lower extremity affected, three the left.

Informed consent was obtained from the patients or their parents before participation. A detailed history was taken of duration of lymphedema, incidence and frequency of previous infections in the involved extremity, previous treatments by other mechanical compression devices, and use of pressure gradient stockings. Three of the nine patients had used a single-cell compression device on the involved extremity but had discontinued use before the examination period. All the patients had continued to use a customized elastic support stocking.

EQUIPMENT

Three types of EPC devices were used in this study. The first was the Hemaflo 2, a three-cell sequentially inflated unit that provides pressures ranging from 30 to 120 mmHg. The commercially available compression sleeve was inflated distal to proximal with a uniform pressure setting and a total cycle time (inflation/deflation/pause) of 5 minutes.

The second device, the Wright Linear Pump, was a triple-compartment, sequentially inflating unit that required a custom-made compression sleeve. In order to establish compression levels for this pump, the mean of the diastolic and systolic blood pressures was recorded for each patient. This figure was used to

Table 1

Characteristics of the patients using each external pneumatic compression device *

	Mean age at onset (years)	Mean age at study (years)	Number of follow-up visits	Length of follow-up (months)
Hemaflo	5.6	16.6	4.7	5.3
	± 7.7	± 1.3	± 1.2	± 2.3
Wright Linear	2.0	10.8	8.7	26.0
	± 2.6	± 7.1	± 5.5	± 9.5
Lympha-Press	3.0	14.7	10.0	19.5
	± 5.5	± 4.8	± 4.3	± 7.9

*n=3 with each device

Table 2

Mean Percentage Decrease in Volume and Circumference Following Treatment during Inpatient Period*

	Decrease in Volume (mean ± SD)	Decrease in Circumference (mean ± SD)
Lympha-Press, Group 1	77.0 ± 57.0	33.0 ± 25.0
Wright Linear Pump	38.0 ± 26.0	60.0 ± 15.0
Hemaflo 2	20.0 ± 11.0	8.5 ± 2.5
Lympha-Press, Group 2†	31.0 ± 25.0	12.0 ± 7.0

*n=3 for Lympha-Press and Hemaflo 2 units, and 2 for Wright Linear Pump

†The patients on the Hemaflo 2 were transferred to the Lympha-Press at 4 months after the Hemaflo units malfunctioned.

Table 3

Percentage Increase of Volume and Circumference Measurements Over Normal Values in Subjects Using the Hemaflo 2*

Time of Measurement	Volume (Circumference) for Subjects		
	1	2	3
Initial Assessment	18 (10)	84 (49)	177 (59)
1 month	8 (7)	55 (36)	140 (59)
2 months	13 (13)	61 (34)	144 (55)
3 months	21 (14)	60 (33)	154 (54)
4 months	26 (13)	76 (40)	154 (48)

*Normal values were determined by measurements of the subject's unaffected leg.

establish the maximum pressure setting in the distal chamber of the pneumatic compression sleeve for each patient. The pressure in each of the next two chambers was set at 20 mmHg lower than in the previous one. The total cycle time was 120 seconds, representing an inflation time of 90 seconds and a deflation and pause time of 30-seconds.

The third unit was the Lympha-Press, which provides a pressure-wave massage through 9 to 12 overlapping cells, resulting in a distal to proximal "milking" action. The total cycle time was 30 seconds with a pressure range of 30-200 mmHg. The devices were assigned randomly to the patients.

PROTOCOL

Eight of the nine patients were admitted to hospital for assessment and one was assessed on an outpatient basis.

An inpatient assessment consisting of a cardiology consultation was performed to rule out any evidence of decompensatory heart function or the presence of deep venous thrombosis or acute infection in the involved limb, thus establishing an EPC device could be safely used. Limb volume and girth measurements were recorded in a uniform fashion. The volumes of both extremities were obtained by immersing the fully extended leg to the base of the patella in warm water and recording the volume displaced in cubic centimeters. Limb girth measurements were obtained at specific sites. The lower leg, from the base of the patella to the tip of the medial malleolus, was divided into thirds. The most proximal point, the one in the upper calf, was used to calculate the circumference of the legs. The inpatient treatment consisted of a two-day period of bed rest, with elevation of the involved extremity. A schedule of two hours on the pump and one-half hour off was followed during waking hours; overnight, the limb was pumped continuously for six hours. On the third day, volume and circumference measurements were repeated by the same examiner. The patients were then discharged.

The outpatient component of the study consisted of a home program of overnight pumping and daily step-up exercises for five minutes. All patients continued to wear an elasticized support stocking during the day. The patients were assessed once a month for the first four months, every other month for the next two, and once every four months thereafter. Both volumetric and circumferential measurements were taken by the same therapist at each visit.

RESULTS

BASELINE DATA

Three patients were assigned to each EPC unit. However, when all three Hemaflo 2 units malfunctioned after four months, these patients were incorporated into the Lympha-Press group. Members of the three groups were similar in age both at the onset of lymphedema and time of evaluation (Table 1). The mean age at onset of the disease was 2.6 years (range 0 to 14) and mean age at the start of the study was 13 years (range 5.5 to 17).

The follow-up period and number of outpatient evaluations were similar for the Wright Linear Pump and Lympha-Press units, but differed for the Hemaflo 2 unit.

Based on the manufacturer's recommendations, the mean pressure settings were 43 mmHg for the Hemaflo 2 unit, 85/65/45 mmHg from distal to proximal for the Wright Linear Pump and 122.5 mmHg for the Lympha-Press. The lower pressure for the Hemaflo 2 was due to its long cycle time compared to the other two units.

Inpatient Evaluation

Responses of the eight patients to the three devices were assessed by calculating the percentage difference between the volumes and circumferences in the involved and normal limbs, using the following formula [13]:

$$\left(\frac{\text{Volume or Circumference of involved limb}}{\text{Volume or Circumference of normal limb}} \times 100\right) - 100$$

Table 2 illustrates the change noted in all groups during the inpatient trial.

Outpatient Evaluation

Using the same formula, the changes in volume and circumference were calculated for the Hemaflo 2 for four months (Table 3). Data were collected for

Table 4

Percentage Increase of Volume and Circumference Measurements Over Normal Values in Subjects Using the Lympha-Press*

Time Measurement	Volume (Circumference) for Subjects					
	Group 1			Group 2†		
	1	2	3	4	5	6
Initial Assessment	200 (89)	78 (34)	169 (94)	24 (16)	81 (48)	178 (60)
1 month	60 (27)	67 (30)	na	29 (15)	67 (36)	150 (51)
2 months	72 (33)	51 (27)	na	17 (11)	62 (37)	147 (48)
3 months	58 (31)	50 (24)	na	16 (12)	64 (31)	134 (47)
4 months	75 (48)	51 (22)	127 (47)	24 (17)	58 (35)	114 (40)
12 months	71 (33)	46 (24)	105 (52)	22 (14)	24 (33)	123 (43)
18 months	56 (34)	47 (27)	83 (37)	22 (20)	24 (26)	na
24 months	na	43 (19)	na	13 (12)	na	135 (46)

*Normal values were determined by measurements of the subject's unaffected leg.

†Subjects in Group 2 were transferred to the Lympha-Press when the Hemoflo 2 units malfunctioned after 4 months.

na=not available