CHAPTER **36**

THE USE OF THE AIRCAST EDEMAFLOW™ LEG BRACE IN THE TREATMENT OF LYMPHEDEMA

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The International Society of Lymphology defines lymphedema as an abnormal collection of excessive tissue proteins, edema, chronic inflammation and fibrosis.[1] All edema, irrespective of the underlying cause, is due to an imbalance between capillary filtration and lymph drainage. Lymphedema occurs when tissue swelling develops through a failure of lymph drainage in the presence of normal lymph load (capillary filtration). Cellular and biochemical changes associated with lymphedema also contribute to its formation. Although macrophages accumulate in the edematous tissues, their proteolytic activity is suppressed. Fibroblasts are also present in increased numbers, but collagenase and other proteolytic enzymes are decreased. This leads to the deposition of collagen and fibrinogen in the subcutaneous tissues, causing the fibrotic changes of brawny edema.[2]

Lymphedema is divided into primary and secondary forms. The primary form may occur as an isolated congenital defect (simple congenital lymphedema), or it may be familial (Milroy's disease or heredofamilial congenital lymphedema). Both of the primary types result from a congenital malformation of the lymphatic vessels (aplasia, hypoplasia, or hyperplasia), and are present from birth. Classically, these disorders involve the lower extremities. A third form of primary lymphedema, known as lymphedema praecox or Meige's disease, usually appears in females between the ages of 10 and 25 years. When it occurs after the age of 35, primary lymphedema is known as lymphedema tarda.[3]

Secondary lymphedema is acquired, and most commonly occurs after a lymphadenectomy in western countries, and in conjunction with parasitic infections such as filariasis worldwide. Other causes of secondary lymphedema include post-inflammatory scarring of lymphatic channels, spread of malignant neoplasms with obstruction of either the lymphatic channels or nodes of drainage, and post radiation fibrosis. Lymphedema is graded according to the criteria of the International Society of Lymphology.[4] Grade 1 denotes pitting edema and reversibility upon elevation; Grade 2, non-pitting edema, fibrosis and irreversibility; and Grade 3, elephantiasis.

The objectives of treatment for lymphedema are to reduce swelling, restore shape, and prevent progression of disease and inflammatory episodes. There are essentially three approaches to lymphedema treatment: physical therapy, drug therapy and surgery.[5] The principle goal of physical therapy is to reduce excessive capillary filtration and improve drainage of interstitial fluid/macromolecules from edematous regions. This is attained through a combination of compression by elastic stockings and pneumatic compression therapy, exercise and massage, or complex and comprehensive lymphedema therapy. These measures encourage lymph flow through collateral lymphatics, and thus lessen the incidence of secondary acute inflammation.

A consensus document on the diagnosis and treatment of peripheral lymphedema, published in 1955 by the International Society of Lymphology Executive Committee[6] recommended comprehensive lymphedema therapy (CLT) as the initial treatment for lymphedema. Theoretically, CLT increases collateral pathways and thereby facilitates drainage to the functioning lymphovenous circulation. This conservative, noninvasive and safe treatment incorporates two phases. The first phase consists of local skin care, manual lymphedema treatment, exercises and compression. Phase 2 focuses on conserving and optimizing the reduction obtained in phase 1. This is achieved through compression with elastic stockings or sleeves, skin care, physical therapy, and repeated manual lymphedema treatment as necessary.

External pneumatic compression therapy, through a single (unicompartmental) or multiple cell sleeve garment, provides a safe and effective treatment for lymphedema. There are three important variables influencing the degree of reduction achieved by external pneumatic compression treatments: 1) absolute pressure, 2) compression cycle, 3) sequence and distribution of compression.[7] The single cell system administers equal compression to all points, but fails to provide a direction for the fluid flow; therefore retrograde flow may be experienced.[8] Also, unicellular devices use a short pressure cycle and the peak compression developed by the unit is usually low (60 mm Hg). In contrast the multiple cell system administers a short pressure cycle at high pressures (100 to 110 mm Hg) and distal to proximal pressure gradient, thus permitting a more physiologic milking action of the lymphedematous limb. Examples of commercially available multiple cell systems are SIPC (Lymphapress), three-celled Hemoflow II unit (Camp International Inc., Jackson, MI) and Wright Linear Pump (Wright Linear Pump Inc., Imperial, PA).

The prevention of subcutaneous fibrosis is directly related to the degree of reduction in girth that is achieved.[9] Previous studies have shown that the accumulation of protein rich lymphoid fluid alone induced an inflammatory reaction that leads to subcutaneous fibrosis.[10] Thus, earlier treatment of lymphedema is strongly recommended.

Drug therapy serves as an adjunct to treatment in the management of lymphedema. Diuretics and the coumarin/flavonoid (benzopyrones) group of drugs are most commonly used. Diuretics alone have very little benefit in lymphedema simply because their main action is to limit capillary filtration by reducing circulating blood volume.[5] Outside the United States, lymphedema has been treated successfully with benzopyrone, also known as coumarin.[5,6] Coumarin is the parent molecule of the dicumerol anticoagulants, but itself has no anticoagulant properties. It is hypothesized that the agent increases the number of tissue macrophages and their proteolytic activity. When the tissue protein is reduced, the osmotically held tissue fluid is reduced.[2]

Surgery for lymphedema is essentially of two types: debulking procedures to remove the fibrosis, and lymphatic microsurgery to reroute draining lymph into surrounding patent veins or lymphatic channels. With the long skin incisions and extensive dissection of subcutaneous tissue required for these procedures, the complication rate is significant. Given these results and improvements in physical therapy and commercially available noninvasive devices, most physicians treat lymphedema by nonsurgical means.

Lymphedema produces not only physical sequelae such as swelling, pain, decreased motor function, paresthesias and loss of mobility, but also medical problems such as recurrent infections, ulcer formation and depression. Treatment for lymphedema frequently is prolonged and restrictive, but every effort should be made to insure patient compliance.

MATERIALS AND METHODS

Aircast EdemaFlow™ Leg Brace

The system tested is the Aircast EdemaFlow™ Leg Brace. It provides intermittent pneumatic compression. This brace can be worn continuously in place of a compression stocking. When the patient is at rest, it can be connected to a compression pump for gradual sequential pneumatic compression. Unlike other systems that provide compression circumferentially, this device provides collateral compression with an elliptical pressure distribution.

Patients

Eleven patients with primary lymphedema were studied over a two-month to six-month period to determine the efficacy of the Aircast EdemaFlow™ Leg Brace in reducing pain and swelling. Nine patients included in the study had persistent complaints of swelling in one lower extremity for longer than two years, and two patients had bilateral complaints of persistent swelling. Their ages ranged from 35 years to 81 years with a mean of 56.83 years. In addition to the primary diagnosis of lymphedema in all studied patients, a number of secondary diagnoses were found including: post-phlebitic syndrome, post-surgical edema, Charcot arthropathy, tarsal tunnel syndrome, reflex sympathetic dystrophy, tendinitis, plantar fascitis, Charcot-Marie-Tooth atrophy, and non-union of a fracture. One of the patients studied had an open ulcer. There were no open skin ulcers in the remaining 10 patients.

Table 1

PRE-TREATMENT AND POST-TREATMENT GIRTH MEASUREMENTS IN INCHES

Patient	Pre Ankle	Pre Mid-Calf	Pre Thigh	Post Ankle	Post Mid-Calf	Post Thigh
BN	10.5	15.5	19.5	9.5	13.0	18.5
MA	5.0	12.5	13.0	7.0	11.5	12.0
EU	13.5	18.5	19.5	11.0	15.0	17.0
GL	8.0	14.0	17.0	8.0	12.5	19.0
DG (r)	12.0	15.0	18.0	9.0	14.0	18.0
DG (l)	12.0	15.5	18.0	9.0	15.0	18.5
WS	9.0	12.5	14.5	8.5	12.5	14.5
LM	10.0	18.0	21.0	8.0	15.0	18.0
MW (r)	9.0	15.5	15.0	9.0	15.0	15.0
MW (l)	9.0	15.5	15.0	9.0	15.0	15.0
SA	7.0	15.0	20.0	6.0	15.0	20.0
EM	9.0	17.0	20.0	10.0	16.0	18.5
KA	9.0	14.0	20.0	7.0	12.0	18.0

Table 2

PAIRED T-TEST RESULTS

	Mean Diff	DF	t-value	p-Value
Ankle	1.154	12	3.29	0.0065
Mid-Calf	1.308	12	4.18	0.0013
Thigh	0.654	12	1.734	0.1086

DISCUSSION

The Wright Linear Pump, Hadomer, and Lympha Press are all sequential pneumatic devices developed for the treatment of lymphedema.[2,5,7,8,11-13] They have been shown to be effective in reducing the girth of a limb affected by lymphedema. Hydrostatic pressure and manual massage have also reduced limb girth secondary to lymphedema.[2,4,5,14,15] There have been no clinical trials utilizing the Aircast EdemaFlow™ Leg Brace in treating lymphedema.

In this study, the Aircast leg brace did reduce ankle and mid-calf edema significantly when used one to two hours daily for a minimum of one month, and a maximum of four months. Thigh edema was not significantly affected, although there was an average reduction of 0.65 in. or 1.65 cm. Other studies have shown either increased edema at the level of the thigh, or less reduction when compared to the ankle and mid-calf.[8,11,15] The authors' results are consistent with results in

the literature. Several studies state that long-term use of a pneumatic compression device will result in further reduction in edema.[11,13]

Subjectively, the patients were satisfied with the results achieved with the use of the brace after a one to four month trial period. An overwhelming majority related decreased size of the affected limb and a reduction in pain. All but one patient intended to continue the use of the brace, and all but two would recommend it to someone who had the same ailment.

CONCLUSION

The Aircast EdemaFlow™ Leg Brace was effective in reducing ankle and mid-calf edema. As with other pneumatic systems the brace was less effective at reducing thigh edema. The device was well received by the patient population. The leg brace has the advantage of functioning both as a passive and a pneumatic assisted compression system. Once adjusted to the patient, the system is easily removed and replaced. Additional studies are required to study the long term affect of the system on limb girth and tissue elasticity.

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