Lymphedema Control for all Breast Cancer Survivors Summary Report (1/02)

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BACKGROUND

Between 20 and 30 % of breast cancer survivors develop lymphedema subsequent to their breast cancer and its treatment (Kiel,1996; Kissen,1986; Paci,1996; Petrak,1998). Lymphedema is defined as a collection of excess fluid, protein and debris in a body area, generally an arm or a leg. Chronic and currently incurable, lymphedema is caused from an inability of the lymphatic system to transport lymph fluid out of the affected area (Olszewski,1991; Mortimer,1998). In cancer-related lymphedema, decreased transport is usually a sequellae of breast cancer treatment including axillary node dissection and/or axillary radiation therapy. Occasionally, metastatic disease occludes lymphatic flow sufficiently to cause lymphedema without previous surgery or radiotherapy (Stanton,1996).

In spite of the large number of women living with lymphedema, significant deficiencies exist in lymphedema management (Smith & Zobec,2001). Two major deficits have been addressed in this project:

- Third party payer reimbursement for compression garments (Goins, 1998; Tanner, 1997)
- Standardized treatment outcome measurement (Gerber, 1998; Petrak, 2000; Sitzia, 1997)

THIRD PARTY REIMBURSEMENT FOR COMPRESSION PRODUCTS

Human skin, designed to expand as needed in order to maintain integrity, does not offer resistance to increasing edema. External compression provides resistant pressure on the skin and subcutaneous tissue to help prevent edema-related skin accommodation (Pallante,1994). Compression must be applied to the *entire* affected extremity. Currently, many types of compression products exist, ranging from non-stretch bandages (with or without padding), pneumatic compression pumps, semirigid support-type products (i.e. Reid & CircAid), and Compression sleeves and stockings (garments). Additionally, Manual Lymph Drainage, a specialized technique used to stimulate lymphatic fluid drainage, is often considered a form of compression therapy (Smith,1998).

Comparative research suggests that bandages are more effective for limb reduction than compression garments (Badger,2000; Mason,2001). Early descriptive research with semirigid support products (i.e. Reid Sleeve[™], Circ-Aid[™]) has demonstrated promising limb reductions over time (Radford,1996; Reid,1996,1998; Smith, 2001). The Contour Sleeve[™] is an adaptation of the Reid Sleeve[™]. This second-generation product does not qualify as semirigid support because it does not contain Velcro closures that delineate semirigid support products. Nevertheless, early research suggests the Contour Sleeve[™] is extremely effective at reducing and maintaining both mild and moderate lymphedema (Smith, 2001, 2002). *Mild lymphedema* signifies less than 20% excess volume in the affected limb over the opposite extremity. *Moderate lymphedema* refers to a 20 to 40 % volume excess in the affected extremity (Bernas, 2001).

Long-term benefits of compression include: edema control (Yasuhara,1996) and reduction (Badger,2000; Berlin,1999; Brorson,1998; Mason,2001), decreased accumulated protein, decreased arterial outflow into tissues, and improved lymphatic valvular function

(LeDuc,1990). Most compression products are bulky, tedious, time consuming, and/or detrimental to activities of daily living (i.e. household chores, employment, driving, care for children and/or other family members and social and recreational activities). Thus, daytime compression needs are generally best met through the use of compression garments (Berlin,1999; Pallante,1994), especially for patients with mild to moderate lymphedema.

All major international lymphedema schools and experts recommend long-term use of compression garments, including the Vodder School (Kasseroller,1998), the Foldi School (Foldi & Foldi,1991), the Lerner School (Lerner,1998), the Casley-Smith School (Casley-Smith & Casley-Smith,1997), Dr. Marvin Boris (Boris,1997), Dr. Peter Mortimer (Mortimer,1997), Dr. Hakan Brorson (Brorson,1998). National and International lymphedema organizations also support the need for lifelong use of external compression: The International Society of Lymphology (ISL,1995) the National Lymphedema Network (Thiadens,1997) and the Lymphedema Association of Australia (Casley-Smith,1997). An international conference sponsored by the American Cancer Society in 1998, designed to foster improvement in lymphedema management, substantiated use of compression products (Brennan,1998). In summary, almost all published lymphedema research assumes the long-term need for compression garments in conjunction with all other therapies.

It is essential to recognize that compression garments are not a cosmetic treatment (and in fact are not cosmetically appealing). Long-term maintenance of limb size helps prevent troublesome complications common to lymphedema patients. The most common complications of lymphedema include:

- Infections (Olszewski,1991)
- Skin complications (Williams, 1996)
- Discomfort and pain (Brennan, 1999)
- Weight gain (Mason,2001;Meek,2001; Werner,1991)
- Self-esteem, body image, sexuality dysfunctions, depression, anxiety (Passik, 1998)
- Fatigue, functional limitations, loss of work time, disability, loss of self-sufficiency, and occasionally the need for skilled nursing care (Bernas, 2001; Smith & Zobec, 2001).

In spite of this documented substantiation for the use of compression garments, third party payer coverage has either been discontinued (Medicare) or become so convoluted and tedious that both patients and health care providers are unable to obtain reimbursement. Denial of lymphedema patient coverage for compression garments can be compared to refusal to provide reimbursement for antibiotics for patients with cellulitis. Basic medical care is not provided. Equally important, ultimate cost is often greater to the third party payer and quality of life is reduced for patients and their families.

OUTCOME MEASUREMENT IN LYMPHEDEMA MANAGEMENT

Indicators have long been used in medicine to investigate and evaluate treatment strategies. Such indicators have often been called clinical measurements or assessments (Sitzia,1997). More recently, outcome measurement has evolved as a way of establishing outcome standards for general medical practice. Outcome measurement in healthcare gained national recognition and priority in 1991 when the Joint Commission of Accreditation of Healthcare Organizations (JCAHO) added outcome to their quality

standards formula. Structure and process, still essential, were ultimately judged by the outcomes they produced (Alsach,1991; Spotlight,1991).

A clinical outcome may be the final result of a clinical investigation or it may denote a change in status. When change is evaluated, outcomes must be collected at intervals and compared (Sitzia,1997). Thus, outcome measurement can refer to ways of measuring changes in response to interventions over time. Chronic disease interventions are particularly suited to interval outcome measurement over time since long-term rather than short term outcomes are important. Brief improvement (no matter how dramatic) that is sustained for only a few weeks or months must be seriously scrutinized. Caution is particularly essential when the improvement strategy is time, labor and cost intensive.

The absence of controlled clinical research and evidence-based outcomes in lymphedema management has promoted haphazard outcomes of limited scope (i.e. volume alone) (Sitzia,1997). As a result, a series of unsubstantiated lymphedema treatment fads have been practiced over the last twenty years and considerable chaos has existed (Foldi,1989; Lerner,1997; Sitzia,1997). Various surgeries, medications (diuretics and benzopyrones), compression products, and other complementary approaches (Smith,1998) have been 'grand-fathered' into practice without controlled clinical trials. Nevertheless, controlled clinical trials have been published in the last few years (Badger,2000; Brorson, 1998; Mason,2001; Johansson, 1998), and lymphedema practice is ready for the development, investigation and establishments of outcome standards.

GRANT IMPLEMENTATION

This project was conducted between 1/1/00 and 12/31/01. Penrose-St. Francis financial assistance staff provided consultation for the development and implementation of the financial assistance component. The Penrose-St. Francis Foundation supervised the entire project. Lymphedema staff from the Centura Rehabilitation at Penrose Hospital assisted with a portion of the product procurement. Thornton Huber Orthopedic Braces of Colorado Springs provided 27 compression products at wholesale prices to study patients. Since retailers normally add a 100% price mark-up, Thornton Huber's generosity allowed procurement of considerably more products for financially needy patients.

The financial assistance fund adhered to the Colorado Indigent Care Program (CICP) guidelines. The grant 'equipment' account was used to purchase compression products for financially needy patients who had no other means of obtaining products. Shirley Ritch, an experienced health benefits advisor at Penrose Hospital, oversaw screening of study patients. Sherry Smith and Jean Appodoca collected financial reports. Several patients had incomes higher than the allowable amount, but were approved because medical expenses were sufficient to offset excess incomes.

Patient accrual began in February 2000. Fourteen patients were entered into the study. Eligibility criteria included breast cancer survivors with cancer-related lymphedema of the upper extremity who qualified for the CICP. All study patients were provided standard lymphedema assessment, instruction, care coordination and other services as needed, separate from the grant activities. The lymphedema nurse case manager (Principle Investigator) oversaw:

- Development and submission of the grant proposal
- Management and implementation of grant activities

- Establishment and management of the financial assistance process
- Product procurement and submission of bills to the Penrose-St. Francis Foundation
- Management of project funds and budgets
- Communication and negotiations with collaborating parties including staff, third party payers and the Foundation
- Development and collection of outcome measures
- Data analysis
- Development of the design for the computerized Lymphedema Outcome Program
- All interim and summary reports
- Communication of project findings.

PATIENT OUTCOME MEASURES:

Lymphedema Outcome Measures included:

- Limb volumes initially and at each follow-up
- Pain level prior to product use and at each follow-up

Limb Volumes

Volumes were derived from 4 cm sequential circumferences applied to the formula for a truncated cone. Small distance (i.e. 4 cm as opposed to 10 cm) was selected in order to improve the accuracy of the volume (Brorson,1998). Several experts report water displacement volume measurement is more accurate than circumferential measurement (Bernas,1996; Brorson,1998; Swedborg,1977). This viewpoint is based on errors inherent to circumference measurement: variances in tissue firmness, the deviation of a human limb from a truncated cone, and inconsistencies of tape measure tension (Brorson,1998). Tissue firmness is affected by muscle tone, age, overall health status, body mass index, and the extent and quality of the lymphedema. In spite of the error rate associated with circumference volumes, several significant practical factors outweighed the accuracy advantage of the water displacement technique: 1) the high cost of water displacement apparatus, 2) the amount of space required for water displacement apparatus, 3) the time and energy required to maintain a sterile, safe water environment, and 3) patients' reported preference for the circumference approach.

Pain

Pain was monitored using Serlin's 0-to 10-pain severity scale (where 0 = no pain) (Serlin,1995). This Likert scale has been endorsed for use in cancer trials because numerical scales are easier to understand and score. Based on the degree of interference with function, severity ratings were established: levels 1-4 = mild pain; 5-6 = moderate pain, and 7-10 = severe pain. Changes in pain level were recorded over time.

PROJECT RESULTS:

PATIENT POPULATION

Number: 14 Colorado Springs breast cancer survivors with lymphedema.

Age: 48 to 85 years; mean (average) age was 63 years.

Duration of Lymphedema: Less than 1 month to 540 months. The mean duration was 108 months; 5 of the 14 patients experienced lymphedema for six months or less.

Extent of Lymphedema: Prior to compression: Mild (< 20%)=4 pts; Moderate(20-40%)=5; Severe (>40%)=5. Following Compression (1 patient left study): No Edema=1; Mild=6; Mod=5; Severe=1. **Financial Eligibility**: Patient incomes ranged from \$3,600 to nearly \$33,000. Eight of 14 patients had incomes below \$14,000.

Complicating Diagnoses: 2 metastatic patients (one an alert 85 year old in a skilled care facility), 1 legally blind elderly patient with severe diabetes, 1 patient with severe complicated multiple sclerosis and depression, 1 Hispanic patient with severe, neglected lymphedema of many years,1 patient with severe asthma disability, and 1 patient with long-term depression.

Psychosocial Factors: Three patients were octogenarians; four were widowed. **Follow-Up**: One patient was lost to follow-up after a physician recommended massage was the best treatment for lymphedema (massage is far more appealing than utilization of life-long compression garments). The remaining 13 patients were followed from 4 to 23 months. The average number of follow-ups was 5.6, with a range of 2 to 10.

Follow-up is a key component of patient management at the Lymphedema Program of Penrose Hospital. Regular patient follow-up is recommended in lymphedema literature (Jeffs,1992; Smith & Zobec,2001; Woods,1993). Twelve study patients continue to follow-up with the nurse case manager, Jean Smith. The remaining patient maintained a normal limb size with regular use of her compression garments and will return only if needed. The Contour SleeveTM provided prevention for this patient.

COMPRESSION PRODUCTS

The total dollars spent on compression products (the equipment account) was \$7,024.95. The mean amount per patient was \$502 with a range from \$50 to \$953.53.

Compression Sleeves & Gloves:

Twelve sleeves and 34 gloves were provided for these 14 patients, charges ranged from \$16 to \$125 per product.

Reid Sleeve™:

One product (\$1720) was provided. Colorado residents must purchase this product from Healthtronix of Dallas. No other study patient required such an expensive product; third party coverage was at 80% and grant coverage was 20%.

Contour Sleeves™ & mitts:

Twelve Contour Sleeve[™] and 4 mitts (a compression hand product designed to accompany the Contour Sleeve[™]) were provided. The Contour Sleeve[™] is an adaptation of the Reid Sleeve[™] and is advertised as useful for: 1) prevention in high risk patients, and 2) control for patients exhibiting mild lymphedema. This product was also useful to patients with moderate lymphedema. Produce longevity, with reasonable care, is two or more years. The power sleeve (applied over the high-low foam sleeve), will generally need to be replaced at least once during this two-years. Contour costs were \$350 per patient for 9 patients. The mitt was purchased with the Contour Sleeve[™] for the first three patients adding a cost of \$185 per patient. This mitt was soon replaced with an "off-the-shelf" glove (made by Medi[™] / Medlven[™]) that proved more effective and comfortable, and considerably less expensive.

OUTCOME RESULTS

Patient outcomes are reported individually and collectively for the 13 patients who completed study. Individual patient outcomes are listed in the SUMMARY REPORT (see Enclosures) in the outcome column containing the patient's last product entry and in the table below. SAMPLE VOLUME GRAPHS (see Enclosures) display the format used to help patients visualize limb volume changes. Patients' self care decision-making was improved by this concrete picture of limb size over time. Graphs were also distributed to health care providers and kept in patient records. The three graphs used to display patient volume outcomes included:

- Line graph bilateral upper limb volumes over time
- Bar graph milliliters (ml) difference between the affected and contralateral non-affected extremity.
- Bar graph percent (%) volume reduction (or increase) of affected extremity compared to initial volume of the affected extremity

Volumes Over Time - The 13 patients completing study achieved volume reductions from 15 to 55% after beginning use of the prescribed compression product. The average (mean) reduction was 37%. Since study completion was based on a set two-year period rather than a specified period of time for each patient, the first study patient was assisted for 23 months while the last patient to enter study was assisted for only 2 months.

VOLUME REDUCTIONS: 13 Study Patients

Patient ID #	1	2	3	4	5	6	7	8	9	10	12	13	14
% Reduction	41	111	27	20	38	62	21	21	55	29	27	19	15

Pain Over Time - All patients either maintained a status of 0 or level 1 pain or they achieved pain reduction after beginning compression product usage. Six of the patients remained pain-free throughout the study period. The remaining seven patients achieved pain reduction as noted individually on the SUMMARY CHART and in the table below. The mean pain reduction for these seven patients was 4 levels lower than the initial level; the range was 1 to 7 levels. Patients who had experienced pain expressed more appreciation for their pain reduction than their limb size reduction and were enthusiastic about the Contour's ability to reduce or eliminate lymphedema-related pain.

Pain Reduction: 7 Study Patients With Pain

Patient #	Initial Pain Level	Final Pain Level	Level of Reduction
2	5	4	1
3	7	0	7
6	2	0	2
7	3	0	3
8	5	0	5
12	5	1	4
14	8	2	6

SUMMARY OF PROJECT CONTRIBUTIONS TO LYMPHEDEMA CARE:

- 1. The financial assistance program substantially improved lymphedema management outcomes (limb volume, and patient pain levels) for 13 patients. Improvements would not have been possible without grant support. It would be interesting to explore establishing a sliding scale patient fee into this CICP format. I suspect such a fee would further increase patient accountability (compliance) in product usage. Perhaps this fee would also have altered the situation for the patient who left the study and probably abandoned use of the compression products she obtained.
- 2. Two evidenced-based outcome measures (volume and pain) were effectively established at Penrose Hospital and are currently monitored for all lymphedema patients.
- 3. A process has been established for developing and collecting outcome measures for patients at the Lymphedema Program of Penrose Hospital. Additional outcome measures have already been established.
- 4. Grant funds allowed development of a computer-generated outcome program.
- 5. Two compression products emerged that demonstrated exceptional outcomes and warrant further research: 1) the Medi™ prefabricated compression glove and 2) the Contour Sleeve™. Nine of 14 study patients utilized the Contour Sleeve. No other product has controlled edema more effectively in patients with mild or moderate lymphedema at the Lymphedema Program of Penrose Hospital. Additionally, these two products were very reasonably priced and contributed to exceptional patient compliance along with pain and limb size reduction.

FUTURE DIRECTION

Additional outcome measures have been added to the two study outcomes developed for this grant project. These outcomes have been included in the nurse case manager's design for a computer-generated 'Lymphedema Outcome Program'. Additional assistance funding will need to be obtained. On a larger scale, a 'planning research investigation' is being developed to identify and summarize relevant outcomes from the lymphedema literature. Long-range goals include: development of collaborative outcome measures that are substantiated through multicenter investigation and foster establishment of outcome standards. Practice-oriented outcome standards should also encourage improved third party payer reimbursement.

ACKNOWLEGEMENT:

In conclusion, I express <u>sincere appreciation</u> for the generous support from the Colorado Springs Affiliate of the Susan G. Komen Breast Cancer Foundation. Thirteen study patients also relay gratitude for the outcomes achieved because of this generosity. Although the project required many more hours than estimated, it also has yielded far greater 'outcomes' than expected.

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