EdemaWear™
Case Studies
(Longitudinal Yarn Compression)

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EdemaWear™ (LYC) Case Studies:

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TA: Radiation Induced Lymphedema of the Lower Extremity
Case Study: HK

LYC Therapy for Refractory Ulcers due to Diabetes, Arterial Insufficiency & Venous Insufficiency

Photo 1: 01/24/05

HK: 77 year-old father of five. Retired Construction Worker

Seven open sores on legs (in spite of 9 months of “wound center therapy”).

Medical Problem List:
- Eight years of oral therapy for Diabetes.
- Heavy smoker and drinker.
- Venous Insufficiency with Grade III:IV Stasis Dermatitis.
- Peripheral Arterial Insufficiency (no pulses below groins).

H.K. had been treated in a community hospital wound center in Iowa for 9 months. (He gave permission to use his full face in this educational report.) He was seen every two weeks. His legs did not respond to Una boots, elastic
compression or the other therapeutic modalities that the Wound Center tried. H.K. has a good sense of humor but after 9 months of unsuccessful therapy, his wife said, “Enough!” His primary doctor referred him to my Vascular Surgery Practice.

Photo 2: 01/24/05 (LYC Therapy Day 5)
Office Visit #2. Following five days of LYC therapy.

Photo 3: 01/24/005 (LYC Day #5)

Observe:
- Multiple sores (seven).
- Right leg with redness and skin edema due to stasis dermatitis.
- “Stocking top” demarcation of calf edema after five days of Prototype 002 LYC therapy. Unfortunately I did not measure his calf diameters at
the 01/19/05 (first) office visit. We estimate calf diameters decreases of about 1½ inches in the first 5 days of therapy.

Photo 4: 01/24/05 (LYC day # 5)

Close up of Right calf skin.
Observe:
- Chronic stasis dermatitis with ulcers,
- Skin erythema and edema of the subcutaneous fat,
- Funky exfoliation of diseased skin,
• “Corn row” ridges from LYC compression
• Dried serum staining the wound “scabs” (a sign of severe lymphatic dysfunction).

Photo 5: 01/24/05 (Note trophic changes in skin of Right toes)
Right ankle bone (Lateral Malleolus) 1.5 cm ulcer with exposed tendon and bone.

Ulcer is now under treatment with a KCI Corporation Wound VAC on Right Lateral Malleolus. (Patient required 20 days of Wound VAC therapy.)
Photo7: 02/23/05 (LYC therapy day 35)

Compare this photo after 35 days of therapy to photo #2.

Observe:
- Healing of 5 of the 7 sores.
- Dramatic decrease of redness due to venous stasis dermatitis. (See photo #3.)
- Calf Diameter Changes remain stable at ~ 13 1/4", 13 1/2".

HK no longer complains of burning pain or itching.
Photo 8: 02/23/05 (LYC Therapy day 35)

Compare this photo to photo #4.

Note:

- Complete healing of one of the pretibial ulcers,
- Marked decrease in subcutaneous fat edema,
- Marked decrease in the funky exfoliative changes
- Absence of crusty yellow dried serum on the remaining “scab.”
- Skin ulcer now shows signs of contraction and epithelial migration (hallmarks of healing).
Observe:
- Right pretibial ulcer is nearly closed. (Patient still has a 7mm skin ulcer on left heel.)
- Skin dermatitis continues to improve.

Summary:
H.K. had 7 leg ulcers due to three diseases, Diabetes, Arterial Occlusion, and Venous Stasis Disease. LYC therapy produced noticeable clearing of the Stasis Dermatitis, pain, and itching after 10 days of therapy.

A Wound VAC was required to heal the Right lateral malleolus ulcer. Malleolar ulcers lead to amputation in 30% of patients prior to Wound VAC therapy. Initial LYC therapy stabilized the skin so that the VAC polyethylene sheeting could be placed around the ulcer without skin maceration.

HK Chapter 2

Photo 10: March 15, 2005   LYC Therapy day #53
Healed Right Pretibial Ulcer
Compare with Photo 7.
Photo 11: Day #53

Right Lateral malleolus ulcer.

Observe: Ulcer is healing.

Note:
- “cornrows from LYC stockinet.
- Skin “tension lines” show that the skin on the ulcer edge is contracting as part of the healing process. This is a “big deal” because the ulcer is on a malleolar prominence “mountain.”
- Recall the anklebone ulcers are notorious for not healing and leading to amputation.
Case Study: IV

February 12, 2007

EdemaWear Therapy for Skin Graft Long Term

In January 2004, Mrs. V. emerged from a brush with death: MI, low cardiac output, sepsis, gut ischemia and DIC. An ischemic insult that led to a full thickness, circumferential skin slough on the Left leg.

Mrs. V has significant edema as a result of CHF. Because of chronic leg swelling, Mrs. V. wears EdemaWear™ daily (since 2004). Thus, researchers have a chance to see the effects of EdemaWear on grafted skin.

Photos show the circumferential left leg graft. Note:

- Smooth skin contour at the borders of the STSG (minimal unsightly skin graft shoulders).

- Robust appearance of the meshed STSG. EdemaWear™ has kept Mrs. V’s grafted skin from growing "knarly" hypertrophic nodular scar in the 36 month post op period.

- Prominent cornrows. When Mrs. V. is not wearing EdemaWear™ her skin graft is easy to overlook on her Left leg. Excellent cosmesis.
EdemaWear™ may be a cost effective alternative to custom made Jobst type Compression Burn Garments. We have included a photo of a burn compression garment. Thank you to Coleen Stice MD, FACS, Mrs. V's plastic surgeon. Dr. Stice was an early EdemaWear™ convert.
Case Study: JG

May 3, 2007

Case Study: EdemaWear for Edema Following Phlebitis and Vein Stripping in an Army Reserve Soldier & Medical Student:

Kudos to John G. Spethman. John is graduating from medical school in June. He will start a Family Practice residency at the U of Nebraska in July. John was a PA prior to going to Med School. John is an Army Reserve Soldier who is a PA. Soon, he will be a Medical Officer. John was on my general surgery service in 1999 as a PA student. John has gone on to do great things.

John wears Small EdemaWear on his right leg. For four years, John has used EdemaWear on his right leg. "Feels better!" is his excuse. John had an episode of phlebitis in his right leg in childhood. After a right saphenous vein stripping, John developed exuberant secondary varicose veins with swelling. The secondary varicose veins were accompanied by considerable edema and discomfort in the right calf. Dr. Spethman has used Small EdemaWear night and day for 48 months. EdemaWear makes his right leg more comfortable.

Photos show John in a parking lot in May 2007. John shows off his skin Cornrows in photo #3. John's use of EdemaWear over four years illustrates the fact that EdemaWear fosters excellent compliance in patients with venous stasis and edema.
Fuzzy nexus is the term our EdemaWear user group physicians use to describe yarn contact with the skin. Fuzzy nexus may be a factor in the beneficial effect of a Rooke Boot. Think, Rooke Boot vs. a pair of wool socks. Dr. Rooke is an internist at the Mayo Clinic in Minnesota. Rooke designed a knee high fake sheepskin "boot" for patients with
ischemic legs. Rooke boots help patients to heal ischemic wounds. Warming of the skin was felt to be the mechanism of healing in the Rooke boot. The "fuzzy contact" (fuzzy nexus) between human skin and fake sheepskin may have a trophic effect on ischemic skin. Fuzzy nexus in EdemaWear stockinet provides patients like John G Spethman a with a "Sensation of Comfort."
Case Study: JK

Therapy for a Third Recurrence of Right Leg Stasis Ulcers (in spite of Wound Center “Best Practice”)

Medical Problems:

1. End Stage Renal Disease
2. COPD on o2
3. ASCAD
4. Insulin for AODM
Right Leg after three months of “Profore Dressing” therapy (three layer dressing). Ulcers reoccurred. Not shown is the patient’s wife in tears of frustration.
05/23/05

After one week of LYC stockinet and a Silver Nitrate wound dressing:

- Pain is markedly better.
- Ulcers are “scabbing over and drying up”.
05/23/05

Right Leg is no longer weeping.

Patient’s wife is smiling.

Note cornrow furrows in skin outside of gauze dressings.
05/23/05

Close up of Right leg skin ulcers after one week of LYC. Note flaking of skin that was chronically wet.
05/23/05

LYC brings a smile to Mrs. K.
05/23/05

Left leg – Venous dermatitis resolving with LYC use.
Case Study: KN

Therapy for Lymphedema following Axillary Dissection

Photo 1: 50 year-old Physician with Left Breast Cancer.

Post Op Day #17 (Lumpectomy & Left Axillary Lymph Node Dissection). Patient removed wedding ring POD #1 because of edema of fingers. Patient bought a wristwatch with wider “more comfortable” band POD #7.
Observe:

- Jackson Pratt Drain tubing. Lymphorrhea on POD #16 output > 200cc/day. Drain output on day #16 is “higher than her surgeon usually sees.” Left arm swelling on POD #3 was worrisome to her.

Photo 2:

Observe:

Healing Axillary incision with red skin “tissue reaction”.
• Gauze covering drain stab wound.
• LYC Compression Stockinet on Left brachium.

Patient continues to use LYC day and night. She was not instructed to wear LYC. She prefers to wear the LYC Stockinet for three reasons, in her words:

• “Decreases swelling.”
• “Arm feels better when I move / sleep.”
• “Decreases ‘pins and needles’ sensations” (due to cutaneous sensory nerve injury (neuropathy) from axillary dissection).
Photo 3: LYC Therapy Day #10, POD #17

Observe:

- “Cornrow Pattern” beneath the Longitudinal Yarns.
- Puffy edema consistent with recent onset of edema in otherwise normal skin. This edema is evidenced by impressions from transverse elastic fibers. These skin impressions are barely perceptible on the skin between the furrows.
- Skin in furrow of cornrow has “normal turgor vitalis” (skin in furrow is pink from normal capillary perfusion versus the edematous skin between furrows).

Summary:

- LYC controls edema following lymph node dissection for cancer.
- LYC improves patient’s feeling of well being following surgical trauma.
- LYC is well tolerated vs. standard elastic compression.
- LYC may improve post surgical neuropathy.
Case Study: CW

February 2, 2007

A new term for the EdemaWear glossary: "stripe sign"

This week's patient is a 50 something journalist in Seattle. She sprained her ankle (lateral deltoid classic sprain). Her hematoma dissected to the medial malleolus. On post injury day 3, she donned EdemaWear (size small). Photos were taken 16 hours after 48 hours of EdemaWear therapy.

Note:

- White skin stripes
- Purple bruise stripes
- Transverse hash marks in the purple bruise due to impressions from Lycra fibers between yarns
EdemaWear Glossary:

Cornrows: Appearance of skin after use of EdemaWear compression.
Furrow: Impression of yarn into the subcutaneous fat.
Skin Islands: Noncompressed fat and skin between the yarns.
Case Study: MB

April 23, 2007

Pretibial Skin Shear Injury Complicated by Stasis, ASPVD, Senile Skin Atrophy and CHF

Photos 1 & 2: Mrs. B presented with a chronic wound with unclear etiology. Wound V.A.C. therapy was started after debridement. Patient used Small EdemaWear with the V.A.C. to control leg edema.
Photos 3, 4 & 5: Note the area of skin maceration from exudate under the V.A.C. plastic film. A complication. Now the patient has two wounds. We stopped V.A.C. therapy and treated patient with Promogram gel matrix (changed every two days) and EdemaWear.
Photo 6: Mrs. B has taken to wearing EdemaWear under her stocking on the uninvolved leg. "Feels better," she explains when asked why she wears EdemaWear. She has 4-6mm pitting pretibial edema due to CHF.
Photos 7, 8 & 9: Note healed wound hidden below Promogram that is adherent to the new epithelium. The wound required 73 days to heal. The V.A.C. maceration was a setback. EdemaWear controlled the right leg edema. Controlling edema, as burn surgeons know, is critical to burn healing. We believe, based on anecdotal observation, that EdemaWear enhanced ("jumpstarts healing") healing in this wound by controlling edema.
Case Study: MG

February 21, 2007

Case Study: Left Heel and Calf Ischemic/Pressure Ulcers Treated with V.A.C., EdemaWear™ and Left Femoral Artery Silver Hawk Catheter Atherectomy

Photos #1 & 2: September 2006 Black eschar pressure sores that occurred po 10 ICU days for low cardiac output. Two consultants recommended BKA. Ulcers did not respond to conservative V.A.C. negative pressure therapy. I recommended Left AKA after debriding heel bone at three wound care sessions. **EdemaWear was used to control extensive edema after debridement of the ulcers.**
Photo #5: October 31, 2006  Left Heel 12 days after Silver Hawk Left femoral artery atherectomy with stenting at the end point by her cardiologist. Results were dramatic: robust granulation over the calcaneus.

Photos #6 & 7: February 2007 Skin Grafts - Left leg will be fitted with Cam Walker. Patient is profoundly deconditioned.
Case Study: NH

N.H. is a 74 year-old father of a female radiologist who is Chairman of a Medical Executive Committee.

Problems:
- AODM
- CHF
Recent increase in edema treated by doubling diuretic.
Ten-week history of nonhealing Right pretibial shear skin injury. Saw multiple doctors.

Right pretibial skin ulcer. Wound care clinic visit #1. April 18, 2005

Note:
- Granulation tissue on surface of ulcer
- Impression in edematous skin by dressing gauze and tape
- Erythema (redness) of skin secondary to stasis dermatitis
Right Pretibial Ulcer

May 16, 2005

Note the areas of dermatitis have shrunk in size.
Lesion healed in 29 days.

Recall patient had ten weeks of therapy before LYC Stockinet. Patient used Johnson & Johnson Regranex (off the shelf recombinant DNA growth factor) on ulcer for 12 days.

Note LYC “cornrows” in skin.
Edema in leg decreased by ~ 2.5 cm in 4 weeks.
Case Study: OLF

Severe Venous Stasis Dermatitis with Ulcers

Photo 1: 01/24/05

OFL presented to the Bergan Wound Center with stasis dermatitis. Her skin had been “breaking down” since Thanksgiving. She would scratch patches of red skin and skin ulcers resulted.

Her family physician had referred her to the Wound Center because he was stymied by how quickly Opal’s skin was “breaking down.”

Observe:

- Epidermis is thin, waxy, and translucent.
- Epidermal cells have died and are replaced by patches of moist pink “granulation tissue.”
• This skin is painful.
• Pink weeping granulation tissue represents end stage dermatitis. Skin cells die from lack of Oxygen. Deoxygenated venous blood is trapped by increased vein pressure in subcutaneous fat. This “high pressure venous blood” prevents arterial blood from entering the capillaries. Lack of capillary perfusion kills the skin cells.

Photograph 2: 01/24/05
Opal L. is a 74 year-old obese female with bilateral total knee replacements. She is a homemaker. She does not have Diabetes. She has strong pedal pulses. Physical exam reveals venous stasis / insufficiency.

Photo 3: 01/24/05

Observe:

- Bright red stasis dermatitis on Left leg.
- Multiple areas of superficial skin break down/ulcerations.
Photo 4: 2/21/05, LYC Therapy Day #25

Observe:

- LYC “Cornrow” indentations in diseased skin on the Left calf. Behold healing of the “pink moist granulation tissue patches” beneath LYC yarns.
- Deep Cornrow indentations in skin with severe dermatitis indicates that LYC is “well tolerated by the patient” (vs. standard elastic compression or UNA boots) on diseased skin that is itchy and painful.
Observe:

- Healed patches of stasis granulation tissue.
- Thicker, healthier epidermis.
- Decreased skin edema and pain. Patient is smiling off camera.
- Decreased erythema (skin redness due to inflammatory chances).
- Longitudinal Yarn Compression was the only therapy used (no steroids, no elastic compression)
Photo 6: 03/07/05 LYC therapy day #42

Patient used foam wedge on bed under legs at night. No steroid cream or elastic compression was used.

Observe:

- Decreased leg diameter.
- Slow resolution of stasis dermatitis (decreased erythema, decreased swelling).
Photo 7: 03/07/05 LYC therapy day #42

Compare this photo to #1 & #2

Observe:

- LYC “cornrows” are shallow on calf (less edema) and deep on foot (foot edema persists).
- Wrinkles are present in skin that had been “stretched” by prior tissue edema.
- Healing of all areas of skin break down and ulcerations.
- Near complete resolution of dermatitis.
- Decrease of skin edema: tiny wrinkles present in the contracting skin. Shallow LYC cornrows.
Case Study: RB

March 23, 2007

**Classic AODM Skin Necrosis:**

This week our patient is a former school teacher. He is athletic, enjoys his grandchildren and travels.

Observe (photos 1 & 2) the black enlarging eschar of a dry diabetic ulcer. The necrosis increased in size from before Thanksgiving until 2/7/07. Note the puckered skin edges. This puckering is evidence of collagen mediated contraction in chronic wounds. The collagen contracts after months and the skin puckers. This puckering is pathonomic for a "stalled" wound. This wound is stalled by the underlying diabetes and because the wound has not been debrided.
Observe (photos 3) the loss of contraction pucker in the surrounding skin seven days after eschar debridement. Observe the edema of the eschar and the red inflammatory reaction in the surrounding skin. Observe skin Cornrows from EdemaWear. On the day of the photos, the wound required another round of sharp debridement. Shortly after these photos were taken, visit # 2, the wound began a rapid healing phase while patient vacationed near Santa Cruz, CA.
Observe (photos 4 & 5) a smiling patient with a healed wound. All we did for this ulcer was debride it with lidocaine jelly for pain and a Ronguer at the first and second visit. Patient used wet to dry 2x2 gauze dressings with NS daily, and of course, EdemaWear.
There is anecdotal evidence that EdemaWear enhances ("jump starts") healing of skin lesions, similar to this classic diabetic ulcer. We believe that wounds heal more rapidly with EdemaWear. We say, "EdemaWear jump starts healing!" Of course, this is anecdotal data at this point, but it gives us a direction for further research.

Why is healing enhanced by Longitudinal Yarn Compression? We believe that skin lymphatic function is enhanced by EdemaWear. Yarns "focus" physiologically useful tissue compression in the cornrow furrows. Compression of the fat under the skin sends lymphatic and venous effluent into adjacent "zero compression zones." The islands of noncompressed subcutaneous fat between furrows act as a "low pressure sink" for lymphatic and venule effluent runoff.

Our theory includes the probability of a motion activated "pump". Limb motion, by lengthening of the Lycra fibers, between yarns fixed in the furrow, translates into elevated compression of the furrow tissues. Intermittent elevated pressure, similar to a massage, may enhance lymphatic flow.

Lymphatic flow is activated by pressure differences of less than one or two centimeters of H2O in normal subjects. Jobst type stockings almost certainly act as a lymphatic tourniquet. Longitudinal Yarn Compression stockinet appears, we believe, to be a lymphatic pump that converts limb motion into pressure driven lymphatic and venule flow. This pumping effect occurs near the skin surface enhancing skin healing and, especially relevant, repair of stasis dermatitis and the healing of injured skin.

The "Kozeny Effect" is our term for the reduction of edema that occurs with LYC stockinet use. The concept of an active lymphatic pump, is a new, non-proven theory. The Kozeny Effect may be the result of an active pump that uses energy to increase lymphatic flow away from the skin. Active pump or not, it is quite likely that a 40mm Hg Jobst stocking is a huge lymphatic tourniquet. Do Jobst type stockings hinder healing? Active lymphatic pump or not, it is quite likely that EdemaWear enhances skin healing. Spend a couple minutes skimming the photos to see what 2 weeks of LYC stockinet use did to this patients stalled wound.
Case Study: RV

Bleaching of Venous Stasis Pigmentation with LYC Therapy

Photo 1: 05/04/04  (LYC stockinet treatment  for 6 months)

RV: 80 year-old college professor. Treated in 12/03 for Right heel neurotrophic ulcer with exposed bone: surgical debridement, Wound VAC & 10 weeks IV antibiotics in the hospital.

Observe:

- Venous Stasis Dermatitis with active inflammation.
- Extensive iron pigment in dermis.
• Edema at Right ankle stocking line.

Photo 2: 05/04/04

Observe:

• “Tender” inflamed skin due to active severe stasis dermatitis. This type of dermatitis is often incorrectly treated with antibiotics.
Observe:

- Cornrow furrows are shallow.
- Skin is indurated and does not “indent” easily.
- Skin feels like “leather” when palpated.
- Calf diameter is at upper limit of LYC 002 prototype. Size mismatch may decrease the compressive tension on longitudinal yarns.
- Impressions from transverse elastic fibers are obvious. This may be a result of excessive stretch due to a 15” calf diameter.
• “VEIN” marks the clear outline of a saphenous vein branch. This change is “dramatic.” Compare to photo #1 & #2. In photo #2, because of chronic edema, you can barely see the saphenous vein branch at the top of the photo (see “vein” insert in photo #2).

• The clear outline of the saphenous vein branch is evidence that the patient is complying with daily stockinet usage. RV’s compliance with LYC stockinet is excellent. We hear “… skin feels better!” frequently.

• Note the flaking skin. This suggests that the dermis is healthy enough to have cells that are dividing. Initially, (see photo #2) Mr. R’s skin was “moist,” edematous, leathery and did not have the metabolic support for cell division. “Healthy” or nearly normal skin cell division is required for the skin to be able to have the large flakes present in photo #3.
RV wears LYC stockinet night and day on his own volition. He needs no physician cheerleading to use LYC. The stockinet has made painful itchy skin “feel better.”
RV is "jazzed" about LYC therapy. "My legs feel better." RV said, "Sure, use my photograph."
Photo 6: 03/15/05  15 mo. of LYC therapy

Observe:

- Note decreased pigment under skin in the photograph box. Compare to photo #2. This color change is small but significant.
- Note iron pigmentation under skin is less brown than is photo #1 & #2. This bleaching of the iron pigment is unheard of in clinical practice. RV is the first patient in whom I have observed documented stasis pigment reabsorption. A Google Scholar Medical literature search turns up no papers claiming improvement of stasis pigment in VSD. RV may be making medical history.
• Healing dermatitis after 15 months of LYC therapy.

Yes, RV still has horrible looking shins. RV knows his skin has made huge progress (see RV’s smile in photo #5). How would LYC compare with Una Paste Boots and Elastic Compression in a controlled study? As scientists, physicians ask for “proof.” RV used UNA boots, Ace Wraps and Compression Stockings, on and off, for 15 years. Each year his Stasis Disease grew worse: painful dermatitis, poor skin healing, recurrent low grade infections and weeping ulcerated skin sores.
Case Study: TA

Radiation Induced Lymphedema of the Lower Extremity

Photo #1: 03/23/05

Skin of Right leg post 27 months of LYC Therapy in a Nursing Home. T.A. is an 83 year-old mother of 5 “born the same year as Pope John Paul.” She lives in an Extended care facility and is proud that Warren Buffett's mother was a resident.
T.A. had Radiation in 1995, followed by Surgery, Chemotherapy and more Radiation for Rectal Cancer. Total radiation dose was 5,040 cGy. Patient is tumor free but she has moderate radiation induced lymphedema (5 to 10 mm pitting edema) by 1998.

OBSERVE:

The shiny tense edematous skin between LYC cornrows.

Photo #2: 03/23/05
In 1995, patient had stricture of both ureters in the radiation field. This obstruction was treated with stents for 24 months. Stents have been removed. Renal function is adequate but may contribute to the extensive edema that developed. Currently creatinine is 2.5.

In 1998, patient developed progressive lymphedema of both legs. The presumptive diagnosis was lymphedema due to pelvic radiation. LYC therapy was initiated in October 2002. Patient had been treated with ACE wrap elastic compression. Edema was progressing in spite of elastic compression.

OBSERVE:
The LYC stockinet is stretched so that the space between the “Cornrow Furrows” is “Five yarns wide” (or, to state it differently, the furrow is one fifth of the skin surface). In spite of first impressions, this ratio seems to be effective in “Wringing” lymphedema out of the leg. In 2002, the calf diameters decreased by ~ 2 inches.

Photo #3: 03/23/05
This overexposed close up shows wrinkles in the skin between the Longitudinal Yarns. These wrinkles represent the aftermath of “squeezing” a good bit of edema fluid out of the subcutaneous fat. The reduction of edema due to LYC seems to hold up over time.

Photo #4: 03/23/05

T.A. in the afternoon sunshine.

The Care facility Wound Care Nurse, Mrs. K. Eslinger RN, was so impressed with T.A.’s results, that sought me out. She asked to use LYC as a chronic care facility “study site.” Nurse Eslinger has used this stockinet with dozens of residents who have skin at risk. Her number one indication for use is as “skin protection” for senile skin atrophy. The number two indication is for the treatment of edema in patients like T.A.