

Positive outcomes with Legassist compression garments treating advanced, Stage 3 lymphoedema and deleterious consequences of coverage denials

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Key words

Compression garments, Non-healing post-surgical wounds

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Abstract

This case study is an example of one patient's journey spanning many decades where denials of proper compression garments resulted in a cascade of failed surgeries, non-healing post-surgical wounds, recurrent cellulitis infections and extended hospitalisations. As her primary lymphoedema progressed to Stage 3 elephantiasis with massive localised lobules, depression and hopelessness set in. Once she was fitted with a custom, compression garment, all aspects of her chronic condition began to improve, including limb volume reduction, prevention of post-surgical wounds, improved functional mobility and improved quality of life. This case study exemplifies the abject waste of healthcare dollars and unnecessary harm caused when compression garments are denied coverage by medical insurance programmes.

Compression is a cornerstone in the management of lymphoedema (Framework, 2006; Moffat et al, 2012; Partsch and Junger, 2006). The application of compression has been shown to have a positive impact on both venous and lymphatic flow (Partsch, 2008; Rabe, 2018). Benefits of compression include decreasing the lymphatic load, shifting fluid into areas with functional lymphatics, increasing lymphatic reabsorption, stimulating lymphangion contractions, reducing venous reflux, improving venous return, reducing venous hypertension, maximising calf muscle pump function, reducing elevated matrix metalloproteinase levels and promoting healing of chronic wounds. In addition, compression also improves trophic changes of the skin and clinical symptoms, such as heaviness, itching, pain and quality of life.

Custom, multi-layered lymphoedema compression bandaging with short-stretch bandages is a core component of Complete Decongestive Physiotherapy (CDT), the gold standard of treatment for lymphoedema (International

Lymphoedema Framework, 2006). Bandaging is responsible for the majority of lymphoedema volume reduction in the acute, decongestive phase of lymphoedema treatment (Ezzo et al, 2015). Application of multi-layered bandaging for lymphoedema incorporates a hygienic layer, padding layer, textured layers and compressive layers. Bandaging is highly customised to an individual's lymphoedema presentation and limb shape, and requires specialised skill and training to apply.

Multiple layers of short-stretch bandages are utilised to create high containment and resistance to expansion of lymphoedema, yet provide enough recoil to accommodate for volume reduction. Textured layers are used to warm and soften fibrotic tissue. Sub-bandage pressure drops as oedema reduces, particularly in the initial applications where large volume reductions are achieved (Moffatt et al, 2012). Consequently, frequent re-application of the bandaging system is required during this acute phase of treatment.

Compression bandaging can be challenging for clinicians, patients and

caregivers alike in cases where there is advanced, Stage 3 (Executive Committee, 2016) lymphoedema (also known as elephantiasis), especially when it involves massive localised lobules (Farshid and Weiss, 1998). In some cases, it may take a team of 2–3 clinicians 45–60 minutes to bandage large and unusually shaped limbs, and keeping the compression bandages from sliding down requires additional problem solving. For these reasons, bandaging is usually reserved as an aggressive treatment for the reduction phase of treatment versus a long-term compression solution. Bandaging for long-term maintenance is laborious and time consuming and, as in this case study, can ultimately lead to burn out and failed compression therapy.

Fortunately, there are custom compression garments on the market that are effective for long-term management of lymphoedema to prevent deleterious complications. However, in many cases, access to these effective compression solutions is impaired by lack of education and absence of reimbursement by medical insurance programmes. This case study is an

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example of one patient's journey spanning many decades where lack of access to proper compression garments resulted in a cascade of preventable surgeries, non-healing post-surgical wounds, recurrent cellulitis, extended hospitalisations, depression and hopelessness. Once she was fitted with a custom, Legassist (Sigvaris Group) compression garment all aspects of her chronic condition began to improve, including limb volume reduction, prevention of post-surgical wounds, improved functional mobility and improved quality of life.

Patient history

Diagnoses

JG, a 53-year-old white female living in Georgia, USA, presented with severe, Stage 3 primary lymphoedema of the right leg, with massive localised lobules (Figure 1 & 2). Her body weight was 554lbs, height 5'9", and BMI 81.8 (morbidly obese). Comorbidities included type 2 diabetes controlled with oral meds and insulin, hypertension, hypothyroidism, heart murmur since birth, and a benign tumour in the right ankle.

Compression history

JG recounts that, at age 6, she stepped on a bee, which triggered chronic lymphoedema and a sequelae of complications in her right leg. In 1973, at age nine, she was diagnosed with primary lymphoedema via lymphoscintigraphy. In her early years, JG's intermittent pneumatic compression pump and custom, flat-knit compression garments were covered by her parents' insurance. Access to compression garments helped her to successfully manage her lymphoedema. Unfortunately, however, at age 26 that coverage ended and, thereafter, she was unable to consistently utilise compression therapies.

Surgeries, hospitalisations, chronic wounds

A series of surgical interventions, in the absence of post-surgical compression therapy or CDT, resulted in complications and extended hospitalisations. In 1976, at age 12, JG underwent a debulking surgery of her right lower leg, using the Wick method, and suffered from post-surgical, non-healing wounds for approximately 6 months. After a C-section in 1990, she developed post-surgical cellulitis and secondary lymphoedema of her abdomen,



Figure 1: Patient's right leg prior to compression consultation, front view.

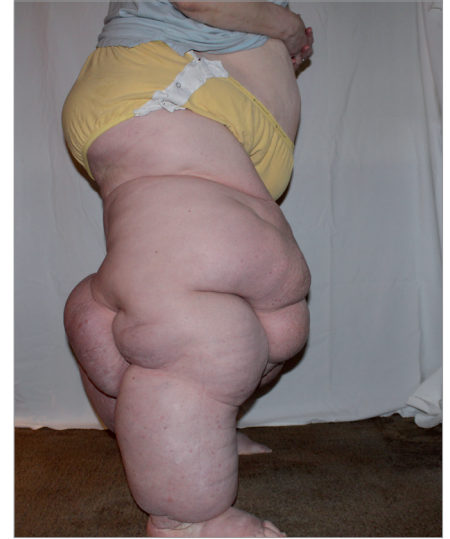


Figure 2: Patient's right leg prior to compression consultation, side view.



Figure 3: Patient fitted with custom, compression garments, front view.



Figure 4: Patient fitted with custom, compression garments, side view.

resulting in an extended hospitalisation. In 1994, JG had debulking surgery of her abdomen to remove the 30lbs of fibrotic tissue that had developed, and again suffered from non-healing incisional wounds for 6 months. By 1999, JG's right leg lymphoedema had reached severe proportions, leading to yet another debulking surgery, this time of the right thigh. No compression was applied post-surgically. JG's thigh swelled more severely after surgery and she again suffered approximately 6 months of non-healing, post-surgical wounds. In her lifetime, JG suffered from 35 cellulitis infections, three requiring hospitalisation. Due to her extensive history of surgical interventions, her right leg presented with significant scarring medially from the ankle to the

groin. Multiple, adhered scars converged at her medial knee and thigh.

Occupation

For 20 years, JG worked as a certified hospital pharmacy technician. She enjoyed her job, as well her role as wife and mother. But, by the age of 40, she was physically disabled by her primary lymphoedema and complications. Therefore, she was formally discharged from the workforce and placed on disability.

Prior lymphoedema treatment

By 2014, at age 50, JG presented with severe, Stage 3 elephantiasis with massive localised lobules. She was granted only five visits from her medical insurance to see a certified lymphoedema therapist. In order to best utilise the time, JG's husband was

taught how to apply multi-layered, short-stretch compression bandaging to her entire right leg, from the toes to the groin. For 2 years they faithfully applied compression bandaging, a laborious process that took over 90 minutes to remove and re-apply clean bandages, plus the time to wash and re-roll the dirty bandages. Frustration and painful recurrent wounds where bandages would slide down and cut into her skin eventually led to abandonment of the treatment.

Quality of life

By age 50, disfigurement and severely limited mobility relegated JG to a life as a shut-in. Reflecting on her condition, she explained: "I felt like I had no future. I was just sitting, waiting to die. I was depressed and hopeless."

Case study interventions

JG was referred by her physician for a compression consultation and for special consideration for a donated compression garment. At her consultation on June 2, 2017, she was measured for a custom, Legassist Full Leg compression garment for her Stage 3 primary lymphoedema of the right leg. The thigh piece included a built-in Lobule Compression System (LCS) for the massive localised lobules of the right medial knee and thigh. She was measured for the Legassist Calf and Foot garment with shelf for the right lower leg and foot (Figures 3 & 4). The custom garments were applied and fitted on July 14, 2017.

These custom garments consist of a inelastic shell, textured foam liner, hook and loop strapping, and customised lobule sling which allows for tightening of the system as the massive localised lobules reduce (Figure 5). The system is designed to be worn 24 hours/day and provides roughly 30-40 mmHg of compression pressure dosage. The entire system can be easily tightened to adjust for lymphoedema volume reductions, and the textured liner helps soften fibrotic tissue. According to a new, published guide and algorithm for compression garment selection to match oedema presentation to appropriate compression textiles, garment selection was appropriate for the lymphoedema severity (Bjork and Ehmann, 2019).

The patient was also measured and fitted for a ready-to-wear, knee-high, 30-40 mmHg, stiffer circular knit (Bjork and Ehmann, 2019) compression garment for the left lower leg, which was also moderately

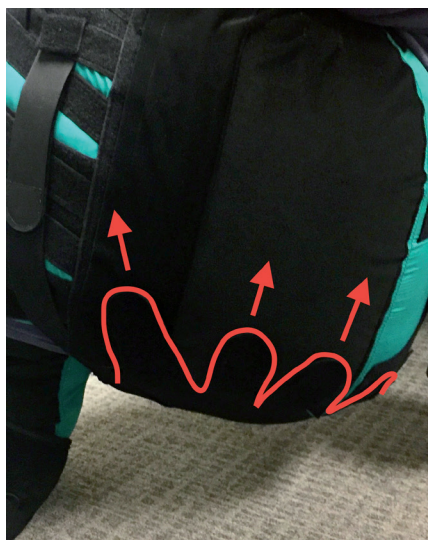


Figure 5: Close up of Lobule Compression System showing reduction adjustments.



Figure 6: Patient's right leg months after surgery, front view.



Figure 7: Patient's right leg months after surgery, side view.



Figure 8: Patient's right leg months after surgery, medial view, wearing LegAssist compression garments.

swollen. A Sigvaris Secure stiffer circular knit garment was selected to provide increased containment as compared to standard circular knit garments. Sigvaris Secure has an average ankle stiffness of 3.18 mmHg/cm, measured using a Zwick CRE machine, as compared to 1.3 mmHg/cm for standard circular knit garments (Bjork and Ehmann, 2019).

JG wore the custom Legassist garments 24 hours a day, from July 14, 2017 until August 14, 2017, as the sole intervention. She received no other lymphoedema treatments during this time. Washable hygienic liners were utilised. During the following month, she wore the custom compression garments 24 hours a day for 8-10 days, and then alternated it with multi-layered, short-stretch

bandaging for approximately 2 days while the garment was being washed and air dried.

By August 2017, JG's steady improvements enabled her to physically access an evaluation for CDT treatment at a lymphoedema clinic, approximately one hour away from her home. Unfortunately, however, it took 7 months from the time of the initial physical therapy evaluation for her to receive the necessary prior-authorisations to begin an intensive course of CDT treatment.

The patient received CDT at the skilled lymphoedema clinic from March 30, 2018-April 24, 2018, at which time custom lymphoedema bandaging only was utilised for her treatment. Upon discharge, the Legassist garments were resumed.

Case study

JG's husband faithfully assisted her with encouragement, compression therapy applications, home manual lymphatic drainage therapy, and progressive activity and exercise as part of her home programme.

By July 6, 2018, approximately 1 year after the initiation of custom, compression garments, JG's overall fluid weight reduction and softening of the massive localised lobule optimised her condition for selective, surgical debulking. Compression bandaging was implemented in preparation for her selective debulking surgery on August 21, 2018. The massive lobe of her right medial thigh and knee was surgically removed, along with a smaller lobe more posteriorly on the thigh. Lymphoedema bandaging was resumed immediately after surgery and continued until post-op swelling subsided. JG was subsequently fitted with her new, custom Legassist garments on November 14, 2018 (Figures 6–8).

Measurement methods

At her consultation on June 2, 2017, circumferential measurements were taken every four centimetres, using a tape measure. Volume was manually calculated using the truncated cone formula for the girth measurements from the ankle to the groin. Follow-up tape measurements were taken 6 months later. On August 7, 2017 volume of her legs were precisely measured using a new technology, the LymphaTech scanner. The LymphaTech scanner and associated software program enables scanning of even unusually shaped limbs in 60 seconds, via an iPad or iPhone, and automatically calculates volumes (Yahathugoda, 2018). She was re-scanned approximately 1 year later on June 25, 2018. Her body weight was tracked at her follow up visits with her physician, using a bariatric scale.

A new scoring tool was utilised to assess the complexity of JG's lymphoedema at regular intervals, the Leg Lymphedema Complexity Score (LLCS) (Bjork and Hettrick, 2020). The LLCS is comprised of 12 domains that assess lymphoedema complexity and help steer individualised plans of treatment. Domains are scored from 0 = nominal complexity to 4 = extreme complexity, with a total score ranging from 1–48. It includes a validated quality of life tool, the Lymphedema Life Impact Scale (LLIS) (Weiss, 2015), which is comprised

Table 1. Volume and weight reductions.

Volume Reduction			
Date	Measurement Method	R LE Volume (ankle to groin)	Total % Volume Reduction from SOC
02/06/2017	Tape Measure	129L	
14/07/2017		Garment Applied	
07/08/2017	3-D Scan	95L	26%
16/01/2018	Tape Measure	77L	40%
25/06/2018	3-D Scan	45L	65%
21/08/2018		Selective Debulking Surgery	
21/07/2019	Tape Measure	32L (vs L LE=15L)	75%
Weight Reductions			
Date	Body Weight	Cumulative Weight Reduction	BMI (Height 5'9")
14/07/2017	554lbs	n/a	82
14/08/2017	473lbs	81lbs	70
22/09/2017	443lbs	111lbs	65
24/01/2018	440lbs	114lbs	65
06/07/2018	387lbs	167lbs	57
8/21/18 pre-op	385lbs	169lbs	57
8/21/2018 post-op	340lbs	214lbs	50
15/09/2018	345lbs	209lbs	51
21/02/2019	335lbs	219lbs	50
31/07/2019	360lbs	194lbs	53

of 18 self-assessment questions scored from 0 = no negative impact to 4 = complete or extreme negative impact on quality of life. The LLIS total score ranges from 0–72.

Results

Weight

In the first month (July 14, 2017 to August 14, 2017) of wearing the Legassist garments without any other treatment interventions, JG's weight was reduced by 81lbs (Table 1). In the following month, wearing the Legassist garments for 8–10 days, alternated with bandaging for approximately 2 days, her weight decreased another 30lbs, for a total 2-month reduction of 111lbs by September 22, 2017.

By January 16, 2018, after 6 months use of the specialised compression garments, the girth of the massive localised lobule of her right medial thigh and knee had reduced by 50 centimetres and approximately 50lbs. This provided tremendous offloading of the knee joint, enabling improved mobility and

less pain. By July 6, 2018, approximately one year after the initiation of the Legassist compression garments, JG's overall weight reduction was 167lbs prior to selective debulking surgery (Table 1).

Driving and walking

Due to reductions in her right leg size and weight, by October 2017, JG was able to fit into the driver's seat of her van and drive herself to the grocery store. For 3 years prior to this, she could not fit her right leg into the van and she eventually had to be transported via a private handicap bus. Her walking tolerance improved from ~100 feet or 20 minutes on July 14, 2017 to ~1,000 feet or 2 hours on December 16, 2017, which enabled her to shop for her own groceries.

LLCS and LLIS

JG's overall score on the LLCS at the time of her fitting for her custom compression garments on July 14, 2017 was 37; Extreme Complexity (Table 2). By 2019, her LLCS

score improved to a low of 23; Moderate Complexity, with decreased pain, and improved skin integrity, transfers, walking and bathing. Initially, her LLIS score was 67 (Table 3). By 2019, the LLIS score had improved to a low of 27 with less pain, heaviness and tightness, and improved mobility, activities of daily living and lymphoedema knowledge.

Time to apply compression

Time to apply compression improved from 90 minutes to apply multi-layer lymphoedema bandaging to 8 minutes when applying the Legassist garments as her primary long-term compression therapy.

CDT

Formal and intensive CDT at the skilled lymphedema clinic commenced on March 30, 2018. Though reduction had plateaued with compression alone prior to this, an additional 15.6 litres of fluid volume reduction of the right leg was achieved with the addition of 18 skilled CDT treatments. Additionally, there was notable softening of the fibrotic tissue of the massive localised lobules with CDT, which helped prepare her for a successful selective debulking surgery.

Volume Reduction

In the initial 6 months of wearing the Legassist garments, JG's right leg volume reduced by approximately 52 litres, per tape measurements (Table 3). There was also a significant volume reduction of 50 litres noted between her two 3D scans, which were approximately a year apart (Table 3). Overall, prior to her debulking surgery, the volume of the right leg was reduced by approximately 65% with the Legassist compression garments. Further, approximately 1 year after her debulking surgery, the right leg volume was improved to 32 litres. Comparatively, the left leg volume was 15 litres, ankle to groin.

Post-surgical Healing

On August 21, 2018, JG underwent a selective debulking surgery. The total mass of tissue excised was approximately 45lbs. After all previous debulking surgeries, Janice had suffered non-healing wounds for 6 months. In contrast, implementing compression bandaging immediately after this surgery and then progressing into new, Legassist garments after post-op swelling subsided, resulted in healing of her surgical

Table 2. Leg Lymphedema Complexity Score (LLCS).

Date	14/07/2017	16/12/2017	06/07/2018	14/03/2019	24/07/2019
LLCS Domain	Score	Score	Score	Score	Score
A. Comorbidities	3	3	4	3	3
B. Limb Edema	4	4	4	3	4
C. Tissue Texture	4	4	4	2	2
D. Scars	3	3	3	3	3
E. Skin Integrity	4	3	2	2	3
F. Skin Changes	2	2	3	1	3
G. Fat Disorders	0	0	0	0	0
H. BMI	4	4	4	4	4
I. Mobility	3	2	1	0	0
J. ADLs	3	2	1	1	1
K. Pain	3	1	2	2	1
L. (LLIS)	4	4	4	2	3
Total Score:	37	32	32	23	27
	Extreme Complexity	Severe Complexity	Severe Complexity	Moderate Complexity	Severe Complexity

Table 3. Lymphedema Life Impact Scale (LLIS).

Date:	14/07/2017	16/12/2017	25/06/2018	14/03/2019	26/07/2019
LLIS Question (Scoring: 0=best to 4=worst; 0-72 total score)	Score	Score	Score	Score	Score
1. Pain	3	1	3	1	2
2. Heaviness	4	3	4	1	2
3. Tightness	4	3	3	1	1
4. Size	4	4	4	1	2
5. Movement	4	3	4	1	2
6. Strength	4	4	3	3	3
7. Body Image	4	4	4	2	4
8. Socializing	4	4	4	3	4
9. Intimacy	4	4	4	2	3
10. Depression	4	4	4	3	3
11. Independence	4	4	3	1	2
12. Knowledge	3	0	0	0	0
13. ADLs	4	3	2	1	2
14. Chores	4	4	3	1	2
15. Leisure	4	4	4	2	3
16. Clothing	4	4	4	2	4
17. Sleep	4	4	3	3	4
18. Infections	1	2	1	0	1
Total Score:	67	59	57	27	44

Case study

incisions without dehiscence or any chronic wounds.

Activities of daily living

Two years into this case study, JG was able to drive, get to her doctor's appointments independently, shop for her own groceries, walk out in the community for 1,200 feet without stopping and up to 3.5 hours with intermittent breaks, and engaged in social activities and outings with friends and her husband (Figures 9 & 10). She was no longer gawked at, pointed at or made fun of when out in public. She was no longer worried about not being able to fit into a taxi or Uber if her car broke down. She could call 911 and not have to wait for a special emergency vehicle with bariatric equipment. Access to proper compression garments gave her dignity, independence and an active, more fulfilling life. Unfortunately, after such tremendous achievements, this was all about to change.

Compression garments' denial of coverage and decline in quality of life

By midyear 2019, JG was ready to progress to a new plan: wearing a custom, flat-knit garment with robust containment during the day combined with wearing the custom, Legassist garment at night. This would provide her with optimal functional mobility and cosmetic concealment of her residual lymphoedema of the right leg during the day, as well as high containment, lymphoedema reduction and softening of residual fibrotic tissue at night. Flat-knit garments and new Legassist garments needed to be purchased and her donated garments were worn out. Unfortunately, no medical compression garments were authorised by her medical insurance.

Erroneously, it was concluded by her provider that her garments were not "medically necessary", and thus coverage was denied. JG became appropriately concerned about relapsing and wondered how she would be able to manage her lymphoedema independently. Discouragement over this situation led to a measurable decline in her quality of life score on the LLIS.

As per a follow-up interview on July 26, 2019, her LLIS score had deteriorated from 27 to 44 (Table 3). When this was further investigated, it was determined that she had become quite discouraged because her garments were denied, which deflated her



Figure 9: JG (right) and medical compression consultant, Robyn Bjork (left).



Figure 10: JG celebrating her success with family and friends.

motivation and hopefulness. Consequently, this also affected her overall quality of life scores.

Discussion

This case study is a 2-year snapshot into the hope and independence that a specialised compression garment can give to a patient, as well as the deleterious physical and emotional effects that lack of access to garments can cause over many decades. From June 2017 to July 2019, JG made steady improvements with her compression garment use, becoming more independent and hopeful, rather than disabled, disfigured and "waiting to die".

However, despite impressive improvements, successful CDT interventions and a successful selective debulking surgery, the very compression garments that were pivotal in these successes and necessary for long-term management were denied based on the egregious conclusion by her medical insurance provider that they were not "medically necessary".

After discussion with certified

lymphoedema therapists, the author found this to be an anecdotal consequence with many patients. After all the time and energy a patient spends in rehabilitation with their certified lymphoedema therapist, a successful discharge plan for long-term management often could not be achieved due to lack of compression garment coverage. Not having the necessary tools to manage their condition, patients become discouraged and deflated rather than empowered.

Ultimately, this also leads to relapse and deleterious medical complications that cost much more than providing compression garments. In this case study, if JG had had access to lifelong, quality compression garments, she likely would have been able to avoid multiple surgeries and would have had less frequent episodes of cellulitis and hospitalisations. She also may have been able to continue working for many more years rather than having to be supported through disability programmes.

Conclusion

Compression bandaging and garments

are a medical necessity for lymphoedema management. This case study demonstrates that even the most severe Stage 3 lymphoedema with massive localised lobules can be effectively treated with proper compression. It also exemplifies the abject waste of healthcare dollars and unnecessary harm caused when compression garments' coverage is denied by medical insurance providers.

In this case study, lack of access to proper compression garments resulted in multiple failed surgeries, non-healing wounds, disfigurement, pain, depression, and also resulted in this productive member of the work force to be placed on long-term disability. In contrast, the custom, Legassist compression garments resulted in limb volume reduction, a successful surgery, prevention of post-surgical wounds, improved functional mobility and improved quality of life. Custom garments enabled her to become

more independent, shop for her own groceries, engage with the community, and participate in activities and outings with her husband. In her own words, JG sums it up: "Before I felt like I had no future. I was just sitting, waiting to die. I was depressed, hopeless and I hated to go out. Now I look forward to the future. I feel like there is hope and promise. I go into the outside world and I laugh now."

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