The THAI Journal of SURGERY 2025;46(4):173-183.
Official Publication of The Royal College of Surgeons of Thailand

Original Article

Efficacy of Customized Pressure Device in Treating Lower Limb Lymphedema: An Observational Study

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Abstract

Objectives: Lymphedema is a chronic, progressive, debilitating disease characterized by the accumulation of protein-rich interstitial fluids in the subcutaneous tissue due to the failure of the lymphatic drainage system. This study sought to evaluate the efficacy of customized pressure devices in treating lower limb lymphedema.

Materials and Methods: 5 patients with lower limb lymphedema who are on customized pressure devices were recruited in this study. The severity of the lymphedema limb(s) was evaluated over 5 months based on both objective and subjective measures. An objective measure was evaluated using limb circumference at different levels measured from the heel, supplemented with the lower extremity lymphedema (LEL) index. Subjective measures were evaluated using the Lymphedema Functionality, Disability and Health Questionnaire for Lower Limb Lymphedema Reliability and Validity (Lymph-ICF-LL).

Results: The study group includes 4 male patients and 1 female between 40 and 55 years old. 2 patients have bilateral lower limb lymphedema, 2 patients have right lower limb lymphedema, and 1 patient has left lower limb lymphedema. Through the LEL index, all patients have significant improvement except 1 patient. Whereas utilizing the Lymph-ICF-LL questionnaire, clinically relevant improvements were observed in 1 patient in the mental function and mobility domain. Minor improvements were identified in others. No patient experiences reduced in functionality. Most patients with lower limb lymphedema experienced a positive effect with the use of customized pressure devices.

Conclusion: Our study demonstrated the role of customized pressure devices in managing lower limb lymphedema. There is a significant decrease in LEL in 80% of our patients. Only 20% reported clinically significant improvement in their Lymph-ICF-LL score. Further evaluation is needed to determine the long-term outcomes of patients with lower limb lymphedema, especially regarding the long-term effects of customized pressure devices on LEL index and the ability to return to physical activities.

Keywords: Lymphedema, Lower limb lymphedema, Lymph-ICF-LL questionnaire, LEL Index, Compreflex

Received for publication 18 March 2025; Revised 23 April 2025; Accepted 6 May 2025

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https://doi.org/10.64387/tjs.2025.274178

Introduction

Lymphedema is a chronic, progressive, debilitating disease characterized by the accumulation of protein-rich interstitial fluids in the subcutaneous tissue due to failure in the lymphatic drainage system.[1] The failure can either be due to structural or functional abnormalities of lymphatic channels in the form of obstruction or hypoplasia.[2] Lymphedema can be classified into primary lymphedema, which is the malformation of lymphatic channels, or secondary lymphedema, which is destruction or obstruction of previously formed channels.[3,4] It can affect any part of the body, but is commonly observed affecting the upper and lower limbs.[1] In Malaysia, lymphatic filariasis is the most common cause of lower limb lymphedema.[5] Lymphatic filariasis has infected approximately 120 million people globally, and approximately 40 million have become incapacitated due to the disease.[5] Approximately 65% of the patients live in Southeast Asia, 30% in Africa, and the remaining patients in other tropical areas.[5] Globally, approximately 90% of lymphatic filariasis infections are caused by Wuchereria bancrofti, and Brugia malayi and B. timori cause the rest.[5] In Malaysia, lymphatic filariasis is caused by W. bancrofti and B. malayi and is transmitted by mosquitoes of the genus Anopheles and Mansonia. It occurs mainly in a few states in Malaysia, namely Sabah and Sarawak (East Malaysia) and Terengganu, Kelantan, Pahang, Selangor, and Johor (Peninsular Malaysia).[5]

Lymphedema can cause severe physical and psychological morbidity and is commonly associated with limb pain and heaviness, skin tightness, recurrent soft tissue infection, decreased range of movement, and secondary malignancy.[1] Psychologically, patients with lymphedema have a higher risk of having body image disturbances, anxiety, and depression. Consequently, lymphedema significantly decreases the quality of life in patients by affecting the ability to work and engage in social activities, reducing the workforce within the community.[1]

Diagnosis of lymphedema in our setting is usually established clinically, followed by blood investigations and imaging studies. Imaging modalities for disease confirmation, like radionuclide lymphoscintigraphy, magnetic resonance contrast lymphography, and indocyanine green lymphangiography, are unavailable in our setting, limiting the team to rely solely on magnetic resonance imaging (MRI).[3,4] In terms of lymphedema quantifications and progress monitoring, a variety of noninvasive methods like the water displacement method, perometry, tissue tonometry, bioelectrical impedance spectroscopy (BIS), computed tomography (CT) scan, magnetic resonance imaging (MRI), and ultrasonography can be used, but are not applicable in our setting.[6] Progress of disease is monitored via limb circumference measurements and monitoring of quality of life through subjective questions.[1]

Treatment of lymphedema is initiated with complex decongestive therapy (CDT) followed by surgical intervention (physiological and ablative surgery) if indicated.[1,3,4] Complex decongestive therapy remains the mainstay of lymphedema treatment worldwide to date and aims to decrease the excessive fluid in the lymphedematous limbs. It consists of skin care, exercise, compression therapy, and manual lymphatic drainage combinations.[1,3,4] Due to the lack of lymphedema paramedics and resources, our center does not offer multilayer bandaging (compression therapy) and manual lymphatic drainage. Self-bandaging challenges our patients due to their restricted mobility and limited resources. Customized pressure devices (Compreflex) were recently available in our setting (Figure 1). This device is more user-friendly, and the comprehensive services offered by the pressure device team and the availability of medical aid funding for the device have greatly benefited patients and lymphedema services in various ways. This device allows easy self-donning with a front stretch panel to secure the garment in place and straps that roll back. The pressure implied by the device is self-adjustable by patients using measuring tapes (Accutab) that come along with the device, which have pre-labeled pressure ranges labeled on them, as shown in Figures 2 and 3. This encourages a patient's self-management and adherence to treatment. In our study, all 5 patients are using the pressure range of 30-40 mm Hg as the pressure device team suggested. This study aims to evaluate the efficacy of customized pressure devices in treating lower limb lymphedema.

Figure 1 A patient wearing customized pressure devices (Compreflex)

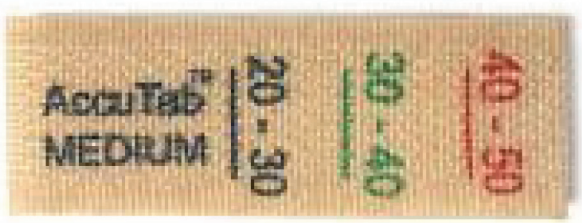

Figure 2 Pre-labelled measuring tape (Accutab)

Figure 3 Customized pressure devices (Compreflex) and Pre-labelled measuring tape (Accutab)

Materials and Methods

The duration of this study is five months from July 2024 until November 2024. 12 patients with lymphedema of the limb who are on customized pressure devices were identified. 2 patients with upper limb lymphedema were excluded from this study. 5 patients with lower limb lymphedema were unable to participate in this study due to various reasons (non-compliance, defaulting on follow-up, uncontactable). 5 patients with lower limb lymphedema (unilateral and bilateral) were recruited in this study. The severity of the lymphedema limb(s) was evaluated based on both objective and subjective measures.

Objective measurements were evaluated in terms of limb circumference at different levels measured from the heel: 5 cm, 10 cm, 15 cm, 20 cm, 25 cm, 30 cm, 35 cm, and 40 cm, taken twice over 3 months, and were supplemented using the lower extremity lymphedema (LEL) index.[7] LEL index was calculated by taking the sum of the squares of all the limb circumferences, then dividing by the respective patients' BMI. The calculation formula is shown in Figure 4.

$$\text{LEL} = \frac{\text{Sum of [Measured limb circumferrences]}^2\ (\text{cm}^2)}{\text{Patient's BMI}\ (\text{kg/m}^2)}$$

Figure 4 Formula for calculation of lower extremity lymphedema (LEL) index

Subjective evaluation was carried out by interviewing patients using the Lymphedema Functionality, Disability and Health Questionnaire for Lower Limb Lymphedema Reliability and Validity (Lymph-ICF-LL) during the first and third clinic visits. It is a descriptive, evaluative tool containing 28 questions about impairments in function, activity limitations, and participation restrictions in patients with lower limb lymphedema.[8] Full questionnaire is shown in Appendix 1.

Both objective and subjective evaluations were taken pre-treatment and 3 months after commencement of the customized pressure device. No surgical intervention has been done for these patients over this period of time.

Results

Demographics of patients and a summary of data obtained from this study were shown in Tables 1, 2, and 3. Lower limb circumference measurements for patients

were shown in Tables 4A to 4E. A total of 5 patients with lower limb lymphedema were recruited in this study. 2 patients had bilateral lower limb lymphedema, 2 patients had right lower limb lymphedema, and 1 patient had left lower limb lymphedema. Through the lower extremity lymphedema index, all patients have significant improvement except 1 patient. Whereas utilizing the Lymph-ICF-LL questionnaire, clinically relevant improvements were observed in 1 patient in the mental function and mobility domain. Minor improvements were still observed in other patients. No patient experiences a decrease in functionality. The majority of patients with lower limb lymphedema experienced a positive effect with the use of customized pressure devices.

Table 1 Demographics of patients

Patient	Age	Gender	Weight (kg)	Height (cm)	BMI (kg/m^2)	Co-morbidities	Affected lower limb(s)	Cause of lymphedema
A	46	Male	158	163	59	Obesity class 3 Hypertension	Bilateral	Lymphedema precox
B	44	Male	85	172	28.7	Pre-obesity	Right	Lymphedema precox
C	48	Female	72	164	30.4	Obesity class 1 Dyslipidemia	Right	Lymphedema precox
D	38	Male	125	165	45.9	Obesity class 3 Hypertension	Bilateral	Lymphedema precox
E	40	Male	95	169	33.2	Obesity class 1	Left	Lymphedema precox

Table 2 Objective outcome following customized pressure device, Lower extremity lymphedema (LEL) index

Patient	Lower Limb (S)	LEL Index 1st Measurement	LEL Index 2nd Measurement	LEL1 -LEL2	Outcome (%)
A	Right	289	286	3	- 1.04
	Left	582	571	11	- 1.89
B	Right	526.5	455.4	71.1	- 13.50
C	Right	383	342	41	- 10.70
D	Right	597.5	506.6	90.9	- 15.21
	Left	1,157.3	1,070.5	86.8	- 7.50
E	Left	654	612	42	- 6.42

Table 3 Subjective outcome following customized pressure device Lymphedema Functionality, Disability and Health Questionnaire for Lower Limb Lymphedema and Validity (Lymph-ICF-LL)

Patient	Physical function		Outcome	Mental function		Outcome	General task/ household		Outcome	Mobility		Outcome	Life domain/ social life domain		Outcome	Total of Outcome
	Pre	Post		Pre	Post		Pre	Post		Pre	Post		Pre	Post		
A	28	26	-2	52	48	-4	23	21	-2	67	65	-2	60	59	-1	-11
B	9	3	-6	36	16	-20 Clinically relevant improvement	17	17	-	48	27	-21 Clinically relevant improvement	30	16	-14	-61
C	19	9	-10	23	14	-9	3	2	-1	25	21	-4	23	16	-7	-31
D	29	18	-11	38	29	-9	17	14	-3	58	51	-7	42	37	-5	-35
E	28	24	-4	8	6	-2	3	0	-3	18	16	-2	15	12	-3	-14

Table 4A.1 Right lower limb circumference measurements for patient A

Affected limb	Measurements from heel	Limb circumference (cm)	Square of limb circumference (cm^2)	Limb circumference (cm)	Square of limb circumference (cm^2)
Right	**5 cm**	41	1,681	41	1,681
	10 cm	39	1,521	38	1,444
	15 cm	37	1,369	39	1,521
	20 cm	39	1,521	39	1,521
	25 cm	44	1,936	42	1,764
	30 cm	44	1,936	45	2,025
	35 cm	56	3,136	57	3,249
	40 cm	63	3,969	61	3,721
Sum of square of limb circumference (cm^2)			17,089		16,926
LEL index			289		286

Table 4A.2 Left lower limb circumference measurements for patient A

Affected limb	Measurements from heel	Limb circumference (cm)	Square of limb circumference (cm^2)	Limb circumference (cm)	Square of limb circumference (cm^2)
Left	**5 cm**	55	3,025	53	2,809
	10 cm	55	3,025	56	3,136
	15 cm	59	3,481	59	3,481
	20 cm	63	3,969	63	3,969
	25 cm	65	4,225	63	3,969
	30 cm	68	4,624	67	4,489
	35 cm	79	6,241	78	6,084
	40 cm	76	5,776	76	5,776
Sum of square of limb circumference (cm^2)			34,366		33,713
LEL index			582		571

Table 4B Right lower limb circumference measurements for patient B

Affected limb	Measurements from heel	Limb circumference (cm)	Square of limb circumference (cm^2)	Limb circumference (cm)	Square of limb circumference (cm^2)
Right	**5 cm**	32	1,024	36	1,296
	10 cm	36.5	1,332.25	34	1,156
	15 cm	44.5	1,980.25	38	1,444
	20 cm	48.5	2,352.25	40	1,600
	25 cm	48	2,304	44	1,936
	30 cm	49	2,401	43	1,849
	35 cm	46	2,116	45	2,025
	40 cm	40	1,600	42	1,764
Sum of square of limb circumference (cm^2)			15,109.75		13,070
LEL index			526.5		455.4

Table 4C Right lower limb circumference measurements for patient C

Affected limb	Measurements from heel	Limb circumference (cm)	Square of limb circumference (cm^2)	Limb circumference (cm)	Square of limb circumference (cm^2)
Right	**5 cm**	34	1,156	32	1,024
	10 cm	30	900	29	841
	15 cm	29	841	29	841
	20 cm	39	1,521	36	1,296
	25 cm	41	1,681	40	1,600
	30 cm	44	1,936	41	1,681
	35 cm	42	1,764	40	1,600
	40 cm	43	1,849	39	1,521
Sum of square of limb circumference (cm^2)			11,648		10,404
LEL index			383		342

Table 4D.1 Right lower limb circumference measurements for patient D

Affected limb	Measurements from heel	Limb circumference (cm)	Square of limb circumference (cm^2)	Limb circumference (cm)	Square of limb circumference (cm^2)
Right	**5 cm**	48.1	2,313.61	46	2,116
	10 cm	48	2,304	44	1,936
	15 cm	45.2	2,043.04	45	2,025
	20 cm	45.5	2,070.25	45	2,025
	25 cm	63.3	4,006.89	60	3,600
	30 cm	72	5,184	63	3,969
	35 cm	73	5,329	65	4,225
	40 cm	65	4,225	58	3,364
Sum of square of limb circumference (cm^2)			27,425.79		23,260
LEL index			597.5		506.6

Table 4D.2 Left lower limb circumference measurements for patient D

Affected limb	Measurements from heel	Limb circumference (cm)	Square of limb circumference (cm^2)	Limb circumference (cm)	Square of limb circumference (cm^2)
Left	**5 cm**	71	5,041	72	5,184
	10 cm	74	5,476	73	5,329
	15 cm	73.6	5,416.9	75	5,625
	20 cm	76	5,776	78	6,084
	25 cm	87	7,569	80	6,400
	30 cm	86.3	7,447.69	84	7,056
	35 cm	92.6	8,574.76	84	7,056
	40 cm	89	7,921	80	6,400
Sum of square of limb circumference (cm^2)			53,122.35		49,134
LEL index			1,157.3		1,070.5

Table 4E Left lower limb circumference measurements for patient E

Affected limb	Measurements from heel	Limb circumference (cm)	Square of limb circumference (cm^2)	Limb circumference (cm)	Square of limb circumference (cm^2)
Left	**5 cm**	41.5	1,722.25	41	1,681
	10 cm	40.5	1,640.25	39	1,521
	15 cm	44	1,936	44	1,936
	20 cm	48	2,304	46	2,116
	25 cm	52	2,704	49	2,401
	30 cm	63	3,969	58	3,364
	35 cm	62	3,844	62	3,844
	40 cm	60	3,600	59	3,481
Sum of square of limb circumference (cm^2)			21,719.5		20,344
LEL index			654		612.8

Discussion

Lymphedema management has always posed challenges in terms of diagnosis, classification, and management. Measuring the circumference is the most common method for objectively evaluating lymphedema.[7] However, this method is inconsistent due to the variability of a reference point for measurement.[7] This is due to anatomical distortion caused by the lymphedema, rendering fixed points such as the patella or malleolus undetectable. Lymphedema also has volumetric changes on top of circumferential increase. Volume is more difficult to quantify due to the asymmetrical distribution of lymphatic fluid.[6] Yamamoto et al. developed the lower extremity lymphedema (LEL) index in 2011, which incorporates the cross-sectional area of the affected limb and patients' BMI.[7] It can be used to assess the severity of the lymphedema through a numerical rating, regardless of body habitus, and for comparison between different patients.[7] It is calculated by using the sum of the squares of circumference in 5 areas of the lower limbs (10 cm above the patella, superior edge of the patella, 10 cm below the patella, lateral malleolus, dorsum of the foot) and divided by the respective patients' BMI.[7] In our study, we modified the calculation of the LEL index using the heel as a reference point and measured the limb circumference at intervals of 5 cm. These measurements are done to get a more accurate representation of the lymphedema throughout the lower limb. All 5 patients recruited in our study are of Campisi clinical stage 4, and due to severe anatomical distortion, a reference point for measurement was difficult to obtain. Thus, instead of using the patella as a landmark for measurement, we measure the circumference of the lower limb at 5 cm, 10 cm, 15 cm, 20 cm, 25 cm, 30 cm, 35 cm, and 40 cm from the heel. The sum of the squares of all the values is then divided by the respective patients' BMI to obtain the LEL index.

The Lymph-ICF-LL questionnaire was developed by Devoogdt et al in 2014 and was tested as reliable and valid for assessing problems in functioning in patients with lower limb lymphedema.[8] The Lymph-ICF-LL is a descriptive, evaluative tool containing 28 questions about impairments in function, activity limitations, and participation restrictions in patients with lower limb lymphedema.[8] The questionnaire has 5 domains: physical function, mental function, general tasks/household activities, mobility activities, and life domains/social life.[8] Patients must complete the questionnaire by themselves and were asked to score the same hobbies and social activities each time.[8] According to Devoogdt et al, for the interpretation of follow-up assessment with the Lymph-ICF-LL questionnaire, a change (increase/decrease) of 20 or more is considered a clinically relevant change for all domains except the life domain/ social life.[8] For the life domain/ social life domain, a change (increase/decrease) of 40 is considered a clinically relevant change.[8] Only 1 of our patients reported clinically significant mental function and mobility changes in Lymph-ICF-LL. However, all of the patients have reported improvement throughout all aspects of the Lymph-ICF-LL questionnaire. This study was conducted in a short period of 5 months, and most patients have not had adequate time to return to their daily activities yet due to various reasons, such as excessive

weight and lower limb weakness. Long-term follow-ups are needed on these patients.

No significant relationship is observed between the decrease in lower limb lymphedema and patients' functionality, disability, and health. This is observed when we compare the LEL1-LEL2 scores to the Lymph-ICF-LL scores. A higher LEL1-LEL2 score does not improve the Lymph-ICF-LL score further. This can be multi-factorial as patients' pre-morbid function, mental health, and existing medical conditions can affect the scores in the Lymph-ICF-LL questionnaire. There is also no relationship between the severity of lymphedema and patients' functionality, disability, and health, as the high LEL1 or LEL2 scores do not cause a lower score in the questionnaire.

Last but not least, obesity was observed in all 5 of our patients. Multiple recent clinical studies have established the significant relationship between obesity and lymphedema.[9] Case of obesity-induced lymphedema of the lower extremities was reported and concluded that lymphedema can develop once a patient's body mass index (BMI) exceeds 50.[10] Unlike other co-morbidities such as diabetes, hypertension, and sleep apnea, which may improve with massive weight loss, obesity-induced lymphedema may not resolve, even with weight reduction due to the irreversibility of lymphatic dysfunction.[10] Several studies have shown that obesity increases the risk of secondary lymphedema following damage to the lymphatic system.[9] Recent research also indicates that morbidly obese individuals can develop lymphedema even without prior surgery or injury, highlighting that obesity alone can impair lymphatic function and lead to the development of lymphedema.[10] Growing evidence suggests a reciprocal relationship between obesity and lymphedema, where obesity impairs lymphatic function, and impaired lymphatic drainage, in turn, promotes fat deposition, but this is limited to animal models for now.[10]

Conclusion

Results from our study demonstrated the role of customized pressure devices in lower limb lymphedema management. There is a significant decrease in LEL in 80% of our patients, hence proving that there is a significant physical and volumetric decrease in lower limb lymphedema. Only 20% of our patients reported clinically significant improvement in their Lymph-ICF-LL score. This is possibly due to the short course of this study, the patient's pre-morbid physical conditions, and existing medical conditions. Patients with chronic malnutrition and anemia were less likely to get back to physical activities. Although treatment with a customized pressure device showed promising results, there is still a need to evaluate the long-term outcomes further.

Conflict of Interest

All authors have nothing to disclose.

Acknowledgement

The authors would like to thank the Director General of Health Malaysia for his permission to publish this paper.

The authors would also like to thank the Director of Hospital Sungai Buloh for his permission to carry out this research in the hospital.

Informed consent

Informed consent and consent to publish the outcomes were obtained from all the individual participants included in this study.

Consent to publish

All individual participants included in the study have consented to the submission of this original article to the journal.

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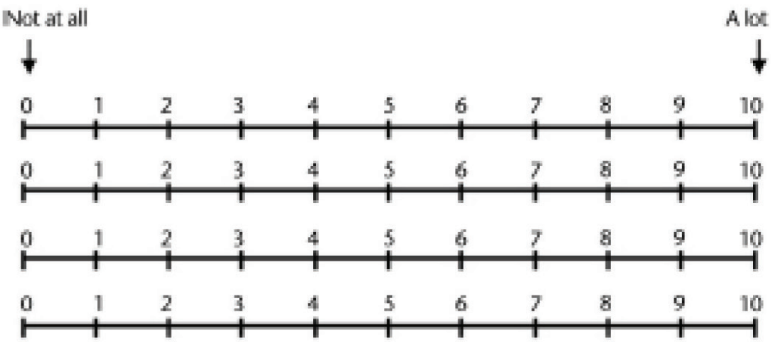
Appendix 1 Lymphedema Functionality, Disability and Health Questionnaire for Lower Limb Lymphedema Reliability and Validity (Lymph-ICF-LL)

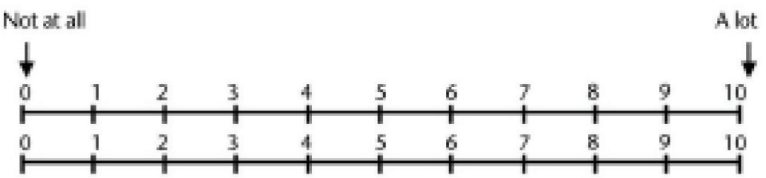
<u>Physical function</u>

Do you have at the level of your leg (legs) and/or foot (feet):



1. Pain?
2. Tense skin?
3. Tingling?
4. Infections (at this time or occasionally)?

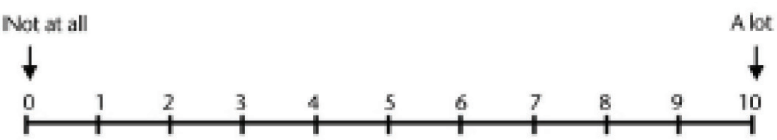
Does your leg (legs) and/or foot (feet) feel:



5. Stiff (reduced mobility)?
6. Heavy?

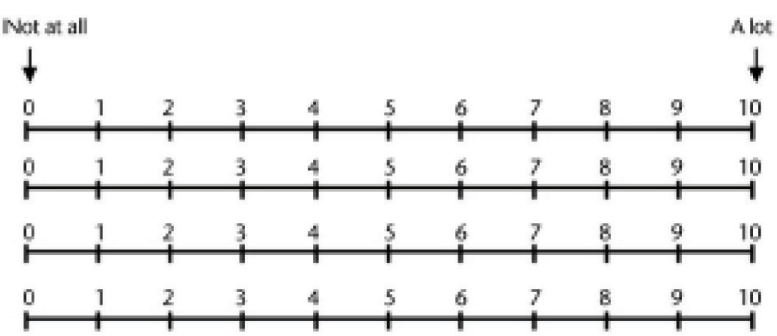
<u>Mental function</u>

Due to your lymphedema, do you have:



7. A lack of confidence?

Due to your lymphedema, do you feel:



8. Sad?
9. Unattractive?
10. Frustrated (tense)?
11. Insecure about the future (eg, your work situation)?
12. Disappointed in medical health care (eg, lack of information?

General tasks/household

Due to your lymphedema, have you:

13. Become more dependent on others?

Not at all — A lot

0 1 2 3 4 5 6 7 8 9 10

Due to your lymphedema, do you have difficulties with:

14. Organizing different matters (eg, chores, appointments)?

0 1 2 3 4 5 6 7 8 9 10

15. Completing household chores?

0 1 2 3 4 5 6 7 8 9 10 ○ Not applicable

Mobility

Due to your lymphedema, can you:

Very well — Not at all

16. Sit for a prolonged period of time?

0 1 2 3 4 5 6 7 8 9 10

17. Stand for a prolonged time?

0 1 2 3 4 5 6 7 8 9 10

18. Kneel?

0 1 2 3 4 5 6 7 8 9 10

19. Walk (>2 km)?

0 1 2 3 4 5 6 7 8 9 10

20. Ride a bicycle?

0 1 2 3 4 5 6 7 8 9 10 ○

21. Drive a car?

0 1 2 3 4 5 6 7 8 9 10 ○

22. Take the stairs (or get on and off a bus)?

0 1 2 3 4 5 6 7 8 9 10 ○ Not applicable

Life domains/social life

Due to your lymphedema, can you:

Very well — Not at all

23. Fulfill your job (paid work)?

My job: _____

0 1 2 3 4 5 6 7 8 9 10 ○

24. Practice sports?

My sport(s): _____

0 1 2 3 4 5 6 7 8 9 10 ○

25. Carry out leisure-time activities?

My leisure-time activities: _____

0 1 2 3 4 5 6 7 8 9 10 ○

26. Carry out social activities with friends (eg, go to a party, go out for dinner)?

My social activities: _____

0 1 2 3 4 5 6 7 8 9 10 ○

27. Wear clothes and/or shoes you like to wear?

0 1 2 3 4 5 6 7 8 9 10

28. Go on a holiday?

0 1 2 3 4 5 6 7 8 9 10 ○ Not applicable