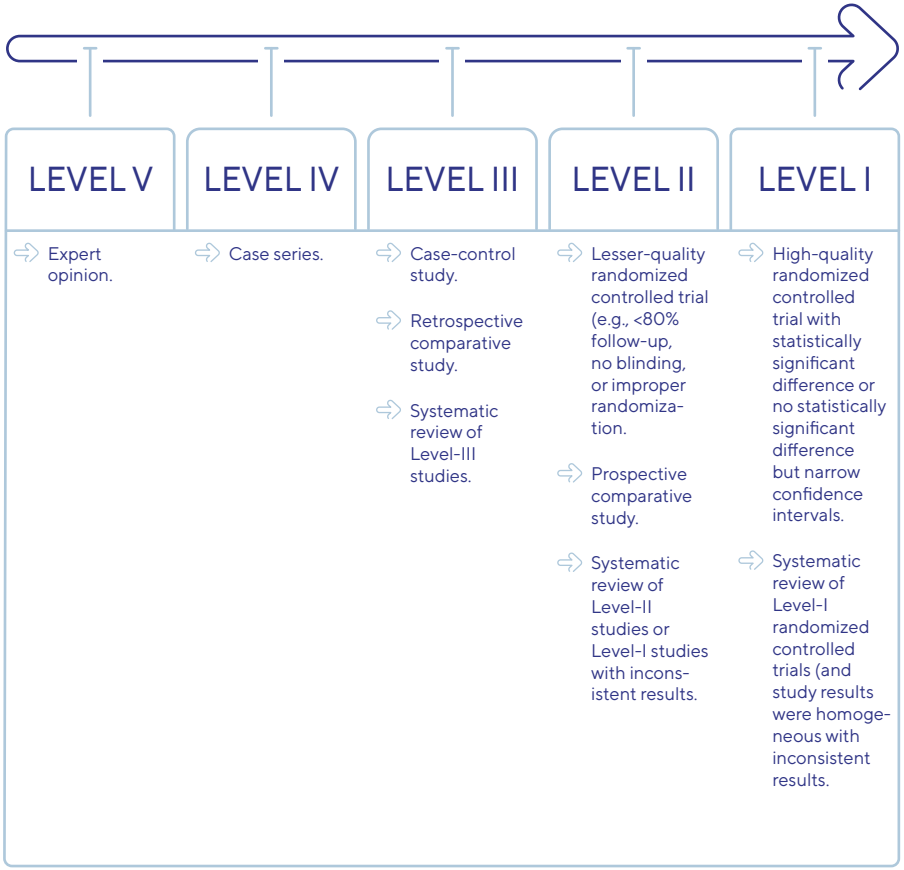
THUASNE

CLINICAL BROCHURE

Lymphedema mobilizing solutions

Level of Evidence Scale

JBJS level of Evidence for Primary Research Question - Therapeutic Studies



BENEFITS OF NIGHTTIME GARMENTS

	MAIN AUTHOR	TITLE	COUNTRY	YEAR	DESIGN	LEVEL OF EVIDENCE*	PRODUCT	POPULATION	LO TYPE
BENEFITS OF NIGHTTIME GARMENTS (products similar to MOBIDERM)	*McNeely*	**Nighttime Compression Supports Improved Self- Management of Breast Cancer– Related Lymphedema**		2022	Prospective, multicenter, randomized, controlled trial	**Level I**	Self-bandages and nighttime garment	120	Upper limb Breast Cancer Related Lymphedema (BCRL)
	Whitaker	**Lymphoedema management at night: views from patients across 5 countries**		2016	Patient's survey	**N/A**	-	94	Upper & lower limb, primary & secondary

MOBIDERM: CLINICAL STUDIES

MOBIDERM FOR LYMPHEDEMA TREATMENT		*Quéré*	**Prospective multicenter observational study of lymphedema therapy: POLIT study**		2014	Prospective multicenter observational study	**Level III**	**MOBIDERM** Bandage and autofit	306	Upper & lower limb
INTENSIVE PHASE	Efficacy of **MOBIDERM** Bandages	*Dhar*	**Safety and efficacy of a MOBIDERM compression bandage during intensive phase of decongestive therapy in patients with breast cancer-related lymphedema**		2022	Prospective, single center, randomized, controlled trial	**Level II**	**MOBIDERM** Bandage	50	Upper limb Breast Cancer Related Lymphedema (BCRL)
MAINTENANCE PHASE	Self-Management with **MOBIDERM** garments	*Todd*	**MOBIDERM autofit: an adjustable sleeve that enables patients to self-manage lymphoedema**		2018	Case series	**Level IV**	**MOBIDERM** autofit	3	2 Upper limb Breast Cancer Related Lymphedema (BCRL) + 1 non-Hodgkin's lymphoma
	Benefits of nighttime **MOBIDERM** garments	*Mestre*	**Interest of an auto-adjustable nighttime compression sleeve MOBIDERM autofit in maintenance phase of upper limb lymphedema**		2017	Prospective, single center, randomized, controlled trial	**Level II**	**MOBIDERM** autofit	40	Upper limb Breast Cancer Related Lymphedema (BCRL)
		Mestre	**An auto-adjustable night garment to control early rebound effect of edema volume after intensive phase of Decongestive Lymphedema Therapy (DLT)**		2017	Prospective, single center, randomized, controlled trial	**Level II**	**MOBIDERM** autofit	40	Upper limb Breast Cancer Related Lymphedema (BCRL)
		Toccafondi	**Clinical use of a nighttime MOBIDERM garment as a treatment modality for breast cancer related lymphedema**		2017	Retrospective observational cohort study	**Level III**	**MOBIDERM** made-to-measure patient	145	Upper limb Breast Cancer Related Lymphedema (BCRL)
MOBIDERM FOR OTHER LOCALIZATIONS		*Mestre*	**Positive impact of a new compressive garment in patients with genital lymphedema**		Under review	Prospective, multicenter, exploratory uncontrolled trial	**Level III**	**MOBIDERM** Intimate Shorts	32	Genital lymphedema

*JBJS level of Evidence for Primary Research Question - Therapeutic Studies.

CLINICAL TRIALS: THE STATE OF THE ART

	MAIN AUTHOR	TITLE	COUNTRY	YEAR	DESIGN	LEVEL OF EVIDENCE*	PRODUCT	POPULATION	LO TYPE
MOBIDERM autofit IN THE INTENSIVE PHASE	*Takanishi*	**The hybrid approach to treating severe lower extremity lymphoedema**		2019	Case report	**Level IV**	**MOBIDERM** autofit	1	Lower limb lymphedema
	Stawomir	**Effectiveness of MOBIDERM autofit in the intensive phase of breast cancer related lymphedema treatment, a case series**		2023	Case series	**Level IV**	**MOBIDERM** autofit	10	Upper limb Breast Cancer Related Lymphedema (BCRL)
MOBIDERM FOR FIBROSIS REDUCTION	*Hodgson*	**Use of a tissue mobilising compression system**		2011	Case report	**Level IV**	**MOBIDERM** Bandage	1	Upper limb Breast Cancer Related Lymphedema (BCRL)
MOBIDERM IN ASSOCIATION TO IPC	*Tchórzewska*	**The use of IPC with MOBIDERM in upper limb lymphoedema treatment**		2018	Prospective, single center, controlled trial	**Level II**	**MOBIDERM** Bandage	60	Upper limb Breast Cancer Related Lymphedema (BCRL)

The studies including Mobiderm products listed above are from the literature and were not conducted under the responsibility of Thuasne.

*JBJS level of Evidence for Primary Research Question - Therapeutic Studies.

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CLINICAL TRIALS: THE STATE OF THE ART

MOBIDERM autofit IN THE INTENSIVE PHASE

MOBIDERM FOR FIBROSIS REDUCTION

MOBIDERM IN ASSOCIATION TO IPC

Nighttime Compression Supports Improved Self- Management of Breast Cancer– Related Lymphedema: A Multicenter Randomized Controlled Trial.

Margaret L. McNeely, Naomi D. Dolgoy, Bolette Skjodt Rafn, Sunita Ghosh, Paula A. Ospina, Mona M. Al Onazi, Lori Radke, Mara Shular, Urve Kuusk, Marc Webster, Kristin L. Campbell and John R. Mackey — Cancer (2022), 128(3):587-596

Country:

Design: prospective, multicenter, randomized controlled trial

Product: Self-bandages (Coban) and nighttime garment

Population: 120 patients with upper limb Breast Cancer Related Lymphedema

Treatment phase: maintenance

Treatment Duration: 24 weeks

Level of evidence: I

Objective

The objectives of this randomized controlled trial were to determine the efficacy of nighttime compression (self-bandages and garments) on arm lymphedema volume maintenance and quality-of-life outcomes in women with breast cancer related lymphedema (BRCL), who were in the maintenance phase of treatment for lymphedema.

Methods

This prospective, controlled, randomized single blind study was realized in 3 cancer centers in Canada. 120 patients with BRCL were included in this study between November 2014 and August 2017 and randomized into 3 groups (40 patients per group) for maintenance phase and followed for 12 weeks :

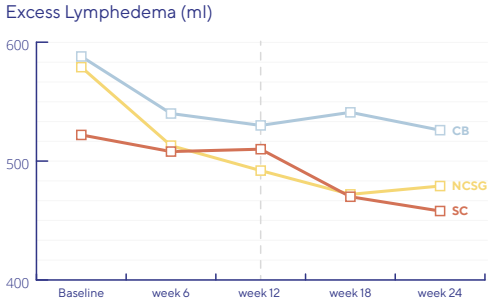
- Group 1: Only day-time compression (with their own sleeve for a min of 12h per day)
- Group 2: Day-time compression + nighttime compression with self-bandages
- Group 3: Day-time compression + nighttime compression with garment

All the patients from the 3 groups wore the nighttime garment for an additional 12 weeks follow-up (total of 24 weeks follow-up).

The main objective of the study was to compare the evolution of excess volume (with the perometer technology), between the 3 treatment groups after 12 weeks of treatment.

The secondary objectives corresponded to the evolution of Quality of Life (Lymph-ICF), sleep and self-efficacy of lymphedema management.

Results



Change in excess lymphedema: baseline to 24 weeks in milliliters. CB indicates compression bandading; NCSG, nighttime compression system garment; SC, standard care.

- After 12 weeks of treatment, there was a significantly larger percentage reduction of excess lymphedema when nighttime compression was applied. The lymphedema reduction after 12 weeks was 1.5% without nighttime compression (SC), 12.1% with bandages for nighttime compression (CB) and 15.9% for nighttime compression system garment (NCSG).
- There was no significant difference between bandages and garment regarding lymphedema volume reduction after 12 weeks.
- After 12 weeks of treatment, all the patients wore a nighttime compression with garment for 12 additional weeks. Patients of the first group without nighttime compression at the beginning of the study showed a volume reduction similar to the other groups after 24 weeks. This result shows that the addition of a nighttime garment for 12 weeks allows a volume reduction even when introduced later.
- A plateau in the lymphedema volume reduction was seen in the 2 original nighttime compression groups when 12 additional weeks of nighttime compression were added. After 12 weeks of day and nighttime compression, the volume reduction seems to be reached for these patients, then the volume remains stable.
- Quality of life, sleep and self-efficacy of lymphedema management were improved similarly in the 3 groups.
- The rates of compliance to nighttime compression were very high whatever the type of used compression (bandages or garments)
- The cost for garment in Canada is around 4 to 5 fold higher than for bandages. Although the cost of a nighttime garment may be prohibitive for some women, its advantages include time efficiency and ease in application, which enable long-term adherence to self-management.

Conclusions

The trial demonstrated a significant improvement in arm lymphedema volume from the addition of nighttime compression whether through the application of compression bandaging or through the use of a nighttime compression system garment.

KEY TAKEAWAYS

- The benefit from the addition of nighttime compression to the use of a daytime compression sleeve during the maintenance phase is demonstrated in this study.
- The nighttime compression with self-bandages and compression garments are similar in terms of volume reduction and adherence to treatment during the maintenance phase.
- Time efficiency and ease in application of nighttime compression garments as compared to bandages could increase long-term adherence to self-management.

Abstract:

https://pubmed.ncbi.nlm.nih.gov/34614195/

Lymphoedema management at night: views from patients across 5 countries

J. C. Whitaker – British Journal of Community Nursing, Vol 21, No 10, Chronic Edema (October 2016)

Country:

Design: patient's survey
Population: 94 patients from UK, USA, Sweden, Australia, Germany with all types of LO (315 nights)
Treatment phase: maintenance
Treatment Duration: various
Level of evidence: N/A

Objective

The aim of this study was to gain a comprehensive insight into the use of nighttime compression in the management of lymphedema in patients who had been suffering from chronic lymphedema for over 12 months.

Methods

94 patients were recruited for interview from five countries (Germany, Sweden, USA, UK and Australia) through lymphedema support networks and clinicians.
Patients suffering from primary or secondary lymphedema had to have been diagnosed at least 12 months before the start of the study and should be using nighttime compression a minimum of once a week in addition to the use of daytime compression. All recruited patients must be beyond the decongestion phase of management.
The severity of oedema of the affected limb, assessed by the patient, was recorded pre and post-compression. Qualitative data were obtained through participants keeping a diary over a 3–5-day period, about experience of nighttime compression benefits, drawbacks and unmet needs.

Results

67% of participants experienced lymphedema of the leg, 30% in the arm or hand and the remaining 3% in both arm and leg.
Data were collected on 207 nights from USA, Sweden and Australia, and 108 nights from Germany and UK.
Nighttime compression therapy is widely recognized and recommended as a common practice in 3 of the 5 countries involved in the study (Australia, USA and Sweden).
89% of patients reported increased swelling overnight when nighttime compression was not worn, which in 49% persisted for 24 hours. The top three reasons given for not using nighttime compression were fatigue, heat and the edema being stable.
61% of patients surveyed started using nighttime compression later than daytime compression.
40% used two or more different products simultaneously at night. The use of products by country is described in the table below:

Types of product used at night		Australia	USA	Sweden	Germany	UK
Compression products/garments	78%	80%	44%	100%	96%	70%
Wrap	26%	-	56%	11%	32%	10%
Bandage	26%	8%	46%	33%	8%	50%
Fabric with foam fill	18%	12%	48%	11%	-	10%
Foam liner with straps	10%	-	28%	11%	-	10%
Short stretch binders	12%	-	32%	11%	4%	10%
		n = 25	*n* = 25	*n* = 9	*n* = 25	*n* = 10

The specific nighttime compression products and classic compression products were not used alone but in 97% (91/94) of cases supplemented by creams, moisturizers, padding, donning aids and the use of intermittent pumps to soften the limb.
While the findings from this study support the use of nighttime compression therapy, they also make clear that the development and refashioning of new and existing products are required to meet the needs of the patient over a 24-hour period. The feedback prioritized addressing issues of comfort, to easier application and to a breathable device.

Conclusions

Positive outcomes from the use of nighttime compression were reported, with all patients identifying benefits of using nighttime compression; the top three being the better management of their edema, reduction in pain and a sense of relief continuing into the daytime.

KEY TAKEAWAYS

- The use of nighttime compression therapy is clearly supported with the study identifying both psychological and physical benefits.
- When nighttime compression was not worn, 89% of patients noticed an increase in swelling.
- Patients using nighttime compression reported benefits of reduced swelling, improved pain management and better sleep.
- Main reasons given for not using nighttime compression were fatigue, heat and the edema being stable.
- Improvement of the nighttime devices regarding, comfort, ease of use and breathability are expected by patients.

Abstract:

https://pubmed.ncbi.nlm.nih.gov/27715142/

MOBIDERM:
CLINICAL STUDIES

MOBIDERM FOR LYMPHEDEMA TREATMENT

Prospective multicentre observational study of lymphedema therapy: POLIT study

I. Quéré, E. Presles, M. Coupé, S. Vignes, L. Vaillant, D. Eveno, S. Laporte, A. Leizorovicz, POLIT Study investigators – Journal des Maladies Vasculaires (2014), 39, 256-263

Country:

Design: prospective multicenter observational study

Product: MOBIDERM bandages and autofit

Population: 306 patients with unilateral upper or lower limb lymphedema (stage 2 and 3)

Treatment phase: intensive and maintenance

Treatment Duration: 7 months

Level of evidence: III

Objective

Lymphedema treatment is based on Decongestive Lymphedema Therapy (DLT) with an intensive phase followed by a long-term maintenance phase. This study aimed to observe volume variation over the intensive phase and 6 months later.

Methods

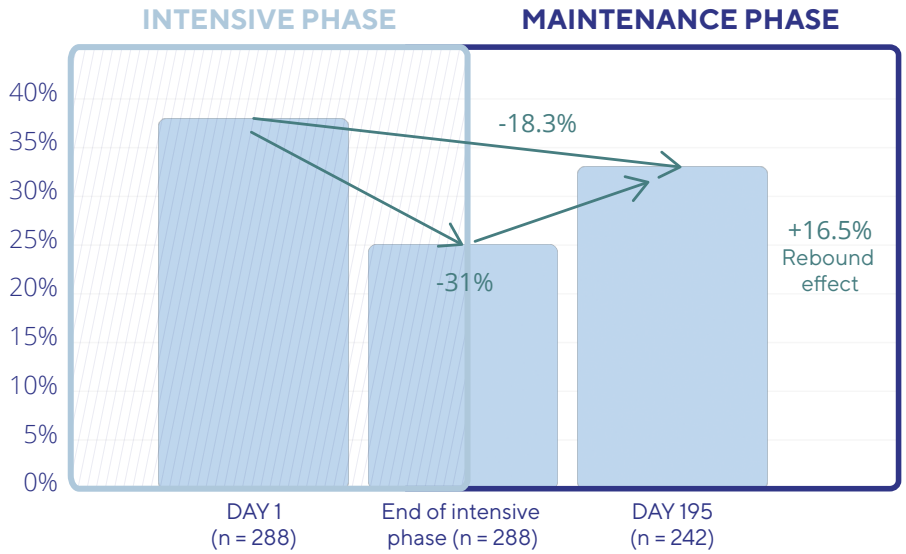
This was a multicenter observational study on patients with unilateral lymphedema.
The primary objective was to assess lymphedema volume variation between baseline, the end of intensive phase and 6 months later.
Secondary objectives were to describe therapeutic protocol applied during intensive and maintenance phase (duration, treatments, health care, compliance...), to assess the evolution of pain, heaviness limiting limb function, quality of life and treatments safety predictors for volume reduction.

Results

Three hundred and six patients (89.9% women; 59.9 ± 14.3 years old) with upper/lower (n = 184/122) limb lymphedema were included.

Volume variation:
At baseline, median relative excess volume was 38.7% as compared to healthy contralateral arm.
At the end of the intensive phase, median excess volume reduction was 31.0% (-41.7; -19.9) followed by a 16.5% (5.9—42.3) median increase over the 6-month maintenance period phase. This last increase was more important regarding lower limbs (19.3%) than upper limbs (13.4%).

Relative excess volume:



The median volume reduction achieved after the first 5 days of treatment in the sub-population of patients treated with daily multilayers bandaging including MOBIDERM padding was –27.4% (Q1, Q3: –36.8, –16.1) and –22.2% (Q1, Q3:–34.1, –15.1) with other types of padding.
The benefit of wearing a nighttime compression during maintenance phase was highlighted by a 20.1% median increase in patients without nighttime compression versus a 15.7% and 12.4% median increase in patients wearing nighttime compression (Hosiery and bandages respectively).

Therapeutic protocol description

Median duration of intensive phase differed between centres and habits of treatment. It was observed that it lasted 5 days (Q1—Q3: 5—9) for patients treated with a daily multilayer bandage including MOBIDERM padding and 10 days (Q1—Q3: 5—11) for patients treated with a daily multilayer bandage with other types of padding material.
The maintenance phase was mainly based on daytime compression for 95.8% of the patients and nighttime compression for 78.9% of the patients (using bandages or hosiery during night treatment). Nighttime compression was based on MOBIDERM orthesis for 46% and multilayers bandages for 43.3% of patients.

Symptoms description

Feeling of heaviness and pain were reported by 75.5% and 53.6% of patients respectively at baseline. As compared to baseline, heaviness limiting limb use was much less frequently reported at the end of the intensive phase (75.5% versus 42.3% respectively), and was more frequent at the end of the maintenance phase (62.6%). The evolution of pain during the study is similar to heaviness.
In contrast to patients without nighttime MOBIDERM hosiery, the proportion of patients who have a good perception of their quality of life increased during maintenance phase for patients wearing nighttime MOBIDERM garment (59.4% at the end of TDI to 67.4%.at the end of follow-up).

Compliance

During maintenance phase, among patients who used compression bandages at night, only 19.8% used them daily as compared to 57.5% of patients using nighttime hosiery.

Adverse events

The most frequent adverse events reported were skin redness and compression marks (18.4 and 15.7% of patients, respectively). Adverse events likely to need treatment discontinuation were rare (0.3% for infection and 1.4% for blister).

Conclusions

We observed a 31% lymphedema volume reduction after the intensive phase. However, part of the benefit was lost 6 months later.
This study confirms that the maintenance phase presents challenges to patients and clinicians. Thus, there is a need to consider how to provide optimal patient care during the maintenance phase.

KEY TAKEAWAYS

- A 31% median excess volume reduction was reported at the end of intensive phase.
- Use of MOBIDERM bandages in reduction phase seems to have better outcomes than other padding after 5 days.
- A shorter median duration of intensive phase is applied in centers using MOBIDERM bandage.
- Benefit of DLT is partially lost after the first 6 months of maintenance phase (+16.5% median volume increase).
- Nighttime compression during maintenance phase is associated with less rebound effect.

Abstract:

https://pubmed.ncbi.nlm.nih.gov/24931830/

References:
I. Quéré, E. Presles, M. Coupé, S. Vignes, L. Vaillant, D. Eveno, S. Laporte, A. Leizorovicz, POLIT Study investigators - Prospective multicentre observational study of lymphedema therapy: POLIT study. Journal des Maladies Vasculaires (2014) 39, 256-263
POLIT Clinical report – 18 December 2012

INTENSIVE PHASE
EFFICACY OF MOBIDERM BANDAGES

Safety and efficacy of a MOBIDERM compression bandage during intensive phase of decongestive therapy in patients with breast cancer-related lymphedema: A randomized controlled trial (MOBILITY study)

Anita Dhar, Anurag Srivastava, Ravindra M Pandey, Prasanna Shrestha, Stéphanie Villet, Arun Rekha Gogia — Lymphatic Research and Biology (2022 June 8)

Country:

Design: prospective, single center, randomized controlled trial
Product: **MOBIDERM** Bandage
Population: 50 patients with upper limb Breast Cancer Related Lymphedema (BCRL)
Treatment phase: intensive
Treatment Duration: 15 days
Level of evidence: II

Objective

The aim of the study was to evaluate the efficacy of the specific mobilizing bandage MOBIDERM on lymphedema volume during the intensive phase of decongestive lymphedema therapy.

Methods

Fifty patients with Breast Cancer Related Lymphedema (BCRL) were randomized to receive either:

- conventional multi-layered bandages (an inner layer of cotton band (Cotton Band; THUASNE); an intermediate layer (ortho cotton wool soft pad, India); and an external layer of elastic short-stretch bandage (Biflexideal; THUASNE);
- bandaging incorporating MOBIDERM: same bandage as the previous one except the intermediate layer that was replaced by MOBIDERM band

The primary outcome was change in affected limb volume between Day 0 and Day 15.
Changes in symptom scores (pain/heaviness) were assessed by visual analog scale. Safety was also assessed.

Results

A reduction in affected limb volume was observed in both study groups after 15 days.
When adjusted for baseline volume, the limb volume reduction was significantly higher in the MOBIDERM group (19% reduction) than in the Control group (8.6% reduction), with a between-group mean difference in volume of 256 ml ($p = 0.003$).
After 15 days of DLT, pain/heaviness scores were significantly lower in both groups with significantly greater mean reductions observed in the MOBIDERM group (-1.84) compared to control ($p = 0.001$).
Both regimens were well tolerated. While lymphangitis was common in patients before starting the study, no new episodes of lymphangitis were observed during treatment period.

Conclusion

Results of this study show that use of MOBIDERM as a compression bandage in intensive phase (DLT) resulted in significantly greater volume reductions and improvements in pain/heaviness than a conventional compression bandage regimen in patients with Breast Cancer Related Lymphedema.

KEY TAKEAWAYS

Use of Mobiderm in multilayer compression bandaging shows a higher efficacy in reduction of lymphedema and in alleviating functional symptoms/pain in patients with Breast Cancer Related Lymphedema as compared to another padding.

Full article:

https://www.liebertpub.com/doi/epdf/10.1089/lrb.2021.0104

MAINTENANCE PHASE
SELF-MANAGEMENT WITH MOBIDERM GARMENTS

MOBIDERM Autofit: an adjustable sleeve that enables patients to self-manage lymphedema

M. Todd, C. Stubbs, S. Pugh – Chronic Edema (2018)

Country:

Design: case series
Product: MOBIDERM autofit
Population: 3 patients with upper limb lymphedema
Treatment phase: maintenance
Treatment Duration: 11 nights
Level of evidence: IV

Context

The often complex nature of chronic oedema and lymphedema (e.g. presence of morbid obesity, chronic wounds, poor concordance, palliative disease) means that practitioners need to have a range of treatment options available to them in order to provide a completely tailored treatment package.
Self-care is a fundamental and integral part of lymphedema management, but it requires assessment of readiness to participate, full patient involvement, support from health professionals, and suitable funding.
Nighttime compression is beneficial in managing lymphedema with reports of reduced swelling, improved pain management and better sleep.
MOBIDERM Autofit is a self-adjustable arm sleeve consisting of padded foam blocks, which applies soft pressure and encourages improved micro-circulation of the arm, and is useful in the nighttime management of lymphedema.

Method and results

This case series illustrates the use of MOBIDERM Autofit for the treatment of arm lymphedema following breast cancer for 2 patients and a non Hodgkin's lymphoma for one patient. They advised to wear MOBIDERM Autofit during nighttime in addition to their daytime usual compression garment.
On return to clinic after 11 days, the 3 patients reported that the garment was comfortable, easy to apply and to adjust, and did not affect their sleep. The tissues in their arm felt softer. Lymphedema volume reduction was observed for 2 out of 3 patients. A small increase of affected arm volume was reported for the patient who stopped wearing any daytime garment during the 11 days despite the physician's advices.

Conclusions

As illustrated by the case studies, the development of MOBIDERM Autofit has provided improvement in lymphedema management by enhancing nighttime compression therapy, and subsequently affording more self-care choice.

KEY TAKEAWAYS

- With the array of complexities involved in patients' healthcare needs, practitioners need a greater range of options to manage the symptoms and any compounding issues.
- MOBIDERM Autofit provides practitioners with a greater range of treatment options.
- MOBIDERM Autofit enhances nighttime compression therapy and patient self-care management.
- Patients reported a comfortable garment, easy to wear and to adjust, and softer skin after MOBIDERM autofit wearing.

MAINTENANCE PHASE

BENEFITS OF NIGHTTIME MOBIDERM GARMENTS

Interest of an auto-adjustable nighttime compression sleeve (MOBIDERM Autofit) in maintenance phase of upper limb lymphedema: the MARILYN pilot RCT

S. Mestre, C. Calais, G. Gaillard, M. Nou, M. Pasqualini, C. Ben Amor, I. Quere – Support Care Cancer (2017), 25:2455-2462

An auto-adjustable night garment to control early rebound effect of edema volume after intensive phase of Decongestive Lymphedema Therapy (DLT)

Mestre S, Gaillard G, Benhamou M, Soulier-Sotto V, Nou M, Pasqualini M, Ben Amor C, Quere I – Lymphatic Research and Biology (2017), 15(4):364-370

Country:

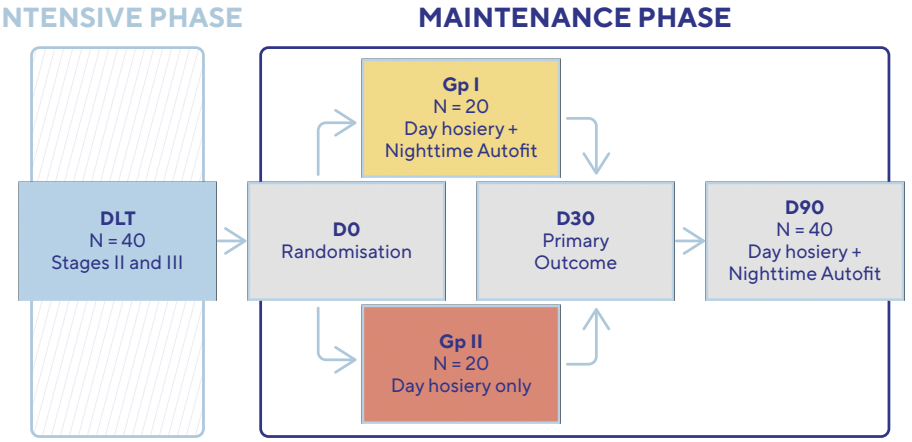
Design: prospective, single center, randomized, controlled trial
Product: MOBIDERM autofit
Population: 40 women with upper limb Breast Cancer Related Lymphedema (BCRL) (stages 2 and 3)
Treatment phase: maintenance
Treatment Duration: 90 days
Level of evidence: II

Objective

Breast cancer-related lymphedema (BCRL) is a debilitating condition. The recommended treatment is based on decongestive lymphedema therapy (DLT) with two separate phases: a short-term intensive phase to reduce lymphedema volume and a long-term maintenance phase to stabilize it.
Optimizing compression therapy and compliance during maintenance phase are key factors for long-term control of lymphedema.
The primary objective of this pilot prospective open-label randomized study was to assess the benefit of a new auto-adjustable nighttime arm sleeve (MOBIDERM Autofit) on lymphedema volume during the maintenance phase after the intensive phase.

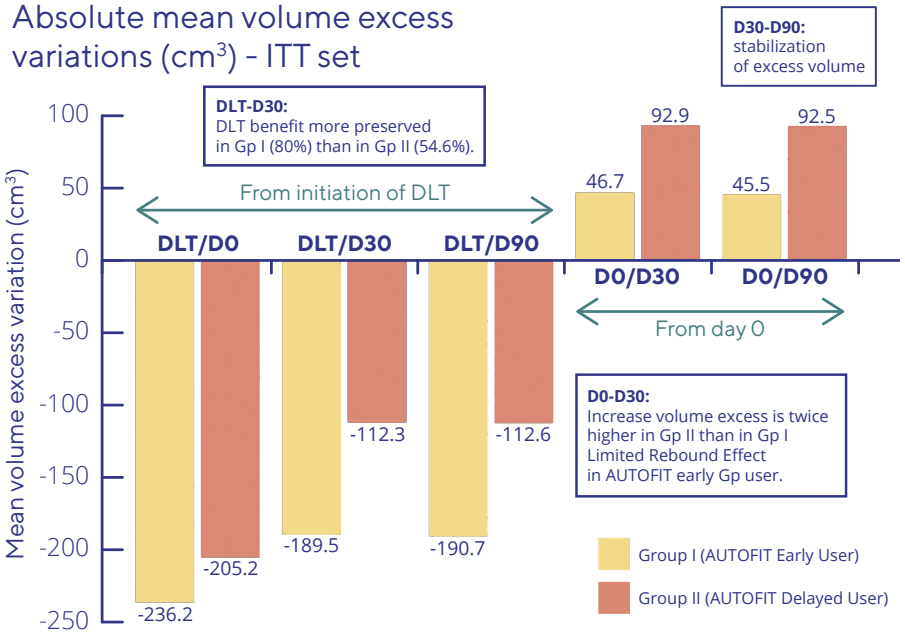
Methods

Forty women with BRCL were consecutively enrolled and randomized for 1 month either in night-use group: with MOBIDERM Autofit (on top of a daytime compression hosiery), or in no night-use group: without MOBIDERM Autofit (daytime hosiery alone). From Day 31 to Day 90, all patients were fitted with MOBIDERM Autofit.
Primary endpoint was lymphedema volume variation between Day 0 and Day 30.
Secondary endpoints were compliance, quality of life (LYMQOL arm questionnaire), functional symptoms (heaviness, limb use limitation, pain), sleep quality, and safety.



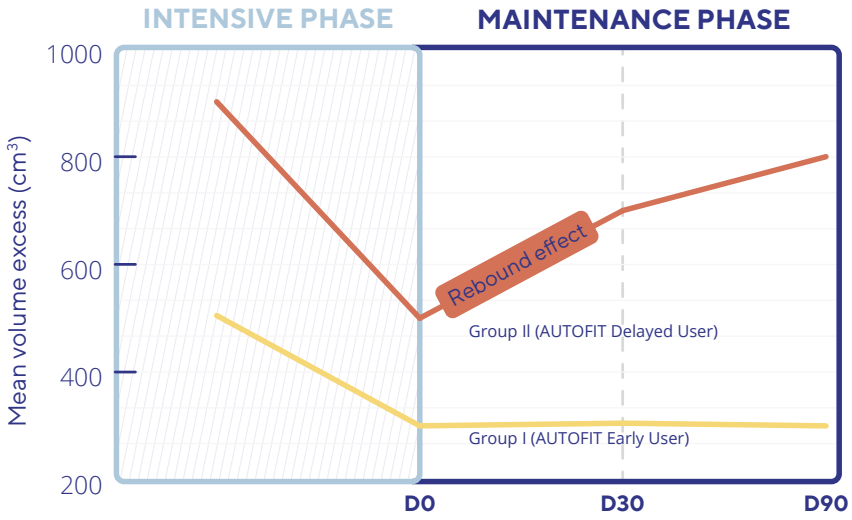
Results

Volume variation:
For most of patients, the benefit of intensive phase on lymphedema volume reduction is partly released during maintenance phase with the observation of a rebound effect.
In MARYLIN study, the lymphedema volume variation from Day 0 to Day 30 of the maintenance phase was lower in patients fitted with MOBIDERM Autofit (night use group) versus the no night-use group (1.8 vs. 3.2%, respectively) (p = 0.757).
From Day 30 to Day 90, when all patients were fitted with the auto-adjustable MOBIDERM Autofit arm sleeve during the night, the lymphedema volume remained stable in both groups, suggesting that the device allowed stabilization of the lymphedema volume as soon as it is putted on.



Subgroups analysis was performed on High responders patients if their lymphedema volume reduction during DLT was ≥ 35%. In this subgroup, the mean lymphedema volume variation between Day 0 and Day 30 was 28.4 mL in the night user group vs 181.4 mL in the no night user group.

Volume variation in high responders (HR) patients (cm^3)



Symptoms evolution

Functional symptoms at baseline were well balanced between groups. At Day 30, a higher proportion of patients in no night-use group complained with functional symptoms (60 vs. 15% reported heaviness and/or pain, and 45% vs. 10% reported limb use limitation in no night-use group vs. night-use group, respectively).
The volume stabilization observed in night-use group between Day 30 and Day 90 is associated with improvement of the functional symptoms as well as the function as assessed by the patients.

Compliance, satisfaction and adverse events

MOBIDERM Autofit was worn overnight almost 85% of the nights. It was well accepted by the patients and no adverse reaction leading to permanent device discontinuation occurred.
Great satisfaction was reported by patients who especially liked the speed to put it on and the autoadjustable nature of the product giving patients autonomy and opportunity to take part of their own treatment.

How would you rate MOBIDERM AUTOFIT ?

Easy/Very easy to put on	→ **70%** of patients	**82% of the patients** already wearing compression do prefer **MOBIDERM** autofit
Quick fitting	→ **85%** of patients	
Useful self adjustement	→ **89%** of patients	
Easy/Very easy to take off	→ **98%** of patients	
Comfortable	→ **90%** of patients	

Conclusions

The results of this study suggest that auto-adjustable MOBIDERM Autofit night sleeve, on top of daily compression, offers benefit to patients during maintenance phase of lymphedema treatment and enhances patient's autonomy.
MOBIDERM Autofit is a promising way to control the early rebound effect during the maintenance phase especially in DLT-high responders.

KEY TAKEAWAYS

- MOBIDERM Autofit limits rebound effect of LO when used right after DLT, especially in patients who were strongly responsive to DLT.
- MOBIDERM Autofit allows stabilization of LO volume when used later during maintenance phase.
- MOBIDERM Autofit increases patient's independence while keeping high level of compliance.

Full article

https://pubmed.ncbi.nlm.nih.gov/28281052/
https://pubmed.ncbi.nlm.nih.gov/29252140/

Clinical use of a nighttime MOBIDERM garment as a treatment modality for breast cancer related lymphedema: a retrospective longitudinal cohort study

Toccafondi A, Bonacchi A, Miccinesi G, Baroncelli TA, Franchi G, Ben Amor C, Pasqualini M, and Muraca MG – Ann Vasc Med Res (2017), 4(4): 1061

Country: 

Design: retrospective observational cohort study

Product: MOBIDERM made-to-measure patient

Population: 145 breast cancer patients using MOBIDERM for over 5 years with lymphedema stage 1 to 4

Treatment phase: maintenance

Treatment Duration: 6 months

Level of evidence: III

Objective

The aim of this observational study was to investigate the use of a nighttime compression sleeve (NTCS) as a routine maintenance therapy for breast cancer-related lymphedema (BCRL).

Methods

A retrospective analysis was performed on 145 breast cancer patients who over a five-year period used the Made-to-Measure MOBIDERM NTCS as nighttime adjuvant treatment for BCRL. The total sum of the percent differences between the two arms (%) after 6 months of NTCS use was the principal criterion.
The circumferences of each patient's arm at the beginning of the NTCS use (baseline measurement=T0), and data from 6 months before (T-1) and 6 months after (T1) the use of the NTCS were considered.

Results

All patients were previously treated for breast cancer. At baseline (T0) the sum of the percent differences between the two arms in the sample of the study (n=145) was 53.1% ± 24.2.
Data showed a significant decrease by 6.6% of the sum of the percent differences between baseline (T0) and 6 months after NTCS use (T1) ($p = 0.010$).
Among the 145 patients, 74 patients (51.0%) were already treated for lymphedema and had received a medical examination 6 months before the NTCS use (defined as treated lymphedema patients), while 46 patients (31.7%) were receiving their first medical examination for lymphedema at baseline (defined as newly diagnosed patients).
In the newly diagnosed patients subgroup, a greater significant reduction of the sum of the percent differences of -13.4% at T1 compared to baseline was observed ($p = 0.013$).
Among the 74 treated lymphedema patients, the sum of the percent differences after NTCS use (T1) was well maintained with a slight tend to decrease (-2.6%), while between before the NTCS use (T-1) and baseline, this percentage significantly increased by 16.9% ($p<0.001$).

Conclusion

The reduction of lymphedema observed in this study during the NTCS use period suggests that MOBIDERM NTCS seems to be associated to a control of lymphedema volume in BCRL patients during the maintenance phase. This night garment might be an adjuvant effective component of the therapy to achieve the volume maintenance goal but its efficacy should be confirmed with a randomized clinical trial.

KEY TAKEAWAYS

- It seems to be beneficial to wear a complementary nighttime compression sleeve to optimize the clinical outcome of patients affected by lymphedema.
- Made to measure MOBIDERM garment could represent a valuable alternative to nighttime self-bandaging.
- In chronic previously treated patients, Mobiderm night garment correlates with lymphedema volume stabilization.
- In newly diagnosed patients, Mobiderm use is associated to a significant volume reduction of LO.

Full article

https://www.lunamedical.com/wp-content/uploads/2020/07/MOBIDERM-4.pdf

Positive impact of a new compressive garment in patients with genital lymphedema: OLYMPY Study

Sandrine Mestre, Stéphane Vignes, Julie Malloizel-Delaunay, Sarah Abba, Stéphanie Villet, Astrid Picolet, Eric Vicaut, Isabelle Quéré – Journal of Vascular Surgery: Supportive care in cancer (under review)

Country:

Design: prospective, multicenter, exploratory uncontrolled trial

Product: MOBIDERM INTIMATE SHORTS

Population: 32 patients with genital lymphedema

Treatment duration: 12 weeks

Level of evidence: III

Objective

Genital lymphedema is a chronic debilitating progressive condition associated with substantial morbidity and highly impaired health-related quality of life (QoL). This prospective multi-center pilot study evaluated the use of a new compressive garment in patients with primary and secondary genital lymphedema.

Methods

32 patients diagnosed for a genital or pelvic lymphedema were enrolled and advised to wear the compressive garment for 12 weeks (day-time and nighttime use) on top of conventional lower limb lymphedema management.
The primary endpoint was change in patient-reported QoL at 12 weeks via the patient global impression of change (PGI-C) instrument.
Secondary outcomes included change in other QoL measures at 12 weeks (VAS, lymphedema quality of life inventory [LyQLI]), EQ-5D). Lymphedema severity was assessed via the Genital Lymphedema Score (GLS) and scrotum perimetric measures; physician assessment of improvement was rated via the Clinical Global Impression – Improvement scale (CGI-I).
Safety and tolerability were also assessed.

Results

Lymphedema description:
13 patients (40.6%) had primary lymphedema (mean duration, 12.7 ±11.9 years) and 19 (59.4%) had secondary lymphedema (mean duration, 5.4 ±5.4 years), chiefly following gynecologic and prostate cancer. Lymphedema severity was mainly stage IIB (53.1%) or stage III (43.7%); lower limb lymphedema was observed in 93.7% of patients.

Genital lymphedema improvement:
After 12 weeks, 78.6% of patients reported an improvement of their condition (PGI-C).
Physician assessment indicated a clinical improvement in 82.8% of patients (CGI-I) and showed a significant 1.76-point reduction of mean global GLS scores evaluating lymphedema severity at week 12 ($p = < 0.0001$). In men, scrotal perimetry indicated a reduction in middle-scrotal circumference by 2.7cm at week 12 ($p = 0.001$). The percentage of patients presenting skin induration fell from 21.9% at inclusion to 3.4% at week 12, and skin suppleness improved in 65.5% of them ($p = 0.009$).
Patient assessment of lymphedema-associated symptoms showed a consistent decrease with mean VAS scores decreasing by over 1.5 points for both swelling ($p = 0.01$) and global discomfort ($p = 0.02$). Patient VAS rating of feeling of heaviness and pain scores also declined, although these reductions were non-statistically significant.
Improvements in lymphedema-specific QoL and global QoL scores were observed. At week 12, scores decreased in each of the LyQLI physical (-0.219, $p = 0.1099$), psychosocial (-0.221, $p = 0.05$), and practical dimensions (-0.143, $p = 0.6842$). The overall QoL was assessed by the EQ-5D-5L, with 60.7% of patients who reported a better QoL at week 12.

Compliance and safety
The compressive garment was well tolerated with high compliance (69%) for daytime wear.
During the study, 30 adverse events were reported, occurring in 23 patients (71.8%). 43.3% of adverse events were considered as related to the device (pruritus, irritation, discomfort, lower limb swelling). Most of these adverse events were considered as usual events in the usual management of genital lymphedema pathology, such as the volume increase in lower limb, or irritation due to the use of compression devices.

Conclusions

Use of a novel genital compression garment over 12 weeks improves QoL and decreases associated symptoms and lymphedema severity in patients with genital lymphedema.

KEY TAKEAWAYS

- This clinical study is the first one that evaluates a medical device for the management of genital lymphedema.
- Patients wearing MOBIDERM Intimate Shorts for 3 months reported a better quality of life, and a clinically significant reduction in genital lymphedema severity and associated symptoms.
- MOBIDERM Intimate Shorts was well tolerated with high compliance for daytime wear.

CLINICAL TRIALS: THE STATE OF THE ART

MOBIDERM autofit IN THE INTENSIVE PHASE

The hybrid approach to treating severe lower-extremity lymphoedema

Yuko Takanishi, Yoshihiro Ogawa, Yuichi Hamada and Robert Harris – Journal of Lymphoedema (2018), Vol 13, No 1

Country:

Design: case report
Product: MOBIDERM autofit (associated to stretch bandages)
Population: 1 female patient with lower limb lymphedema
Treatment phase: intensive
Level of evidence: IV

Objective

This case study illustrates how using different approaches provided a longer-term solution for a patient. A combination of traditional combined decongestive therapy, self-care and surgery were used to provide a successful outcome.

Case description

The patient presenting a left lower extremity lymphedema with severe deformation of the limb started receiving an intensive reduction-phase of CDT over 1 month corresponding to daily moisturising skin care, manual lymph drainage, compression therapy using short-stretch multi-layer lymphedema bandaging and physical exercises. This treatment led to oedema improvement.
This improvement proved difficult to maintain at home, despite the use of a compression garment, with a large increase in swelling. Reduction-phase therapy was, therefore, continued at 6-month intervals.
Three years after the start of therapy, the multi-layer lymphedema bandaging protocol was adapted slightly. MOBIDERM Autofit was used under the medium and short stretch bandages. MOBIDERM applies uneven pressure to the tissues and was reported to help improve the softening of fibrosis and fluid mobilisation. The change in bandaging technique provided enhanced reduction of the oedema and softening of the tissues. The patient found the self-application of these materials easier than the short-stretch bandages alone.

Conclusions

Over the course of just over 4 years, the patient had a significant and consistent reduction in oedema volume using a combined approach to treatment. The effectiveness of each strategy appears to be cumulative and complementary. Use of MOBIDERM Autofit associated to medium and short stretch bandages participated to oedema reduction and softening of tissues.

KEY TAKEAWAYS

- A combined approach to lymphedema treatment provides successful outcome.
- Use of MOBIDERM autofit associated to stretch bandages participated to oedema reduction and softening of tissues.

Full article

https://www.lunamedical.com/wp-content/uploads/2020/07/MOBIDERM-7.pdf

Effectiveness of MOBIDERM Autofit in the intensive phase of breast cancer related lymphedema treatment, a case series

Mazur Stawomir, Dorota Szczesniak and Hanna Tchorzewska-Korba – Lymphatic Research and Biology (2023), In press

Country:

Design: case series
Product: MOBIDERM autofit
Population: 10 patients with Upper limb Breast Cancer Related Lymphedema (BCRL)
Treatment phase: intensive
Level of evidence: IV

Objective

This case series illustrates the use and the benefit of MOBIDERM autofit for the intensive phase of upper limb lymphedema treatment in patients with Breast Cancer Related Lymphedema (BRCL).

Methods

Ten men and women with stage II BCRL underwent a Complete Decongestive Therapy (CDT)-reduction phase for 12 days, combining MOBIDERM Autofit compression garment with manual lymphatic drainage.
Arm volume was calculated by a formula for truncated cone using circumferential measurements taken at each appointment. The pressure under the garment, the skin suppleness and the overall satisfaction of patients and physicians were also assessed.

Results

The mean lymphedema volume excess decrease was 343.11 mL ±266.14 which represents a 36.68% decrease between day 1 and day 12, whereas the mean affected limb volume decrease was 420.03 mL ± 251.27 corresponding to a 10.12% decrease during this same period.
All patients reported an improvement of their skin suppleness between the first and last day of decongestion phase, with nine patients (90%) presenting a total or moderate improvement.
The mean device pressure by using the PicoPress was 30.01 ± 0.45 mmHg
The majority of patients were satisfied with the ease of use and the comfort of wearing MOBIDERM Autofit. Such positive assessment was confirmed by the physicians.
During the follow-up of this case series, no adverse event was reported.

Conclusion

A lymphedema volume decrease of the upper limb was reported after 12 days of treatment with MOBIDERM Autofit during the CDT intensive phase. Moreover, the device was well tolerated and its use was appreciated by the patients and the physicians.

KEY TAKEAWAYS

- A significant reduction of lymphedema volume can be reached with the use of MOBIDERM Autofit during the intensive phase of lymphedema treatment.
- MOBIDERM Autofit may be studied as an alternative to bandages for intensive treatment of lymphedema with the opportunity of easier self-management.
- The use of MOBIDERM Autofit is associated with an improvement in skin suppleness.

MOBIDERM FOR FIBROSIS REDUCTION

Use of a tissue mobilising compression system

Pamela Hodgson, Marie-Eve Letellier, Katrin Schumann, Linda Henry – Journal of Lymphoedema (2011), Vol 6, No 2

Country:

Design: case report
Product: **MOBIDERM** Bandage
Population: 1 female patient with Upper limb Breast Cancer Related Lymphedema (BCRL) associated to fibrosis

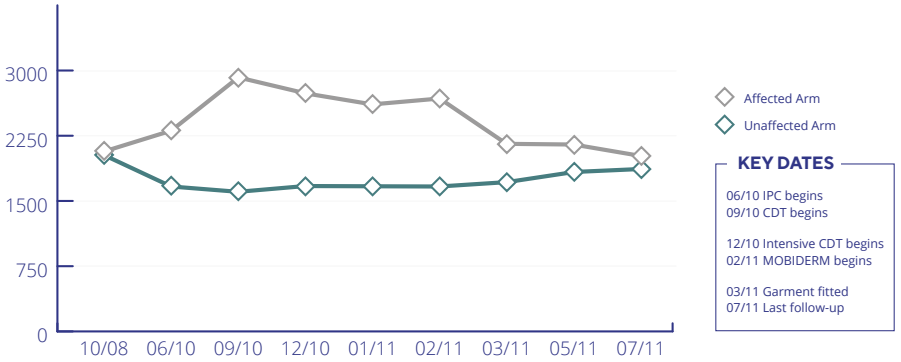
Treatment phase: intensive and maintenance
Level of evidence: IV

Objective

This paper reports the use of MOBIDERM to treat a patient with Breast Cancer Related Lymphedema (BCRL) and associated lymphostatic fibrosis.

Case description

This case reports on the use of the MOBIDERM system to soften lymphostatic fibrosis and continue volume reduction after lymphedema stabilisation had been achieved with conventional short-stretch bandaging.
The patient started her lymphedema treatment with Intermittent Pneumatic Compression (IPC). After 15 sessions with IPC, she felt that there was no more improvement. Effectively, her arm measurements showed a significant increase of lymphedema, with the affected arm 81% greater than the unaffected arm. Furthermore, fibrotic tissue was now noted in the forearm.
After 15 treatments of conventional multilayer bandaging and self-bandaging, measurements had stabilised with the volume difference at 62%.
The MOBIDERM system of bandaging was started because the patient was not satisfied with the effects of inelastic bandaging and wanted a better reduction before being fitted for a sleeve.
After 10 treatments and self-bandaging at home with a bandage including MOBIDERM, the lymphostatic fibrosis had softened and measurements had again decreased and stabilised to a volume difference of 27%.
The patient was satisfied with her lymphedema outcome and she was measured for a compression sleeve. Four months later, the volume had further reduced to a 11% volume difference, with no fibrotic tissue palpable in her forearm. She has continued self-bandaging at night and wearing her garment during the day.
The evolution of patient's lymphedema volume is illustrated in the graph below:



Conclusions

This case reports on the impact of the MOBIDERM bandages to reduce lymphostatic fibrosis and achieve further volume reduction in a patient with Breast Cancer Related Lymphedema.

KEY TAKEAWAYS

- MOBIDERM bandages seem to help in reducing lymphostatic fibrosis and achieving further lymphedema volume reduction.
- Additional randomized controlled trials would be necessary to confirm the fibrosis reduction.

Full article

https://www.woundsinternational.com/download/wint_article/7197

The use of IPC with MOBIDERM in upper limb lymphoedema treatment

Hanna Tchórzewska – Korba, Paulina Karbowska, Jolanta Golinowska, Piotr Kowalski Department of Rehabilitation in Oncology Center – Maria Sklodowska-Curie's Institute in Warsaw

Country:

Design: prospective, single center, controlled trial
Product: **MOBIDERM** Bandage
Population: 60 patients with Upper limb Breast Cancer Related Lymphedema (BCRL)

Treatment phase: intensive
Treatment duration: 10 days
Level of evidence: II

Objective

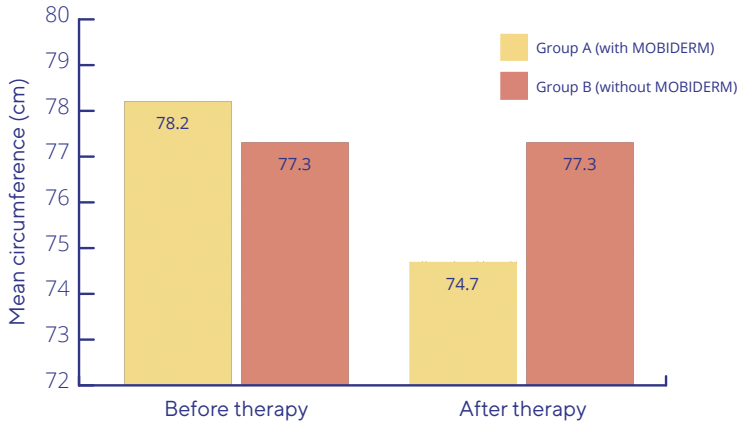
The aim of the study was to compare the effectiveness of single-chamber Intermittent Pneumatic Compression (IPC) procedure with MOBIDERM vs. single-chamber IPC procedure alone.

Methods

Two groups of 30 patients with upper limb lymphedema after axillary lymphadenectomy, treated with Complex Decongestive Therapy (CDT) have been included.
Group A (research group): 30 patients, in which single-chamber IPC with MOBIDERM has been applied. The pressure applied was 40mmHg, and time of treatment was 30 minutes.
Group B (control group): 30 patients, in which single-chamber. IPC has been applied. The pressure applied was 40-80mmHg, and time of treatment was 40 minutes.
Circumference measurements have been taken twice: Before therapy and Approx. 14 days after the therapy.

Results and conclusion

The mean circumference of limb with LO before and after therapy



Poster extract

The use of MOBIDERM in single-chamber IPC improves therapy effectiveness, reducing the mean circumference of the limb from 78.2 to 74.7 cm as compared to the absence of decrease in the control group without MOBIDERM.

KEY TAKEAWAYS

- Compression plays very important role in conservative Lymphedema treatment.
- Association of MOBIDERM bandage with IPC may help to decrease lymphedema volume.

Reference:
Hanna Tchórzewska – Korba, Paulina Karbowska, Jolanta Golinowska, Piotr Kowalski. The use of IPC with MOBIDERM in upper limb lymphoedema treatment– poster in lymphology congress – 2018.

The MOBIDERM Technology

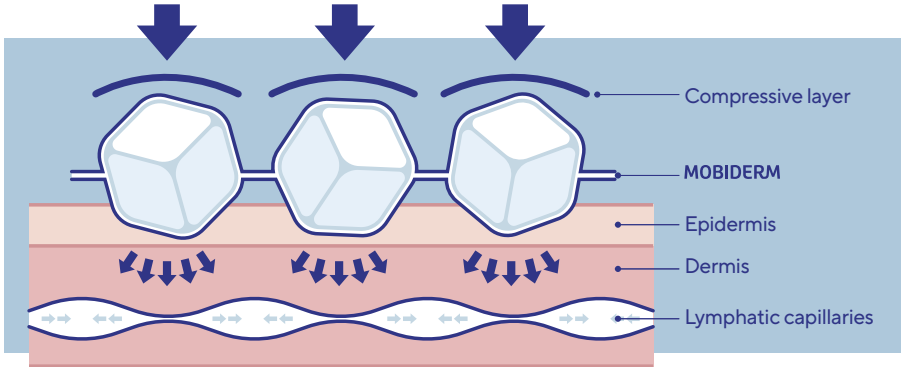
MOBIDERM is a medical device made up of foam blocks encased between two non-woven bandages. The **MOBIDERM** Technology can be used under a reducing bandage (in its bandage or pad forms), or incorporated into mobilizing garments.
Due to the difference in pressure created between the support area of the blocks and their surrounding area, **it promotes the flow of lymphatic fluid and optimizes the drainage efficacy[1].**

Patented device[3]

EFFECTIVE
- Rapid volume reduction of the edema[2].

PRACTICAL
- Light and comfortable, it enables the patient to keep their freedom of movement[4].

COMFORTABLE
- Ability of the product to contour the extremity provides an adapted anatomical fit.



MOBIDERM devices

(1) Todd – MOBIDERM Autofit: an adjustable sleeve that enables patients to self-manage lymphedema – Chronic edema – April 2018 – Page 6
(2) Quéré - Prospective multicenter observational study of lymphedema therapy: POLIT study - Vascular Desease Journal – 2014 – Pages 4 and 5
(3) Only in following countries: Algeria, Austria, Belgium, Canada, China, Czech Republic, Denmark, Finland, France, Germany, Hungary, India, Morocco, Italy, Netherlands, Poland, Portugal, Romania, Russian Federation, Slovakia, Slovenia, Spain, Sweden, Switzerland, Tunisia, United-Kingdom
(4) Mestre – Interest of an auto-adjustable nighttime compression sleeve (MOBIDERM Autofit) in maintenance phase of upper limb lymphedema: the MARILYN pilot RCT Support Care Cancer (25:2455-2462) – 2017 – Page 7

WINGS
FOR YOUR HEALTH

MOBIDERM Pads & Bandages - Indications: acute or chronic edema management (e.g. lymphedema). Contraindications: skin infection of the limb or acute inflammation, known allergy to components used, septic thrombosis, severe peripheral neuropathy of the limb. Lower limb - PAD (peripheral arterial disease) of lower limbs with ABPI < 0.6, congestive heart failure, advanced diabetic microangiopathy, phlegmasia cerulea dolens, extra-anatomic bypass. Upper limb - pathology of brachial plexus, vasculitis of the extremities.
MOBIDERM Autofit, Standard and Made-to-Measure garments - Indication: maintenance of volume reduction in lymphedema. Contraindications: skin infection of the limb or acute inflammation, known allergy to components used, septic thrombosis, severe peripheral neuropathy of the limb. Lower limb - PAD (peripheral arterial disease) of lower limbs with ABPI < 0.6, congestive heart failure, advanced diabetic microangiopathy, phlegmasia cerulea dolens, extra-anatomic bypass. Upper limb - pathology of brachial plexus, vasculitis of the extremities.
MOBIDERM Intimate Shorts – Indication: treatment of pelvic and genital lymphedema. Contraindications: skin infections on the pelvis or legs; pregnant women (from the first month); known allergies to any of the components; lower limb peripheral arterial disease (PAD) with ankle brachial index (ABI) < 0.6; decompensated heart failure; septic thrombosis of the proximal veins; phlegmasia cerulea dolens (painful blue edema with arterial compression) in the thighs; posthectomy (circumcision) within the past three months; female patient with marked localized edema of the labia minora only.

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