3M Science. Applied to Life.™

Clinical evidence summary

3M™ Coban™ 2 two-layer compression system

Clinical evidence overview.

Venous leg ulcers 3–9

Mixed etiology 10–11

Lymphoedema 12–13

Compression therapy is widely recognized as the 'gold standard' for treatment of VLUs.[1–10]

Compression therapy is recommended for the treatment of VLUs by all the following government bodies and societies:

- American Venous Forum
- Scottish Intercollegiate Guideline Network
- Haute Autorité de Santé
- Wound Ostomy and Continence Nurses Society
- Initiative Chronische Wunden (GE)
- Wound Healing Society
- Society for Vascular Surgery
- Deutsche Gesellschaft für Phlebologie
- Agency for Healthcare Research and Quality
- NICE National Institute for Health and Core Excellence
- Conferencia nacional de consenso sobre ùlceras de la extremidad inferior
- Nederlands Hufsartsen Genootschap

Faster healing can have a significant impact on patients quality of life.[1–7]

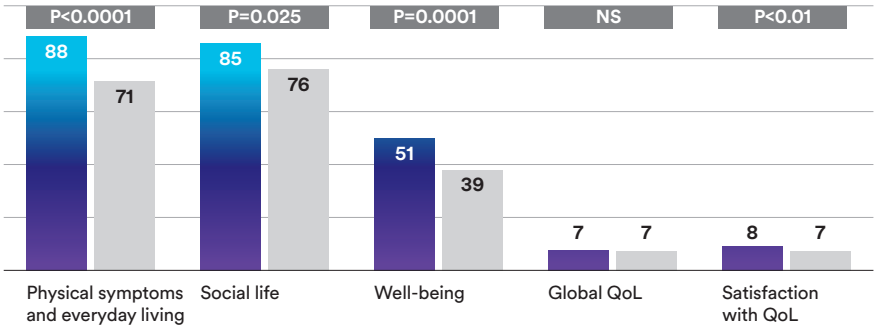
Patients with healed ulcers saw significant improvement in their physical symptoms, every day living, social life and well-being, as well as general satisfaction with their quality of life (QoL).

Scores were based on the Cardiff Wound Impact Schedule tool.

124 patients (64.5% leg ulcers, 35.5% diabetic foot ulcers).

- Healed ulcers
- Unhealed ulcers

Mean quality of life scores for patients with healed and unhealed ulcers[7]



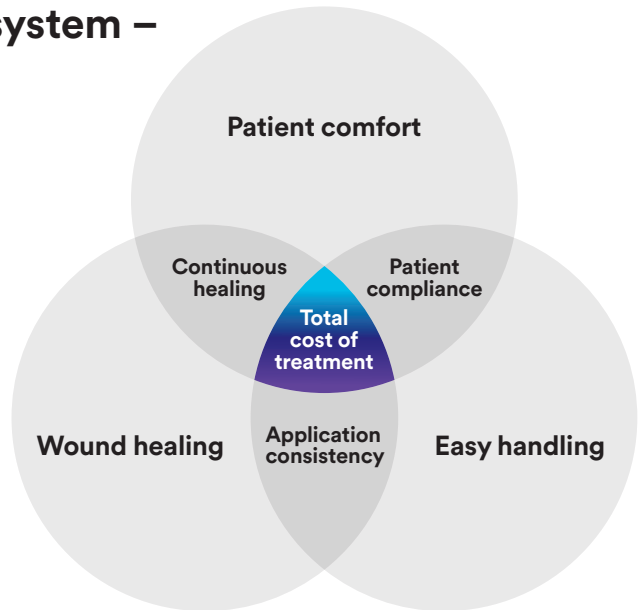
Treatment of VLU patients without compression is at least 2x more costly than when compression therapy is used.

KPMG economic evaluation for the treatment of VLUs in Australia (2012/13) found that the use of compression therapy could provide an average savings of AU$6,328/patient in health care costs.[8]

Costs	Benefits
General practitioner (GP) consulation time associated with VLU diagnosis and management (direct patient time)	Improved VLU management practices
Community Nurse (CN) time associated with VLU management (direct patient time)	Improved VLU healing times
CN travel costs associated with VLU management and care	Reduced number of GP consultations per wound
Outpatient wound clinic costs associated with VLU management and care	Reduced CN treatment and travel time (associated with improved VLU healing times)
Cost of consumables associated with VLU care	Reduced VLU complications requiring hospital admission
	Reduced reoccurrence of VLU

3M™ Coban™ 2 two-layer compression system – evidence clusters for venous leg ulcers.

The evidence available for the 3M™ Coban™ 2 two-layer compression system in the context of venous leg ulcers will be presented along the three main clusters shown here.



3M™ Coban™ 2 two-layer compression system improves patient comfort and adherence to therapy

- Clinical trials have shown a significant reduction in slippage for Coban 2 versus competitor systems[9,10]
- In an 8 week cross-over trial, patients wearing Coban 2 reported a significant improvement in their physical symptoms and daily living[9]
  - Reduced slippage may improve patient comfort and provide more consistent compression
  - Pain was significantly reduced[33]
- Coban 2 allows patients to wear their own footwear which...
  - Improves mobility,
  - Reduces the risk of falls, and is
  - Is aesthetically pleasing
- 72% of patients in a randomized control trial showed a preference for Coban 2[1]

Patient comfort

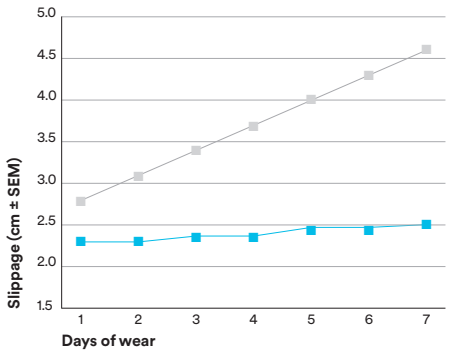
Improving patient quality of life while receiving therapeutic compression may improve compliance, which has been shown to increase healing time.

Coban 2 significantly reduces slippage which may result in improved patient adherence and uninterrupted healing.[9]

Statistical model estimate of bandage slippage (centimetre +/- standard error of the mean) recorded during 697 bandage changes from 81 subjects.

- Coban 2 Layer
- Profore

Estimated bandage slippage



- **There was a significant difference in slippage between the two- and four-layer systems in favor of the two-layer system at days 3 to 7.**

Slippage was 2.48cm for Coban 2 Layer system and 4.17cm for the four layer system (p<0.001).[9]

Coban 2 significantly reduces slippage, maintaining therapeutic pressure over time.[41]

Study design

- Results from a controlled laboratory study demonstrating slippage
- Both legs of 56 healthy volunteers were wrapped with 7 different commercial 2-layer compression bandage systems
- Bandages were:
  A = 3M™ Coban™ 2 Lite two-layer compression system
  B = LR Rosidal TCS
  C = Urgo K2
  C-Lite = Urgo K2 Lite
  D = Jobst Compri2
  D-Lite = Jobst Compri2 Lite
- Study included a total of 120 legs (60 healthy volunteers, both legs wrapped) and the bandages were worn for 48 hours
- A pressure sensor placed at the B1 position on each leg recorded resting, standing, and minimum and maximum plantar/dorsal flexion pressures at baseline, 24 and 48 hours

3M™ Coban™ 2 may improve patient adherence by reducing bulk, which allows patients to wear their own footwear.

72% of patients in a randomised control trial reported a strong preference for Coban 2 over a 4-layer compression bandage.[9]

Patient adherence with compression therapy is central to successful treatment.[11–17]

The materials used in the Coban 2 bandage create a thin, lightweight, breathable sleeve enabling patients to wear their own shoes and clothing, so they can return to their regular daily activities.

Allowing patients to wear their own footwear may improve patient mobility, which has been shown to optimize the benefits of compression therapy.[15]

Falls in the geriatric population have been attributed to unsafe footwear and use of restrictive devices;[15] A low-profile bandage that allows for the use of normal shoe wear may reduce falls.

> "I'm less aware of this bandage than I was of the four-layer one. It's quite comfortable, and I can get a sock on over it. With the four-layer bandage, the leg gets very hot and, of course, you're wearing it in bed and it can get very uncomfortable. I'm not aware of this [bandage] at all.
>
> Male, 80 years of age"

Coban 2 has been shown to improve patients daily activities.[9]

Change in HRQoL between Coban 2 and Profore from baseline to pre-crossover[9] using the CWIS QoL instrument.[7]

Patients using Coban 2 reported significant improvement (p = 0.046) in their physical symptoms and daily living (e.g. sleep, comfort, mobility, ability to perform everyday tasks, etc.) compared to a 4-layer compression bandage.

HRQoL assessments	Compression system	Change of within-patient scores: mean ± SD	Difference between treatment groups (95% CI)	*P* value
Well-being	Coban 2 Layer Profore	4.1 ± 16.0 3.4 ± 13.3	0.74 ± 14.6 (-0.6, 7.5)	0.827
Physical symptoms and daily living	Coban 2 Layer Profore	8.7± 17.9 1.2 ± 13.8	7.5 ± 15.7 (0.1, 14.9)	0.046
Social life	Coban 2 Layer Profore	6.8 ± 15.2 1.3 ± 14.9	5.6 ± 15.1 (-1.4, 12.6)	0.118
Overall HRQoL	Coban 2 Layer Profore	0.6 ± 2.0 0.2 ± 1.8	0.4 ± 1.9 (-0.5, 1.3)	0.376
Patient satisfaction with overall HRQoL	Coban 2 Layer Profore	0.4 ± 2.4 0.3 ± 2.3	0.1 ± 2.4 (-1.0, 1.2)	0.860

HRQoL= health related quality of life
CWIS = Cardiff Wound Impact Schedule
N=74: Coban™ 2, n=32; Profore n=42

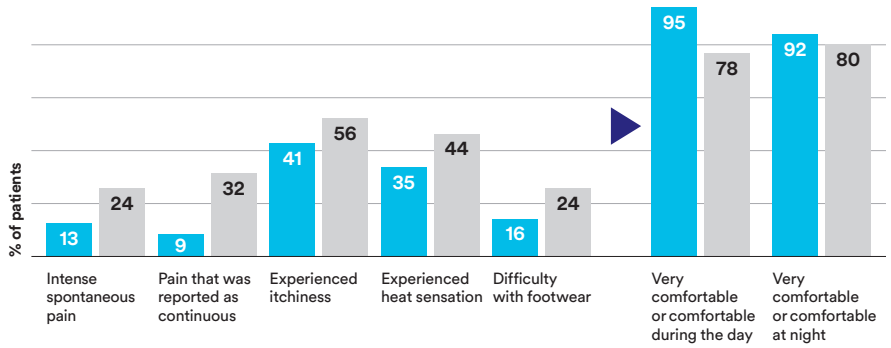
See reference 9

Coban 2 has been shown to significantly improve patients daily living.[9]

42 outpatients across 12 centers were recruited to switch from their current compression system to Coban 2 and were asked about the impact on their quality of life.[17]

50% and 40% reported that general comfort during the day and at night, respectively, was <u>better than</u> with their previous system

- Coban 2 Layer
- Previous compression system



3M™ Coban™ 2 two-layer compression system is easy to handle for practitioners.

- Practitioners find Coban 2 easy to learn[18]
- Clinical studies have shown that experienced practitioners are able to apply Coban 2 more consistently than the bandage they normally use[17]
- Practitioners find Coban 2 easy to apply

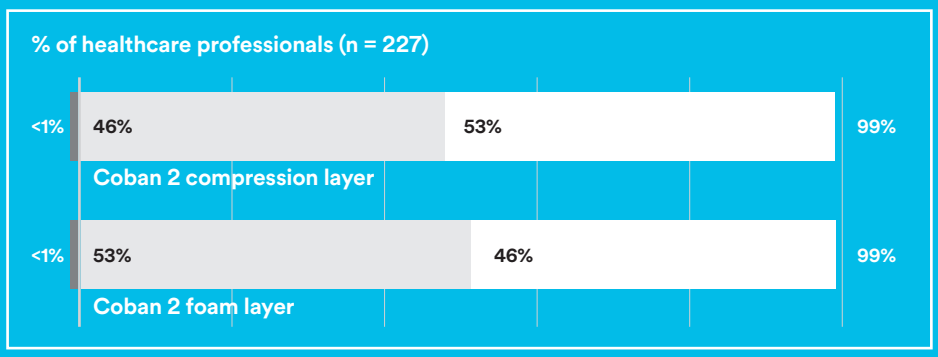
Easy handling

Ease of learning and consistent application may reduce time to train and improve application consistency.

Healthcare professionals say Coban 2 is easy to learn and apply[17]

Ease of application can both facilitate ease of nurse training and reduce bandage application time.

- Difficult
- Easy
- Very easy

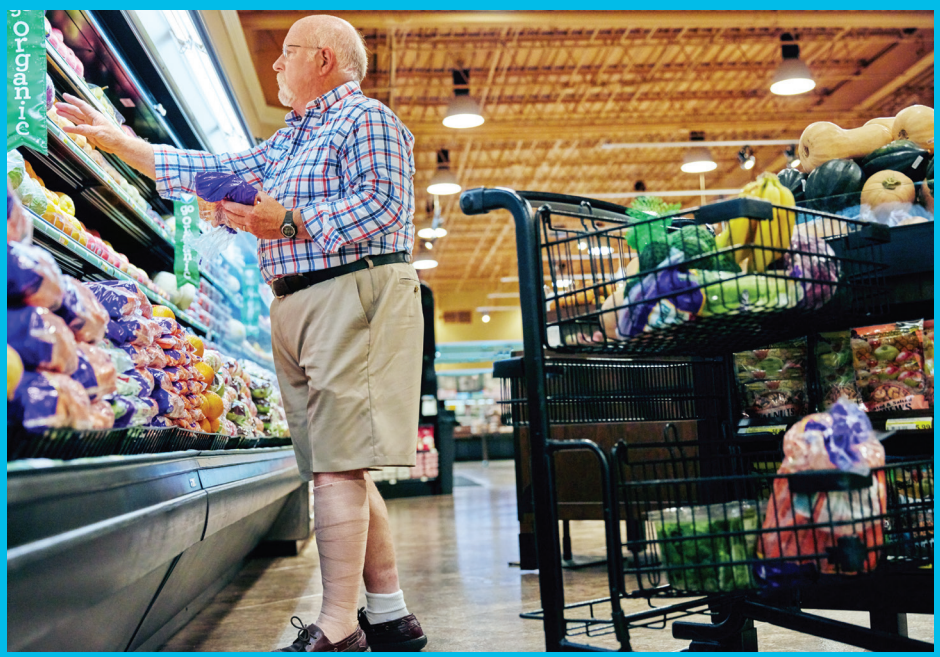


99% of healthcare professionals found Coban 2 'easy' or 'very easy' to apply.[17]

"As Head physio of The Clinic Belgium and Lymphhouse Antwerp, I like to use the Coban 2 two-layer compression system for several reasons:

- It is easy to apply
- It works fantastic in the decongestive phase of chronic edema
- Because of the intelligent compression dynamics of the material, I'm sure that my colleagues don't put it on too tight
- My patients still fit in their own shoes and can wear comfortable clothes"

Tim Decock, PT
Head Physio, Lymphouse Antwerp
Head Physio, The Clinic Belgium
Teachter Dr. Vodderschool Belgium/
The Netherlands

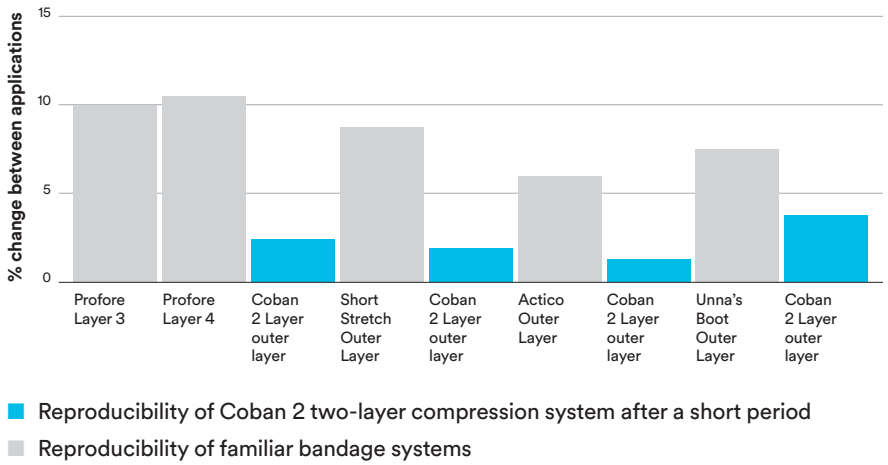


3M™ Coban™ 2 two-layer compression system is designed to be applied at full stretch, reducing application variability, for consistent compression every time.[17]

Thirty-two experts in the application of compression bandages applied Coban 2 more consistently – at the same stretch – compared to a familiar compression system.[17]

- For some elastic bandage systems, it can be difficult to attain the appropriate stretch (30% – 70%) resulting in variable pressure and clinical results
- Both regular short stretch and 4-Layer users achieved consistently higher and more reproducible pressures when applying Coban 2 two-layer compression system compared to familiar applications
- Expert evaluations also demonstrated that Coban 2 two-layer compression system is easy and fast to learn, no matter which bandage the applier normally uses

Results from an international multi-centre comparative evaluation demonstrating reproducibility of applied stretch



Coban 2 two-layer compression system provided the most consistent level of compression.

3M™ Coban™ 2 two-layer compression system has been shown to heal venous leg ulcers.

- Real world evidence from the UK THIN database showed improvement in healing time with Coban 2[19]
- The data revealed that 51% of wounds treated with Coban 2 healed by six months compared to 40% (p=0.03) and 28% (p=0.001) in the two-layer and four-layer compression system groups, respectively
- Coban 2 may improve patient compliance, through improvements in comfort and ability to wear their normal footwear
  - Coban 2 has been shown to reduce variability in applications[17]
  - Less variability in applications results in consistent compression which may improve healing time
- Coban 2 has shown effective wound size reduction in venous leg ulcers[33]
- Improved patient compliance has been shown to improve healing time[20–24]

Wound healing

The final objective of applying compression therapy is to achieve ulcer healing. This has been proven when using the Coban 2 two-layer compression system.

The Coban 2 two-layer compression system is proven to effectively heal leg ulcers.[19]

Real world evidence from the UK THIN database* revealed that 51% of wounds treated with Coban 2 healed by six months compared to 40% (p=0.03) and 28% (p=0.001) in the two-layer and four-layer compression system groups, respectively.

*THIN database = The Health Improvement Network (THIN) database (Cegedim, London, UK) contains computerised information on >9 million anonymised patients entered by GPs from 500 practices across the UK.

**There were no significant differences in patients' age, gender, age of patients' wound, initial wound size and the percentage of new wounds between the three groups TLCCB = Coban 2, a two-layer cohesive compression bandage; TLCS = Ktwo, a two-layer compression system; FLCS = Profore, a four-layer compression system.

Reference 19	TLCCB (Coban 2)	TLCS	FLCS
Matched cohort**	250	250	175
Patients in each group whose VLU healed (%)	51%	40% (p=0.03)	28% (p=0.001)
Patients whose VLU healed while using their initial compression bandage for the six months' study period (%)	26%	11% (p<0.02)	2% (p<0.02)
Patients whose VLU healed after switching from their initial compression bandage (%)	60%	56% (p<0.01)	41% (p<0.01)
Reduction in wound size (%)	60%	58%	57%
Mean time to wound healing per patient (months)	2.5±0.2	2.4±0.2	2.5±0.3

Published data relating to compression therapy and total cost of treatment.

Clinical outcomes and cost-effectiveness of three alternative compression systems used in the management of venous leg ulcers.[19]

Real world evidence from the UK THIN database* has demonstrated the cost savings that can be achieved through using Coban 2 compared to other compression systems.

TLCCB: two-layer cohesive compression bandage (Coban 2)

TLCS: two-layer compression system (K-Two)

FLCS: four-layer compression system (Profore)

*The Health Improvement Network (THIN) database (a nationally representative database of clinical practice among patients registered with general practitioners in the UK).

Mean six-monthly amount of healthcare resource used per patient, over the six months study period

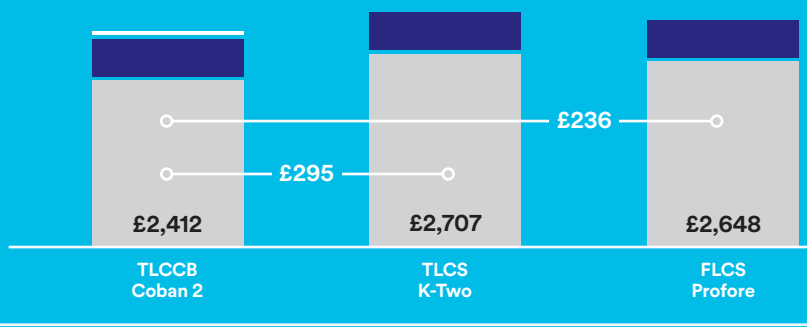
Health care resource use	TLCCB	TLCS	FLCS
Community nurse visits	51.6 ± 4.6	54.7 ± 4.6	57.8 ± 5.5
Practice nurse visits	7.5 ± 1.2	12.5 ± 1.2	9.9 ± 1.4
Tissue viability nurse visits	0.03 ± 0.01	0.01 ± 0.01	0.03 ± 0.02
GP consults	2.4 ± 0.3	1.6 ± 0.3	2.5 ± 0.4
Hospital outpatient visits	0.5 ± 0.1	0.3 ± 0.1	0.7 ± 0.2
Diagnostic tests	0.3 ± 0.1	0.31 ± 0.1	0.18 ± 0.1
Hospital admissions	0.08 ± 0.02	0.03 ± 0.02	0.05 ± 0.02
Accident and emergency admissions	0.12 ± 0.03	0.09 ± 0.03	0.14 ± 0.04
Dressings and bandages			
Dressings	106.6 ± 8.0	96.2 ± 8.0	125.4 ± 9.8
Compression bandages	51.9 ± 3.4	59.8 ± 3.5	56.1 ± 5.2
Other bandages	37.5 ± 4.7	21 ± 4.7	69.8 ± 5.7
Prescribed medication			
Prescriptions for topical treatments	0.6 ± 0.1	0.09 ± 0.1	0.47 ± 0.1
Prescriptions for analgesics and NSAIDs	126.0 ± 11.3	130 ± 11.5	143 ± 17.6

Overall, 51% of wounds in the TLCCB group healed by six months compared to 40% (p=0.03) and 28% (p=0.001) in the TLCS and FLCS groups, respectively.

- Outpatient costs
- Consumables
- Other costs

N= 675 (TLCCB=250; TLCS=250, FLCS=175). Costs are in 2012/13 prices.

A savings up to £295 per patients[19]



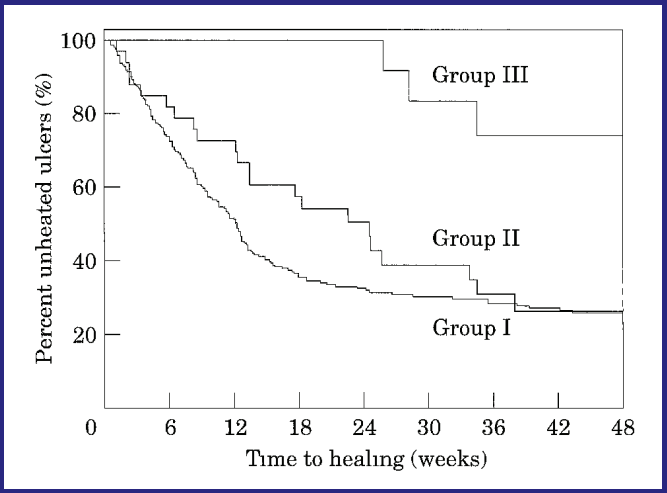
Compression therapy under clinical supervision can help achieve healing of mixed etiology ulcers.

Baseline characteristics of the three study groups (median values with range shown)[36]

	Group 1	Group 2	Group 3
Patients	202	30	12
Male/female	74/128	11/19	5/7
Age/years	76 (27–93)	82 (50–94)	82 (70–91)
Limbs	221	33	13
Duration/months	6 (1–480)	4 (1–108)	6 (1–240)
Recordable ABPI	1.1 (0.86–1.5)	0.73 (057–0.85)	0.46 (0.31–0.5)
Ulcer diameter/cm	2.5 (0.5–14)	2.5 (0.5–12)	3.5 (0.5–14)
Deep venous insufficiency	117 (53%)	5 (15%)	6 (46%)

The diagnosis and management of mixed arterial/venous leg ulcers in community-based clinics

A. S. K. Ghauri, I. Nyamekye, A. J. Grabs, J. R. Farndon and K. R. Poskitt



Eur J Vasc Endovasc Surg 16, 350–355 (1998)

Group I: Weekly application of Four Layer

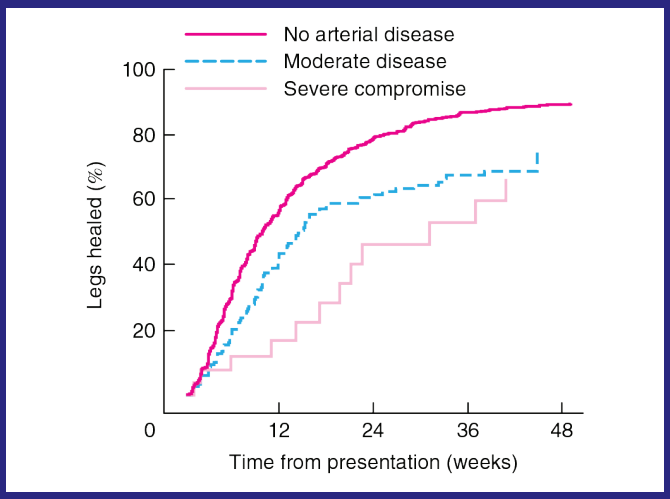
Group II: Modified four-layer bandaging but at half the usual stretch

Group III: Modified Four Layer bandage but at half the usual stretch + revascularisation

Management of mixed arterial and venous leg ulcers

M. L. Humphreys, a. H. R. Stewart, M. S. Gobel, M. Taylor, M. R. Whyman and K. R. Poskitt

A protocol including supervised modified compression and selective revascularisation achieved good healing rates for mixed arterial and venous leg ulceration.



British Journal of Surgery 2007; 94; 1104–1107

In a prospective study, 3M™ Coban™ 2 Lite two-layer compression system was shown to be safe to use for mixed etiologoy ulcers.[37]

Objective

- To assess the safety and tolerability of the Coban 2 Lite 2 two-layer compression system in patients with an ankle brachial pressure index (ABPI) of 0.5-0.8
- To evaluate blood microcirculation during Coban 2 Lite two-layer compression system wear

Application schedule

- Treatment for 14 day
- Application at day 1, 2, 3, 4, 7, 10 and 14
- Full stretch application at one study leg
- 101 bandage applications

Main outcome of Coban 2 Lite study

- No symptoms of underperfusion
- No skin damage under bandage
- No AEs related to underperfusion
- Reduced subbandage pressure (28mmHg) under full stretch application
- No reduction of cardiac pulse signal in capillary system
- Reduction of respiratory reflux likely due to improvement of relative venous valve insufficiency
- Increase of myogenic activity (vasomotion) with Coban 2 Lite
- Increased vasomotion implies improved capillary blood velocity within dermal- and wound tissue
- Microcirculation is one of the key parameters for sufficient nutrient supply and oxygenation
- Beside the good safety profile and tolerability
- Coban 2 Lite might have additional beneficial effects with respect to capillary perfusion and tissue nutrition

In a case series treating patients with chronic lower limb wounds, it was shown that Coban 2 Lite supported wound healing.[42]

Objective

- Record initial clinical experiences
- Evaluate the performance of the reduced compression bandage in treating chronic lower limb wounds of either venous (VLU) or mixed aetiology (MLU)
- Patients were included if ABPI ≥ 0.5 and ≤ 0.8 was measured within up to 12 weeks prior to enrolment
- Patients unable to tolerate high compression bandaging with normal arterial perfusion (ABPI > 0.8)

Main outcome

A total of **30** patients

14 chronic mixed aetiology leg ulcers (ABPI ≥ 0.5 and ≤ 0.8)

16 painful VLU (ABPI > 0.8) and unable to tolerate high compression

Complete healing was achieved in **20%** of the patients

MLU patients had a **63%** reduction in wound surface area

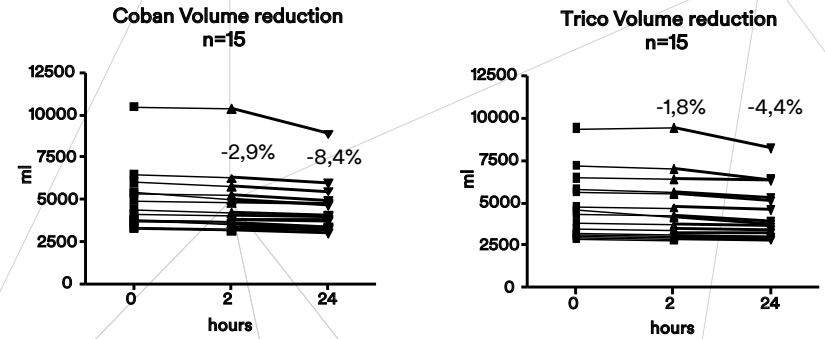
A reduction in wound pain was self-reported in **40%** of the patients

Conclusion

3M™ Coban™ 2 Lite is safe and effective in the treatment of venous aetiology leg ulcers unable to tolerate high compression (35–40 mmHg) and chronic leg ulcers of mixed aetiology (ABPI ≥ 0.5 and ≤ 0.8).

3M™ Coban™ 2 two-layer forms a suitable alternative for multi layer in the conventional treatment of moderate to severe lymphedema.[38]

The median initial (T0) standing interface pressures



Pressure: 54 mm Hg

60 mm Hg

Source
D-A.A. LAMPROU, BSC, ROBERT J. DAMSTRA, MD, PHD Prospective, Randomized, Controlled Trial Comparing a New Two-Component Compression System with Inelastic Multicomponent Compression Bandages in the Treatment of Leg Lymphedema. Dermatol Surg 2011;37:1–7 DOI: 10.1111/j.1524-4725.2011.02002.x

Patients and clinicians value 3M™ Coban™ 2 two-layer compression systems.[39]

Treatment with the Coban 2 was reported:

- Quicker and easier to apply
- Increased mobility
- Enhanced patient confidence
- Provided a sense of control and well-being

Coban 2 compression system provides good clinical outcomes.

- 24 patients Included
- 8 women with arm lymphedema. 16 man and women with lower limb lymphedema
- After 19 days, the reduction of limb volume was measured

3M™ Coban™ 2 two-layer compression system provides:

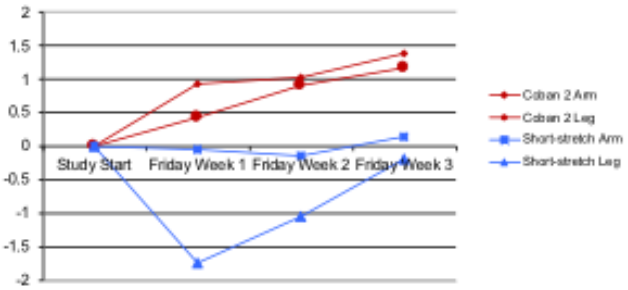
Good oedema reduction in both arms and legs to reduce limb volume and improvements in symptoms associated with lymphoedema.

The 3M™ Coban™ 2 two-layer compression system gives the patient a high degree of mobility.[40]

		Legs		Arms	
% volume reduction	n	Mean %	Standard deviation	Mean %	Standard deviation
3M – 5x/week	11	-12	10.48	-8.47	6.37
3M – 3x/week	10	-7.43	7.55	-6.78	7.03
3M – 2x/week	9	-18.65	14.50	-10.48	8.33
Short-stretch – 5x/week	8	-10.87	5.20	-8.19	3.13

Overall mobility

Absolute Change over Time on a 10-Point Rating Scale



Freiburg Life Quality Assessment (FLQA)

2x/week	Coban 2	Comprilan
Physical ailments	15%	10%
Everyday life	14%	-19%
Social life	-2%	-15%
Psycho social well-being	10%	10%
Treatment of lymph condition	9%	-17
Global score	8%	-9%

Results

- The highest lymphoedema volume reduction was achieved with the Coban 2 system applied two times per week
- The mean reduction of 18,7% in legs and 10,5% in arms was achieved
- Relevant change in overall mobility was achieved during the use of the Coban 2 system

Ordering information for venous and mixed etiology leg ulcers

Roll 1: comfort layer, roll 2: compression layer

Main application	3M reference	Content	Roll dimensions and packaging
For mixed aetiology leg ulcers ≥0.5 	2794E 	3M™ Coban™ 2 Lite two-layer compression system kit (2 rolls) ABPI ≥0.5	Layer 1: 10cm x 2.7m Layer 2: 10cm x 3.2m 1 kit per box, 8 boxes per case
	20714* 	Comfort Foam Layer 1#	10cm x 2.7m 18 rolls per box, 2 boxes per case

Main application	3M reference	Content	Roll dimensions and packaging
For venous leg ulcers ≥0.8  	2094 	3M™ Coban™ 2 two-layer compression system kit (2 rolls) ABPI ≥0.8	Layer 1: 10cm x 2.7m Layer 2: 10cm x 3.5m 1 kit per box, 8 boxes per case
	2094XL 	3M™ Coban™ 2 two-layer compression system kit (2 rolls) ABPI ≥0.8	Layer 1: 10cm x 3.5m Layer 2: 10cm x 4.5m 1 kit per box, 8 boxes per case
	20014* 	Comfort Foam Layer 1#	10cm x 3.5m 18 rolls per box, 2 boxes per case

Main application	3M reference	Content	Roll dimensions and packaging
Moccasin/toe boot bandaging  	20012 	Comfort Foam Layer 1#	5cm x 1.2m 32 rolls per box, 4 boxes per case
	20022 	Compression Layer 2#	5cm x 2.7m 32 rolls per box, 2 boxes per case
	2092 	3M™ Coban™ 2 two-layer compression system kit (2 rolls) ABPI ≥0.8	Layer 1: 5cm x 1.2m Layer 2: 5cm x 2.7m 1 kit per box, 8 boxes per case

Main application	3M reference	Content	Roll dimensions and packaging
Individual toe bandaging 	20721 	Compression Layer 2#	2.5cm x 3.5m 36 rolls per box, 4 boxes per case

*Comfort foam layer may be purchased as as single item for those clinicians wishing to use additional comfort foam layer material to reshape dysmorphic limbs.

Ordering information for chronic oedema/lymphoedema

Main application	3M reference	Content	Roll dimensions and packaging
3M™ Coban™ 2 Lite two-layer compression system For legs, arms, shoulders, fingers and toes 	20713 	Comfort Foam Layer 1#	7.5cm x 2.7m 18 rolls per box, 4 boxes per case
	20714 	Comfort Foam Layer 1#	10cm x 2.7m 18 rolls per box, 2 boxes per case
	20716 	Comfort Foam Layer 1#	15cm x 2.7m 10 rolls per box, 4 boxes per case
	20721 	Compression Layer 2#	2.5cm x 3.5m 36 rolls per box, 4 boxes per case
	20723 	Compression Layer 2#	7.5cm x 3.5m 32 rolls per box, 4 boxes per case
	20724 	Compression Layer 2#	10cm x 3.5m 32 rolls per box, 2 boxes per case
	20726 	Compression Layer 2#	15cm x 3.5m 15 rolls per box, 4 boxes per case

Main application	3M reference	Content	Roll dimensions and packaging
3M™ Coban™ 2 two-layer compression system For legs, hips and torso 	20012 	Comfort Foam Layer 1#	5cm x 1.2m 32 rolls per box, 4 boxes per case
	20014 	Comfort Foam Layer 1#	10cm x 3.5m 18 rolls per box, 2 boxes per case
	20016 	Comfort Foam Layer 1#	15cm x 3.5m 10 rolls per box, 4 boxes per case
	20022 	Compression Layer 2#	5cm x 2.7m 32 rolls per box, 4 boxes per case
	20024 	Compression Layer 2#	10cm x 4.5m 32 rolls per box, 2 boxes per case
	20026 	Compression Layer 2#	15cm x 4.5m 15 rolls per box, 4 boxes per case

The kits 2094 and 2794E can obviously also be used for lymphoedema applications.

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