

**The
Centre For
Research
and
Implementation
of Clinical
Practice**

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***Randomised Trial Comparing Four Layer with
Actico Cohesive Short Stretch Compression Bandaging
in the Management of Chronic Venous Ulceration***

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on behalf of the*

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Four Layer Versus Actico Cohesive Short Stretch Bandage Background

Cochrane Systematic Review 6/2/01

- "Five small studies found no difference in healing between multi-layer high compression (4-layer bandage or gauze plus long stretch bandage) and two forms of inelastic compression;
- *Unna's boot [Knight 1996]*
- *Short stretch bandage [Duby 1993, Scriven 1998, Danielsen 1998, Moody 1999].*
- The relative benefit increase for healing in multi-layer high compression bandages was 8% (95% CI, -21% to +49%) not statistically significant).

Profore Austrian Dutch Study (PADS)

Partsch et al (2001)

Randomised controlled trial of four layer versus short stretch bandaging for up to 16 weeks of treatment. Used SSB as treatment of choice.

	Profore	SSB
patients	53	59
healing	62%	73%
median healing time (days)	57	63

No significant difference for healing or median time to heal

Potential Benefits in the use of Short Stretch Bandaging

- less bulky, may allow for improved footwear
- some may be washed and reused
- application at 100% stretch. Less chance of applying high pressure in error
- low resting pressure, may be more comfortable
- reduce oedema (used in lymphoedema management)

Key Issues in the use of Short Stretch Bandaging

- less evidence on their use in large randomised controlled trials
- no consensus on the method of application
- may be less useful in patients with poor mobility
- may require more frequent application

Choice of Actico

- new concept in short stretch bandaging
- simple spiral technique
- cohesive nature should allow for less bandage slippage
- may require fewer re-applications than other short stretch regimens



Four Layer Versus Actico Cohesive Short Stretch Bandage Trial

Compare the time to ulcer healing of two high compression bandage systems in patients suffering from chronic venous ulceration

Four Layer Bandage System

Flexiban	(Activa Healthcare)
Setocrepe	(SSL)
Elset	(SSL)
Coban	(3M)

Cohesive Short Stretch System

Flexiban	(Activa Healthcare)
Actico	(Activa Healthcare)

Methods

- Prospective randomised open, stratified, parallel groups, multi-centre factorial trial
- Stratified by total area of ulcer on reference limb
 - <10cm²
 - >10cm²
- Bilateral ulceration
 - Reference limb larger total area of ulceration
 - Both limbs treated using same bandage regimen

Factorial Design

- Patients randomised to both a dressing and a bandage system

		Bandage	
Dressing		A	B
	1	50	50
	2	50	50

Methods

- Weekly follow up to assess the ulcer and change the dressings and bandages (up to 24 weeks)
- More frequent dressing changes when clinically indicated
- Randomised foam dressing
 - Allevyn (Smith & Nephew)
 - Mepilex (Molnlycke AS)

Patient Entry Criteria

- At least 18 years old
- Gender - Males
 - Females, providing they were not pregnant
- Ulcer - below knee
 - present >2 weeks, initially <six months
 - following protocol amendment <one year
- Ankle brachial pressure index (>0.8)
- Patient able to understand the trial and willing to give informed consent

Patient Exclusion Criteria

- Significant arterial disease (ABPI<0.8)
- Patients with other causes of ulceration
 - Rheumatoid vasculitis
 - Diabetic foot ulceration
 - Malignancy
 - Other
- Patients with dry non exuding wounds
- Patients who participated previously
- Unable to give informed consent
- Known history of non compliance
- Active cellulitis

Primary Objective

- Time to complete healing up to 24 weeks of treatment
- Healing - complete epithelialisation of all areas of ulceration on the reference limb

Sample Size

- On the basis of an expected healing rate of 80% and expected improvement in healing by 15%, with a power of 90% and 5% level of significance 200 patients (100 in each group) would be required
- Following a protocol amendment to increase ulcer duration from 6 months to 12 months expected healing was set at 70%. With the same criteria this would lead to an increased sample size of 240 patients (120 in each group)
- 159 patients randomised from 12 centres
 - median recruitment 14 (range 3 to 29)
 - >80% power for the trial
- post randomisation exclusions
 - 2 significant arterial disease (ABPI<0.8)
 - 1 refused to sign consent form

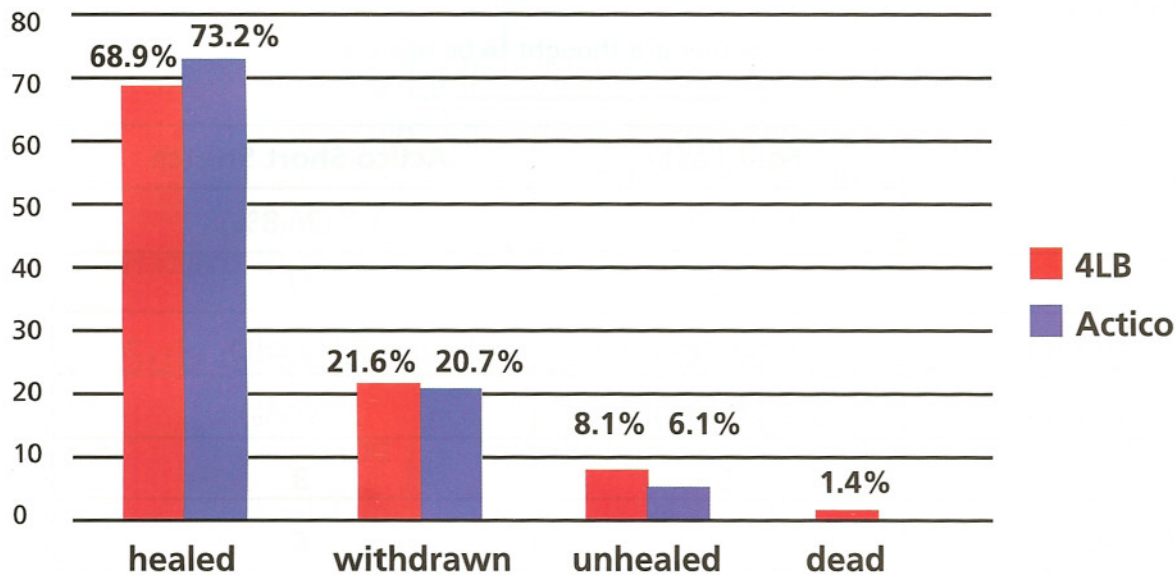
Screening undertaken in five centres

- 39.8% screened were randomised
- 11.4% long duration ulceration (>entry criteria)
- 10.4% arterial disease
- 6.5% other non venous ulcer
- 5.5% patient refusal
- 5.5% known non compliance

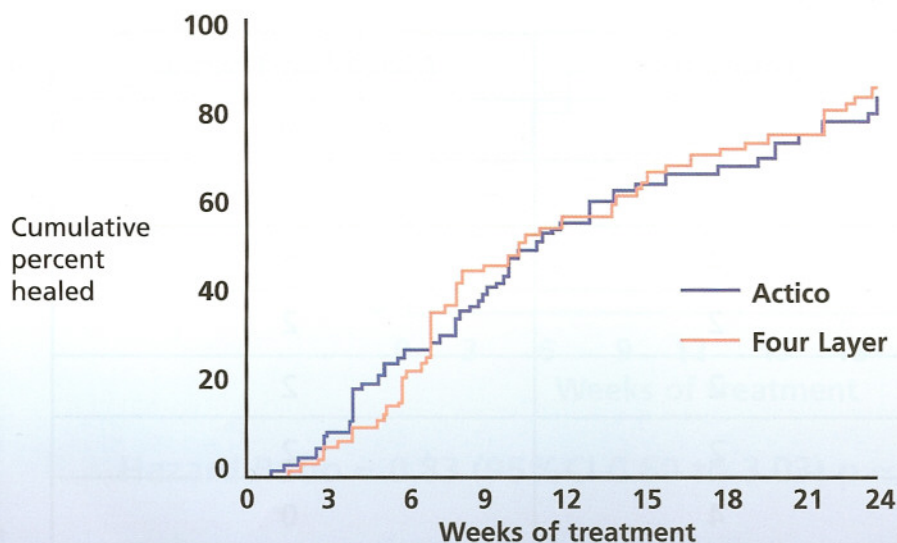
Study Results

	Four Layer	Actico Short Stretch
n =	74	82
Age - years	67.5	70.9
Gender - %women	63.5%	58.5%
Ulcer size - median	5.0	3.5
>10cm ²	20.3%	18.3%
Ulcer duration - median weeks	8.0	8.0
Mobility unaided	75.7%	81.7%
with aid	24.3%	17.1%
bed/chair bound	0	1.2%
Limb mobility full	74.0%	89.0%
limited	23.3%	11.0%
fixed	2.7%	0

Study Discontinuation



Kaplan - Meier Plot: Time to Healing (ITT)



Hazard Ratio = 1.08 (95%CI 0.63 to 1.85) p = 0.79
(Hazard Ratio adjusted for centre, dressing and ulcer size)

Reason for Patient Withdrawal

	Four Layer	Actico Short Stretch
n =	16	17
Wound/ Bandage problem	7	6
Patients request	2	2
Lost to follow up	5	9
Dressing related w/d	1	0
Missing	1	0

Adverse Event

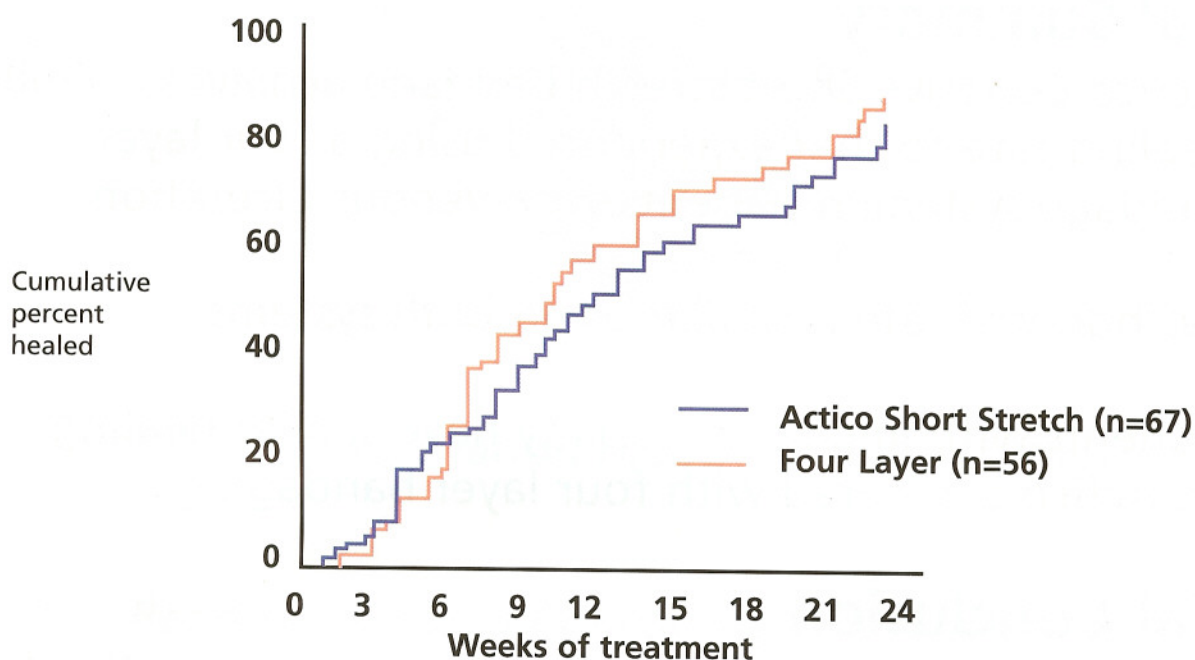
'Any undesirable clinical occurrence in a patient whether it is thought to be related to the investigational product or not'

	Four Layer	Actico Short Stretch
Patients	23 (31.1%)	22 (26.8%)
Events	30	36
Bandage related definite	6 (20.0%)	7 (19.4%)
possible	6 (20.0%)	2 (5.6%)
Effect - None	5	3
- Discontinued	7	6

Device Related Adverse Events

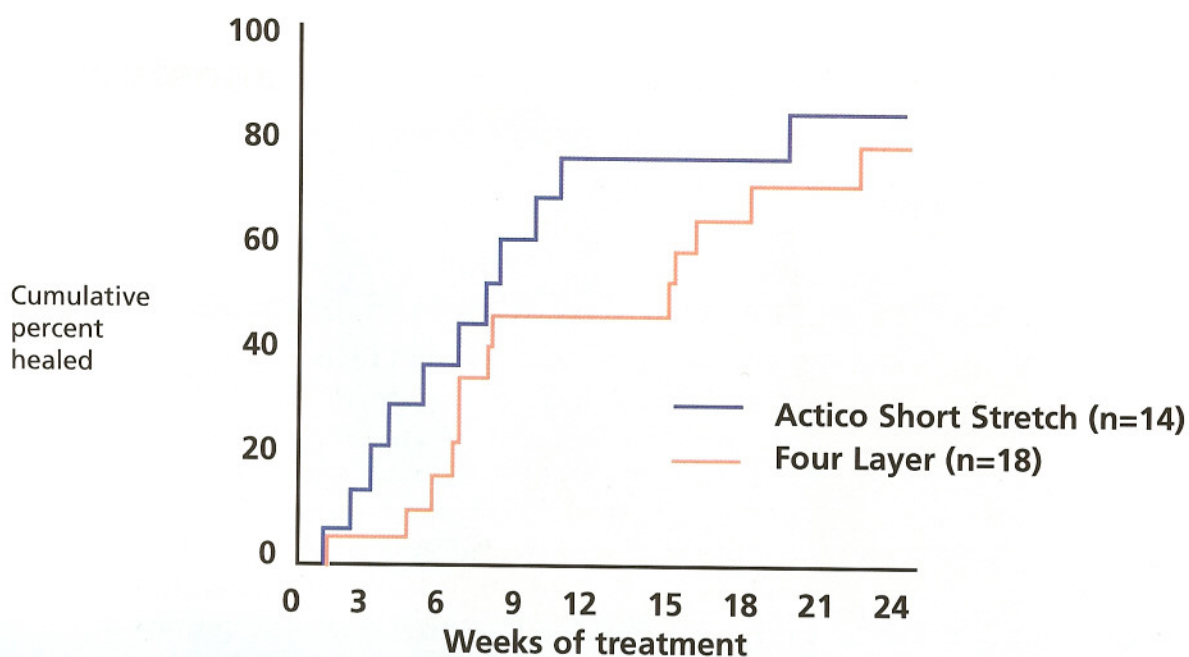
	Four Layer	Actico Short Stretch
Total Events	12	9
Tissue Damage/New Ulcer	2	3
Eczema/reaction to bandage	2	2
Pain	2	2
Maceration	2	2
Other	4	0

Sub Group Analysis: Walking Freely



Hazard Ratio = 0.83 (95%CI 0.56 to 1.25) $p = 0.37$

Sub Group Analysis: Require Walking Aid



Hazard Ratio = 0.83 (95%CI 0.60 to 3.03) $p = 0.46$

Trial Summary

- Actico Cohesive Short stretch bandage achieves a similar healing rate to that experienced using a four layer bandage system in patients with venous ulceration
- Withdrawal rate is similar using both systems
- Patients with impaired mobility have similar healing on Actico compared with four layer bandaging

Trial Conclusion

- Actico Cohesive Short stretch bandages are an effective alternative to four layer bandaging in the management of patients with chronic venous ulceration.

