

Enhancing Healing of Venous Leg Ulcers with Compression Therapy

Grand Rounds-Style
CE-Accredited Activity



Sponsored by North American Center for Continuing Medical Education, LLC



Supported by an educational grant from 3M Skin & Wound Care Division.

Enhancing Healing of Venous Leg Ulcers with Compression Therapy

Course Chair/Faculty Presenter

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Medical Director
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Montgomery, Alabama

Faculty Presenters

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St Luke's - Roosevelt Hospital Center
New York, New York

John Macdonald, MD, FACS
Miller School of Medicine
University of Miami
Miami, Florida

Susie Seaman, NP, MSN, CWOCN
Sharp Rees-Stealy Wound Clinic
San Diego, California

Target Audience

This activity is intended to meet the educational needs of medical directors at wound care clinics, physicians, nurses, podiatrists, physical therapists, and other healthcare professionals involved in the management of venous leg ulcers.

Learning Objectives

After completing this activity, participants should be able to:

- Define the physiological and biochemical disorders that cause venous leg ulcers
- Explain the science behind compression therapy and compression bandages for venous leg ulcers and the swollen limb
- Compare and contrast the various compression bandage modalities for managing venous leg ulcers
- Apply contemporary evidence-based treatment strategies for venous leg ulcers based on individual patient needs

Activity Overview

This CE-accredited activity consists of a 1-hour interactive presentation that is given by one of our noted faculty members. Select sessions in this series will be broadcast in real time over the Internet for individuals from other cities and states who wish to participate in the activity via the Web and ask questions via live chat.

To be eligible for documentation of credit, participants must attend an entire live meeting or webcast event and complete the online evaluation form. After successful completion of the evaluation form online at <http://www.naccme.com/program/2010-373/post/>, participants may immediately print their documentation of credit.

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There is no fee associated with this activity.

For questions regarding this educational activity, please call 609-371-1137.

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All educational activities are accessible via a computer with 650 MHz PC, 128 MB RAM, Windows or MAC operating system, Internet Explorer, Netscape, or Safari browsers. Windows Media Player, sound card, and speakers are required for streamed audio. Flash Player, sound card, and speakers are required for video programs. A PDF reader is required for print publications. Please direct technical questions to webmaster@naccme.com.

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NACCME designates this educational activity for a maximum of 1 *AMA PRA Category 1 Credit*™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Enhancing Healing of Venous Leg Ulcers

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Provider approved by the California Board of Registered Nursing, Provider #13255 for 1 contact hour.

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Physical Therapists: North American Center for Continuing Medical Education, LLC (NACCME) has applied for preapproved accreditation in only the states that require preapproval: Arizona, Florida, Illinois, Louisiana, and Texas. If you practice in any other state, simply forward a copy of your Certificate of Completion to the PT Board in your area.

Independent Clinical Reviewer: David J. Margolis, MD, PhD, Associate Professor, Dept. of Dermatology, University of Pennsylvania, Philadelphia, Pennsylvania

Nurse Reviewer: Edna Atwater, RN, BSN, Past-President, Dermatology Nurses' Association, Dermatology Nursing Institute Founding Board Member, Administrative Director, Wound Management Institute, Health Center Administrator, Dermatology, Duke University Medical Center, Durham, North Carolina

Planning Committee

The planning committee comprises Terry Treadwell, MD, FACS; John Macdonald, MD, FACS; Edna Atwater, RN, BSN; David J. Margolis, MD, PhD; Mike Kearney, Donna Kruggel, Emilie McCardell, Tiffany Oliver, Randy Robbin, and John Savage, NACCME.

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All educational materials are reviewed for fair balance, scientific objectivity of studies reported, and levels of evidence.

The faculty has reported the following:

Dr. Treadwell: Grant/Research Support—Celgene, HealthPoint, Organogenesis Inc., Sorbion AG; Consultant—Celgene; Promotional Speakers' Bureau—Organogenesis Inc., Systagenix

Dr. Macdonald: Scientific Advisor—3M; Promotional Speakers' Bureau—3M

Dr. Lantis: Grant/Research Support—ARK Therapeutics, HealthPoint, Medline, sanofi-aventis; Consultant—MacroCure Ltd.; Nitric Bio Therapeutics, Smith & Nephew; Scientific Advisor—Nitric Bio Therapeutics; Promotional Speakers' Bureau—HealthPoint, KCI, Smith & Nephew, Systagenix

Ms. Seaman: Scientific Advisor—Mölnlycke Health Care; Promotional Speakers' Bureau—Mölnlycke Health Care

Ms. Atwater: Disclosed no relevant financial relationships with any commercial interests

Dr. Margolis: Scientific Advisor—CoDa, Intercytex, Organogenesis, Pfizer, Wound Solutions Ltd.

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Faculty will make verbal disclosures at this meeting.

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Grant Support

Supported by an educational grant from 3M Skin & Wound Care Division

Enhancing Healing of Venous Leg Ulcers with Compression Therapy

Case-Based
Grand Rounds-Style
CE-Accredited Activity

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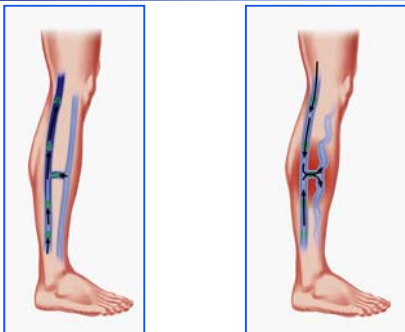
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Valvular Incompetence



Venous Disease and Ulceration



Edema



Lipodermatosclerosis and Ulceration

Pathophysiology of Venous Insufficiency

- Incompetence of valves in perforating veins
 - Long-standing saphenous incompetence
 - Local trauma
 - Undetected venous thrombosis
- Chronic ambulatory venous hypertension
- Capillary and venular dilatation
- Calf muscle pump failure

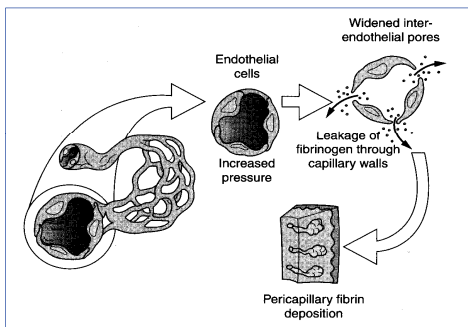
Angle N, et al. *Br Med J*. 1997;314(7086):1019-1023. Burton CS. *Am J Surg*. 1994;167(1A):37S-40S.

Venous Leg Ulcers: Potential Mechanisms Leading to Ulceration

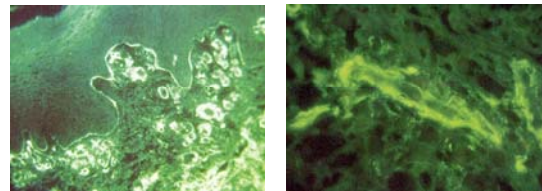
- Fibrin cuff hypothesis
 - Fibrinogen leaks through endothelial pores
 - Pericapillary fibrin cuff prevents oxygen and nutrient diffusion
- "Trap" hypothesis
 - Macromolecules trap growth factors
 - Growth factors unavailable to repair or maintain tissue
- Leukocyte trapping
 - Leukocytes accumulate and occlude capillaries
 - Activated leukocytes release toxic metabolites
 - Free radicals and proteolytic enzymes damage endothelium

Browse NL, et al. *Lancet*. 1982(8292):2:243-245. Falanga V, et al. *Lancet*. 1983;341:1006-1008. Coleridge Smith PD, et al. *Br Med J (Clin Res Ed)*. 1988;296(6638):1726-1727.

Venous Hypertension with "Leaky" Vessels



Pericapillary Fibrin in Venous Insufficiency



Falanga V, ed. *Cutaneous Wound Healing*. London, England: Martin Dunitz Ltd; 2001:157. Ouahes N, et al. *Curr Probl Dermatol*. 1995;7(4):114-142.

Why Won't These Ulcers Heal?



Early Venous Ulcer Treatment



*"For an obstinate ulcer,
sweet wine and
a lot of patience
should be enough"*

Hippocrates describing treatment of a patient with varicose veins and ulcer

Majno G. *The Healing Hand: Man and Wound in the Ancient World*. Cambridge MA: Harvard University Press, 1975.

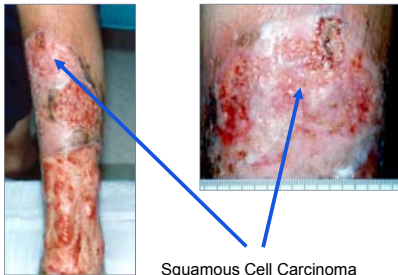
Good Therapy?



Are You Sure What You Are Treating?



Venous Leg Ulcer?



Squamous Cell Carcinoma

Risk Factors for Development of Venous Ulcer: Review of 581 Patients

- Venous insufficiency
- Hypertension*
- Decubitus ulcer
- Older age
- Female
- Previous hospitalization (within 2 years)*
- Diabetes*
- Renal insufficiency*
- CHF*
- Peripheral vascular disease
- Peripheral neuropathy
- Arthritis (both degenerative and inflammatory)
- Hypothyroidism
- Falls*
- Depression*

* Not significant after multivariate analysis.
CHF = congestive heart failure.
Takahashi, et al. *Wounds*. 2009;21

Predictors of Nonhealing of Venous Ulcers

- History of DVT
- Advanced age
- Male gender
- Obesity
- History of CHF
- Postmenopausal state (estrogen deficiency)
- HIV infection
- Activated protein C resistance/factor V Leiden mutation
- History of serious leg injury
- Previous total hip or total knee replacement
- History of previous venous ulcer
- Venous ulcer with high exudate volume
- Large size of ulcer
- Ulcer of long duration

DVT = deep vein thrombosis.
Taylor RJ, et al. *J Wound Care*. 2002;11(3):101-105.

Optimal Wound Bed Preparation

- Complete debridement of devitalized and poorly functioning tissue
- Restoration of bacterial balance
- Maintenance of optimal moisture balance
- Control of edema/lymphedema

Schultz GS, et al. *Wound Repair Regen*. 2003;11(Suppl):S1-S28.

Treatment of Venous Ulcers

Compression!



Compression!!



COMPRESSION!!!

Effects of Edema/Lymphedema Fluid

- Inactivates normal antistreptococcal properties of skin
- Inhibits mitogenic activity and DNA synthesis
- Has higher levels of proinflammatory cytokines
- Has higher levels of protease activity
- Has reduced levels of growth factors

Compression Therapy

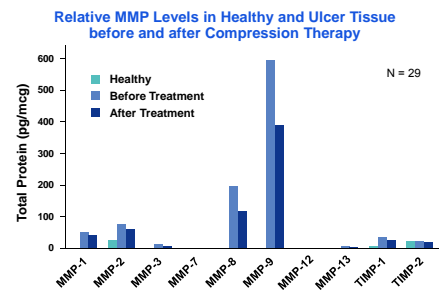
- Short stretch or inelastic
- Elastic
- Single layer
- Multiple layers
- Higher pressure better than lower pressure



Compression therapy significantly increases healing compared to *no* compression

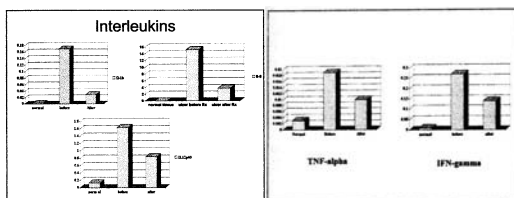
Fletcher A, et al. *BMJ*. 1997;315(7108):576-580. Cullum N, et al. *Cochrane Database Syst Rev*. 2000;(3):CD000265. Franks PJ, et al. *Wound Repair Regen*. 2004;12(2):157-162.

Proteases and Compression Therapy



MMP = matrix metalloproteinase; TIMP = tissue inhibitor of metalloproteinase. Beidler SK, et al. *Wound Repair Regen*. 2008;16(5):642-648. Beidler SK, et al. *J Vasc Surg*. 2009;49(4):1013-1020.

Inflammatory Cytokines and Compression Therapy



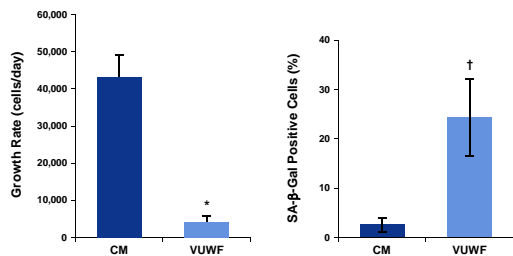
TNF = tumor necrosis factor; IFN = interferon. Beidler SK, et al. *Wound Repair Regen*. 2008;16(5):642-648. Beidler SK, et al. *J Vasc Surg*. 2009;49(4):1013-1020.

Fibroblast Senescence and Venous Ulcers

Patient	Normal (%)	Wound (%)
KM	1	14.9
BB	1	12.6
SK	0.33	4.0
AS	0.66	17.6
OB	1.33	14.3
RG	0.33	21
FF	2.33	26.3

Stanley A, et al. *J Vasc Surg*. 2001;33(6):1206-1211.

Fibroblasts and Chronic Wound Fluid



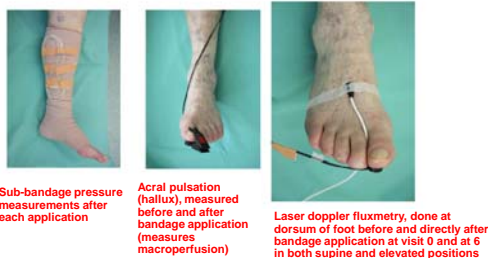
* $P = .006$; † $P < .03$.
 CM = complete media; VUWF = venous ulcer wound fluid; SA-β-Gal = senescence-associated β-galactosidase activity.
 Mendez MV, et al. *J Vasc Surg*. 1999;30:734-743.

Compression Therapy and Circulation

ABI	Bandage	Sub-bandage Pressure (mm Hg)
≥0.8	4 layers	35-40
0.7	2 or 3 layers	17-25
0.6	2 or 3 layers	17-25
<0.5	Only with medical supervision	—

ABI = ankle-brachial index.
 Stacey M, et al. *J Eur Manage Assoc*. 2002;2(1):9-13. European Wound Management Association. Understanding compression therapy. Position document. <http://ewma.org/english/position-documents/all-documents.html#c506>. Accessed May 25, 2010.

Safety in Patients with Pre-existing Peripheral Arterial Occlusive Disease ABI between 0.5-0.8



ClinicalTrials.gov. Open label clinical study to assess the clinical safety of a new compression device in subjects with peripheral arterial vascular disease. <http://clinicaltrials.gov/ct2/show/NCT00854516?term=ABPI+of+0.5.8&rank=1>. Accessed May 7, 2010.

Compression and Arterial Insufficiency

- 15 patients suffering from peripheral arterial occlusive disease with an ankle brachial pressure index ABPI of 0.5-0.8
 - 5 patients with ABPI of ≥0.5 and ≤0.6
 - 4 patients with ABPI of >0.6 and ≤0.7
 - 6 patients with ABPI of >0.7 and ≤0.8
- All patients treated with 2 layer compression system (Lite)
- Bandage remained on the leg 1 - 4 days
- Study stopped after 14 days

ClinicalTrials.gov. Open label clinical study to assess the clinical safety of a new compression device in subjects with peripheral arterial vascular disease. <http://clinicaltrials.gov/ct2/show/NCT00854516?term=ABPI+of+0.5.8&rank=1>. Accessed May 7, 2010. Sakurai T, et al. *Am J Physiol Heart Circ Physiol*. 2006;291(4):H176-H1767.

Results of 2 Layer Compression System (Lite) Study

- An average supine sub-bandage pressure of ~ 28 mm Hg was measured directly after bandage application
- No pressure-related skin damage occurred in patients with reduced arterial perfusion
- No pain related to tissue hypoxia was detected

ClinicalTrials.gov. Open label clinical study to assess the clinical safety of a new compression device in subjects with peripheral arterial vascular disease. <http://clinicaltrials.gov/ct2/show/NCT00854516?term=ABPI+of+0.5.8&rank=1>. Accessed May 7, 2010. Sakurai T, et al. *Am J Physiol Heart Circ Physiol*. 2006;291(4):H176-H1767.

Results of 2 Layer Compression System (Lite) Study

- Laser Doppler Fluxmetry demonstrated positive effects on microcirculation including:
 - Increased vasomotion (myogenic activity) rhythmic contractions of the peripheral arteries required for overall tissue microperfusion
 - Reduced respiratory reflux was seen for those patients with concomitant venous insufficiency
 - Maintained cardiac pulse signal (stable capillary perfusion)
- High wearing comfort
- Limb volume reduction compared to baseline

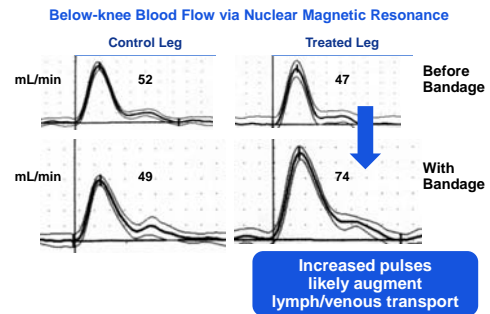
ClinicalTrials.gov. Open label clinical study to assess the clinical safety of a new compression device in subjects with peripheral arterial vascular disease. <http://clinicaltrials.gov/ct2/show/NCT00854516?term=ABPI+of+0.5.8&rank=1>. Accessed May 7, 2010. Sakurai T, et al. *Am J Physiol Heart Circ Physiol*. 2006;291(4):H176-H1767.

Conclusions: 2 Layer Compression System (Lite) Study

- Compression with 2 layer compression system (Lite) is safe and well-tolerated by patients with reduced peripheral arterial perfusion
- Results of the Laser Doppler Fluxmetry measurements indicate significant improvements of the dermal microcirculation under this compression therapy

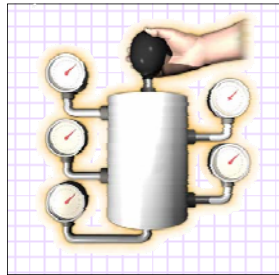
ClinicalTrials.gov. Open label clinical study to assess the clinical safety of a new compression device in subjects with peripheral arterial vascular disease. <http://clinicaltrials.gov/ct2/show/NCT00854516?term=ABPI+of+0.5.8&rank=1>. Accessed May 7, 2010. Sakurai T, et al. *Am J Physiol Heart Circ Physiol.* 2006;291(4):H176-H1767.

Arterial Flow Pulses



Mayrovitz HN, et al. *Clin Physiol.* 1997;17(1):105-117.

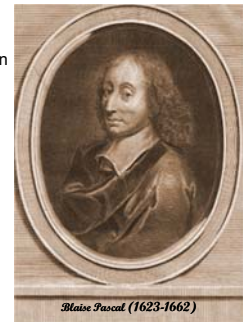
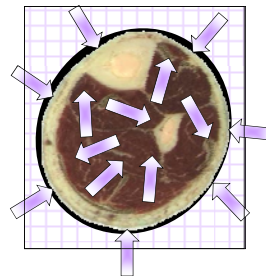
Pascal's Law



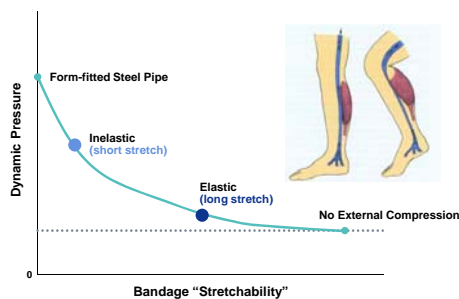
If pressure is applied to a non-flowing fluid in a container, then that pressure is transmitted equally in all directions within that container

What Pascal Said

If pressure is applied to a non-flowing fluid in a container, then that pressure is transmitted equally in all directions within that container

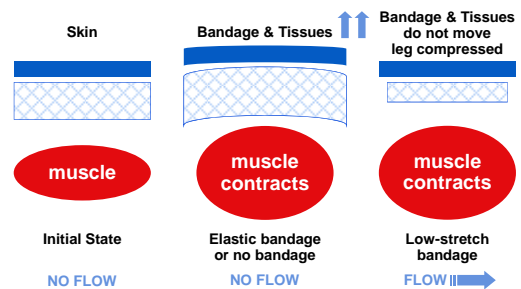


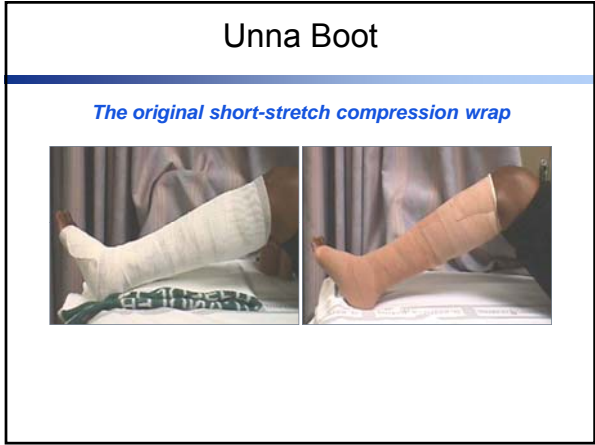
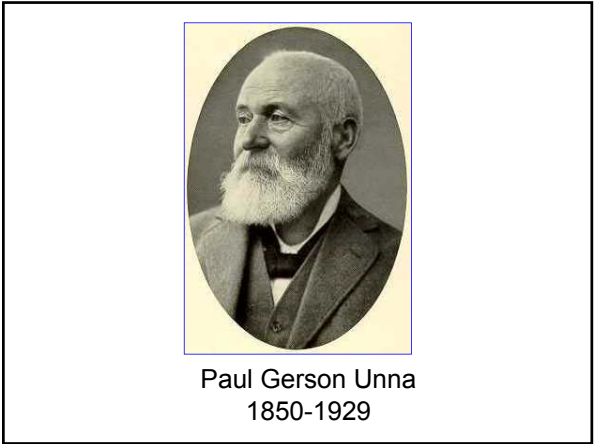
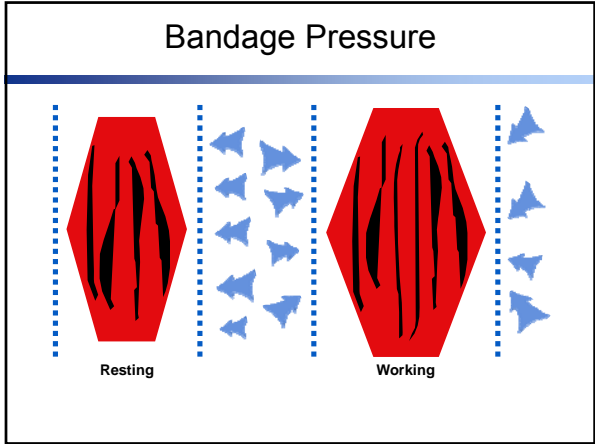
Dynamic Pressure Depends on Bandage Material Features



Macdonald JM, et al. *Surg Clin North Am.* 2003;83(3):639-658.

Bandage Effects





Effect of Compression Therapy



1 Week of Compression

Venous Ulcer



Healed at 33 Weeks

Venous Ulcer



99-year-old female with ulcer for 8 months
Started as a scratch on ankle
Informed that below-knee amputation was the only therapy



Compression Bandage Too Tight over Bony Prominences



Cellulitis of Leg

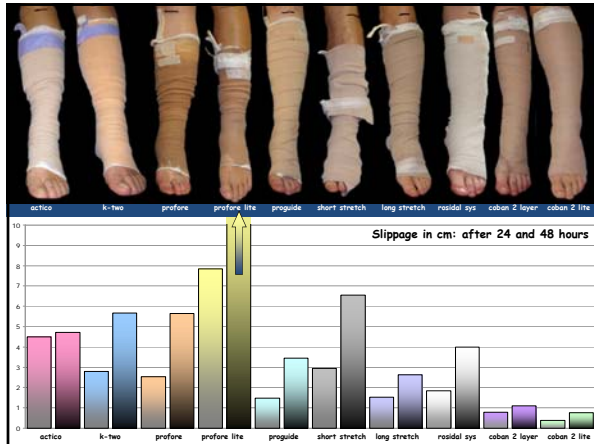


Healed after 10 days of antibiotics and 5 weeks of compression therapy



When a Bandage Won't Stay Up!





Compression Therapy Institute for Advanced Wound Care, June, 2009

- 1507 total patient visits
- 526 visits for compression therapy (35% of visits)
- 211 visits required single-leg wrap
- 315 visits required both legs wrapped = 630 dressings
- 841 total compression dressings applied

Data on file, Institute for Advanced Wound Care.

Compression Therapy Institute for Advanced Wound Care, June, 2009

- Only 12% (100) of compression dressings were Unna Boots
- 88% (741) compression dressings were not reimbursed

Data on file, Institute for Advanced Wound Care.

Compression Bandage Reimbursement

- 29580—Unna Boots
- 29581— All other multilayer compression bandages

Data on file, Institute for Advanced Wound Care.



"It is the individual patient who we treat, not the disease. It is the patient who recovers or dies, not the illness."

Peck J. *Am J Surg*. 2004;187(S):569-574.

Looking for the Evidence??



Question-and-Answer Session

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