Why is it so hard to do the right thing in wound care?

Caroline E. Fife, MD,
CMO, Intellicure
Medical Director, St. Luke’s Wound Center, The Woodlands, TX
Patient A

- 30-year-old white male with a one-year history of a small non-healing ulcer on the dorsal aspect of his right great toe.
- Followed for a year at another wound center in my city, using a variety of topical products.
Patient A

- Careful history reveals claudication.
- Non-invasive vascular studies show severe PVD and MRA confirms single vessel run-off.
- MRI showed osteomyelitis of the great toe.
- The patient underwent peripheral by-pass surgery.

TCOM of 4 mmHg on the right foot; monphasic Doppler waveform
Patient B

- 32 y.o. African American woman diabetic peripheral neuropathy
- Non healing plantar foot ulcer failed to respond to numerous topical interventions over 12 months including bilaminate skin.
Patient B: Healed with off-loading

- Neuropathic foot ulcer healed in 8 weeks with a total contact cast.
54-year-old male with a 10 year history of non-healing, bilateral circumferential lower extremity ulcerations.

He has never been provided compression.

He thinks he might have had some blood clots in the past.
Patient C: Healing with compression

- He was taught short stretch bandaging and later compression stockings.
- Near complete healing over 10 months.
- Hypercoagulable state confirmed with blood tests.
  - He has near complete occlusion of his deep venous system.
What is the explanation?

- I am a genius and I make “House” look like an intern.
- These highly technological interventions are known to only a few experts in the field.
- Clinicians find it difficult to appropriately implement either basic or advanced wound care properly.
- Why?
ICLS Definition of “Supervised Neglect”

- A faulty medical treatment that fails to inform patients of more effective treatments for their aliment.
  - The treating physician enforces therapies that are either not up to date or ineffective.
  - Patients receive attentive follow-up and frequent medical exams.
  - This conduct enforces the *illusion* of being properly treated due to close medical supervision when, in effect, ineffective care is being given.

International Center for Limb Salvage (ICLS), Geneva

[www.gfmer.ch/ICLS/Homepage.htm](http://www.gfmer.ch/ICLS/Homepage.htm)

Ineffective care is expensive!
Medical Therapy up to 1850 AD

- Purging
- Blistering
- Bleeding
- Flamed Cautery
- Oral Arsenic, Mercy & Lead
- Sulfuric Acid for wounds

NOW we believe in “evidence based medicine.”

“I die by the help of too many physicians”
Alexander the Great, died at 33
We do not provide therapies which are more likely to do harm than benefit.

The therapies we provide have an “evidence base” for their effectiveness derived from scientific studies.

How is that working for us?
Results of 9 Total Contact Cast (TCC) Studies for DFU

- **Average Healing Time:** 43.73 days
- **Percent Healed:** 88.9%

Helm 1984; Sinacore 1987; Walker 1987; Mueller 1989; Meyerson 1992; Birke 1992; Lavery 1997; Armstrong 2001; Birke 2002
Off-Loading: What is DONE

- TCC is the gold standard for DFU, confirmed by RCTs and espoused by every consensus committee.
- Only 1.7% of wound centers use TCC’s majority of time
  - 45.5% of centers do not use TCC’s at all
  - Shoe modifications are the most utilized pressure mitigation modality, despite data showing this is ineffective in healing
- There is a disconnect between what works and what is used for DFU healing.
Comparison of Diabetic Wound Treatments

- **Total Contact Cast**: Average Outcomes of Studies by Helm 1984; Meyerson 1992; Walker 1987; Birke 1992; Sinacore 1987; Lavery 1997; Armstrong 2001; Mueller 1989; Birke 2002
- **Dermagraft**: Marston, Hanft, et al; The efficacy and safety of Dermagraft..., Diabetes Care 2003, 26:1701-05.
- **Regranex**: Kantor, Margolis; Expected Healing Rates for Chronic Wounds, Wounds 2000, 12:155-158.
Data contained EHRs of wound centers from 34 states is de-identified, pooled and placed on a dedicated server. The U.S. Wound Registry used to create benchmarking for facilities and for cost effectiveness research. Overseen by independent IRB.
Results of USWR Analysis of TCC

- 108,000 patient visits to 18 outpatient wound centers in 16 states.
  - 264 patients with Diabetic foot ulcers
- 6% of DFU got TCC
- Average total cost of treatment with TCC was $11,946 USD per patient.
- Average total cost of a DFU without TCC was $22,494 USD per patient.
  - These patients DID get semisynthetic human skin, Becaplermin and other high tech interventions.
Clear evidence that compression is superior to no compression for healing of venous ulcers.

- Multi-component systems are more effective than single-component systems.
- Multi-component systems containing an elastic bandage appear more effective than those composed mainly of inelastic constituents.
Compression with Unna’s Boots

Paul Gerson Unna: 1850-1929
German dermatologist

Compression of venous ulcers is the most exhaustively validated treatment in wound care, Unquestioned for 20 years (available for >100 years)
26 hospital based, outpatient wound centers in 16 states.

Analysis performed as part of national “PQRI” (physician quality reporting initiative) from U.S. Medicare

- Records of 17,160 patients were assessed.
- 2,139 patients reported 4,364 venous ulcers.

Adequate compression was documented in only 17.1% of visits.

We have a problem with knowledge transfer!
What was used for “compression” by wound care doctors?

- Kerlix (no compression)
- “TED” hose (inadequate compression- only DVT prophylaxis)
- Ace wraps
- “Elevation”
- Tubigrip (~18 mmHg)
What determines compliance with clinical practice guidelines?

- **Inversely proportional to complexity:**
  - The harder it is to DO, the less likely we are to do it.

- **Directly proportional to knowledge (conviction and/or cognitive effort):**
  - Strong clinician knowledge/belief in effectiveness increases use

- **Directly proportional to compensation**
  - If you can’t get paid for it you are not likely to do it.

Wound Rep Reg (2010): 18; 154–158
Complexity: The more difficult it is to do something, the less likely a clinician will do it.

- Example: hand washing
1847, Vienna Hospital maternity clinic
- Introduced hand washing with chlorinated lime solutions for interns who had performed autopsies before they attended deliveries.
- Reduced incidence of fatal puerperal fever from ~10% (range 5–30%) to ~1%
- His hypothesis that lack of cleanliness caused disease was ridiculed.
  - Dismissed from the hospital and harassed by the medical community.
  - Died in a mental institution.
- Vindicated after his death when Pasteur developed the germ theory of disease
Currently, physicians in our hospital wash their hands approximately 50% of the time that they conduct a patient encounter. . . We have poor compliance with this basic requirement and a not inconsiderable incidence of hospital acquired infections.
Complexity factors which affect hand washing (from WHO)

- How educated the clinician is to importance (understanding)
- How far away the hand washing station is (convenience)
- How much time it takes or how much it affects work flow (efficiency)
- How often it is necessary/total time spent washing and comfort factors like skin cracking (negative impact)
Compensation System: In GENERAL (although not always)
- We cannot provide services for which we are not compensated
- The higher the compensation, the more likely it is the service will be provided.
Table 1. Estimate of return on investment comparing total contact casting vs. LSE application

<table>
<thead>
<tr>
<th>Item</th>
<th>TCC</th>
<th>LSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>192.68</td>
<td>1,893.77</td>
</tr>
<tr>
<td>Expenses</td>
<td>111.00</td>
<td>1,372.00</td>
</tr>
<tr>
<td>Expenses (overhead)</td>
<td>100.00</td>
<td>100.00</td>
</tr>
<tr>
<td>Margin</td>
<td>-18.32</td>
<td>421.77</td>
</tr>
</tbody>
</table>

Calculations assume 30 minutes of staff for either application, and that staff time and overhead for a facility room (building rent, energy, front desk, housekeeping) will approximate US$100. These calculations do not include the physician fees, because for the most part, physicians do not usually apply the TCC, although they might. All figures are US$. 

A Helpful Primer On Total Contact Casts
http://www.podiatrytoday.com/article/1853
Compression Bandaging not “Medically Necessary” (Noridian: 2/21/2007)“Since the high compression bandage systems maybe safely applied by the patient or caregiver, reimbursement for the application or materials used will be denied as not medically reasonable and necessary.”
We are getting better at compression:

- In 2011 CMS provided a procedure code for compression bandaging
- USWR data in 2012 showed that the % of venous stasis ulcer visits with adequate compression had increased to 55%
- Indicates that compensation might have an effect on compliance
Many physicians were *ignorant* that compression is the standard treatment for venous ulcers
- 82% thought evidence base was lacking
- Many physicians think compression is just too dangerous.

You just diagnosed a DVT...

- After writing orders for anticoagulation, what is the next order you write?
- a) STRICT BED REST
- b) ENCOURAGE AMBULATION
- c) APPLY COMPRESSION STOCKING
- d) START THROMBOLITICS
Early mobilization in patients with acute deep vein thrombosis does not increase the risk of a symptomatic pulmonary embolism.
2 studies compared 30-40 mmHg compression stockings vs. no compression
Compression stockings resulted in highly statistically significant reduction in the incidence of PTS (The incidence of severe PTS was reduced from OR 0.39 (95% CI 0.20 to 0.76).
No difference in the incidence of pulmonary embolism was found.
A significant reduction (P < 0.05) was found in pain, swelling and clinical scores, favoring the compression group.
After 60 minutes sitting: Hematocrit of blood leaving the foot *increased* by 9.6% in controls and 25.6% in patients with CVI (Suggests fluid leaves vasculature and concentrates blood).

Controls showed a 5.0% decrease in the relative number of WBCs leaving the foot vs. *28% decrease* in patients with CVI. (Suggests increased white cell trapping in the dependent legs of patients with CVI.)
Sitting is a Problem for CVI

Changes in Hct and WBC in patients with and without venous hypertension

%
75% of patients with stasis ulcers in the USWR are obese.

WBC and Hct changes happen within 60 minutes of the legs becoming dependent.

What do obese people with venous disease really need to be doing?

- How about walking while their legs are in effective compression?
Risks of Compression Bandaging

- Ischemic injury to leg by cutting off arterial in-flow
- Traumatic wounds or Localized pressure sores over bony prominances (requires lots of padding)
- Disuse problems in ankle joints
- Presumably this is the excuse clinicians use for not implementing compression.

Ischemic ulcers from high stretch product
## Compression Therapy

**Determine Ankle-Brachial Index**

<table>
<thead>
<tr>
<th>Measurement Value</th>
<th>Diagnosis</th>
<th>Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.8 – 1.0</td>
<td>Venous</td>
<td>High Compression</td>
</tr>
<tr>
<td>0.5 – 0.7</td>
<td>Mixed</td>
<td>Modified / Low Compression</td>
</tr>
<tr>
<td>&lt; 0.5</td>
<td>Arterial</td>
<td>No compression</td>
</tr>
</tbody>
</table>
Resting and Working Pressure

- **Resting pressure** (RP) produced directly by the passive tension exerted by the compression system.
- **Working pressure** (WP) produced intermittently on exertion when the muscle is exercised.
  - The difference between these 2 pressures corresponds to the static stiffness index of the bandage.
    - The higher this index is, the more rigid the bandage and the more it fits into the short-stretch (low-elasticity) category.
    - The lower this index is, the more elastic the bandage it and the more it fits into the long-stretch category.
Short Stretch Advantages

- Short stretch bandages have limited extensibility under tension (50%), in contrast to high stretch bandages (e.g. Ace bandages ~300%).
- Made of cotton, and because of the material's weave pattern, they have limited extensibility (i.e., low resting pressure => low risk of ischemia)
Short Stretch Advantages

- Concept is that they act as a “shell” against which muscles contract thereby activating the calf muscle pump.
- They have a high “working pressure” and a low resting pressure.
  - Less likely to cause ischemia
- Compression reduces ultrafiltration rate of lymphatic fluid

So, just check an ABI and if you are worried at all, use a short stretch option.
Some Systems Are Easy to Apply
Velcro Devices Provide Another Option
HIMSS survey: Why do practices implement EMRs?

Reasons:
- Decrease medical errors
- Improve efficiency
- Decrease ERRORS OF OMISSION

Physicians increased their orders in 46.3% of instances when they received a reminder compared with 21.9% of controls.

With reminders, 51% of eligible patients got the flu vaccine vs. 30% without a reminder.
Incorporation of at least ONE clinical practice guideline is part of the “meaningful use” criteria for a physician to get bonus money for HIT adoption.

CPGs incorporated into wound care EHRs may be the way to FINALLY get compliance with basic wound care interventions.
The Affordable Care Act (ACA) and "Value Based Payment"

- As part of the ACA, in 2015, a new value-based payment modifier will be used to provide differential payments to doctors based on quality and cost of care.
  - The payment adjustments are “budget neutral” Some physicians will receive bonuses and some will be penalized
  - Doctors who report will be paid with money taken from doctors who don’t
What are the Current PQRS Measures for Wound Care?

1. **Prescribe venous compression **ONE **TIME in a 12 month period**
2. Patient education of diabetic foot care
3. **NOT performing saline wet to dry dressings of a wound**
4. **NOT performing a wound swab culture**
5. Patient education of venous compression

We have 5 quality measures!

None of them are good measures of wound care quality.
What’s Your Excuse for Not Using Compression?

- I have to get a venous Doppler to rule out a DVT (wrong—compression can help prevent PTS)
- I have to get an arterial Doppler before I can start compression (wrong—for most non-diabetic patients an ABI is good enough)
- Elevation is good enough to heal the ulcer (totally wrong—that’s why they came to you for help)
- Compression bandaging is time consuming to put on and hard to learn.
- Patients don’t like it.
All venous ulcers require adequate compression
All neuropathic foot ulcers require adequate off-loading
All chronic non-healing leg ulcers require vascular screening

If you got bonus money for doing these things, would you be more likely to do them?