Advanced Care Practices “Off Loading DFU’s”

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President, Assoc. for the Advancement of Wound Care, AAWC
Chief, Podiatric Surgery VA Healthcare New England, RI
Director, Research, Wound Healing RI Hospital
Director, Research Fellowship Program

Objectives:

- Understand advanced tenants for DFU's, debridement, off loading and advanced therapies.
- New Off-Loading Consensus Guidelines
- TCC, Overwhelming Evidence
- Patient Selection & Tips

PECORARO: Diabetes Care 1990

Advanced Therapy for DFUs: Team Approach

- Elliot Joslin, diabetologist
- Founded first hospital based foot care clinic at New England Deaconess Hospital in 1928
- Team approach including foot care, medical nutrition, exercise, prompt treatment of foot infections, specialized surgical care

Advanced Therapy for DFUs: Team Approach

- NE Deaconess Hospital legacy
  - 1940s - Leland McKittrick – TMA
  - 1950s - Frank Wheelock – vascular surgery
  - 1980s – Gary Gibbons, David Campbell, Frank Pomposelli
  - 1990s – Frank Logerfo (1984 NEJM)
    - Extreme distal revascularization (Gibbons 1993)
  - 1990s – Frykberg, Habershaw, Chrzan, Giurini, Rosenblum – podiatry / foot preservation
Advanced Therapy for DFUs: Team Approach

**CLINICAL BENEFIT**

Reducing Amputation Rates in Patients with Diabetes at a Military Medical Center

- Limb Preservation Service (LPS) – multidisciplinary foot care clinic for diabetics at Madigan Army Medical Center
- Evaluation of program structure and success in reducing lower extremity amputations

Driver et al, DiabetesCare, 2005

**LPS: Focused care for high risk diabetic feet**

- Prevention and education: complete LE exam
- Infection management, Vascular intervention
- Foot surgery: emergent, routine or reconstructive
- Wound care team
- Surgical/hospital management
- Orthotics, prosthetics, specialized shoeing
- Community and regional education

Driver et al, DiabetesCare, 2005

**LPS: Treatment Principles**

- Aggressive treatment of infection – surgical
- Diagnose ischemia and prompt revascularization
- Relief of pressure to wound – offload
- Improve wound environment with debridement and advanced care treatments

Driver et al, DiabetesCare, 2005

**LPS Clinical Outcomes – Summary**

- 82% decrease in LE amputations (33 → 9) despite 48% increase in diabetic patients
- More distal amputations – 71% foot, ankle or toe – Quality of life impact

Driver et al, DiabetesCare, 2005

**The role of interdisciplinary team approach in the management of the diabetic foot**

(Joint Statement from SVS and APMA, JVS 2010)

- Link efficiently and coordinate team of specialists to manage complex comorbidities, in addition to foot pathology
- Leadership role in education, dissemination of information
- Infrastructure to design and implement clinical research trials, develop algorithms for optimal management
Advanced Therapy for DFUs: Team Approach

**ECONOMIC BENEFIT**

The Costs of Diabetic Foot

- **Magnitude** – 80% LE amputations preceded by ulcer
- **Costs**
  
  Diabetics with LE ulcer 2.4X higher cost of care – more inpt stays and ED visits
  
  - Avg cost/ulcer episode >$13,000, increased with Wagner grade (2K -> 28K)

Driver et al, JVJS, 2010

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Limb Salvage Team reduces costs

- Larsson / Sweden 1995 – 78% decrease in major amputations after team implemented
- Ragnarson 2001 – Markov model → implementation of guidelines (IWGDF) prevention strategy → 25% decline DFU & amps

Driver et al, JVJS, 2010

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Diabetic Foot Disorders

![Image of diabetic foot disorders diagram]

**Diabetes Mellitus**

- Neuropathy
- Vascular disease

**Motor**

- Abnormal muscle weakness, atrophy
- High plantar pressures

**Autonomic**

- Loss of protective sensation
- Decreased sympathetic tone

**Sensory**

- Dry skin, fissures

**Trauma**

- Impaired response to infection

**Osteoarthropathy**

- Amputation

**Diabetic foot ulceration**

- Amputation

**Macrovascular**

- Atherosclerosis
- Ischemia

**Microvascular**

- Structural: Capillary BM thickening
- Functional: A-V shunting (increased blood flow)

**Autonomic**

- Anhidrosis
- Dry skin, fissures

**Motor**

- Abnormal stress, weakness, atrophy

**Sensory**

- Loss of protective sensation

**Final Amputation Triggers**

- Ischemia: 5%
- Faulty wound healing: 14%
- Gangrene: 40%
- Infection: 41%

Pecoraro RE, Reiber GE, Burgess DM. Pathways to diabetic limb amputation. Basis for prevention. Diabetes Care 13

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Many Factors Affect Wound Care Outcomes

- Setting of care
  - Experience / knowledge of provider(s)
- Type of wound and its chronicity
- Health status of patient / co-morbidities
- Concomitant medications may interfere
- Timely selection of interventions that address defects in wound microenvironment

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**NATURAL HISTORY OF DIABETIC FOOT ULCERS**

Metaanalysis of placebo arms of 9 RCTs (total 10 control arms)

- **Total n of pts**: 622
- **Ulcers**: non infected, non ischemic neuropathic DFUs

**Follow up 20 wks**: 6 RCTs (450 pts)
**Follow up 12 wks**: 2 RCTs (138 pts)

Follow up 18 wks: 1 RCT
Follow up 10 wks: 1 RCT

Margolis et al. Diabetes Care 1999
GOOD ULCER CARE

- Pressure Control (offload or compression)
- Debridement
- Metabolic Control and Nutrition
- Bacterial Burden
- Chronic Inflammation
- Moisture Balance

NATURAL HISTORY OF DIABETIC FOOT ULCERS
NON INFECTED, NON ISCHEMIC, SUPERFICIAL NEUROPATHIC DFU
GRADE 1A ULCERS

HEALING AT 12 WKS: 24.2% > ¼ DFUs
HEALING AT 20 wks: 30.9% > 1/3 DFUs

Margolis et al. Diabetes Care 1999

PRESSURE CONTROL (OFFLOAD OR COMPRESSION)

DEBRIDEMENT

METABOLIC CONTROL AND NUTRITION

BACTERIAL BURDEN

CHRONIC INFLAMMATION

MOISTURE BALANCE

GOOD ULCER CARE

Diarhetic Foot Ulcers (DFUs)

IS IT POSSIBLE TO IMPROVE THE OUTCOME?

AGGRESSIVE OFFLOADING OF NEUROPATHIC PLANTAR ULCERS IN DIABETIC PATIENTS IS NOT AN ADJUNCT TO TREATMENT

IT IS THE MOST EXTENSIVELY STUDIED TREATMENT

NATURAL HISTORY OF DIABETIC FOOT ULCERS
IS IT POSSIBLE TO IMPROVE THE OUTCOME?
NON INFECTED, NON ISCHEMIC, SUPERFICIAL NEUROPATHIC DFU

OFFLOADING (12 wks = 84 days)

<table>
<thead>
<tr>
<th>RCTs</th>
<th>% healing</th>
<th>Average healing time</th>
<th>Ulcer grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>TCC</td>
<td>5</td>
<td>73-90%</td>
<td>31-69 days</td>
</tr>
<tr>
<td>TCC</td>
<td>1</td>
<td>90%</td>
<td>85 days</td>
</tr>
<tr>
<td>Shoes</td>
<td>4</td>
<td>52-72%</td>
<td>35-85 days</td>
</tr>
<tr>
<td>Rem. Boot</td>
<td>2</td>
<td>35-52%</td>
<td>49-58 days</td>
</tr>
<tr>
<td>Felted Foam</td>
<td>1</td>
<td>Not reported</td>
<td>75 days</td>
</tr>
</tbody>
</table>


The rubber heel, which is placed under the midfoot, permits ambulation. Soft black foam covers the anterior portion of the foot to prevent injury. The cast is changed 24 to 48 hours after application and then weekly.

Cross-Section of a Total-Contact Cast Formed to a Patient's Foot.
Removable cast walkers (RCWs)

Removable cast walkers are hypothesized to decrease forefoot plantar pressure by keeping the ankle at 90 degrees and subsequently limiting propulsion.


Orthosis and Shoes

PTB orthosis
- Used in conjunction with therapeutic shoes
Prefabricated walking braces and custom fabricated AFO
Commercially available walking braces
CROW (Charcot restraint orthotic walker)
- Edema control
- Effective ankle and foot immobilization
- Near normal ambulation

Orthosis and Shoes

Half-Shoe

The half-shoe helps confine weight-bearing to the heel or the forefoot.


Useful off-loading mechanisms include reduction of walking speed, alteration of foot rollover during gait, and transfer of load from affected areas to other areas of the foot or the lower leg.


NATURAL HISTORY OF DIABETIC FOOT ULCERS
IS IT POSSIBLE TO IMPROVE THE OUTCOME?
NON INFECTED, NON ISCHEMIC, SUPERFICIAL NEUROPATHIC DFU

OFFLOADING (12 wks= 84 days)

<table>
<thead>
<tr>
<th>RCT</th>
<th>N of pts</th>
<th>% healing At 12 weeks</th>
<th>Ulcer grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>TCC vs. rem cast walker vs. half shoe</td>
<td>63</td>
<td>89 vs. 61 vs. 28</td>
<td>UT1A</td>
</tr>
<tr>
<td>Non rem cast walker vs. rem cast walker</td>
<td>50</td>
<td>83 vs. 52</td>
<td>UT1</td>
</tr>
<tr>
<td>TCC vs. non rem cast walker</td>
<td>41</td>
<td>74 vs. 80</td>
<td>UT1A</td>
</tr>
<tr>
<td>Fiberglass TCC vs. non-rem cast walker</td>
<td>40</td>
<td>95 vs. 85</td>
<td>UT1A</td>
</tr>
</tbody>
</table>

Armstrong et al. Diabetes Care 2001;24:1019-22
Armstrong et al. Diabetes Care 2005; 28: 551-4

NATURAL HISTORY OF DIABETIC FOOT ULCERS
IS IT POSSIBLE TO IMPROVE THE OUTCOME?
Real World TCC

Patient groups

% Healed

prp    inf    pad    inf + pad

Prospective cohort of 90 patients
Average healing rate: 79%
Average healing time: 33 days

COMPLICATIONS
9% new ulcers (average healing time under modified TCC: 13 days)
Preliminary lesions: 28% (resolved with adaptation of the TCC)

THE MANAGEMENT OF DIABETIC FOOT ULCERS THROUGH OPTIMAL OFF-LOADING.

Building Consensus Guidelines and Practical Recommendations to Improve Outcomes


Consensus statements

<table>
<thead>
<tr>
<th>Grade</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔</td>
<td></td>
</tr>
</tbody>
</table>

The panel endorses the Charcot foot in diabetes consensus report1 The Charcot Foot in Diabetes ADA & APMA Guidelines Diabetes Care, 2011

Total contact casting (TCC) is the preferred method for off-loading diabetic plantar foot ulcers, as it has most consistently demonstrated the best healing outcomes and is a cost-effective treatment

The likelihood of DFU healing is increased with off-loading adherence

Off-loading options by condition

Products:
A: Total contact cast; B: CROW cast; C: Prefabricated walker; D: DH walker; E: IPOS shoe; F: Ortho wedge; G: PostOp shoe; H: Healing sandal; I: Reverse IPOS; J: L’nard splint; K: PTB brace; L: MABAL shoe.

Off-loading options BY Amount of evidence

Products:
A: Total contact cast; B: CROW cast; C: Prefabricated walker; D: DH walker; E: IPOS shoe; F: Ortho wedge; G: PostOp shoe; H: Healing sandal; I: Reverse IPOS; J: L’nard splint; K: PTB brace; L: MABAL shoe.
Despite extensive clinical evidence documenting its efficacy, TCC is not widely used!

Only 3.7% ‘TCC-eligible’ patients received TCC

How can this be improved?

Patient satisfaction was equal for all modalities.

TCC resulted in more patients achieving wound closure*

TCC resulted in faster healing*

Patient outcomes

USWR DFU Results

Amputations

\[ P = 0.001^* \]

Infections (per year)

\[ P = 2.1 \times 10^{-10}^* \]

* Data are not stratified

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**Proven Clinical Efficacy for TCC, 2014**

<table>
<thead>
<tr>
<th>Finding of 7 RCTs and 1 Meta-analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>TCC has healing rate of about 90% within 6-8 weeks*</td>
</tr>
</tbody>
</table>

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**USWR DFU “Off-loading in Practice” Project**

96 clinics in 23 states and Puerto Rico 5 year, 2008-2013

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**USWR DFU “Off-loading in Practice”**

Only 2.2% of visits reported any off-loading

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**Table: Patient outcomes**

<table>
<thead>
<tr>
<th>OPTION</th>
<th>VISIT COUNT</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-op shoe*</td>
<td>803</td>
<td>36.6</td>
</tr>
<tr>
<td>TCC</td>
<td>781</td>
<td>16.0</td>
</tr>
<tr>
<td>Shoe modification</td>
<td>652</td>
<td>13.3</td>
</tr>
<tr>
<td>DH walker</td>
<td>469</td>
<td>9.6</td>
</tr>
<tr>
<td>Half shoe</td>
<td>266</td>
<td>6.4</td>
</tr>
<tr>
<td>Custom insert</td>
<td>299</td>
<td>5.3</td>
</tr>
<tr>
<td>CROW walker</td>
<td>174</td>
<td>3.6</td>
</tr>
<tr>
<td>Other</td>
<td>492</td>
<td>10</td>
</tr>
</tbody>
</table>

* The post-operative shoe was used 2 times more than any other off-loading device despite the lack of evidence to support its efficacy

Based on EHR billing data. Only TCC billable so other off-loading probably underreported.
How Does It Work?

- TCC decreases pressure in 1st met by 69% and decreases heel pressure by 45%.
- Full contact with weekly custom fit cast provides control of shear.
- Reduced foot pressure and shear allows skin to heal.
- Ensures 100% compliance.


How Total Contact Casting Works

- Reduces shearing forces and stride
- Removes pro-pulsive phase of gait and looks ankle
- Reduces pressure - catches weight on the calf


Patient Selection

Indications:
- Non-infected neuropathic foot ulcers without deeper structures
- Post-operative care (Charcot reconstructing, delayed primary closure)
- Charcot Neuroarthropathy
- Pre-ulcerative conditions
- Adequate blood supply to heal (Vascular consult recommended)

Contraindications
- Ulcer has signs of infection
- Vascular status not adequate for healing
- Ulcers deeper than they are wide
- Non-compliance with visits
- Allergy to casting material
- Excessive leg or foot swelling and fragile skin
- Claustrophobia
- Wounds that probe to tendon, capsule and bone and are abscessed

TCC Indications & Contraindications


How to use TCC- with Charcot

- TCC- Charcot Boots (Large & XL)
- Foam insert has 3 levels, each progressively firmer to prevent bottoming out
- Easily customizable (cut out extra foam, cushion possible problem areas
Lessons from Practice

TCC is vastly underutilized in DFU treatment
  • There is a BIG "Gap in Practice"

Easier-to-apply kits may increase the % of DFUs treated with TCC

In a real world setting, TCC decreases amputation rate by 50% and lowers infection incidence
  • We can assume this translates to overall cost savings
  • We NEED Cost savings . . .

TCC IS USED AS FIRST CHOICE BY LESS THAN 2% OF CENTERS

Survey on 895 private and academic Centers involved in the management of DFUs

Good Ulcer Care

• Pressure Control (offload or compression)
• Debridement
• Metabolic Control and Nutrition
• Bacterial Burden
• Chronic Inflammation
• Moisture Balance

Maintenance Debridement

Definition:
Repeated removal of necrotic tissue throughout the lifespan of the chronic wound
• Required for chronic wounds
  – Fibrotic and necrotic tissue continue to accumulate in the wound
• Continually prepares the wound bed for healing

Debridement

Enables the true dimensions of the ulcer to be perceived

Allows drainage of exudate and removal of dead tissue rendering infection less likely

Enables a deep swab to be taken for culture

Encourages healing

Edmonds et al. 2000
SHARP DEBRIDEMENT IN THE CLINIC: AVAILABLE EVIDENCE

SERIAL DEBRIDEMENT IMPROVES TIME TO HEALING IN VLU AND DFU


VLU (n= 366)  DFU (n= 310)

Debridement at every visit

DEBRIDEMENT

 Sharp debridement with a scalpel seems to influence the healing time of DFU

AGGRESSIVE-CONSERVATIVE MANAGEMENT OF THE DIABETIC FOOT: CONCLUSIONS

Real Life

Clinical Evidences of PRP in Wound Care

<table>
<thead>
<tr>
<th>Author</th>
<th>Study</th>
<th>Treatment</th>
<th>Notes</th>
<th>Δ%</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Driver VR et al.</td>
<td>Faster healing of wound</td>
<td>42.9</td>
<td>47.4</td>
<td>*</td>
<td>9.49</td>
</tr>
<tr>
<td>Mazzucco L et al.</td>
<td>Healing rate (days)</td>
<td>3.5</td>
<td>6</td>
<td>0.0001</td>
<td>41.67</td>
</tr>
<tr>
<td>Knighton DR et al.</td>
<td>Healing rate (weeks)</td>
<td>8.6</td>
<td>15</td>
<td>0.0002</td>
<td>42.67</td>
</tr>
<tr>
<td>Driver VR et al.</td>
<td>Higher rate of healing</td>
<td>81.30%</td>
<td>42.10%</td>
<td>*</td>
<td>93.11</td>
</tr>
<tr>
<td>Knighton DR et al.</td>
<td>% of healing</td>
<td>100%</td>
<td>85%</td>
<td>*</td>
<td>17.65</td>
</tr>
<tr>
<td>Mazzucco L et al.</td>
<td>Shorter hospital stay</td>
<td>15</td>
<td>35.5</td>
<td>&lt; .0001</td>
<td>71.43</td>
</tr>
<tr>
<td>Mazzucco L et al.</td>
<td>Hospital stay dehiscent sternal wounds (days)</td>
<td>31.5</td>
<td>52.5</td>
<td>&lt; .0001</td>
<td>40</td>
</tr>
</tbody>
</table>

Highly Significant P Values

*p value not available

PRP Application of TCC
Case 2

Ulcers for 17 years
Scleroderma PAD, DM
Obesity & Depression
Infection

Surgical Debridement

- Debrided via curettage, scalpel and Versajet

Combined Therapy

- Ultra Sound + PDGF bb + NPWT + Skin Graft

Case 3

Not all Cases Require Products

Limb Salvage?

What is the next step?
### TCC-EZ® Reimbursement: Medicare 2015

Payment for the application of TCC-EZ® based on site of care:

<table>
<thead>
<tr>
<th>CPT® Procedure Code</th>
<th>Description</th>
<th>HOSPITAL OUTPATIENT FACILITY PAYMENT*</th>
<th>Physician Payment**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>APC</td>
<td>Hospital Office</td>
</tr>
<tr>
<td>29445</td>
<td>Application of rigid total contact cast</td>
<td>0058 Level II Casting</td>
<td>$223.20 $107.76 $138.81</td>
</tr>
</tbody>
</table>


**Physician CPT® rates reflect a conversion factor of $35.8013. Federal Register notice [CMS-1612-FC], November 13, 2014.

Supplies such as TCC-EZ® are included in the APC payment and may be billed separately in the office setting based on payer contract.

Disclaimer: This has been intended for informational purposes only. It does not represent a guarantee, promise or statement by Derma Sciences Inc. concerning availability of reimbursement, levels of reimbursement, payment or charges. It is not intended to increase or maximize reimbursement. The decisions as to procedure code selection, completion of a claim form, and the amount to bill, are exclusively the responsibility of the provider.

### Summary:

- Advanced tenancy for DFU's, debridement, off loading and advanced therapies have their place.
- A comprehensive interdisciplinary approach is needed to manage complex patients with DFU's and non-healing ulcers.

Thank You