The Great Debate: Offloading Diabetic Foot Ulcers: TCC vs. CAM Walkers

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Activities:
- President American Board of Wound Healing
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Disclosures

Medical/Scientific Boards:
- Medline
- Convatec
- Acelity
- ULURU

Consultant:
- ULURU
Diabetes

• 135 million Diabetics worldwide
• United States 20.8 million Diabetics (7% of population)
• 1.5 million new cases yearly
• 25% diabetics develop foot ulcer during their lifetime
• 50% or more of amputations occur in diabetics
Diabetes Fact:

85% of all diabetes-related lower extremity amputations are preceded by a diabetic foot ulceration.
5 year Mortality Rate in Diabetics after amputation:

- 5 year Mortality Rate after amputation:
- Neuropathic: 45%
- Ischemic: 55%

Data Thru 11/15/07
26 Healed Patients
Avg Weight = 196#
  • High = 285#
  • Low = 88#
Avg Healing Time = 41 Days
  • High = 118 days
  • Low = 6 days
Avg # Casts = 7.2
Results of 9 TCC Studies

• 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
• Patient must be non-infected.
• Adequate blood supply to heal ABI ≥ 0.8
• Wagner classifications – Grade 1 and 2 go can go into TCC’s and be managed effectively on an out-patient basis.
  – Good complement to HBO
• Wounds that probe to tendon, capsule or bone, or with abscesses do not go into TCC’s!
TCC Patient Selection

Plantar Diabetic & Neuropathic Foot Ulcerations – Wagner Grade 1-2

– Diminishes the vertical & shearing forces of walking, allowing a plantar/lateral lesion to heal

Non-Infected with Reasonable Vascular Status

Charcot Neuroarthropathy Fractures

– Eliminates the stresses of weight bearing, allowing the condition to consolidate

Post-operative management

– To immobilize the surgical site to allow healing by minimizing the weight-bearing & shear forces
Total Contact Cast Contraindications

- Acute Infection
- Severe Ischemia
- Claustrophobia
- Wagner Grade 3,4
- Non-Compliance
- Allergy to casting material
- Excessive or fluctuating edema
- Excessive drainage
TCC Functional Attributes

• Allows for healing while ambulating
• Forced Compliance
• Immobilization, “total contact” with forefoot, arch, heel, Achilles tendon, and cone of lower leg. No “pistoning”
• Ankle locked at 90%.
  • Eliminates the propulsive phase of gait
  • Shortens stride length
• Minimizes vertical (Ground Reactive Pressures) and shear stresses
• Protects affected limb from trauma
“The device has been shown to decrease plantar pressures to nearly imperceptible levels of 0.34 n/cm². The near complete elimination of motion in the TCC also substantially curtails shearing forces.”

- Todd, WF; Ostomy & Wound Management, August, 1995
How does the cast offload?

- Cast offloads by transferring weight bearing to the leg itself (Load Sharing)
- Total contact weight bearing on plantar surface (Load Redistribution)

F-Scan Pressure Measurement
Tekscan Measurement System
<table>
<thead>
<tr>
<th>Location/Cast Type</th>
<th>Traditional TCC</th>
<th>Hybrid Cast System</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Avg 8.4 psi</td>
<td>Avg 7.2 psi</td>
</tr>
<tr>
<td>Full Plantar Surface</td>
<td>Max 50.3 psi</td>
<td>Max 49.9 psi</td>
</tr>
<tr>
<td>Pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forefoot Pressure</td>
<td>Avg 8.5 psi</td>
<td>Avg 7.1 psi</td>
</tr>
<tr>
<td></td>
<td>Max 48.3 psi</td>
<td>Max 47.2 psi</td>
</tr>
<tr>
<td>Mid-foot Pressure</td>
<td>Avg 6.2 psi</td>
<td>Avg 5.6 psi</td>
</tr>
<tr>
<td></td>
<td>Max 23.9 psi</td>
<td>Max 12.6 psi</td>
</tr>
<tr>
<td>Rear-foot Pressure</td>
<td>Avg 10.8 psi</td>
<td>Avg 9.3 psi</td>
</tr>
<tr>
<td></td>
<td>Max 40.5 psi</td>
<td>Max 48.8 psi</td>
</tr>
</tbody>
</table>
Advanced Therapies

Comparison of Diabetic Wound Treatments

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Days to Healing</th>
<th>Avg Days to Heal</th>
<th>Percent Healed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Contact Cast</td>
<td>84</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Apligraf</td>
<td>84</td>
<td>56.0%</td>
<td>0%</td>
</tr>
<tr>
<td>Dermagraft</td>
<td>84</td>
<td>30.0%</td>
<td>0%</td>
</tr>
<tr>
<td>Regranex</td>
<td>140</td>
<td>50.0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

TCC - 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
Off-Loading the Diabetic Foot Wound
Armstrong, et al   Diabetes Care, June 2001

<table>
<thead>
<tr>
<th>Method</th>
<th>Percent Healed</th>
<th>Mean Days to Healing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Contact Cast</td>
<td>89.5%</td>
<td></td>
</tr>
<tr>
<td>Removable Cast</td>
<td>65.0%</td>
<td></td>
</tr>
<tr>
<td>Walker</td>
<td>58.3%</td>
<td></td>
</tr>
</tbody>
</table>

The graph illustrates the percentage of wounds healed and the mean days to healing for different off-loading methods: Total Contact Cast, Removable Cast, and Walker.
Healing/Days to Heal
TCC vs iTCC vs RCW

Implementation Of Contact Cast in a Multi Physician Clinic

• Contact Cast is Gold Standard for Offloading

• Physician Barriers
  • Too time consuming 20 mins
  • Not in my training
  • Not worth the time

• Clinic Barriers
  • Complex application
  • Nursing not familiar with casting
Implementation Strategy

- Physician Education via Webinar Conference Call
- Nursing in serviced to apply dressing, stockinet, felt padding, protective sleeve
- Physicians applied the fiberglass cast sleeve
TCC Impact on Healing

Case 1 Clinical Course

Wound Volume vs Weeks in Care

- Cast/Powder
- Healed

Graph showing the impact of TCC on healing with a decrease in wound volume over weeks.
TCC Impact on Healing

Case 2 Clinical Course

Wound Volume vs. Weeks in Care

- Cast/Powder
- Healed
TCC Impact on Healing

Weeks to Heal

Volume Reduction

- Series1
- Series2
- Series3
- Series4
- Series5
- Series6

Weeks to Heal
Compliance with Therapy

Case 3 Clinical Course

Weeks in Care

Wound Volume

Cast/Powder

Healed
Contact Casting and Days to Heal

• Days to heal dropped from 41 days to 15.2 days
• Physicians accept contact casting as best offloading for Diabetic Foot Wounds
Learning Curve

Time per Application

Minutes

Cast Application
## Product Trial

<table>
<thead>
<tr>
<th></th>
<th>Cast application</th>
<th>Felt and Foam</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nursing Time</strong></td>
<td>5.5</td>
<td>26.25</td>
</tr>
<tr>
<td><strong>Nursing Cost</strong></td>
<td>$1.86</td>
<td>$22.00</td>
</tr>
<tr>
<td><strong>Material cost</strong></td>
<td>$96.60</td>
<td>$6.58</td>
</tr>
<tr>
<td><strong>Total Cost</strong></td>
<td>$98.46</td>
<td>$28.58</td>
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<tr>
<td><strong>Reimbursement</strong></td>
<td>$146.00</td>
<td>$0.00</td>
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<tr>
<td><strong>Net Difference</strong></td>
<td>$47.54</td>
<td>-$28.58</td>
</tr>
<tr>
<td><strong>Total impact</strong></td>
<td></td>
<td>$76.12</td>
</tr>
</tbody>
</table>
Cost Impact on Clinic

Cost Impact

<table>
<thead>
<tr>
<th>Material cost</th>
<th>Total Cost</th>
<th>Reimbursement</th>
<th>Net Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Cast</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Felt and Foam</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Cost Impact for Physicians and Clinics

• CPT 29445: Application of rigid total contact leg cast
• Reimbursement National Ave $110.00
• CPT 29445 Clinic Code links to APC 0426
• National Ave Reimbursement $148.00
Hybrid Casting Systems addresses barriers to utilizing the TCC as a “Gold Standard”

- Easy to use – Little or no learning curve
- Shortened application time
- Not messy
- Lighter
- Cooler
- Increased patient acceptance
- Functionality of traditional TCC
• Patients treated with a removable device wore the device for a total of 28% of their daily activity²
• Most compliant population not exceeding 60%²
• TCC significantly decreases the amount of ambulation and activity of the patient. This reduces the number of cycles of repetitive stress on the open ulceration.¹

Benefits Of TCC vs RCW

• Reduces and treats edema\(^1\)
• Reduces risk of infection\(^1\)
• Forced Compliance\(^2\)
• TCC heals higher percentage of wounds in shorter time\(^6\)

Compression safe to use

- Compression safe in treating Diabetics with Ulcers
- Compression 18-25 mmHg controlled edema
- No reduction in ABI, TBI or SPP
- Mild compression can safely and effectively be used in Patients with Diabetes and edema.


Contact Casting Complications

- TCC iatrogenic complications
  Complication rates have ranged from 11% to 30% of high risk patients, though the vast majority of these complications are minor.
- Most of the reported major complications are due to previously undiagnosed osteomyelitis and patient noncompliance.
- Most common are minor complications are dermal abrasions.
- Wukich and Motko found that 93% (13/14) of their complications were minor pressure ulcers and did not require a change in the treatment protocol.

Other complications include:

- Maceration
- Fungal infection
- Claustrophobic-like response to the cast
- Cast being too tight
- Difficulty ambulating
- The most important factor for decreasing the risk of iatrogenic complications is frequent cast changing.

Available Hybrid Contact Cast Systems
Thanks for your attention
Complications of Casting

• Major complications:

• Dermal abrasions Stage 1
  • Did not require change in treatment