Evidence-based richtlijn in het gebruik van schoeisel en drukontlasting in de behandeling van de diabetische voet

Dr. Sicco Bus
Senioronderzoeker en Hoofd Bewegingslaboratorium
Afdeling Revalidatie, AMC, Amsterdam
Clinical importance

Univariate models: OR 3.2-3.9
Multivariate models: OR 2.0-2.1

Frykberg et al., 1998; *Diab Care* 21(10):1714-9
Pham et al., 2000. *Diab Care* 23(5):606-11
Footwear and Offloading
Healing percentage of diabetic foot ulcers

- Extra-depth shoes
- Athletic footwear
- Custom molded insert + arch support + pad
- Post-operative shoes
- Rocker shoes
- Custom molded inserts
- Cast shoe (Mabal)
- Felted foam dressing in post-op shoe
- Removable walker (Vacodiaped, low-cut)
- Removable walker (CAM Walker)
- Removable walker (Vacodiaped, high-cut)
- Forefoot off-loading shoes
- Removable walker (Aircast)
- TCC bivalved
- TCC with walking sole
- Non-Removable walker (DH Pressure Relief)
- TCC with walking heel

% Peak pressure reduction at MTH1 compared to control

Time to healing (days)

Peak plantar pressures

Therapeutic footwear

Total Contact Cast
TCC and wound isolation

Barefoot

Region of Interest (ROI)

Pliance Sensor Array

Pliance Cable

Conventional TCC

Fiberglass

Compliant Foam Padding

Stockinette

Wound-Isolation TCC

Padding Under the ROI

Peak Pressure (kPa)

≥300

≥220

≥150

≥100

≥60

≥40

≥20

Petre M et al. Diab Care 2005;28:929-930
Evidence-based guidelines

1998: consensus
1999: consensus
2003: consensus update
2006: evidence-based
2014: update
2007: evidence-based and specific
2015: update
Reviews and specific guidelines

- **Footwear and Offloading**
  - The effectiveness of footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in diabetes: a systematic review
  - Review Article
  - S. A. Bus1, G. D. Valk2

- **Wound management**
  - A systematic review of the effectiveness of interventions to enhance the healing of chronic ulcers of the foot in diabetes
  - Review Article
  - R. J. Hinchcliffe1, G. D. Valk1, A. Apelqvist2, H. G. Armstrong1, R. Bakker2, F. L. Geuze1, A. Harrenfelt3

- **Osteomyelitis**
  - Diabetic foot osteomyelitis: a progress report on diagnosis and a systematic review of treatment
  - Review Article
  - A. R. Berends1, R. E. J. G. Peters1, R. Bakker2, J. M. van der Ende1, R. J. Hinchcliffe1, W. J. Jellicoe3, B. A. Lipsky1, E. Senneville4, J. Tah1, G. D. Valk1

Specific guidelines on footwear and offloading

- Keywords: footwear; diabetic; offloading; guidelines
- This article is a specific guideline on footwear and offloading for the diabetic foot which is based on conclusions from the systematic review on available evidence and consensus agreement within the International Working Group on Foot Ulcers and Diabetes
- S. A. Bus1, G. D. Valk2, B. W. van de Weerd3, D. G. Armstrong1, C. Carney2, R. Hlavicka2

Specific guidelines on wound and wound-bed management

- Keywords: wound; diabetic; foot; wound-bed management; guidelines
- This article is an evidence-based guideline based on the consensus report on the effectiveness of interventions to enhance the healing of chronic ulcers of the foot
- R. J. Hinchcliffe1, G. D. Valk3, J. Apelqvist1

Specific guidelines for treatment of diabetic foot osteomyelitis

- Keywords: diabetic foot; osteomyelitis; treatment; guidelines
- This article is based upon “The management of diabetic foot osteomyelitis – a

Diabetes Metab Res Rev 2008; 24(Suppl 1)
Pressure-relieving interventions for treating diabetic foot ulcers (Review)

Lewis J, Lipp A

Comparison of the clinical effectiveness of different off-loading devices for the treatment of neuropathic foot ulcers in patients with diabetes: a systematic review and meta-analysis

Judy K. Morona¹*
Elizabeth S. Buckley¹
Sara Jones²
Edith A. Reddin¹
Tracy L. Merlin¹

Summary
Effective off-loading is considered to be an important part of the successful clinical management of diabetic foot ulcers. The aim of this systematic review is to investigate the safety and effectiveness of different off-loading devices for the treatment of diabetic foot ulcers. The medical literature was extensively...
Evidence on offloading

- The total contact cast (TCC) is the preferred treatment for non-infected, neuropathic diabetic plantar forefoot ulcers in patients with no signs of critical limb ischemia.

- Adverse effects of TCC include: immobilization of the ankle, reduced activity level, difficulty with sleeping or driving a car, and pressure ulcers due to poor casting technique.

- If TCC not available, then removable walkers with an appropriate interface should be considered. Preferably, these walkers should be made irremovable as this “forced adherence” increases healing rates.

Diabetes Metab Res Rev 2008; 24(Suppl 1)
Evidence on offloading

- The use of half-shoes or cast shoes for neuropathic plantar ulcer treatment is recommended if TCC or below knee removable walkers are contra-indicated or cannot be tolerated by the patient.

- Conventional or standard therapeutic shoes should not be chosen for treatment of plantar foot ulcers as, usually, many devices that are more effective are available.

- If other forms of biomechanical relief are not available, felted foam in combination with appropriate footwear can be used to provide accommodative offloading at an ulcer site. It should not be used as a single treatment method.
Non-removable versus removable

- Meta-analysis on ulcer healing. Non-removable devices are:
  - More effective than removable devices (RR 1.17, 95%CI 1.01-1.36, p=0.04, k=5, n=230).
  - Healing time 4-8 weeks in non-removable devices, 5-10 weeks in removable devices

- Meta-analysis on ulcer healing. Non-removable devices are:
  - More effective than removable devices (all devices together) (RR 1.43, 95%CI 1.11-1.84, p=0.001, k=10, n=524)
  - Equally effective to RCWs (RR 1.23, 95%CI 0.96-1.58, p=0.09, k=5, n=220)
  - More effective than therapeutic footwear (RR 1.68, 95%CI 1.09-2.58, p=0.004, k=6, n=318)
  - Equally effective as TCCs (RR 1.06, 95%CI 0.88-1.27, p=0.31, k=2, n=81).

Cochrane Systematic Review, 2013

Morona et al., DMRR, 2013
Clinical practice

US nationwide survey in 901 centers on use of methods for plantar offloading of diabetic foot ulcers:

- 2% uses the TCC as primary method
- 46% do not use TCC as method
- 58% do not consider the TCC the “gold standard” treatment
- 17% use removable walkers
- 14% employed complete offloading
- 47% modify the shoe

Wu et al., 2008; Diab Care 31(11):2118-9
Clinical practice

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

Caroline E. Fife, MD¹; Marissa J. Carter, PhD, MA²; David Walker, CHT³

1. Department of Medicine, Division of Cardiology, The University of Texas Health Science Center, Houston, Texas,
2. Strategic Solutions Inc., Cody, Wyoming, and
3. Intellicure Inc., The Woodlands, Texas

Retrospective US study in 18 outpatient wound centers in 16 US states:

- 264 patients with a foot ulcer
- 6% of patients received a TCC
- Average cost of treatment with TCC was $11,946 versus $22,494 in treatment where TCC was not used.

Fife et al., 2010; Wound Rep Reg 18 154–158
Clinical practice

European prospective study in 14 specialized diabetic foot centers (Eurodialae):

- 1232 patients with a foot ulcer
- 41% already treated with offloading at study entry (50% adequate)
- 50% of ulcers on plantar foot surface
- Use of TCC in 18% of cases, other casting techniques in 17% of cases
- Most ulcers treated with temporary footwear
Factors affecting TCC use

- Patient tolerance (55.3%)
- The time needed to apply the cast (54.3%)
- Cost of materials (31.6%)
- Reimbursement issues (27.5%)
- Familiarity with method of application (25%)

Wu et al., 2008; Diab Care 31(11):2118-9
<table>
<thead>
<tr>
<th>Category</th>
<th>Median (range)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of awareness</td>
<td>54.5% (1%-84%)</td>
</tr>
<tr>
<td>Lack of familiarity</td>
<td>56.5% (0%-89%)</td>
</tr>
<tr>
<td>Lack of agreement</td>
<td>(1%-91%)</td>
</tr>
<tr>
<td>Lack of self-efficacy</td>
<td>13% (1%-65%)</td>
</tr>
<tr>
<td>Lack of outcome expectancy</td>
<td>26% (8%-90%)</td>
</tr>
<tr>
<td>Inertia of previous practice</td>
<td>42% (23%-66%)</td>
</tr>
<tr>
<td>External barriers</td>
<td>&gt; 10%</td>
</tr>
</tbody>
</table>

* Percentage of respondents identifying category as a barrier

Cabana et al., 1999; JAMA 282 (15): 1458-1465
How to bridge the gap?

- Professional societies should adopt and implement guidelines
- Expectations on time to healing should be changed
- Barriers should be removed
- Improve health care organization (e.g. reimbursement, training of staff)
- Change in the burden of financial responsibility
- Requirement of measurable and effective offloading
- Establish specialized referral centers
- Prove the effectiveness of current practice

Cavanagh and Bus, 2010. *J Vasc Surg; JAPMA; 2011 PRS*
The complicated foot ulcer

- Neuro-ischemic (49%) and infected (58%) ulcers are more prevalent than purely neuropathic ulcers (24%)
- The evidence base is related entirely to the treatment of neuropathic foot ulcers
- Offloading is as important in complicated wounds because of biomechanical stress and enhanced risk of limb loss

Prompers et al., 2007, Diabetologia
Offloading the complicated ulcer

- 98 patients (all neuropathy, 44% PAD, 29% infection)
  - No PAD, no infection: 90% healing
  - No PAD, infection: 87% healing
  - PAD, no infection: 69% healing
  - PAD, infection: 36% healing

Nabuurs-Franssen et al., 2005. Diabetes Care
Conclusions

- Offloading is an important aspect of treatment of plantar neuropathic foot ulcers in diabetes
- Inadequate offloading is poor treatment
- Non-removable devices are significantly more effective than removable devices in promoting ulcer healing
- The gap between evidence and practice needs to be bridged
- More data needed on the role of offloading in healing complicated foot ulcers
“Voetenplein” (Foot Square), AMC

s.a.bus@amc.uva.nl