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



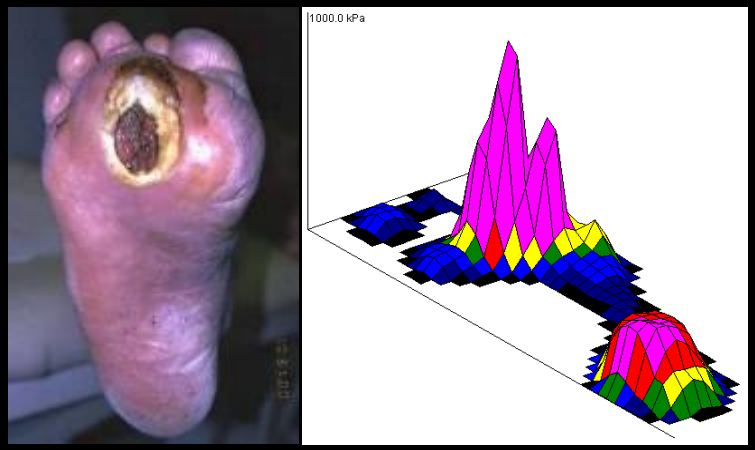
Dr. Sicco Bus

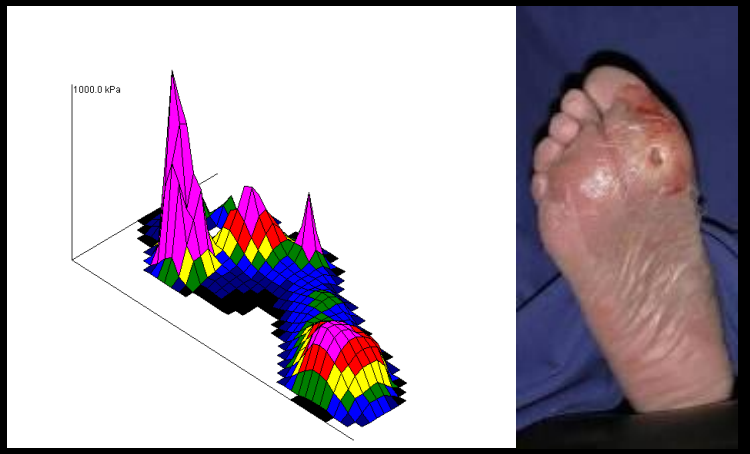
Senioronderzoeker en Hoofd Bewegingslaboratorium

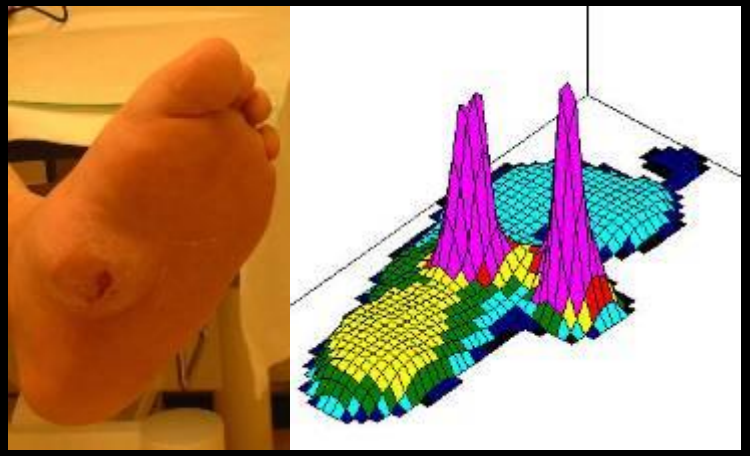
Afdeling Revalidatie, AMC, Amsterdam

Academic Medical Center
University of Amsterdam

Clinical importance







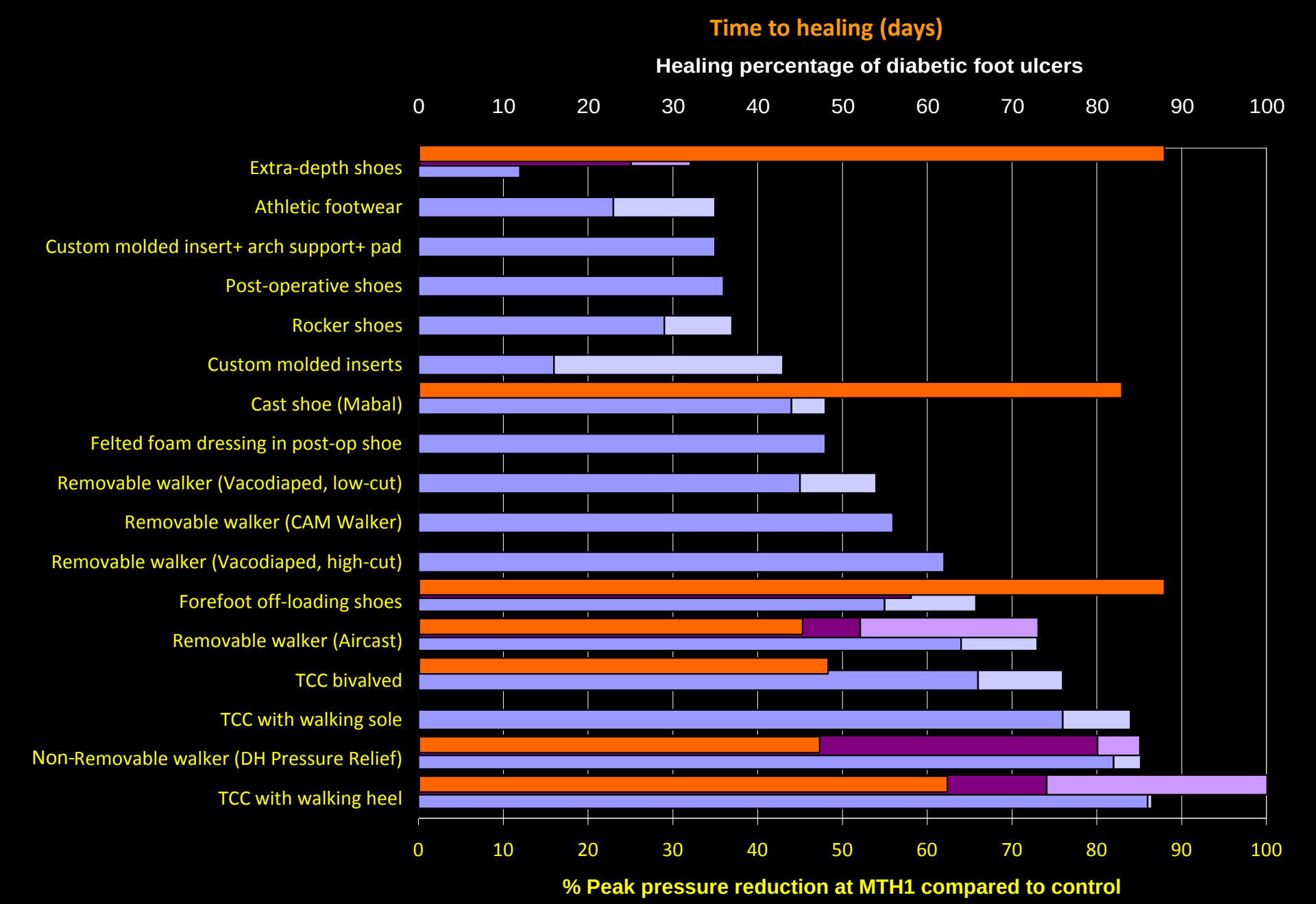
Univariate models: OR 3.2-3.9

Multivariate models: OR 2.0-2.1

Frykberg et al., 1998; *Diab Care 21(10):1714-9*

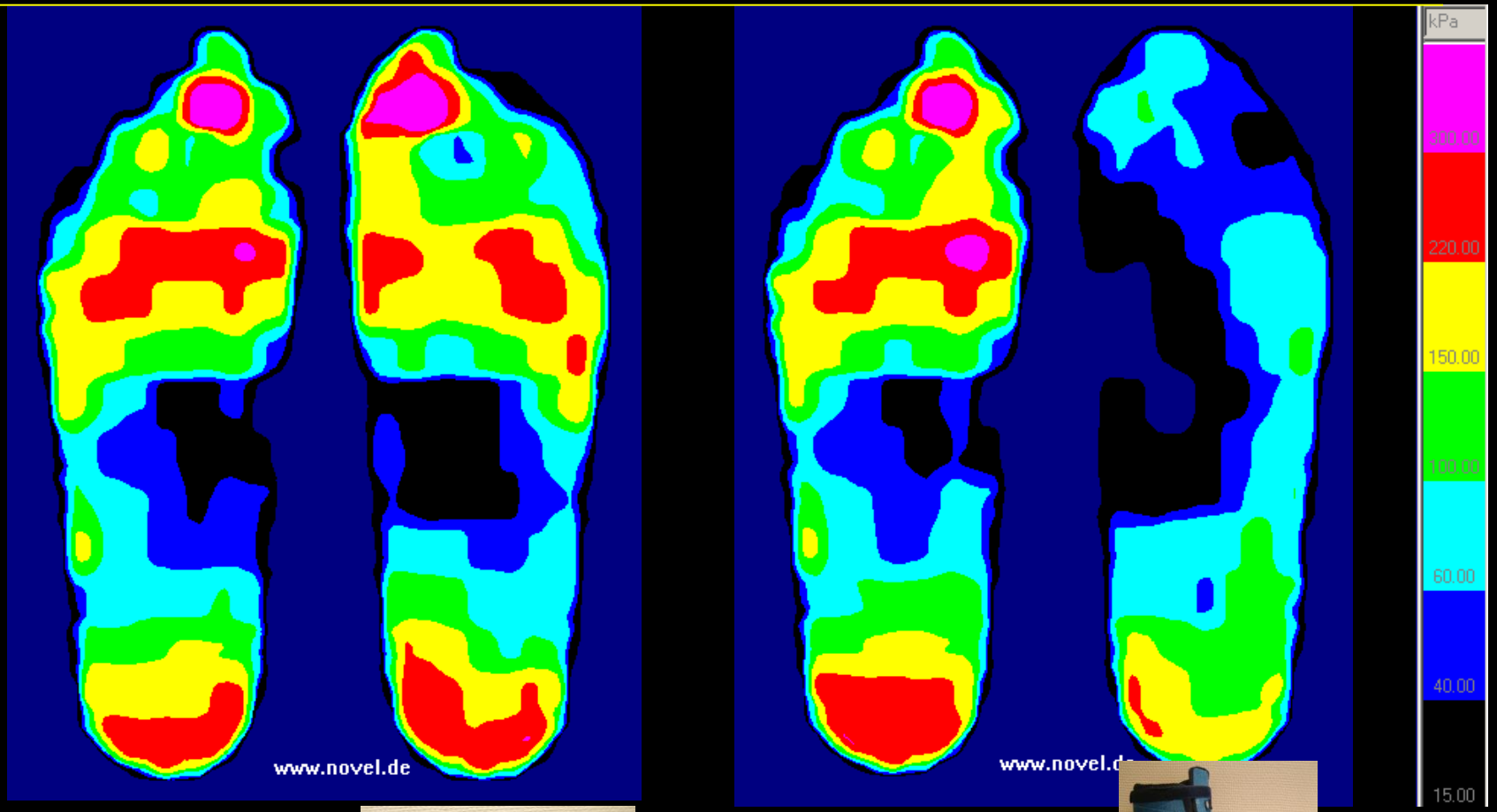
Pham et al., 2000. *Diab Care 23(5):606-11*

Footwear and Offloading



Cavanagh and Bus, 2010. *J Vasc Surg* 52(3 Suppl):37S-43S

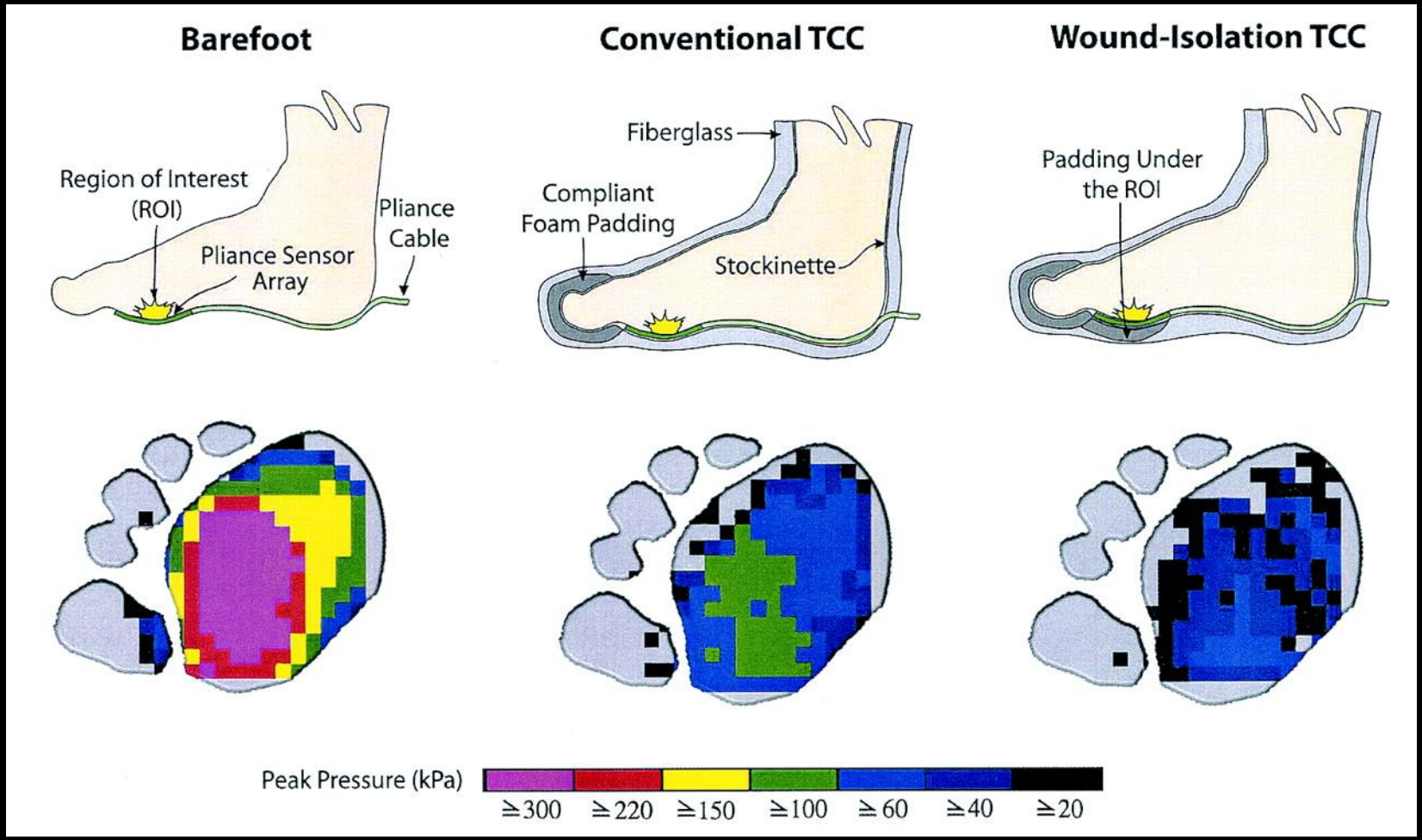
Peak plantar pressures



Therapeutic footwear

Total Contact Cast

TCC and would isolation



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

Evidence-based guidelines

HOOFDSTUK 8

2.2 'Total contact cast' (TCC)

Uitgangsvragen:

2.2A *Leidt de behandeling van een voetulcus bij patiënten met diabetes mellitus met een 'total contact cast' vaker en sneller tot wondgenezing in vergelijking met een 'cast walker' of therapeutisch schoeisel?*

2.2B *Treden er bij de behandeling van een voetulcus bij patiënten met diabetes mellitus met een 'total contact cast' vaker specifieke nadelige bijwerkingen op in vergelijking met een 'cast walker' of therapeutisch schoeisel?*

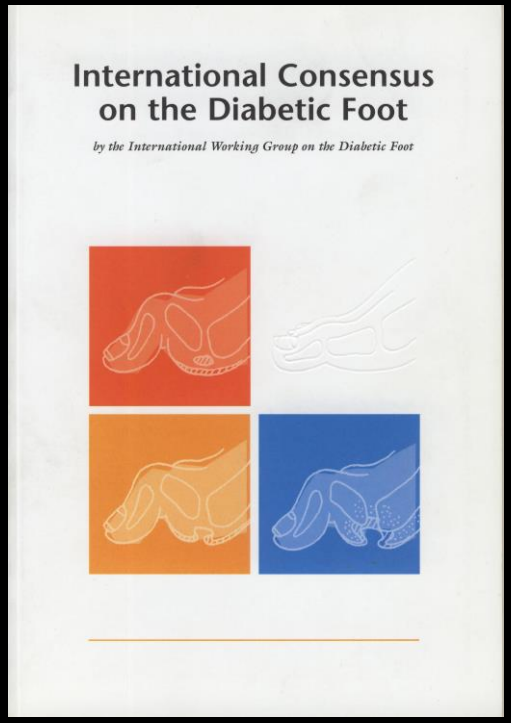
Wetenschappelijke onderbouwing

Drie RCT's bestudeerden het therapeutisch effect van een niet-afneembare TCC bij patiënten met diabetes mellitus en een neuropathisch plantair ulcus, zonder tekenen van ischemie of infectie. Er werd vergeleken met adequaat of aangepast schoeisel (zoals 'healing sandal' of semi-orthopedisch schoeisel),[14] een afneembare 'cast walker',[15] een 'half-shoe',[15] of verbandschoeisel.[16] De TCC en de 'cast walker' bleken het meest effectief te zijn. Na 12 weken follow-up was er bij de TCC volledige wondgenezing bij 90% van de patiënten, bij de 'walker' 65% en de 'half-shoe' 58%. De gemiddelde tijd tot aan genezing was significant korter bij de TCC (34 dagen) in vergelijking met de 'half-shoe' (61 dagen), maar niet in vergelijking met de 'walker' (50 dagen).[15] Ook de mix van 'healing sandals' en semi-orthopedisch schoeisel[14] of het verbandschoeisel[16] bleek minder effectief dan de behandeling met een TCC.

Deze drie RCT's waren minder systematisch opgezet ten aanzien van optredende nadelige bijwerkingen. Nadelige bijwerkingen die vaker bij behandelingen met een TCC optreden in vergelijking met de mix van 'healing sandal' of semi-orthopedisch schoeisel, zijn: verstoring van dagelijkse activiteiten, klachten over moeite bij het lopen en tijdens slapen, en schimmelinfectie.[14] Het vroegtijdig staken van een behandeling omdat deze als te hinderlijk wordt ervaren, trad in het onderzoek van Armstrong et al. bij een TCC bij 21% van de patiënten op. Dat was significant vaker dan bij een 'half-shoe' (0%; p = 0,03) en niet-significant verschillend met een 'cast walker' (15%). Patiënten met een TCC waren significant minder actief dan patiënten met een 'half-shoe'. Het verschil tussen de TCC en de 'cast walker' was niet significant.[15]

Conclusies

Niveau 3	Er zijn aanwijzingen dat de behandeling van een diabetisch neuropathisch plantair ulcus met een TCC significant effectiever is dan verbandschoeisel met kunstmatige afwikkeling aan de buitenzool en een 8 mm dikke Plastazote-inlegzool met een uitsparing ter hoogte van het plantair ulcus. *A2: Caravaggi*[16]



1998: consensus
2006: evidence-based
2014: update

1999: consensus
2003: consensus update

2007: evidence-based and specific
2015: update

Reviews and specific guidelines

DIABETES/METABOLISM RESEARCH AND REVIEWS
Diabetes Metab Res Rev 2008; **24**(Suppl 1): S162–S180.
Published online in Wiley InterScience (www.interscience.wiley.com) **DOI:** 10.1002/dmrr.850

REVIEW ARTICLE

The effectiveness of footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in diabetes: a systematic review

S. A. Bus[1]*, G. D. Valk[2],

Summary

DIABETES/METABOLISM RESEARCH AND REVIEWS
Diabetes Metab Res Rev 2008; **24**(Suppl 1): S119–S144.
Published online in Wiley InterScience (www.interscience.wiley.com) **DOI:** 10.1002/dmrr.825

REVIEW ARTICLE

A systematic review of the effectiveness of interventions to enhance the healing of chronic ulcers of the foot in diabetes

R. J. Hinchliffe[1,2], G. D. Valk[3], J. Apelqvist[4], D. G. Armstrong[5], K. Bakker[6], F. L. Game[2], A. Hartemann-

Summary

The outcome of management of diabetic foot ulcers is poor and there is uncertainty concerning optimal approaches to management. We have

DIABETES/METABOLISM RESEARCH AND REVIEWS
Diabetes Metab Res Rev 2008; **24**(Suppl 1): S145–S161.
Published online in Wiley InterScience (www.interscience.wiley.com) **DOI:** 10.1002/dmrr.836

REVIEW ARTICLE

Diabetic foot osteomyelitis: a progress report on diagnosis and a systematic review of treatment†

A. R. Berendt[1]*, E. J. G. Peters[2], K. Bakker[3], J. M. Embil[4], M. Eneroth[5], R. J. Hinchliffe[6], W. J. Jeffcoate[7], B. A. Lipsky[8], E. Senneville[9], J. Teh[10], G. D. Valk[11]

Summary

The International Working Group on the Diabetic Foot appointed an expert panel to provide evidence-based guidance on the management of osteomyelitis in the diabetic foot. Initially, the panel formulated a consensus scheme for the diagnosis of diabetic foot osteomyelitis (DFO) for research purposes, and undertook a systematic review of the evidence relating to treatment. The consensus diagnostic scheme was based on expert opinion;

DIABETES/METABOLISM RESEARCH AND REVIEWS
Diabetes Metab Res Rev 2008; **24**(Suppl 1): S192–S193.
Published online in Wiley InterScience (www.interscience.wiley.com) **DOI:** 10.1002/dmrr.855

GUIDELINES

Specific guidelines on footwear and offloading

S. A. Bus[1]*, G. D. Valk[2], R. W. van Deursen[3], D. G. Armstrong[4], C. Caravaggi[5], P. Hlaváček[6],

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 on consensus agreement within the International Working

DIABETES/METABOLISM RESEARCH AND REVIEWS
Diabetes Metab Res Rev 2008; **24**(Suppl 1): S188–S189.
Published online in Wiley InterScience (www.interscience.wiley.com) **DOI:** 10.1002/dmrr.854

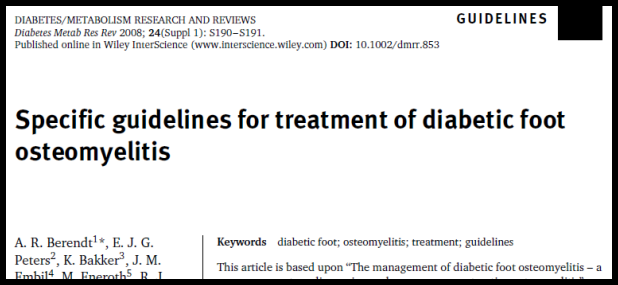
GUIDELINES

Specific guidelines on wound and wound-bed management

R. J. Hinchliffe[1,2]
G. D. Valk[3]
J. Apelqvist[4]

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



DIABETES/METABOLISM RESEARCH AND REVIEWS
Diabetes Metab Res Rev 2008; **24**(Suppl 1): S190–S191.
Published online in Wiley InterScience (www.interscience.wiley.com) **DOI:** 10.1002/dmrr.853

GUIDELINES

Specific guidelines for treatment of diabetic foot osteomyelitis

A. R. Berendt[1]*, E. J. G. Peters[2], K. Bakker[3], J. M. Embil[4], M. Eneroth[5], R. J.

Keywords diabetic foot; osteomyelitis; treatment; guidelines

This article is based upon "The management of diabetic foot osteomyelitis – a

Footwear and Offloading

Wound management

Osteomyelitis

Diabetes Metab Res Rev 2008; 24(Suppl 1)

Recent systematic reviews

Pressure-relieving interventions for treating diabetic foot ulcers (Review)

Lewis J, Lipp A

DIABETES/METABOLISM RESEARCH AND REVIEWS
Diabetes Metab Res Rev 2013; **29**: 183–193.
Published online in Wiley Online Library (wileyonlinelibrary.com) **DOI:** 10.1002/dmrr.2386

REVIEW ARTICLE

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. Morona[1]*
Elizabeth S. Buckley[1]
Sara Jones[2]
Edith A. Reddin[1]
Tracy L. Merlin[1]

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.

Diabetes Metab Res Rev 2008; 24(Suppl 1)

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

Cochrane Systematic Review, 2013

- 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).

Morona et al., DMRR, 2013

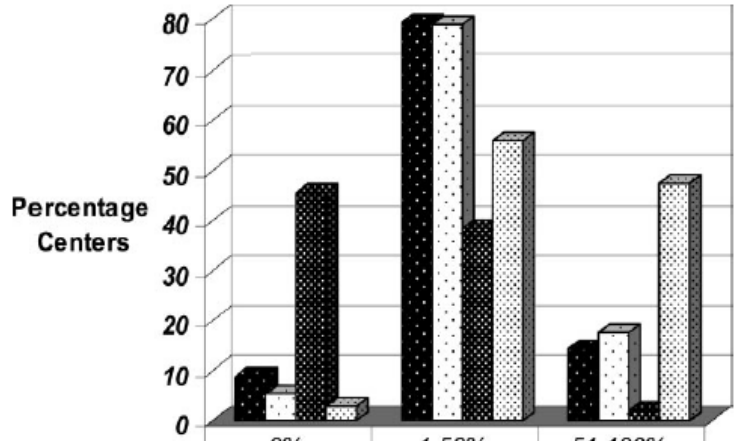
Clinical practice

Use of Pressure Offloading Devices in Diabetic Foot Ulcers

Do we practice what we preach?

Stephanie C. Wu, dpm, msc[1]
Jeffrey L. Jensen, dpm[2,3]
Anna K. Weber, dpm[3,4]
Daniel E. Robinson, dpm[3]
David G. Armstrong, dpm, phd[1,5]

survey recorded informati
usage frequency and charac
sessment and treatment of



	0%	1-50%	51-100%
NWB	8.7	79.4	14.1
RCW	5.4	79	17.4
TCC	45.5	38.3	1.92
shoe mod.	2.68	55.8	47.3

Figure 1—*Type and frequency of plantar offloading used across 895 clinics.*

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, MD[1]; Marissa J. Carter, PhD, MA[2]; David Walker, CHT[3]

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 would centers in 16 US states:

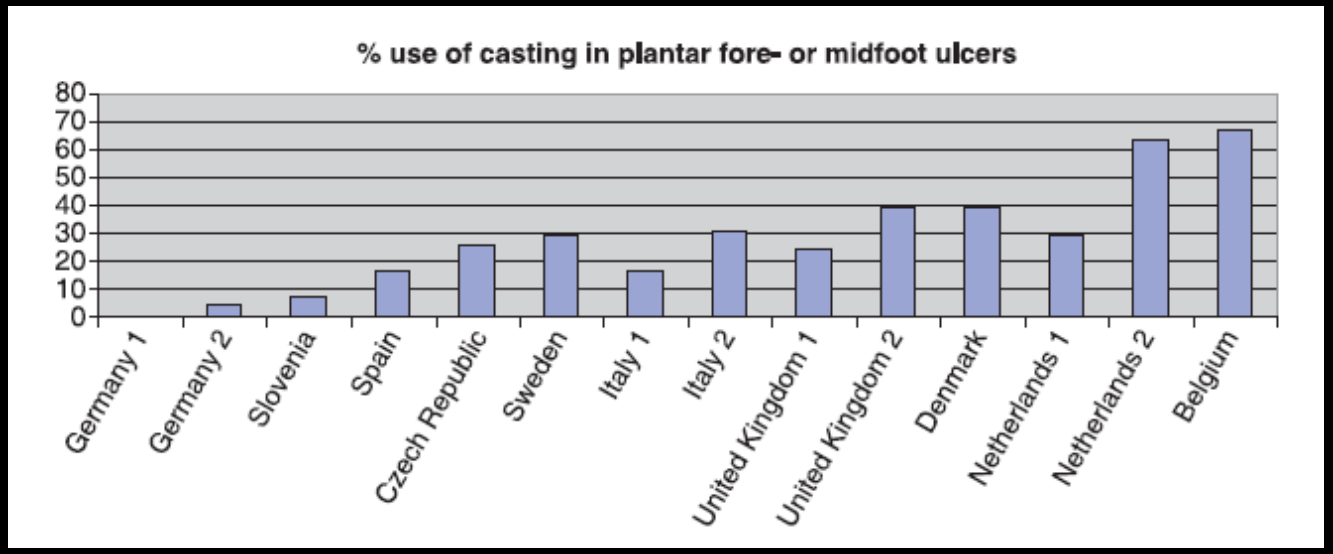
- 264 patients with a foot ulcer
- 6% of patients received a TCC
- Average cost of treatment with TCC was $11,946 versus $22,494 in treatment where TCC was not used.

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

Clinical practice

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

- 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



Prompers et al., 2008; *Diabet Med 25(6):700-707*

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

Barriers

Why Don't Physicians Follow Clinical Practice Guidelines?
A Framework for Improvement

Category	Median (range)*
Lack of awareness	54.5% (1%-84%)
Lack of familiarity	56.5% (0%-89%)
Lack of agreement	(1%-91%)
Lack of self-efficacy	13% (1%-65%)
Lack of outcome expectancy	26% (8%-90%)
Inertia of previous practice	42% (23%-66%)
External barriers	> 10%

* 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

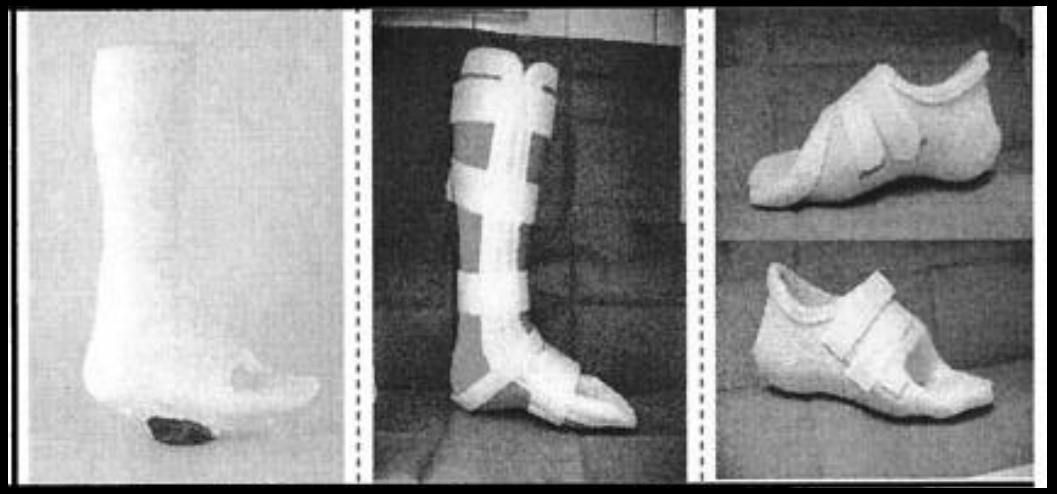
Cavanagh and Bus, 2010. *J Vasc Surg; JAPMA; 2011 PRS*

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

Academic Medical Center
University of Amsterdam

Human Performance Lab
movement analysis and rehabilitation
Academic Medical Center Amsterdam

s.a.bus@amc.uva.nl