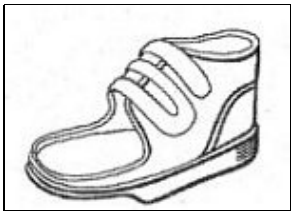

Footwear and off-loading for the diabetic foot -an evidence based guideline-

Prepared by the IWGDF working group on Footwear and off-loading

Content

Chapters:

Appendices:

Addendum

1. Introduction

There is a long clinical tradition in the use of footwear and off-loading techniques for the prevention and healing of plantar ulcers in the diabetic patient. However, the research literature in this area has lagged behind clinical practice, often leading the clinician to recommend interventions based on opinion and past experience rather than published evidence. The origins of scientific studies that have provided insight into the role of plantar off-loading for the diabetic patient can be traced to the landmark article by Bauman, Girling, and Brand published almost 45 years ago in the Journal of Bone and Joint Surgery[1]. Unfortunately, this early progress was not sustained and a recent article by Maciejewski et al.[2] pointed out, for example, that evidence for the use of therapeutic footwear to prevent the recurrence of plantar ulcers was not yet strong.

There is, therefore, a strong need for a systematic review of the current literature to provide interpretation of the data that does exist and to give conclusions that can be used in clinical practice. The guidelines presented here are intended to facilitate such decision- making by the provision of a systematic review of the refereed literature in the areas of footwear and off-loading that was available in May 2006.

As a basis for its deliberations, the committee of clinicians and scientists that generated the present guidelines drew on the experience and expertise of previous consensus groups of the International Working Group on the Diabetic Foot. In addition (as is described below) a number of new approaches were incorporated such as the use of the Patient-Intervention- Comparison-Outcome (PICO) and the Scottish Intercollegiate Guidelines Network (SIGN) instrument for quality assessment. All of our work was linked to supporting evidence and individual papers were graded according to the strength of the evidence. Judgments were made about generalisability, applicability, and the clinical impact of evidence to create a linkage between the evidence and recommendations. While much insight has been gained from studies of normal subjects, only studies which drew from the target population of diabetic patients have been included. As might be expected, some published work of members of the committee was considered in the review and strict guidelines were implemented to guard against conflict of interest.

The interventions that are considered in this review cover the spectrum of techniques commonly used throughout the world in clinical practice. This includes the use of conventional and therapeutic footwear, custom insoles and modifications, various casting techniques, felted foam, socks, together with removable and non-removable walkers. Surgical approaches to off-loading are also reviewed along with traditional approaches such as bed rest, walking aids and wheelchairs.

The committee has been careful to make recommendations that can be implemented regardless of the available facilities and the geographical location where the patient is being treated. While advanced techniques are being developed to generate individualized interventions, these often depend on access to technology that is only available in more affluent settings.

It is our hope that these guidelines will prove to be immediately useful in the clinical management of patients with diabetic foot disease. It is also our intention that they will provide a foundation from which future recommendations can be made as the literature base expands.

---

2. Methodology

2.1. Introduction

This evidence-based guideline was developed by a multidisciplinary group of clinicians and scientists working in the field of footwear and off-loading for the diabetic foot. The by the IWGDF Editorial board invited, IWGDF working group on footwear and off-loading, had four weekend meetings between October 2005 and May 2007 to select the interventions of interest, discuss the methodology of literature search and grading, carry out the methodological assessment of the literature, agree on the results, and write the guideline, which was approved by the IWGDF Editorial board.

2.2. Key characteristics

The population of interest for this guideline was patients with diabetes mellitus. The clinical problem addressed was the plantar foot ulcer. The guideline was organized around the following main outcomes:

- Ulcer prevention
- Ulcer healing
- Reduction of plantar pressure

2.3. Interventions

The guideline focused on interventions within the context of the above-mentioned outcomes. Selected interventions were categorized into four sub-categories:

1. Casting techniques
    a. Total contact cast (TCC)
    b. Cast shoes
2. Footwear related techniques
    a. Shoes
    b. Insoles
    c. Orthoses (in-shoe)
    d. Socks / padding
3. Surgical techniques
    a. Achilles tendon lengthening (ATL)
    b. Silicone injections / tissue augmentation

c. Callus debridement
d. MTH resection
e. Osteotomy / Arthroplasty / Ostectomy / Exostectomy
f. External fixation

4. Other techniques
   a. Bed rest
   b. Crutches / Cain / Wheelchair
   c. Bracing (patella tendon bearing, ankle-foot orthosis)
   d. Walkers
   e. Off-loading dressings
   f. Felted foam / padding
   g. Plugs

For each outcome a PICO (Patient-Intervention-Comparison-Outcome) question was generated per intervention category which consisted of the following general format:

"Is there evidence for the effectiveness of [INTERVENTION CATEGORY] in [OUTCOME] in patients with diabetes mellitus?"

2.4. Systematic literature review

The evidence base for this guideline was compiled by carrying out a systematic review of the scientific literature using an explicit search strategy and assessment protocol devised by the working group. The general format for this procedure is described in the general methods section.

2.4.1. Search strategy

The search for suitable articles focused on diabetic patients only; studies on healthy subjects or patients with other diseases were not considered. The search covered references in all languages and was not limited by date. The search was performed on May 1st 2006. Only original research qualified for inclusion; reviews, conference proceedings, abstracts, and books were not considered in the search. Study designs that were included were: randomized controlled trials (RCT), case-control, cohort, and control before-and- after (CBA) studies, interrupted time series (ITS), prospective and retrospective uncontrolled studies, cross-sectional studies, case series, and case studies. Bibliographical tracking of included articles was not performed. Previously performed systematic reviews and Cochrane reviews on the topic of footwear and off-loading the diabetic foot were sought to determine the need for a separate extensive literature search. Only one Cochrane review[3] was located. Thus, we decided that a more extensive search of more recent studies was needed. The literature databases that were assessed were Medline, Embase, Cinahl, Cochrane database of systematic reviews, Cochrane central controlled trials register, DARE, NHS EED, and HTA Database. Search strings were synthesized for each database search. These consisted of four category levels: Patient, Study design, Outcome, and Intervention. Search strings for each intervention category can be found in Appendix A.

2.4.2. Literature assessment

The database search resulted in a total of 1639 unique references (i.e. after exclusion of duplicates between databases and between intervention sub-categories). The assessment of these 1639 references was performed in three stages.

Stage 1: One assigned reviewer for each of the 4 intervention sub-categories assessed references by title and abstract to determine possible eligibility on three of the four criteria mentioned above (patient, outcome, and intervention). This first round of assessments resulted in 212 possibly eligible articles.

Stage 2: Full-paper copies of all 212 possibly eligible articles were retrieved. Each article was assessed independently for definite eligibility by two reviewers on all four above criteria (including

study design) using a simple inclusion and exclusion form. Findings were discussed between co-reviewers and a final decision regarding inclusion and exclusion was made. This round of assessment resulted in 135 included articles.

Stage 3: The 21 articles with a RCT, CBA, Cohort, Case-control, or ITS study design were assessed for methodological quality (i.e. possibility of bias) by at least two independent reviewers using standard scoring lists which were based on the methodological scoring of the Dutch Cochrane Centre (www.cochrane.nl). Throughout the entire process reviewers were not allowed to assess, or to write about, their own articles to prevent any potential conflict of interest. Data on study characteristics, patient population, intervention, and outcomes were extracted using standard data extraction sheets. Findings were discussed between co-reviewers and a final decision was made on methodological quality. Quality items were rated as 'done', 'not done', or 'not reported'. Only the 'done' rating added to the total quality score. Extracted data was summarized in evidence tables (Appendix B). Conclusions were drawn and recommendations were made based on the strength of the available evidence in these tables. Evidence tables were thoroughly discussed in the working group.

Evidence grading of each article was based on study design and the total score for methodological quality using multiple items. The SIGN guidelines were used for this purpose. The possibility for bias was scored differently for each study design using the following system:

- RCT (9 items): score 1-4 (-), score 5-7 (+), score 8-9 (++)
- Cohort (8 items): score 1-3 (-), score 4-6 (+), score 7-8 (++)
- CBA and Case-control (7 items): score 1-3 (-), score 4-5 (+), score 6-7 (++)
- ITS (5 items): score 1-2 (-), score 3-4 (+), score 5 (++)

2.5. Guideline writing and peer review

After discussing the content of the guideline the same two individuals who co-reviewed the methodological quality of each intervention sub-category were assigned to write the corresponding section of the guideline, except, as noted above, when there was a conflict of interest.

A first draft of the guideline was reviewed within the working group. After internal approval by all members of the working group, subsequent draft versions were reviewed by the Editorial Board of the IWGDF and the 80 members of the IWGDF. The final draft of the guideline was presented by the working group to all IWGDF members in an international open meeting on the 8th of May 2007 in Noordwijkerhout, the Netherlands.

3. Ulcer prevention

3.1. Introduction

The PICO question for the selected outcome of ulcer preventions is:

"Is there evidence for the effectiveness of FOOTWEAR, SURGICAL OFF-LOADING, AND/OR OTHER OFF-LOADING INTERVENTIONS in preventing foot ulceration in patients with diabetes mellitus?"

We did not consider casting techniques in the context of ulcer prevention.

3.2. Footwear

The effect of footwear for prevention of ulceration is thought to rely on moulding of an insole placed within a shoe or sandal and on additional individualized interventions (such as metatarsal pads and bars). Such moulding and interventions may relieve pressure by accommodation or transfer of load to other areas of the foot. No studies in the literature were found related to the primary prevention of plantar ulceration. However, several level 1 and 2 studies have assessed the effects of footwear on ulcer recurrence (i.e. secondary prevention).

One large RCT by Reiber et al.[4] (quality 1-) found no significant difference in the number of ulcer occurrences or the proportion of people with ulcers over a 2 year period between therapeutic shoes and control shoes. In this study ulcer was badly defined, multiple ulcers could have occurred in one person, there were low re-ulceration rates in all study groups and many patients were not neuropathic. A much smaller RCT by Uccioli et al.[5] (quality 1-) found a significant difference in the proportion of people with ulcers over a 1 year period between therapeutic shoe and own shoe groups. In both the Reiber et al. and Uccioli et al. studies plantar pressure and shoe use (treatment adherence) were not measured. A large RCT by Litzelman et al.[6] (quality 1-) investigated footwear within the context of a multi-faceted educational intervention including recommendation for footwear where appropriate. The control intervention was not clearly defined but seems to been standard care. Because only one patient reported owning and wearing the recommended special footwear and no information on outcome in the control group was reported, no relevant conclusions can be drawn.

A medium-sized CBA study by Dargis et al.[7] (quality 2-) compared clinical treatment and education including therapeutic footwear with treatment at a different clinic which did not include therapeutic footwear. A significant difference in ulcer occurrence was found in 2 years although treatment adherence was not measured. A medium-sized cohort study by Viswanathan et al.[8] (quality 2-) found that therapeutic sandals resulted in a significantly lower ulcer occurrence at 9 months compared to a control group wearing sandals with a hard leather board insole. In this study, plantar pressure was measured although inconsistencies between the body of text and Figure 1 reporting the peak pressure cast doubt on the accuracy of these results. For instance the peak pressures appear to be an order of magnitude too low and a possible change in calibration of the equipment over a 9 month period is not addressed. Also, selection bias cannot be excluded since group assignment seems to have depended on whether subjects could afford custom-made footwear.

One prospective uncontrolled study (level 3) provides some support that footwear can be effective in ulcer prevention[9].

3.3. Surgical off-loading

There have been several level 1 or 2 studies detailing various surgical techniques aimed at the secondary prevention of plantar ulceration (recurrence).

A RCT from Mueller et al.[10] (quality 1+) compared ulcer recurrence rates after treatment with Achilles tendon lengthening (ATL) in addition to TCC (ATL group) with TCC alone (TCC group) in patients affected by forefoot neuropathic plantar ulceration. At a follow-up period of 7 months the percentage of plantar ulcer recurrence was significantly lower in the ATL group than in the TCC group: 4/27 (15%) versus 16/27 (59%) patients, P=0.001, RR=4.0, 95%CI=1.8-8.9. This difference remained after 2 years follow-up: 38% versus 81%, respectively, P=0.002, RR=2.1, 95%CI=1.7-9.6. Piaggesi et al.[11] (RCT, quality 1+) studied patients affected by plantar ulcers of the forefoot. The patients were randomized to receive either conservative treatment consisting of relief of weight-bearing and regular dressing or surgical excision of the ulcer, eventual debridement and removal of bone segments underlying the lesion and surgical wound closure. After ulcer healing, the results showed a significant reduction in ulcer recurrence during 6 months follow-up in the surgical group: 14% (3/21 patients) compared to 41% (8/19 patients) in the conservative treatment group (P<0.01).

A cohort study by Armstrong et al.[12] (quality 2-) investigated the effect of metatarso- phalageal (MTP) joint arthroplasty of the great toe versus conservative treatment (i.e. TCC) in a diabetic population affected by neuropathic non-infected plantar ulcers. After primary healing, recurrence rates at 6 months follow-up were significantly lower in the arthroplasty group when compared with the TCC group: 5% versus 35% (P=0.02, OR= 7.6, 95% CI=1.1-261.7). Another cohort study by Armstrong et al.[13] (quality 2-) on the effect of metatarsal head (MTH) resection in diabetic patients with neuropathic plantar ulcers also demonstrated lower ulcer recurrence rates in 6 months follow-up after healing in the surgical group when compared to a conservative treatment group treated with "aggressive off-loading": 5% versus 28% (P=0.04, OR=8.3, 95%CI=1.1-67.9).

3.4. Other off-loading interventions

There are no level 1, 2, or 3 studies relevant to primary or secondary ulcer prevention that have investigated off-loading interventions other than footwear or surgical off-loading.

3.5. Conclusions and Recommendations

Only limited studies of sufficient methodological quality are available regarding the effectiveness of footwear and surgical off-loading in preventing ulceration.

Conclusions:

- There are indications that therapeutic shoes may reduce ulcer recurrence compared to standard footwear, although one of the studies reviewed has found no effect (evidence: 1-, 2-).
- Lengthening of the Achilles tendon and a combination of surgical excision, debridement and removal of bone segments appears to reduce the risk of ulcer recurrence in diabetic patients with forefoot neuropathic plantar ulceration when compared to conservative off-loading treatment (evidence: 1+, 1+).
- MTP joint arthroplasty and MTH resection may reduce risk for ulcer recurrence compared with conservative off-loading treatment in patients with neuropathic plantar ulceration (evidence 2-, 2-).
- Clearly, research on off-loading interventions other than footwear and surgical off- loading is required to build up an evidence base before clinical effectiveness can be properly assessed.

Recommendations:

- From the available evidence we recommend the use of therapeutic footwear for the prevention of ulcer recurrence in the diabetic foot. However, there is a wide diversity of interventions and control conditions in the studies performed and the lack of standardization prevents us from making clear recommendations regarding the optimum design of footwear to prevent ulcer recurrence.
- In carefully selected patients certain surgical off-loading techniques such as Achilles tendon lengthening, surgical excision, joint arthroplasty and MTH resection, may be considered for the prevention of ulcer recurrence in the diabetic foot. However, more studies are needed before a definitive statement can be made about the safety and efficacy of preventive surgery to reduce risk of plantar ulcer recurrence.

4. Ulcer treatment

4.1. Introduction

The PICO question for the selected outcome of ulcer treatment is:

"Is there evidence for the effectiveness of CASTING, FOOTWEAR, SURGICAL OFF-LOADING, AND/ OR OTHER OFF-LOADING INTERVENTIONS in treating foot ulceration in patients with diabetes mellitus?"

4.2. Casting

The central tenet for healing any wound is reduction of pressure through pressure redistribution, also known as "off-loading", in a manner that optimizes adherence to therapy. A number of studies have explored the potential utility of a variety of techniques, devices and modalities to accomplish this goal.

Several level 1 studies have emerged assessing the effect of TCC on healing of plantar ulcers in patients with diabetes. Most of these studies compared the effectiveness of a TCC to some type of

off-loading shoe, others to standard treatment or removable walkers. In the first RCT on this topic (Mueller et al.[14]) (quality 1-) the TCC was shown to heal a higher percentage of plantar ulcers at a faster rate when compared with standard treatment (i.e. accommodative footwear). In another RCT, Caravaggi et al.[15] (quality 1-) compared windowed TCC treatment to therapeutic footwear treatment and showed significantly higher healing proportions in TCC after a short follow-up time of 30 days. In a RCT of several commonly used devices for ulcer treatment, including prefabricated removable modalities, Armstrong et al.[16] (quality 1-) showed a TCC to be superior to a removable walker (RW) and half-shoe both in percentage of healed ulcers in 12 weeks and in time to healing. However, data for the RW and half-shoe were pooled for the primary outcome and this prevents specific conclusions from being drawn. Interestingly, patients wearing TCC were much less active than patients wearing half-shoes, a result that may have contributed to improved healing in TCC.

In a low-quality CBA study by Ha Van et al.[17] (quality 2-) with undefined study duration, healing proportions were 81% and 70% for TCC and half-shoes respectively (P-value not reported). The survival curve was significantly different in favour of TCC (hazard ratio: 1.68, 95%CI:1.04-2.70). Adherence to treatment was found to be much larger in the TCC (98%) than in the half shoes (10%). Despite this large difference in adherence, surprisingly the absolute percentage difference in healing proportion was only 11%. In a low-quality cohort study by Agas et al.[18] healing proportions of non-ischemic and non- infected ulcers were 83% in a windowed TCC and 25% in two types of offloading shoes.

The level 3 evidence largely describes clinical outcomes from various off-loading techniques [19-38]. These studies, predominantly prospective and retrospective epidemiological studies, have evaluated healing percentages and time to healing of patients in TCC, fibreglass cast shoes, Scotch-cast boots, windowed casts, and custom splints. Between 73 and 100% of wounds were reported to have healed in studies of TCCs with healing times ranging between 30 and 63 days[23,29,39]. In a retrospective design, a study of fiberglass cast shoes has reported 91% of subjects healing in an average of 34 days[32]. Additional studies of Scotch-cast boots, windowed casts, and custom splints have reported between 70% and 81% of subjects healing between 42 and 300 days[23,40,41].

4.3. Footwear

In a RCT by Caravaggi et al.[15] (quality 1-) of patients with a plantar ulcer, the use of a TCC was compared to a specialized cloth shoe with a rigid sole and an unloading insole. After a brief follow-up period of 30 days, the reduction in ulcer area was reported to be more rapid in the cast group (P=0.0004) and the number of ulcers completely healed was 13 (50%) in the cast group vs. 5 (20.8%) in the shoe group. Mueller et al.[14] (quality 1-) compared the TCC with a combination of accommodative footwear and instructions to avoid bearing weight on the involved extremity. Fewer infections developed and significantly more ulcers healed in the TCC group (19 of 21 ulcers; mean time 42 +/- 29 days in TCC vs. 6 of 19 ulcers; mean time 65 +/- 29 days in footwear; P<0.05). Armstrong et al.[16] compared the use of a half-shoe with a TCC and a removable walker (RW) in a RCT (quality 1-). The results showed healing in 17/19 patients in the TCC group, 13/20 in the RW group, and 14/24 in the half-shoe group. The statistical interpretation of this study is complicated by the pooling of data and the apparently greater loss to follow-up of patients in the TCC group. Ha Van et al.[17] compared a half-shoe or heel relief shoe with a TCC in a CBA design (quality 2-) which followed non-infected, non-ischemic, neuropathic plantar ulcers to healing or further complication. They reported healing in 81% of ulcers in the TCC group compared to 70% in the half shoe group (P=0.017). The mean times to healing were 68.6 +/- 35 days in the TCC group vs. 134.2 +/- 133 days in the footwear group.

The level 3 evidence for the use of footwear in ulcer healing includes a number of case studies, case series, epidemiological studies, and cross-sectional studies. Within the limitations of their experimental designs, these studies suggest that moulded and EVA boots can play a role in ulcer healing,[42,43] that various types of shoes and off-loading insoles can, under some circumstances, result in healing[44-47], and that half-shoes can be effective in the treatment of plantar ulcers[23,48,49].

4.4. Surgical off-loading

Surgical off-loading treatment of neuropathic plantar ulcers has been described in five level 1 and level 2 studies.

A RCT by Mueller et al.[10] (quality 1+) compared treatment with Achilles tendon lengthening (ATL) in addition to TCC (ATL group) with TCC alone (TCC group) in patients affected by forefoot neuropathic plantar ulceration. In the ATL group, 100% of ulcers healed while in the TCC group 88% of ulcers healed. This difference was not significant. The ulcers healed faster in the ATL group than in the TCC group: mean duration of 41 versus 58 days (P>0.05, NS). In another RCT, Piaggesi et al.[11] (RCT, quality 1+) studied patients affected by plantar ulcers of the forefoot. The patients were randomized to receive either conservative treatment consisting of relief of weight-bearing and regular dressing (Group A) or surgical excision of the ulcer, eventual debridement and removal of bone segments underlying the lesion and surgical wound closure (Group B). The healing percentage was lower in Group A compared to Group B (79% = 19/24 ulcers versus 95% = 21/22 ulcers) (P<0.05), although there is some doubt over whether this difference is significant. Time to healing was significantly shorter in group A than in group B (47 versus 129 days (P<0.001))

Two level 2 studies on the efficacy and safety of MTP joint arthroplasty as curative surgical procedure for plantar interphalangeal joint ulcers were identified. In a case-control study, Lin et al.[36] (quality 2-) demonstrated that a Keller arthroplasty in addition to TCC does not heal more ulcers under the interphalangeal joint of the great toe than the TCC alone (both groups 100% healed in 26 weeks). However, the arthroplasty plus TCC does heal ulcers at a faster rate (23 versus 47 days (no inferential statistics performed)). In a cohort study, Armstrong et al.[12] (quality 2-) confirmed these results by showing no difference in healing percentage between groups treated with arthroplasty and with TCC (both 100% healed in 67 days) but significantly faster healing times in the surgery group (17 versus 67 days (P=0.0001)). Additionally, this study showed no difference between study groups in infection or amputation rates. Investigating the efficacy of 5th metatarsal head resection compared to conservative "aggressive off-loading" treatment in cases of recalcitrant plantar ulcers, Armstrong et al.[13] (cohort study, quality 2-) found no differences between groups in healing percentage (both 100% healed in 8.7 weeks), although shorter healing times were observed in the surgery group (5.8 versus 8.7 weeks). However, this latter difference did not reach statistical significance (P=0.4).

The majority of uncontrolled level 3 studies focused on descriptions of surgical procedures and case reports/series of outcomes[50-79]. Carefully selected surgical procedures such as arthroplasties of affected joints with limited joint mobility in the forefoot may have value in promoting wound healing[51]. Furthermore, exostectomy procedures have been reported to be relatively reliable methods of treatment for rigid, prominent deformities secondary to Charcot's neuro-osteoarthropathy[58,59].

4.5. Other off-loading interventions

Many other off-loading interventions that could have an effect on ulcer healing have not received a lot of attention in the literature. These interventions include bed rest, crutches, canes, wheelchairs, bracing (PBT, AFO), prefab removable walkers, off-loading dressings, felted foam/padding, and plugs. Of these, only removable walkers, bracing, and felted foam have been studied using level 1 or 2 study designs.

Removable walkers have been compared with TCC and therapeutic shoes in a number of studies. A medium-sized RCT by Armstrong et al.[16] (quality 1-) demonstrated that removable walkers (RW) were less effective than the TCC as measured by the proportion ulcers healed. However, the data for the RW and a second comparison group, half-shoes, were pooled in this analysis making it difficult to draw specific conclusions. In two medium- sized RCTs by Armstrong et al.[80] (quality 1+) and Katz et al.[81] (quality 1+), the RW was made non-removable and compared to either the standard RW or the TCC. Making the RW non-removable significantly increased the proportion of

healed ulcers[80]. Compared to the TCC no significant differences were found in the proportion of healed ulcers[81]. None of these studies reported plantar pressure results and thus the degree to which the wound area was off-loaded in the various studies is unknown. Although adherence was not specifically measured, the positive effect of making the RW non-removable points to the importance of constant use of devices intended to promote wound healing.

A medium-sized RCT by Zimny et al.[82] (quality 1-) examined the effect of felted foam in post-operative shoes compared to a forefoot off-loading shoe for the treatment of neuropathic plantar forefoot ulcers. The study appears to be identical to an earlier report by the same authors[83] which may indicate that the data overlaps between the studies. A significantly shorter healing time was found for the felted foam condition. No information was provided on the number of ulcers healed. Furthermore, there is no statistical analysis on wound area reduction after 10 weeks. It is surprising that a randomization scheme led to 24 patients in one group and 30 in the other. This would suggest a loss of subjects to the study which was not reported and has implications for the interpretation of the results. Plantar pressure and treatment adherence were not measured.

In a small CBA study, a walking brace (plantar healing orthosis) and topical ulcer care was compared with topical ulcer care alone[84] (quality 2-). The study did not demonstrate significant differences in ulcer healing percentages but may have been underpowered. Plantar pressure and treatment adherence were not measured. Unfortunately, the study was poorly described which limits its value to the evidence base.

Several level 3 studies have evaluated the effect of other off-loading devices on ulcer healing. In a biased retrospective analysis of forefoot ulcer healing, in which the off-loading method was selected based on location of ulcer, patient age and duration of ulceration, Birke and colleagues[23] showed that accommodative dressing (felted foam) worn in a surgical shoe, a healing shoe, or a walking splint was as effective as the TCC with healing percentages ranging between 81 and 93% and healing times between 36 and 51 days.

Two case studies of patients with recalcitrant plantar ulceration after treatment with a variety of other off-loading modalities showed that continued treatment with a Cam walker with plastazote arch filler[85] or an ankle-foot orthosis[86] resulted in healing within 4 months and 12 weeks, respectively.

4.6. Conclusions and Recommendations

Conclusions:

- It appears that a total contact cast (TCC) heals a higher proportion of neuropathic plantar ulcers at a faster rate than removable modalities such as a removable walker (RW), off-loading shoes (i.e. half-shoes) and therapeutic footwear (evidence: 1-, 1-, 1-, 2-).
- Alternative off-loading devices such as cast shoes and cast boots may heal the same percentage of neuropathic plantar foot ulcers and at a similar rate as in TCC although this will require further confirmation (evidence: 3).
- Based on the available evidence, footwear such as half shoes, off-loading shoes, shoes with reliefs or extra-depth shoes with plastozote insoles appear to be less effective than the TCC for healing plantar neuropathic foot ulcers (1-, 1-, 1-, 2-, 2-).
- It appears that a RW which is made non-removable is more effective than a RW and similarly effective as a TCC in healing diabetic neuropathic plantar foot ulcers (evidence: 1+, 1+, 1-).
- In one study, a plantar healing orthosis (walking brace) did not appear efficacious for ulcer treatment when compared with topical ulcer care (evidence: 2-).
- The use of felted foam in post-operative shoes, healing shoes or a walking splint in the treatment of neuropathic plantar forefoot ulcers appears to lead to a reduced healing time when compared with a forefoot off-loading shoe and to comparable healing percentages

and healing times when compared with TCC treatment. Whether this effect should be attributed solely to the use of the felted foam or the potential (additional) effect of the type of shoe in which it was tested is unclear (evidence: 1-, 3).

- The use of surgical off-loading techniques such as Achilles tendon lengthening, surgical excision and debridement, joint arthroplasties or MTH resection, whether or not in addition to TCC treatment, does not appear to improve the percentage of healed plantar neuropathic foot ulcers when compared to using TCC alone. However, with the exception of ATL, they do significantly improve the healing time (evidence: 1 +, 1+, 2-, 2-, 2-).
- Exostectomy procedures appear to be relatively reliable methods of treatment for rigid, prominent deformities secondary to Charcot's neuro-osteoarthropathy although a control condition to which this procedure could be compared is not available (evidence: 3).

Recommendations:

- A preponderance of evidence in the area suggests that a dedicated focus on adequate pressure relief is an important and likely essential component of successful, consistent and predictable healing for the majority of neuropathic diabetic foot wounds. Because of its effect on pressure reduction and adherence to therapy, we recommend consideration of the use of a TCC in treatment of neuropathic, non-infected, non-ischemic plantar diabetic foot ulcers.
- Cast shoes and cast boots may be considered as alternative modalities to TCC for off-loading treatment of neuropathic plantar foot ulcers in selected patients with adequate treatment adherence. However, the efficacy of these approaches should be evaluated in a randomized study design using the TCC as comparative condition before their widespread use can be recommended.
- Neither conventional shoes nor plantar healing orthoses (walking brace) are recommended for the healing of foot ulcers in diabetic patients.
- In general, we do not recommend the use of special footwear for the treatment of plantar neuropathic foot ulcers in diabetic patients. Instead a casting device such as TCC should be employed. Such an approach should be considered only when casting techniques are not available, casting technicians are not skilled, patient adherence can be ensured, and/or patients decline treatment with a TCC. Furthermore, it should be recognized that there are many other factors such as adherence, quality of life, and mobility, that determine the outcome of a given footwear prescription in ulcer healing.
- When using a prefabricated removable device such as a removable walker (RW) for treatment of neuropathic plantar foot ulcers, it should be made irremovable as this can increase healing percentages to a level comparable with the TCC.
- The evidence base for the use of other off-loading modalities such as bed rest, crutches, canes, wheelchairs, bracing (PBT, AFO), walkers, and plugs is small or non- existent. More high-quality studies should be performed before these modalities can be recommended for use in treating plantar diabetic foot ulcers.
- More studies are needed to confirm the usefulness of felted foam in the treatment of neuropathic plantar foot ulcers before it can be recommended in clinical practice.
- Achilles tendon lengthening seems to have limited additional value to treatment with TCC alone in healing patients with plantar forefoot ulceration and is therefore currently not recommended for this purpose.
- RCT designs may not always be appropriate in studies on the efficacy of surgical off-loading treatment. The evidence seems to indicate that surgical options may be considered in the treatment of neuropathic plantar foot ulcers in diabetic patients. However, more studies are needed to better define the role of this approach in relationship with

conservative treatment.

- More studies with adequate control conditions are needed before exostectomy procedures can be recommended in the treatment of plantar ulcers in Charcot's neuro-osteoarthropathy.

5. Plantar pressure reduction

5.1. Introduction

The PICO question for the selected outcome of plantar pressure reduction is:

"Is there evidence for the effectiveness of CASTING, FOOTWEAR, SURGICAL OFF- LOADING, AND/OR OTHER OFF-LOADING INTERVENTIONS in reducing plantar pressure in patients with diabetes mellitus?"

5.2. Casting

We did not find any level 1 or 2 studies on the effectiveness of casting devices in reducing plantar pressure in the diabetic foot. We identified five manuscripts focusing on pressure reduction that met the criteria for inclusion and description under level 3 evidence [87-91]. TCCs appear to off-load the affected extremity effectively. This effective degree of off- loading is most likely an important aspect of diabetic plantar foot ulcer healing using this device. While one manuscript suggested no substantive difference between standard fracture casts and TCCs in the ability to off-load [91], this has not been replicated in a robust manner in subsequent trials.

5.3. Footwear

The effect of footwear for ulcer prevention or healing is thought to rely on plantar pressure reduction over the at-risk or previously ulcerated area.

There were no level 1 studies that reported on the effect of footwear in terms of plantar pressure reduction. One cohort study by Viswanathan et al. [8] (quality 2-) reported reductions of plantar load in therapeutic sandals of 10-19% but inconsistencies between the body of text and Figure 1 reporting the peak pressure shed doubt on the accuracy of these results (see above).

There are quite a number of level 3 studies that report on plantar pressure reduction for various footwear interventions. These include a variety of prefabricated and custom-made therapeutic footwear designs, hosiery and running shoes. In total, 24 studies investigating plantar pressure reduction were included in this review. These studies were predominantly cross-sectional designs and one un-controlled design. Most of these studies included footwear with some sort of moulded insole and, in general, this intervention provided significant reductions in plantar pressure [89,90,92-102]. Flat insoles were less effective [99]. The results for (padded) hosiery are not conclusive.

5.4. Surgical off-loading

Surgical approaches to reduce plantar pressure have not been widely investigated. There are only two level 1 and 2 studies on this subject. The RCT from van Schie et al. [103] (quality 1+) gave information about the use of liquid silicone injection under the MTH with callus in order to reduce peak pressure. Two groups of 14 patients were subjected to 6 injections of 0.2 ml of liquid under the MTH at 3, 6, 12 and 24 months: one group with silicone and one with saline (placebo). At 12 months, plantar tissue thickness in the silicone group had increased by a mean 1.6 +- 0.9 mm (P=0.001) and remained increased at 24 months (1.1 +- 0.7 mm, P=0.003); peak plantar pressure was reduced in the silicone group at 12 months (-165.0 +- 253.5 kPa, P=0.03) but not at 24 months. No changes were observed in the placebo group. These results suggest that silicone injections should be considered only as a temporary method for reducing peak of plantar pressure. The efficacy of long-term use of this approach is still in question. In a second RCT, Maluf et al. [104] (quality 1+) carried out a subset analysis of Mueller et al. [10] and evaluated peak plantar pressures, ankle dorsiflexion range of motion (DFROM), and plantar flexor power in two groups of patients subjected to TCC + ATL or TCC alone. The study showed a significant reduction of forefoot plantar

pressure (Pre ATL 89.24 +- 17.66 N/cm2 to 64.72 +- 30.67 N/ cm2 post ATL (P=0.001) but no significant difference at 8 months (P=0.932) while pressure-time integrals remained lower at 8 months (P=0.001) along with ankle DFROM (P=0.005). These data show that ATL causes at least a temporary reduction in forefoot pressure by reducing plantar flexor power during gait. These functional changes may explain the reduction of risk of ulcer recurrence in the forefoot found by Mueller et al. [10].

Several level 3 studies detailed the effect of various surgical off-loading procedures on plantar pressure, suggesting that Achilles tendon lengthening and MTH resections reduce pressure in the forefoot [53,105]. Furthermore, regular callus removal has been reported to have a beneficial effect on the reduction of plantar pressure [106], while the presence of callus has been associated with a relative risk of 11 for the development of a plantar ulcer [120]. However, MTH resections or trans-metatarsal amputations may cause increases in pressure in other areas of the foot residuum [107,108].

5.5. Other off-loading interventions

None of the other off-loading interventions that could have an effect on pressure reduction have been studied using level 1 or 2 study designs. However, several well-conducted level 3 cross-sectional studies have investigated the effect of a variety of off-loading modalities on plantar pressures at sites of previous ulceration. Removable walkers were shown to be as effective as a TCC in reducing peak pressures in the forefoot and more effective than half shoes and extra depth shoes [88,89]. Half shoes were found to be more effective than accommodative felt and foam dressings (worn in a post-operative shoe) or post-operative shoes alone [88]. The heel region was found to be best off-loaded with a TCC, followed by removable walkers, which, themselves, were more effective than depth-inlay shoes [87].

Polyurethane foam sheets applied at forefoot ulcer locations and tested inside the patients' own shoes showed a significant 38% reduction in peak pressures compared with wearing shoes alone [109]. Whether or not such an effect lasts for consecutive days requires further investigation.

5.6. Conclusions and Recommendations

It should be kept in mind that the conclusions and recommendations in this section apply solely to the relief of plantar pressure in the foot, not to any clinical outcome related to prevention or treatment of ulceration.

Conclusions:

- Total contact casts are very effective in reducing plantar pressure at sites of ulceration and high peak pressure in the neuropathic diabetic foot (evidence: 3).
- Plantar pressure reduction can be achieved with footwear that includes a moulded insole when compared with standard footwear although the amount of reduction will differ (evidence: 3).
- Insole material and soft padding on its own does not seem to have a large effect on plantar pressure although some studies have found significant differences (evidence: 3).
- Removable walkers appear to be very effective (similar to the TCC) in reducing plantar pressures at plantar ulceration sites in the forefoot but the dependence of this effect on interface characteristics have not been well explored (evidence: 3).
- Half shoes appear to be effective in reducing plantar pressures when compared with accommodative felt and foam dressings worn in a post-operative shoe or with a post-operative shoes alone (evidence: 3).
- Polyurethane foam sheets worn in shoes appear to be effective in reducing forefoot plantar pressures when compared with wearing shoes alone. However, further research into this is essential before clear conclusions can be drawn (evidence: 3).

- Liquid silicone injected under the plantar MTHs, in one clinical trial, appears to reduce plantar pressure better than saline over a 12 month period, but not for longer periods (evidence: 1+).
- Achilles tendon lengthening appears to reduce pressure in diabetic patients with neuropathic plantar forefoot ulcers in the immediate postoperative period, but this pressure reduction may not persist (evidence: 1+, 3).
- MTH resection appears to reduce pressure in neuropathic diabetic patients in the immediate postoperative period, but this may cause increases in pressure in other areas of the foot (evidence: 3, 3).
- Regular callus removal appears to have a beneficial effect on the reduction of plantar pressure in the neuropathic diabetic foot (evidence: 3).

Recommendations:

- We recommend the use of TCC for effective reduction of plantar pressures at sites of ulceration and high peak pressures in the diabetic neuropathic foot.
- For small reductions in peak plantar pressures we recommend the use of footwear that includes a custom moulded insole. There is a wide diversity of interventions and control conditions in the studies performed and the lack of standardization prevents us from making clear recommendations regarding the optimum design of footwear to reduce plantar pressures.
- We do not recommend the use of standard flat insoles and soft padding for pressure reduction in the diabetic foot.
- We recommend the use of removable walkers for pressure reduction in the neuropathic diabetic foot although adherence issues must be considered (see above).
- If removable walkers or TCCs can not be applied to the patient, we recommend the use of half-shoes for reducing pressures in the neuropathic diabetic foot.
- Limited research on the use of felted foam currently prevents us from recommending this intervention for the reduction of plantar pressures in the diabetic foot. Further studies of the sustained pressure relieving effect of felted foam over time and its use as an additional component of treatment with casting or removable walkers would be required before felted foam can be recommended for widespread use in clinical practice.
- Liquid silicone injections under the MTHs are not currently recommended for plantar pressure reduction in the diabetic foot. If the efficacy of this approach is confirmed by future trials, then silicone injections may be considered for appropriately selected patients.
- Achilles tendon lengthening may be considered in selected patients to reduce plantar pressures in the immediate postoperative period.
- We recommend the use of regular callus removal in the neuropathic diabetic patient to reduce plantar pressures.
- Further research on the side-effects of MTH resections is needed before this approach can be recommended for pressure reduction in the diabetic foot.

---

6. Other considerations

6.1. Shoe and cast-making process

A major obstacle to the development of footwear guidelines is a lack of standardization in prescription, manufacture, and material properties of footwear and insoles. This situation likely leads to substantial variability in therapeutic outcome and complicates the comparison of studies in

the literature. For example, while the term "custom insole" almost always implies a device made in reference to the shape of the foot, many practitioners will add other modifications which alter the pressure distribution and the unloading potential of the final product. We strongly recommend the development and documentation of standard procedures in the future.

6.2. Surgical off-loading interventions

We acknowledge the difficulties inherent in trial design of surgical procedures. Regional variations in equipment, technique and surgical practice makes randomized trials perhaps more challenging than in other interventions in this area. For this reason, we accept that the key factors of pressure reduction, wound healing and/or prevention of recurrence may be suitable endpoints for other types of investigations in this area. Furthermore, we also suggest that individual centers do not abandon publication of technique-driven studies.

Furthermore, when suggesting a surgical off-loading intervention for the prevention or treatment of plantar foot ulceration or the reduction of plantar foot pressure, one should always take into consideration the disadvantages and potential complications. For Achilles tendon lengthening, the influence on locomotion and other functional tasks should be considered [110,111].

6.3. Adherence

The effectiveness of off-loading in ulcer healing and prevention is always likely to be complicated by patient adherence to treatment. It is self evident that even the most effective device will not be successful if it is not worn. Self-report studies have suggested that, when given the choice, patients only wear their prescribed footwear for a small portion of the day (e.g. Knowles and Boulton [112] reported that shoes were worn for only 25% of active time). Only recently have systematic attempts been made to directly measure footwear use simultaneously with activity profiles and the results of these studies have provided further insight into lack of adherence. Armstrong et al. [113] reported that patients who had been prescribed a removable walker to heal neuropathic diabetic foot wounds only wore the device only 28% of their total daily activity. While non-removable devices such as the TCC can overcome this problem during ulcer healing, there is clearly still much to learn regarding ways to encourage patients to adhere to footwear treatment that can influence primary and secondary prevention. It is likely that the provision of more attractive footwear will help in this regard. Williams and Nester [114] have reported that 35% of diabetic patients feel that "style" is the most important factor in a shoe compared to only 11% of patients with rheumatoid arthritis.

6.4. Quality of life

Diabetic patients with foot ulcers experience a marked decline in their quality of life [115,116] and thus rapid ulcer healing and sustained ulcer free survival are important to patient well- being. Since footwear and off-loading techniques can be effective in both of these domains, a greater awareness among clinicians of successful approaches to healing and prevention through footwear should be encouraged.

6.5. Economic factors

When seen in isolation, the cost of footwear and off-loading devices are often considered to be substantial, particularly when this cost has to be borne by the patient. However, it is important that such costs are viewed in relation to the total cost of care for a foot ulcer and the inherent increased risk of amputation. Although the direct costs of a foot ulcer have been variously estimated at between $17,500-$27,987 USD, the question of cost effectiveness of the various treatments still remains to be determined [117]. The very high recurrence rate for plantar ulcers, despite present treatments, is a critical issue that needs to be addressed in future both in terms of cost and quality of life.

6.6 Ulcer recurrence

The literature shows that ulcer recurrence remains a very significant problem. Various authors have reported between 27-100% rates of recurrence at 1 and 4 years respectively [5,49]. Future

research needs to emphasize not just healing the first ulcer, but preventing recurrence.

6.7 Shoes with rigid soles

A number of studies in healthy people have shown that making the outsole rigid and either "rockered" or "rollered" can be extremely effective in reducing plantar pressure in the forefoot [118,119]. While similar results have been observed clinically in diabetic patients, definitive studies in this patient group are required before recommendations for their use can be made.

Biomechanics of the foot

Evaluation and examination of the foot is usually a somewhat static procedure that is conducted with the patient seated or lying down. However, many important aspects of foot function can only be determined by a dynamic examination using more than just visual analysis. In this presentation, we will introduce and preview the visualizations of diabetic foot function that are contained in the diabetic foot biomechanics section of the DVD that has been provided to all conference participants. The development of the foot is briefly discussed together with a presentation of foot anatomy. The biomechanics of normal gait are demonstrated through the use of slow motion video, force platforms which measure ground reaction force, pressure distributions from barefoot walking and pressure measurements made at the foot-shoe interface. Using these same tools in combination with radiographs and magnetic resonance images, the impact of diabetic neuropathy on the foot is explored. The importance of off-loading in both ulcer prevention and healing is highlighted by plantar pressure measurements with a variety of interventions. Finally, a series of case studies are presented illustrating altered foot mechanics in Charcot's neuro-osteoarthropathy and partial amputation. The techniques presented here could be helpful in practice to enhance the understanding of individual cases.

Foot biomachanics in diabetes