Available online at www.sciencedirect.com
SCIENCE DIRECT®
Clinical Biomechanics 19 (2004) 629–638
CLINICAL BIOMECHANICS
www.elsevier.com/locate/clinbiomech

Pressure relief and load redistribution by custom-made insoles in diabetic patients with neuropathy and foot deformity

Sicco A. Bus [a], Jan S. Ulbrecht [b], Peter R. Cavanagh [c,*]

[a] Department of Internal Medicine, Academic Medical Center, University of Amsterdam, 1100 DE Amsterdam, The Netherlands
[b] Departments of Biobehavioral Health and Medicine, Pennsylvania State University, University Park, PA 16802, USA
[c] Department of Biomedical Engineering/ND20, Lerner Research Institute, The Cleveland Clinic Foundation, 9500 Euclid Avenue, Cleveland, OH 44195, USA

Received 22 May 2003; accepted 19 February 2004

Abstract

Objective. To study the effects of custom-made insoles on plantar pressures and load redistribution in neuropathic diabetic patients with foot deformity.

Design. Cross-sectional.

Background. Although custom-made insoles are commonly prescribed to diabetic patients, little quantitative data on their mechanical action exists.

Methods. Regional in-shoe peak pressures and force-time integrals were measured during walking in the feet of 20 neuropathic diabetic subjects with foot deformity who wore flat or custom-made insoles. Twenty-one feet with elevated risk for ulceration at the first metatarsal head were analysed. Load redistribution resulting from custom-made insoles was assessed using a new load-transfer algorithm.

Results. Custom-made insoles significantly reduced peak pressures and force-time integrals in the heel and first metatarsal head regions; pressures and integrals were significantly increased in the medial midfoot region compared with flat insoles. Custom-made insoles successfully reduced pressures in and integrals at the first metatarsal head in 7/21 feet, were moderately successful in another seven, but failed in the remaining seven. Load transfer was greatest from the lateral heel to the medial midfoot regions.

Conclusions. Custom-made insoles were more effective than flat insoles in off-loading the first metatarsal head region, but with considerable variability between individuals. Most off-loading occurred in the heel (not a region typically at risk). The load transfer algorithm effectively analyses custom-made-insole action.

Relevance

Because similar insole modifications apparently exert different effects in different patients, a comprehensive evaluation of custom designs using in-shoe pressure measurement should ideally be conducted before dispensing insoles to diabetic patients with neuropathy and foot deformity.

Keywords: Diabetic foot; Neuropathy; Foot deformity; Plantar pressure; Footwear; Custom-made insoles; Load distribution; Biomechanics

1. Introduction

Custom-made insoles (CMIs) are routinely used in clinical foot care settings for diabetic patients with neuropathy and foot deformity. The success of such insoles and the associated footwear is primarily evaluated based on whether the patient remains free of ulceration while wearing the footwear and insoles. Elevated barefoot plantar pressure has long been associated with plantar ulceration (Boulton et al., 1983; Veves et al., 1992). Therefore, one of the major goals of any footwear intervention must be to protect the foot at sites that are at risk for plantar ulceration or re-ulceration by reducing pressure to a level below some (currently unknown) threshold for ulceration.

* Corresponding author.
E-mail address: cavanagh@bme.ri.ccf.org (P.R. Cavanagh).

0268-0033/$ - see front matter © 2004 Published by Elsevier Ltd.
doi:10.1016/j.clinbiomech.2004.02.010

CMIs are prescribed primarily, if not exclusively, to protect the plantar surface of the foot. However, little quantitative data is available on if and how CMIs achieve their action. Among the putative methods that have been discussed is the redistribution of load to adjacent foot regions through accommodative moulding—the "total contact" concept—and the incorporation of additional "reliefs" or, conversely, elevated contact surfaces such as medial arch supports and metatarsal pads, which go beyond merely providing a mirror image of the plantar contour (Bowker et al., 1993; Cavanagh et al., 2001; Janisse, 1995).

Several authors have reported successful relief of dynamic plantar pressures and load at the metatarsal heads (MTH), a plantar region where ulcers commonly occur (Albert and Rinoie, 1994; Brown et al., 1996; Lord and Hosein, 1994; Novick et al., 1993; Postema et al., 1998). However, others have found no significant off-loading effects of moulded insole interventions (Ashry et al., 1997; Hewitt et al., 1993; Uccioli et al., 1997). The discrepant results from these various studies are likely a function of different approaches to insole manufacture, subject selection, and experimental procedure.

The lack of a standard and comprehensive method of pressure and load analysis in these studies has prevented a better understanding of the mechanisms by which insole modifications act to relieve pressure and redistribute load under the foot. One of the methods by which this relief can be achieved is through comparison of the load distribution patterns from a CMI and some controlled condition, such as a flat insole, worn sequentially both on the same foot and in the same shoe, from which load transfer analysis can be performed. Therefore, the purpose of the present study was to compare the mechanical behaviour at the foot–insole interface of CMIs and flat insoles in diabetic patients with neuropathy and foot deformity and to use this comparison to define a calculation method for assessing load redistribution.

2. Methods

2.1. Subjects

Twenty diabetic patients with neuropathy and foot deformity (13 men, 7 women), recruited from a specialist diabetic foot clinic, participated in the study after giving informed consent. The mean (SD) age, height, and weight of the subjects were 64.4 (11.2) years, 1.73 (0.10) m, and 99.5 (15.7) kg, respectively. Neuropathy was confirmed by a loss of protective sensation on the plantar surface of the foot, as determined by the inability to feel the 10-g Semmes–Weinstein monofilament on the hallux of both feet. All subjects normally wore some form of prescription footwear.

Twelve subjects had prior plantar ulcers (8 unilateral, 4 bilateral). At the time of the experiment, all these subjects had remained healed for at least 3 months while wearing their prescription footwear. Foot deformity, which was a criterion for participation, was assessed subjectively. Among the deformities present were claw toes, hammer toes, hallux abducto valgus (HAV), limited joint mobility (LJM) at the first metatarsal–phalangeal joint, forefoot/rearfoot varus or valgus, prominent MTHs, midfoot Charcot's neuroarthropathy, and amputation of the toes. Subjects also had to be able to walk independently with only minor assistance, in case of balance problems. All procedures were approved by the Institutional Review Board of the Pennsylvania State University, where the work was conducted.

2.2. Instrumentation

Both barefoot and in-shoe plantar pressures were measured during level walking. A Novel EMED-SF pressure platform (Novel USA, Minneapolis, MN, USA), consisting of 1984 capacitance-based sensors, each with an area of 0.5 cm^2, was sampled at 70 Hz to collect dynamic barefoot plantar pressures during five barefoot left and right foot contacts using a first-step collection method. The platform had been recently calibrated over a range of 0–1300 kPa.

The Novel Pedar system was used to measure in-shoe dynamic pressures. This system comprised 2-mm thick flexible pressure-sensing insoles that were connected by a 10-m long trailing cable to a computer. The pressure-sensing insoles, each consisting of approximately 100 capacitance-based sensors sampling at 50 Hz, were placed between the sock and the insole of the shoe. Directly prior to the experiment, the Pedar insoles used for a particular subject were calibrated over a range of 0–600 kPa, according to the guidelines provided by the manufacturer. Four different Pedar insole sizes were used to accommodate the range of foot sizes in the group. On average, 30 steps for each insole condition were recorded from three trials, with the subject walking within ±10% of a comfortable speed established prior to data collection using photocells placed along a 9-m walkway. No correction was made to allow for differences in sensor dimensions between in-shoe and barefoot pressure systems.

2.3. Footwear and insoles

Two different types of insoles that are frequently prescribed in diabetic foot practice were tested in each subject. The first was a standard 0.95-cm thick flat insole (Fig. 1A) made of PPT® (Langer, Inc., Deer Park, NY, USA), a soft, durable, non-mouldable, open-cell polyurethane foam. The second was a CMI (Fig. 1B)

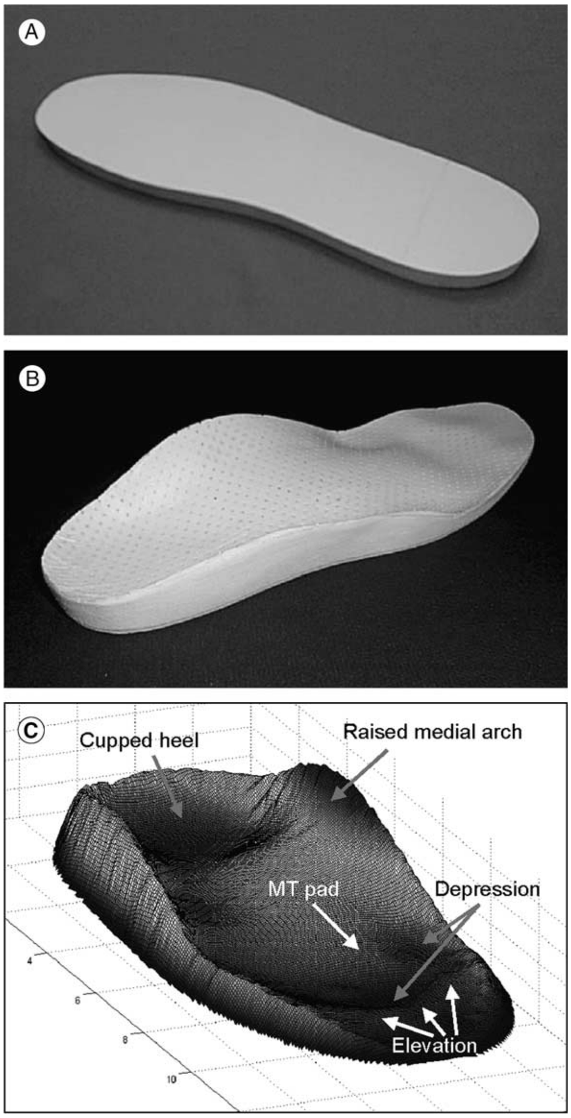

Fig. 1. Example of a flat PPT insole (A) and a CMI used in the study (B). A digital representation of the CMI with specific characteristics emphasised is shown in (C).

manufactured from open-cell urethane foams of hardness 60–80, assessed using an ASTM type 00 tester. Each CMI was specifically fabricated for this project by a CAD-CAM process in which the barefoot plantar pressure data, footprints and tracings of the subject's feet were sent to a trained orthopaedic shoemaker via the Internet. No designated areas of interest were communicated to the shoemaker. No specific algorithm was used in the design of the CMIs. Rather, the skill and experience of the shoemaker were exploited to produce a CMI that was typical of a device that might be produced in a clinical setting. It is recognised that CMIs are often manufactured based on a negative mould of the foot, a technique not employed here.

The main off-loading techniques used for the CMIs were the removal of material under high-pressure areas and the build-up of material at other locations by the provision of what was effectively a metatarsal pad and a medial longitudinal arch support built into the insole, such as might be accomplished by making a mould of the foot. Substantial "heel cups" were also a feature of the CMIs. A digital representation of a typical CMI is shown in Fig. 1C. Once the design was complete, the CMI was fabricated by a numerically controlled milling machine from a homogeneous block of urethane foam. A 0.7-mm top cover and a 2-mm base were subsequently added. Both insoles were tested in the same super-depth shoe (PW Minor & Son, Batavia, NY, USA) with the subject wearing thin seamless nylon socks.

2.4. Data analysis and reduction

The pressure data were analysed using Novel-Win, Novel-Ortho and Pedar mobile software (Novel USA). Using the "Automask" and "Create a Mask" programs for the barefoot and in-shoe pressure data, respectively, the foot was divided into 10 anatomical regions: medial and lateral heel, medial and lateral midfoot, first, second and lateral MTHs, hallux, second toe, and lateral toes (Fig. 2A and B) (Cavanagh et al., 1987).

For each region, peak pressure (PP) and force–time integral (FTI) were calculated. The FTI is a measure of

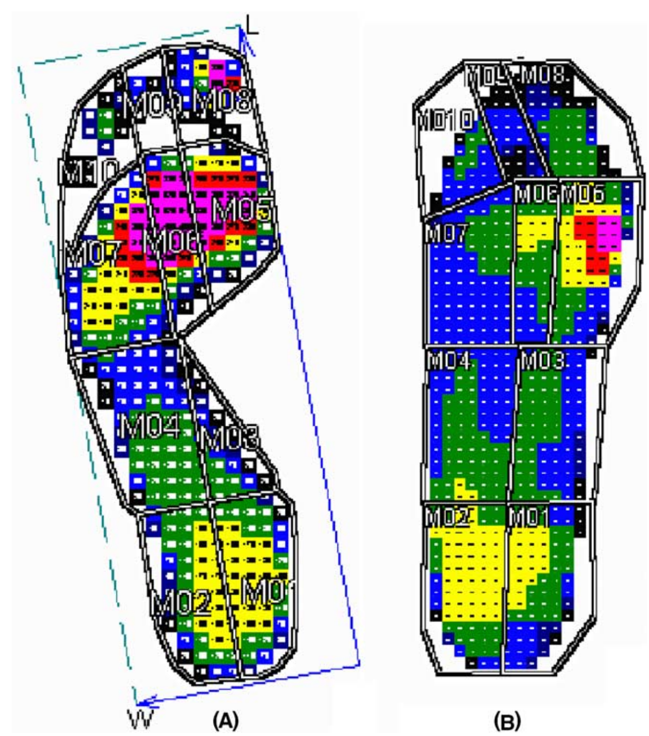

Fig. 2. The anatomically based division of the foot into 10 regions (M01–M10) for the barefoot pressure data (A) and the in-shoe pressure data (B). Note the oblique orientation of M08, representing hallux valgus deformity, in this example.

the force impulse or the load applied to the foot in a given region. (The descriptors "load" and "FTI" are used interchangeably throughout this article.) The PP within a region was defined as the maximum pressure recorded by any sensor, even partly loaded, in the region during the stance phase of the walking cycle. The FTI for a region was defined as the total sum of pressure multiplied by sensor area and sensor contact time of all sensors encapsulated by the region. Because the FTI value depends on the regional surface contact area, a single mask was created and superimposed on all single-step pressure pictures from both flat insole and CMI conditions for a given subject so that a valid comparison between the two insoles could be made.

Twenty-one of the 40 feet in which MTH1 was the region of interest (RoI) were selected. MTH1 was chosen as the RoI because it was the most common region for prior ulcers (6/19 ulcers) and/or high barefoot pressures (>700 kPa, 19/40 feet) to occur. These 21 feet (from 14 different subjects) were analysed as a group and individually. The success of each CMI in off-loading MTH1 in comparison with the flat insole was based primarily on changes in PP—because this parameter has been associated with plantar ulceration—and secondarily on changes in FTI. The CMI was considered successful when both PP and FTI at MTH1 were significantly reduced, moderately successful when only PP was significantly reduced without change in FTI, and a failure when no significant reduction occurred in PP, irrespective of the effect on FTI.

2.5. Load transfer algorithm

Although one of the clinical objectives of therapeutic footwear is to reduce PP at a given site, the mechanical strategy to achieve this reduction is, most frequently, transfer of load from one region to another. For example, a CMI with a very high medial arch support may transfer load from the forefoot to the midfoot compared with a flat insole. Although the regional impulse or load may change, the total impulse on different insoles does not change if the gait remains the same. Thus, the integral of the force–time curves in the same anatomical regions in two different insoles can be directly compared to determine the transfer of load from one region to another that has been achieved by a given insole.

Inter-regional load transfer or redistribution was assessed quantitatively in the 21 selected feet using a new load transfer algorithm (LTA). The basic principle used in the calculations is that transfer of load takes place from a region where load is reduced by the CMI to a region where load is increased in comparison to loads of the flat insole. However, certain "rules" for this calculation are required, since the 10 regions are an underdetermined system for which more than one solution is possible. Details of the algorithm used are presented in Appendix A.

2.6. Statistical analysis

The data were analysed statistically with univariate analysis of variance using SPSS. For the analysis of the group average data, "insole condition" was the fixed factor and "subject" the random factor in the model. Bonferroni adjustments (significance level of 0.05 divided by number of comparisons) were used for the multiple comparisons made. For the analysis of the individual data, "insole condition" was the fixed factor and "trial" was the random factor in the model ($P < 0.05$). Pearson correlation coefficients were calculated between selected variables of interest ($P < 0.05$).

3. Results

The mean (SD) walking speed with both flat insoles and CMIs was 0.83 (0.31) m/s. The mean absolute intra-subject difference in walking speed between the two insole conditions was 1.6% (range 0–4.7%).

3.1. Group data ($n = 21$)

PP was significantly lower in the CMIs than in the flat insoles in the medial and lateral heel and MTH1 region. In the medial midfoot and lateral toes, PP was significantly higher with CMIs. In the other foot regions, no significant differences between the conditions existed (Table 1). Total FTI was slightly, but not significantly, lower for the CMIs than for the flat insoles. FTI in the CMIs was significantly lower in the lateral heel, MTH1, and lateral MTHs. In the medial midfoot, FTI was substantially larger by 154% in the CMIs ($P < 0.05$). No differences in FTI were present between the insoles for the other foot regions (Table 1).

3.2. Individual feet

The CMIs were successful in seven feet, moderately successful in another seven, and failed in the remaining seven in their effects on PPs and FTIs at MTH1 when compared with flat insoles (Table 2; see Section 2.4 for definitions of success). The correlation coefficient between change in PP and FTI at MTH1 was 0.06 ($P = 0.80$).

All 21 feet examined showed an increase in medial midfoot FTI (range 10.7–82.6 N.s) and a decrease in lateral heel FTI (range 8.6–58.4 N.s) when compared with measurements from the flat insoles, and these changes were significantly correlated ($r = -0.80$, $P < 0.001$). The correlation coefficient between load

Table 1
Mean (SD) values of barefoot and in-shoe PPs and in-shoe FTIs for 21 feet in which MTH1 was the RoI

Region	Peak pressure (kPa)			Force–time integral (N.s)			
	Barefoot	CMI	Flat insole	CMI	%[a]	Flat insole	%[a]
Medial heel	414 (222)	189 (45)	239 (71)[b]	86.6 (29.3)	14	90.0 (27.9)	15
Lateral heel	318 (105)	188 (42)	245 (73)[b]	101.4 (30.9)	17	131.8 (38.0)[b]	21
Medial midfoot	67 (51)	118 (23)	90 (28)[b]	65.0 (33.5)	11	26.6 (26.9)[b]	4
Lateral midfoot	174 (182)	121 (25)	113 (33)	76.3 (46.7)	13	73.6 (44.4)	12
MTH1	911 (217)	255 (81)	302 (109)[b]	82.7 (33.8)	14	91.8 (33.2)[b]	15
MTH2	534 (268)	183 (35)	190 (58)	55.5 (18.9)	9	58.8 (20.2)	9
Lateral MTHs	465 (241)	153 (28)	145 (44)	77.4 (25.4)	13	86.3 (28.3)[b]	14
Hallux	485 (383)	201 (83)	197 (91)	30.3 (11.8)	5	32.7 (12.6)	5
Toe2	156 (161)	130 (54)	110 (38)	14.2 (5.3)	2	15.0 (5.1)	2
Lateral toes	140 (103)	120 (47)	96 (42)[b]	18.4 (10.5)	3	15.7 (10.6)	3
Total				607.9 (147.6)		622.3 (154.8)	

[a] Percentage of total FTI.
[b] Significantly different from CMI ($P < 0.05$).

Table 2
Distribution of 21 feet with MTH1 as RoI into "success" categories

		Force–time integral		
		Increased	Decreased	Unchanged
Peak pressure	Increased	0	1[c]	1[c]
	Decreased	0	7[a]	7[b]
	Unchanged	0	3[c]	2[c]

"Success" was based on the statistical effect of the CMIs on MTH1 PP and FTI when compared with the flat insoles.
[a] Successful.
[b] Moderately successful.
[c] Failures.

changes in the medial midfoot and MTH1 was not significant ($r = -0.31$, $P = 0.17$).

3.3. Load transfer algorithm

The LTA revealed that the largest mean load transfer achieved by the CMIs occurred between the lateral heel and medial midfoot (Fig. 3). This was 3.3% of the total load and 15.6% of the lateral heel load applied to the flat insoles. Load transfer between MTH1 and medial midfoot was on average 7.8 N.s and amounted to 1.2% of the total load and 8.6% of the MTH1 regional load. The total amount of load (mean (SD)) transferred due to the CMI action was 59.4 (23.7) N.s or 9.4% of the total applied load in the flat insole condition.

3.4. Case studies

A case in which the CMI was highly successful in achieving pressure relief and load redistribution is shown in Fig. 4A. The patient was a 60-year-old man (1.87 m, 119 kg). He had a long history of neuropathic ulcers at multiple sites on both feet. He had experienced prior ulcers at MTH1 on the right foot. Acquired foot deformities included a clawed fourth toe, HAV and LJM. Barefoot PP at MTH1 was 1058 kPa. In-shoe PP at this site was significantly lower with the CMI than the flat insole (mean 278 kPa vs. 441 kPa) and FTI was also significantly lower, by 24.6 N.s or 25%. Nearly all load transferred from MTH1 was directed towards the medial midfoot. This load equalled 3.8% and 22.7% of the total load and regional MTH1 load, respectively. Moreover, this transfer contributed most to the load increase in the midfoot region (57% of 40.6 N.s).

An example of a failure in the mechanical action of the CMI in shown in Fig. 4B. This profile is from a 64-year-old man (1.82 m, 90 kg) with a history of ulceration on the second toe of the left foot and several acquired deformities (LJM, clawed third toe, prominent first to fifth MTHs, and HAV). His barefoot PP at MTH1 was 957 kPa. In-shoe PP was 231 kPa in the flat insole and 216 kPa in the CMI, which was not significantly different. The FTI at MTH1 was larger by 0.5 N.s in the CMI (not significant). A net load transfer of only 0.1 N.s occurred between MTH1 and the medial midfoot, whereas much larger transfers occurred from the lateral heel and lateral MTHs to the medial midfoot.

4. Discussion

This study has shown that, on average, this type of CMI, intended for at-risk neuropathic feet, can reduce PP and FTI at MTH1 by 16% and 8%, respectively,

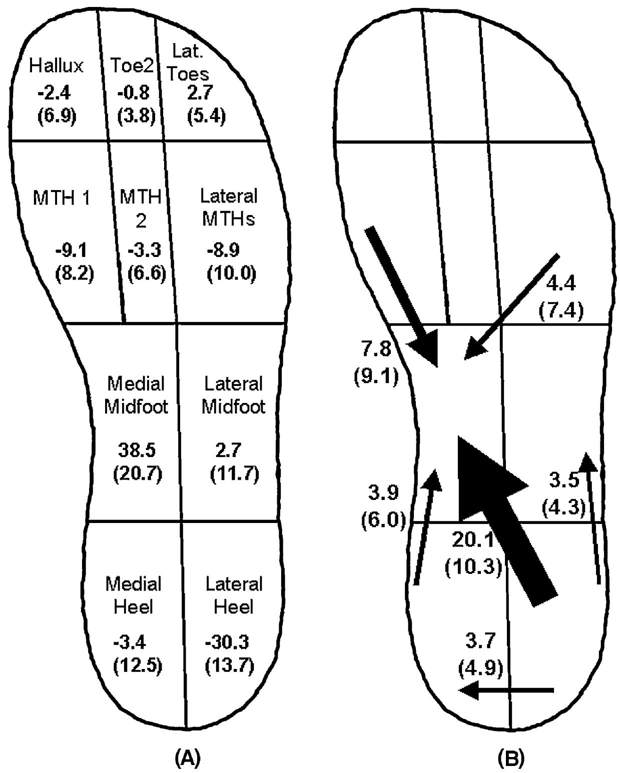

Fig. 3. Mean (SD) regional differences in normalised FTI (in N.s) between the CMIs and flat insoles for all 21 feet with MTH1 as RoI are shown in (A). Mean (SD) inter-regional load transfer (in N.s) due to the action of the CMIs when compared with the flat insoles is shown in (B). The breadth of the arrows is proportional to the absolute amount of load transfer. Load transfers <3.0 N.s are discarded. Note that the load transfer shown in (B) is not a direct result from the application of the LTA to (A), but the average of inter-regional load transfers that were calculated in each individual foot.

compared with a thick, flat, over-the-counter cushioned insole. It remains to be demonstrated whether or not such alterations are sufficient to reduce tissue loading at this site below the threshold for injury. Neither is the relative importance of reductions in PP or FTI for prevention of tissue injury established. These results show a lower therapeutic effect than that reported by Lord and Hosein (1994), who found a reduction of 34% in PP under MTH1 in six diabetic patients wearing moulded inserts. Novick et al. (1993) found a 78% reduction in PP at this site in healthy subjects wearing CMIs. Others, however, found no significant changes in PP (Ashry et al., 1997; Brown et al., 1996; Postema et al., 1998) and FTI (Postema et al., 1998) at this location. These discrepant results are likely related to the use of different insoles, subjects, and experimental procedures, which makes these studies difficult to compare.

Although use of CMIs produced a significant overall reduction in PP and FTI at MTH1, an important finding of this study was that 7 of 21 insoles designed by an experienced orthopaedic shoemaker were not successful in off-loading the foot at MTH1 compared with a simple over-the-counter flat insole. It should be recalled that, in an effort to model the delivery of footwear to a remote location, the orthopaedic shoemaker did not actually examine the subjects in the study, but built the insoles based on an examination of barefoot plantar pressures, footprints, and foot outline data. A subjective analysis of the demographic data, the type of acquired foot deformity, and MTH1 barefoot PP, together with observations of the shape and structure of the CMIs, could not discriminate between successful cases and failures. It is possible that more information (such as three-dimensional foot shape, internal foot architecture, and gait characteristics) and/or a more systematic analysis may be required for finding the individual determinants of successful off-loading and thus for prescription footwear to be effective. The above results suggest that the effectiveness of a CMI should be measured, where possible, with in-shoe pressure devices to ensure efficacy before it is dispensed to the patient.

A low and non-significant correlation was found between change in PP and FTI at MTH1 ($r = 0.06$). Several methodological factors may have played a role in this outcome. First, PP is obtained from a *single* sensor in the region, whereas FTI is measured over the *whole* region and, as such, is also dependent on contact area and time. In addition, dividing the foot into 10 major anatomical regions may have obscured significant effects of the CMI *within* the boundaries of a region, for example, in MTH1, where intra-regional pressure redistribution would have reduced PP but kept FTI unchanged. Distal parts of the medial arch support may have been included in the MTH1 mask, which likely affected regional FTI to a greater extent than PP.

In each of the 21 analysed feet, the medial arch support proved to be highly effective in transferring load from adjacent regions to the medial midfoot. It was responsible for a 31% increase in PP and a 144% increase in FTI in the medial midfoot when compared with the flat insole. This region accounted for 4% of the total FTI with flat insoles, but for 11% with CMIs (Table 1). The LTA showed that the four largest inter-regional load transfers occurring within the foot were directed towards the medial midfoot (Fig. 3). It is likely that increases in contact area and contact time in this region contributed to the large increase in load and, presumably, explained why this increase was larger than the increase in PP. Although neuropathic plantar ulcers due to repetitive stress are rarely found in the midfoot, avoiding a large increase in PP at the medial midfoot is important so as to avoid any localised damage to the soft tissue of the medial arch, which is not well adapted for weight bearing. Brown et al. (1996) also found increased midfoot PPs in 10 healthy subjects wearing CMIs or arch supports inside an extra-depth shoe. Novick et al. (1993) found midfoot PP to be increased by 114% in CMIs when compared with flat insoles in

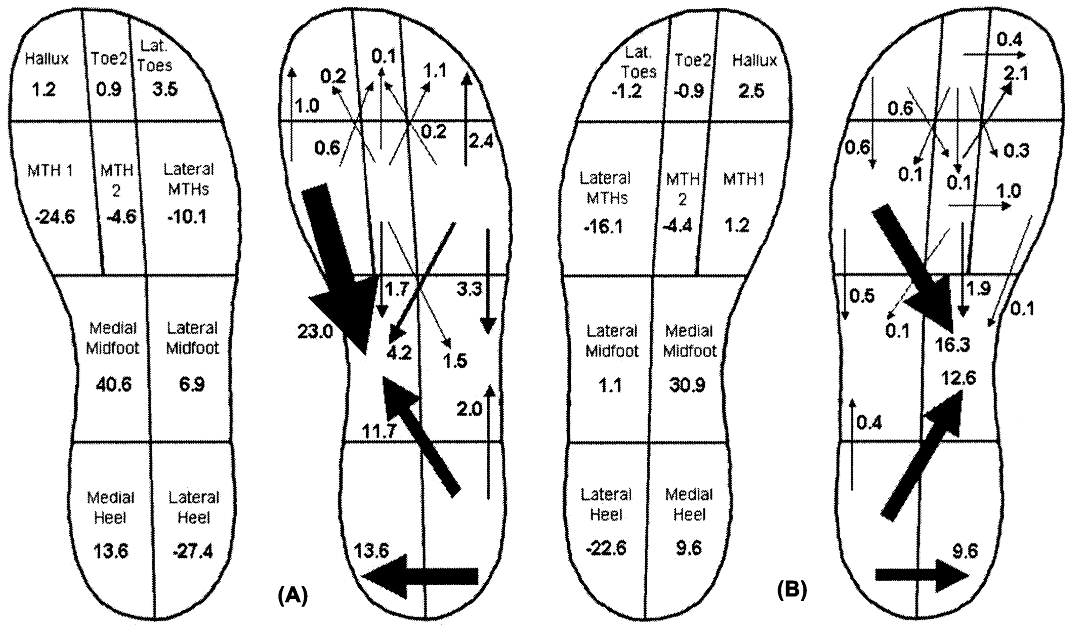

Fig. 4. Two case studies in which the CMI was successful (A) and not successful (B) in transferring load from MTH1 to other foot region. The regional differences in normalised FTI (in N.s) between the CMI and flat insole are shown in the left side of each pair and the resulting inter-regional load transfer values in the right side of each pair. The breadth of the arrows is proportional to the absolute amount of load transfer.

10 healthy participants. These results suggest that a medial arch support should be a consistent feature in the design and fabrication of CMIs for diabetic neuropathic patients with foot deformity.

The CMIs were also very effective in the heel region. PP decreased substantially in both medial and lateral heel regions in comparison to the flat insoles, and FTI decreased significantly in the lateral heel (Table 1). In the medial heel, pressure may have been redistributed within the boundaries of the region by the arch support, which almost certainly extended into the medial heel mask in some cases. Thus the medial heel FTI was unchanged. The decrease in PP and FTI in the heel is most likely caused by two mechanisms: pressure redistribution through the effect of the medial arch support and bilateral cupping of the heel. The LTA calculations clearly demonstrate that load was transferred away from the lateral heel to the medial midfoot (Fig. 3). Heel cupping is established by moulding the insole around and up the periphery of the heel. The soft tissue of the heel pad is presumably maintained by the CMI in position underneath the bony prominences of the calcaneus, whereas it is displaced in a flat insole. Brown et al. (1996), in healthy subjects wearing CMIs, and Albert and Rinoie (1994), in diabetic patients using custom-made medial arch orthotics, also showed significantly reduced heel PPs. Novick et al. (1993) and Ashry et al. (1997), however, did not find significant effects of CMIs on PP in the heel. Potential differences in size of the medial arch support and/or degree of heel cupping may explain these opposing results.

4.1. Load transfer algorithm

Most investigations that study the mechanical behaviour of CMIs or custom orthoses simply draw conclusions on the pressure-redistributing effect of these interventions based on changes in PP in one or two adjacent regions in the foot. Postema et al. (1998) raised the complexity of the analysis by examining changes in FTI in selected regions of the forefoot. However, when FTI is measured over the *entire* surface of the foot, the principle that load decrease in one region automatically results in load increase in another can be used to determine, by altered load distribution, the mechanism by which CMIs work. The LTA was developed with this principle in mind.

As the analysis shows, the largest transfer of load was established between the heel and midfoot regions. A high and significant correlation between load loss and gain in these regions ($r = -0.80$) confirms this association. Presumably, this strong relationship also explains the low and non-significant correlation found between load decrease in MTH1 and load increase in the medial midfoot ($r = -0.31$); the large change in midfoot loading is a result of off-loading the heel, not the forefoot. Thus, the dominant effect of the CMIs was expressed in regions that are less at risk for plantar ulceration. The lower absolute values and large inter-subject variability in MTH1 to medial midfoot load transfer (Figs. 3 and 4) demonstrates the inconsistency in successful off-loading of MTH1 by the CMIs used in this experiment. It should be kept in mind that the load transfer patterns reported here apply specifically to the conditions and subjects tested in this study and are examples of the range of possibilities. A different set of patterns could have been obtained had a different orthotist produced insoles for a different set of feet.

5. Conclusions

This study provides a perspective on alterations in the loading of the feet in a group of patients with diabetic neuropathy and foot deformity who were using CMIs. On average, the CMIs significantly reduced PPs and FTIs in MTH1 (RoI) when compared with flat insoles, but their mechanical effects were much larger in more proximal regions of the foot, which are less at risk for plantar ulceration. In particular, dramatic pressure reductions were achieved in the heel as a result of load redistribution by the highly effective action of the medial arch support and, presumably, by cupping of the heel. These effects were very consistent across subjects. Despite significant group results at MTH1, the CMIs were variable in their pressure-relieving and load-redistributing effect on an individual level, and no improvement compared with flat, over-the-counter insoles was achieved at this target site in seven of the 21 analysed feet.

These results suggest, as have several prior studies, that based on present knowledge, whether derived from information on barefoot plantar pressure and foot outline alone or from a negative or positive cast from the patient's foot, experts cannot predictably make efficacious customised devices. Although this statement is based only on measured off-loading, high re-ulceration rates in specialty clinics are consistent with this statement as well. We therefore conclude that the effects of CMIs must be thoroughly and systematically examined before we can confidently prescribe such insoles to diabetic neuropathic patients with foot deformity. We suggest that clinicians need to evaluate measurements of in-shoe plantar pressures, including load redistribution patterns (obtained by using a method such as the LTA), to prescribe effective CMIs.

Acknowledgements

The authors thank Mary Becker, RN, for her contributions in subject recruitment and screening, data collection and data analysis. This work was supported by NIH grant HD037433 and by ConvaTec, Inc. Jan Ulbrecht and Peter Cavanagh are principals in DIApedia LLC (State College, PA, USA), a company that performs research and development in the area of diabetic foot disease.

Appendix A. Load transfer algorithm

The FTI values in the flat insoles were first normalised to those in the CMIs to account for small discrepancies (average 3.8%, maximum 7.4%) in total foot FTI between the flat insoles and CMIs. Normalisation was achieved by multiplying all regional FTI values in the flat insoles by the ratio of the total FTI in the CMIs and flat insoles.

Because there is not a unique solution to the calculation of load transfer between anatomical regions in the foot when comparing a CMI with a flat insole, a set of "rules" for the calculation were formulated:

Rule 1. The foot is divided into three levels: heel (level 1), midfoot (level 2), and forefoot (MTHs and toes, level 3). Load transfer calculation starts in the heel, followed by the forefoot regions in order of decreasing load gain and, finally, by the midfoot.

Rule 2. Load transfer can occur between adjacent anatomical regions only.

Rule 3. Transfer to one or more adjacent regions of opposite polarity (load gained or lost) is proportional to the amount lost or gained.

Rule 4. Load is evenly distributed over adjacent regions in the neighbouring level, in case none of the adjacent regions are of opposite polarity as the principal region.

Rule 5. When the amount of load lost in adjacent regions is not sufficient to completely solve the principal region, this amount is transferred and calculation should continue with the next region.

Rule 6. To balance the solution at the end of the calculation process, regions with residual loads are solved (in order of decreasing load gain) by transferring load along the shortest route from non-adjacent regions.

The application of these LTA rules is presented in Fig. 5A–D for one complex example in the study, chosen because all rules had to be applied to solve the problem. First, the heel is solved (*Rule 1*). The only adjacent region of opposite polarity to the two heel regions is the medial midfoot (*Rule 2*, Fig. 5A). The total load that needs to be transferred from the heel ($20.7 + 15.1 = 35.8$ N.s) exceeds the load gain in the medial midfoot (26.2 N.s). By proportion (*Rule 3*), 20.7/35.8 ($= 58\%$) of the load in the medial midfoot ($= 15.1$ N.s) will be transferred from the lateral heel, and the rest from the medial heel ($26.2–15.1 = 11.1$ N.s, solid arrows in Fig. 5B). The remaining load in the lateral and medial heel regions is now -5.6 and -4.0 N.s, respectively. Because the midfoot regions now have a polarity that is not opposite to that of the heel regions (i.e., load lost),

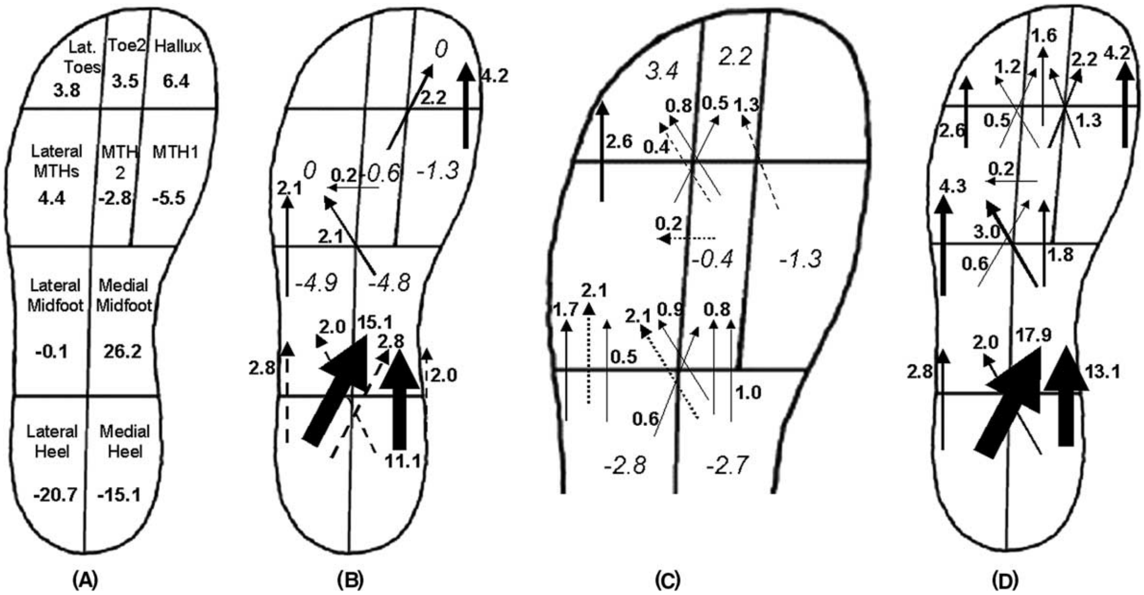

Fig. 5. The load transfer algorithm (LTA) explained using one complex example in the study. (A) Regional differences in FTI between the flat insole and CMI. (B) Inter-regional load transfer solving the two heel regions, the hallux and lateral MTHs. The large-font italic style numbers indicate loads remaining after the hallux region was solved. (C) Inter-regional load transfer solving all forefoot and midfoot regions. The large-font italic style numbers are remaining loads before the residuals were solved. (D) Final load transfer diagram in which the breadth of the arrows reflects the amount of load transferred.

these remaining loads are evenly distributed over the midfoot regions (*Rule 4*). Thus 2.8 N.s from the lateral heel and 2.0 N.s from the medial heel are transferred to both midfoot regions (dashed arrows in Fig. 5B).

In the forefoot, the hallux region has the largest load gain and is therefore solved first (*Rule 1*). Proportional to the amount of load lost in the adjacent MTH1 and MTH2 regions (*Rule 3*), 66% of the load gained in the hallux is transferred from MTH1 (4.2 N.s) and 34% from MTH2 (2.2 N.s). The remaining loads in MTH1 and MTH2 are now −1.3 and −0.6 N.s, respectively (Fig. 5B). The lateral MTHs, the next largest load-gaining region in the forefoot, is solved by proportionate load transfer from MTH2, and the medial and lateral midfoot (*Rule 3*).

After solving this region, the remaining load lost in MTH2 (−0.4 N.s) is not large enough to completely solve the lateral toes region (dashed arrow in Fig. 5C). According to *Rule 5*, after having transferred these 0.4 N.s, we continue with the next load-gaining region, which is Toe2. MTH1 is the only adjacent region with opposite polarity, but again the load lost in MTH1 (−1.3 N.s) is not large enough to completely solve Toe2 (dashed arrow in Fig. 5C).

Both Toe2 and lateral toes regions are solved by transfer of residual loads in the non-adjacent midfoot regions (*Rule 6*, solid arrows in Fig. 5C). This is done in order of decreasing load gain (the lateral toes are therefore considered first) and along the shortest route. The remaining loads in the two midfoot regions are approximately equal (−2.8 and −2.7 N.s). Therefore, half of the 3.4 N.s in the lateral toes is transferred from the lateral midfoot via the lateral MTH region, whereas the other 1.7 N.s is transferred from the medial midfoot, via MTH2 and the lateral MTHs region (0.8 and 0.9 N.s). In the same manner, Toe2 is solved. The final result is a load transfer diagram (Fig. 5D) in which the breadth of the arrows reflects the amount of inter-regional load transferred.

References

Albert, S., Rinoie, C., 1994. Effect of custom orthotics on plantar pressure distribution in the pronated diabetic foot. J. Foot Ankle Surg. 33, 598–604.

Ashry, H.R., Lavery, L.A., Murdoch, D.P., Frolich, M., Lavery, D.C., 1997. Effectiveness of diabetic insoles to reduce foot pressures. J. Foot Ankle Surg. 36, 268–271.

Boulton, A.J., Hardisty, C.A., Betts, R.P., Franks, C.I., Worth, R.C., Ward, J.D., Duckworth, T., 1983. Dynamic foot pressure and other studies as diagnostic and management aids in diabetic neuropathy. Diabetes Care 6, 26–33.

Bowker, P., Condie, D.N., Bader, D.L., Pratt, D.J., 1993. Biomechanical Basis of Orthotic Management. Butterworth-Heinemann, Oxford, UK.

Brown, M., Rudicel, S., Esquenazi, A., 1996. Measurement of dynamic pressures at the shoe–foot interface during normal walking with various foot orthoses using the FSCAN system. Foot Ankle Int. 17, 152–156.

Cavanagh, P.R., Rodgers, M.M., Iiboshi, A., 1987. Pressure distribution under symptom-free feet during barefoot standing. Foot Ankle 7, 262–276.

Cavanagh, P.R., Ulbrecht, J.S., Caputo, G.M., 2001. The biomechanics of the foot in diabetes mellitus. In: Bowker, J.H., Pfeifer, M.A.

(Eds.), Levin and O'Neal's The Diabetic Foot, sixth ed. Mosby, Inc., St. Louis, MO, pp. 125–196.

Hewitt, F.G., Ulbrecht, J.S., Becker, M.B., Derr, J.A., Cavanagh, P.R., 1993. The effect of molded insoles on in-shoe plantar pressures in rockered footwear. Diabetes 42, 194A.

Janisse, D.J., 1995. Prescription insoles and footwear. Clin. Podiatr. Med. Surg. 12, 41–61.

Lord, M., Hosein, R., 1994. Pressure redistribution by molded inserts in diabetic footwear: a pilot study. J. Rehabil. Res. Dev. 31, 214–221.

Novick, A., Stone, J., Birke, J.A., Brasseaux, D.M., Broussard, J.B., Hoard, A.S., Hawkins, E.S., 1993. Reduction of plantar pressure with the rigid relief orthosis. J. Am. Podiatr. Med. Assoc. 83, 115–122.

Postema, K., Burm, P.E., Zande, M.E., Limbeek, J., 1998. Primary metatarsalgia: the influence of a custom moulded insole and a rockerbar on plantar pressure. Prosthet. Orthot. Int. 22, 35–44.

Uccioli, L., Toffolo, M., Volpe, A., Pasqualitto, P., Ferri, A., Monticone, G., Menzinger, G., 1997. Efficacy of different shoes and insoles in reducing plantar pressures in diabetic neuropathic patients. Diabetologia 40, A-489.

Veves, A., Murray, H.J., Young, M.J., Boulton, A.J., 1992. The risk of foot ulceration in diabetic patients with high foot pressure: a prospective study. Diabetologia 35, 660–663.