

PRESSURE RELIEF AND LOAD REDISTRIBUTION BY A CUSTOM MOLDED INSOLE

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INTRODUCTION

Custom molded insoles (CMI) are routinely used in the care of diabetic patients with neuropathy. CMI are thought to relieve plantar pressures in regions 'at risk' for (re)ulceration by redistributing load to other regions of the foot. However, little quantitative evidence is available on the efficacy of CMI in achieving these goals. Therefore, the purpose of this study was to investigate the effect on pressure relief and load distribution of a CMI compared with a flat compliant insole in neuropathic diabetic patients with acquired foot deformity.

METHODS

Twenty diabetic patients (13 male, 7 female) with neuropathy and some degree of foot deformity participated in the study. Mean (\pm SD) age, height, and body mass was 64.4 ± 11.2 years, 1.73 ± 0.10 m, and 99.5 ± 15.7 kg, respectively. Using a first step approach, dynamic barefoot plantar pressures from each subject were recorded at 70 Hz with the Novel EMED-SF pressure platform. In-shoe plantar pressures from subjects wearing flat and custom molded insoles (Figure 1) were measured at 50 Hz with 99 element pressure sensing insoles (Novel PEDAR) that were placed between the sock and the insole of the shoe. A correction was made for sensor element size to allow barefoot and in-shoe pressure values to be compared. Approximately 30 mid-gait steps per foot per condition were collected as subjects walked at a preferred, and in subsequent

trials, controlled walking speed along a 10m walkway.



Figure 1. Flat and custom molded insole

All pressure data were analyzed with Novel Win, Ortho or Pedar Mobile software. The foot was divided into 10 anatomical regions as described by Cavanagh et al. (1987). For each region, mean (\pm SD) peak pressure (PP) and force-time integral (FTI) were calculated.

A sub-group of 21 feet was selected in which the first metatarsal head (MTH1) was the region of interest (ROI) based on either high barefoot pressure (>700 kPa) or prior plantar ulceration at this site. A comparative regional analysis of PP and FTI between the two insoles was performed for these 21 feet by analysis of variance, ($p < 0.01$). Load redistribution by the CMI compared to the flat insole was assessed using a new Load Transfer Algorithm (LTA) which, based on a series of assumptions, allows the direction and magnitude of inter-regional transfer of load within the foot to be determined. Since a metatarsal pad (MT) was incorporated into many of the CMIs a secondary analysis explored pressure relief and load distribution by metatarsal pads.

RESULTS

In-shoe PP was lower than barefoot pressure in all regions except the medial midfoot, 2nd toe and lateral toes regions (Table 1). Comparing insoles, PP and FTI were significantly decreased by the CMI in the lateral heel and 1st MTH and increased in the medial midfoot region. PP alone was significantly decreased in the medial heel and increased at the 2nd and lateral toes. FTI alone was significantly decreased at the lateral MTHs.

Table 1. Mean values for barefoot PP and in-shoe PP and FTI for all 21 feet with MTH1 as a region of interest in flat and CMI conditions.

Region	PP (kPa)			FTI (Ns)	
	Bare	CMI	Flat	CMI	Flat
Med. heel	409	236	305 ^a	87	88
Lat. heel	323	236	311 ^a	101	129 ^a
Med. midf.	72	131	101 ^a	65	26 ^a
Lat. Midf.	162	133	123	76	72
1 st MTH	892	314	373 ^a	83	90 ^a
2 nd MTH	522	228	240	55	57
Lat. MTHs	454	189	186	77	85 ^a
Hallux	477	303	297	30	32
2 nd toe	150	195	169 ^a	14	15
Lat. Toes	133	176	142 ^a	18	16

^a significantly different from CMI ($p < 0.01$)

Individual analysis indicated that in 6 of the 21 feet, the CMI was successful in significantly reducing both PP and FTI at the 1st MTH when compared to the flat insole. In another 9 feet, either PP *or* FTI at MTH1 was significantly lower in CMI and this was considered moderately successful. In the remaining 6 feet, either PP or FTI were increased or unchanged in CMI and thus the intervention could not be considered to be successful.

The LTA revealed a large load transfer from the lateral heel region to the medial midfoot and a smaller transfer from the 1st MTH to the same midfoot region (Figure 2).

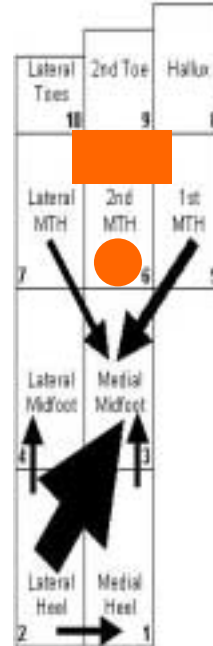


Figure 2. Load transfer (LT) between selected regions of interest (Size of arrow = amount of LT, values < 3.0 Ns are discarded).

Table 2. Inter-regional LT (in absolute, % of Total load, and % of Regional load values)

Region	Ns	% T	% R
R2-R3	20.3 ± 10.3	3.3	15.8
R5-R3	7.0 ± 8.4	1.1	7.8
R7-R3	4.8 ± 7.2	0.8	5.4
R1-R3	3.9 ± 6.0	0.6	2.6
R2-R1	3.7 ± 4.9	0.6	4.5
R2-R4	3.5 ± 4.3	0.6	3.1

At the location of the MT pad (● in figure 2), PP and FTI were significantly increased in 11 out of 14 feet analyzed when compared to the flat insole. At the effective area (■ in figure 2), load was decreased in all feet and PP in 9 feet.

DISCUSSION

Peak pressure and/or load at MTH1 were significantly reduced in 15/21 feet examined. These results demonstrate that an individual approach is required to the prescription and analysis of a CMI in a diabetic patient with neuropathy and acquired foot deformity. The data also show that 'cupping' of the heel in the CMI significantly reduced pressure and load in the lateral heel. The Load Transfer Algorithm offers a unique way to examine the mechanism of altered load distribution by a CMI.

REFERENCES

Cavanagh, P.R., Rodgers, M.M., Iiboshi, A. (1987). *Foot and Ankle*, 7, 262-276.

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