TalarMade™

Made with clinical excellence in mind

FOOTSHIELD II

Clinical Evidence

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Contents:

Contact Us:

Edinburgh House
Millenium Way
Chesterfield
Derbyshire
S41 8ND

01246 268 456

info@TalarMade.com

www.talarmade.com

Footshield II Testing

Background

Temporary footwear is often used in healthcare for the management of differing foot problems such as accommodation of dressings and deformity and to reduce/redistribute plantar foot pressures for feet considered "At-Risk".

TalarMade Ltd have designed and manufactured the Footshield II shoe to address this clinical requirement. Its design is based on a systematic review conducted by our Research & Development Team fronted by TalarMade's Clinical Director, to find the best evidence-based design for a shoe which reduces and redistributes plantar forefoot pressures. Following the development of this shoe, an independent systematic review and meta-analysis relating to sole shape/design was published by Professor Chris Nester (see appendix 1) which drew the same conclusions from our internal systematic review justifying the design of the Footshield II shoe.

Scrutiny of the published literature relating to the pressure reduction created by comparable products on the global healthcare market showed a surprising lack of evidence to support the widely held belief that temporary footwear reduces plantar foot pressures.

The purpose of this study is to compare the pressure relieving effects of the Footshield II shoe to competitor products, patients own footwear and barefoot pressures.

The null hypothesis for any temporary shoe is that temporary footwear will reduce plantar forefoot pressures in individuals in comparison to barefoot and their own footwear.
It is not yet clinically understood how much pressure needs to be reduced uniformly or locally around at risk area's to have a positive impact on pain or the healing response required for diabetic foot plantar ulceration.

Method

The testing was conducted at TalarMade Ltd Headquarters using volunteers without pathology.

Pressure measurements were taken with each subject walking at the same speed, for 10 seconds, on the Zebris instrumented treadmill.

This system has the benefit of allowing testers to view the raw and filtered results of multiple steps of data, rather than collecting data from one "targeted" foot strike on a fixed force plate rigidly fixed in the floor. At its most basic level, used in this small study, Zebris also measures interface pressure and Integral with extremely high granularity between thousands of sensors.

5 normal non-pathological volunteers walked at the calibrated speed (4.0Km/hr). They walked in bare feet (see appendix), in their own shoes and then in an example of a left shoe marketed as "healing shoes," "pressure reduction shoes" or those marketed as "offloading". Shoes were tested at random, chosen by the volunteer, with all markings/labelling being covered. The volunteers wore their own shoe on the right foot and the correctly sized test shoe on the left foot.

Testing was focussed on the 2nd and 3rd metatarsal heads since this is believed to be the prevalent area for which pressure reduction shoes are supplied in healthcare systems. But the data presented covers the whole plantar aspect of the foot and shoe. Two of the testing examples; non-disclosed shoes manufactured by global market leaders; were included as part of the testing group. The goal of this study was to investigate if the TalarMade Ltd Footshield II approximated or improved upon the functional characteristics already available around the world. Examples tested represent those presently available in the United Kingdom.

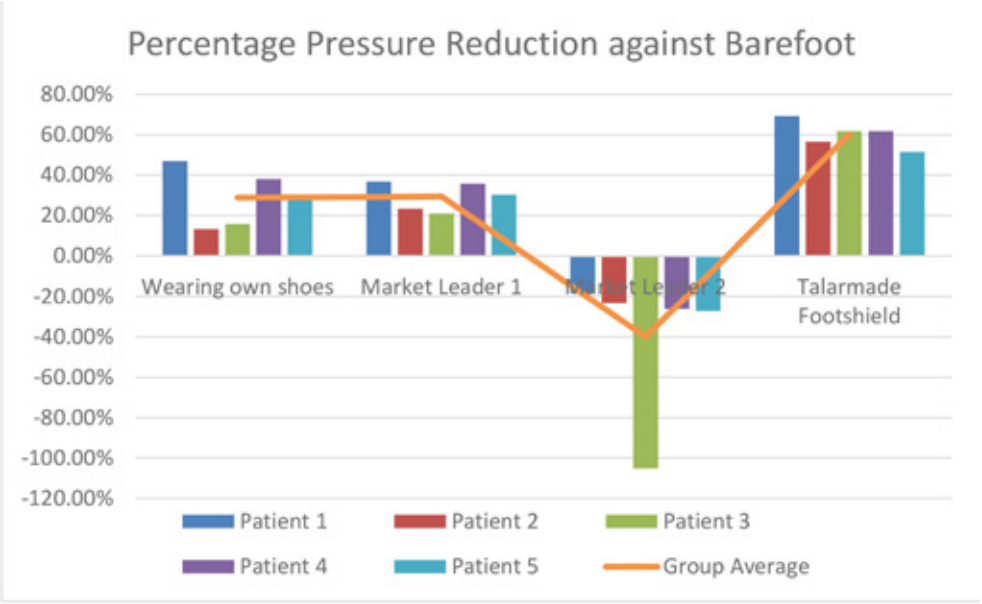
The data gathered was normalised to a common scale of pressure measurement 40 N/cm2 to improve visual clarity of presented result, ensuring no ostensible, conscious, unconscious, or other unintended bias was stimulated in the reader. This is the only data manipulation that was carried out as the base settings of the calibrated treadmill system (Zebris) were utilised otherwise.

Results

Significant differences were found between all test examples and between volunteers. These results are included below with the TalarMade Ltd Footshield II being labelled, here, as such and all others being anonymised. Further detail is also supplied withn the appendix.

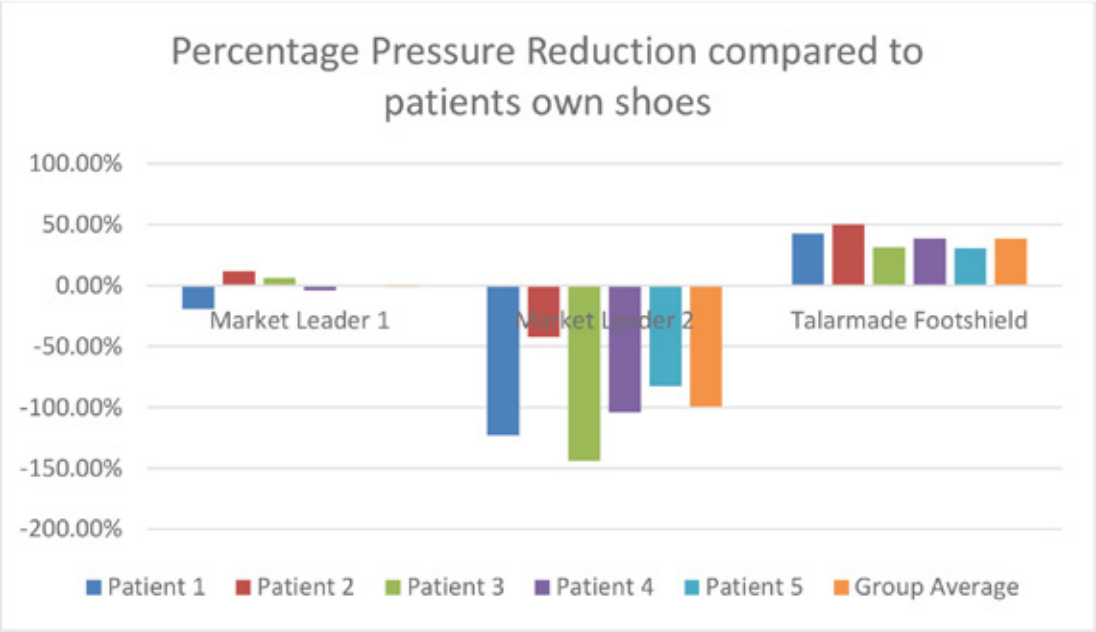
Pressure reduction against Barefoot Walking

Drops in pressure were significant in all shoes when compared to barefoot walking, except for the results obtained from Market Leader 2, which showed a marked percentage increase in pressure across all volunteers.



The TalarMade Footshield II signifiicantly outperformed all other conditions in the above test condition.

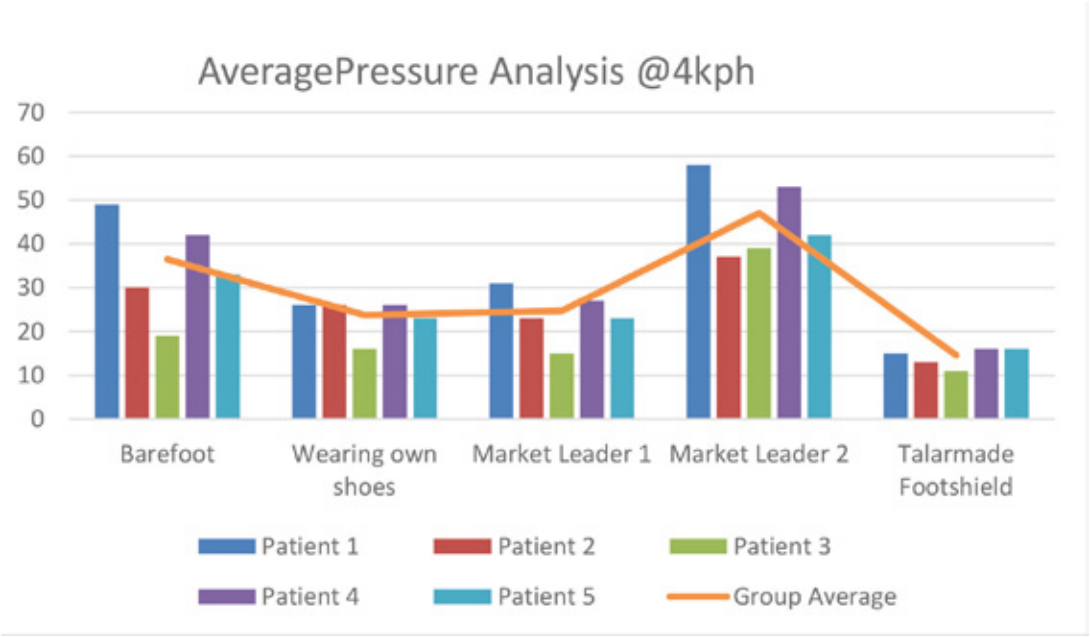
In all test conditions, bar one, drops in pressure were clearly shown in the pressure reduction shoes when compared to walking in Volunteers own shoes. Walking in their own shoes.



The TalarMade Footshield II signifiicantly outperformed all other products in the above test condition.

Average Pressure Analysis

Average pressure in all conditions is presented below, where less is considered to be more clinically effective. The highest pressures measured, in all testing conditions, was reported with Market Leader 2.



The TalarMade Footshield II signifiicantly outperformed all other products in the above test condition.

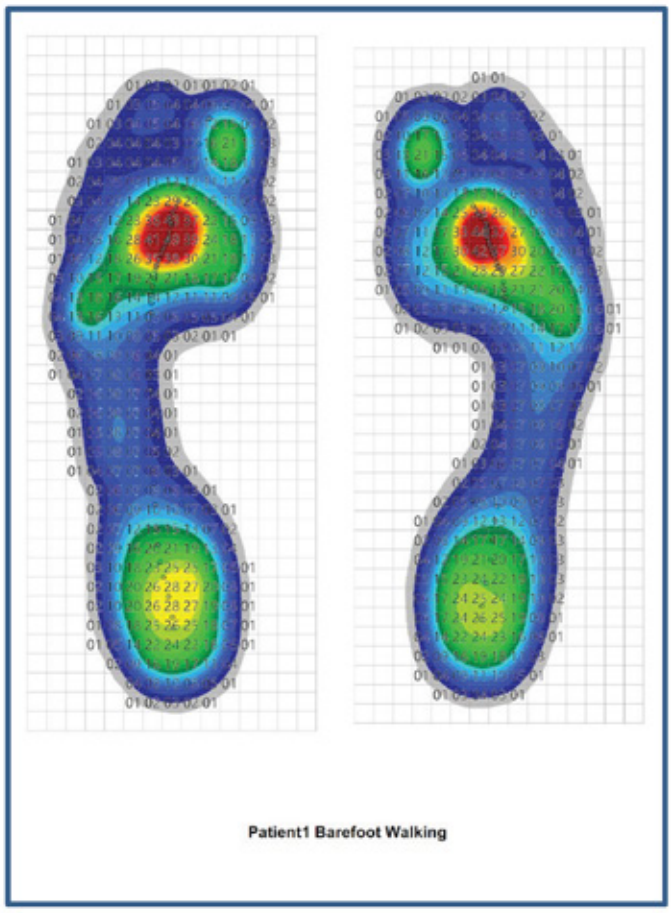
At a walking speed of 4.0Km/hr, the TalarMade Ltd Footshield II showed significant reductions in pressure which averaged out as 21.86N/cm2 less than initial testing in Barefoot walking, 13.14N/cm2 in own shoes. Comparison between Market Leader 1 and Footshield II showed a pressure reduction of 9.57N/cm2 and 32.43 N/cm2 less than Market Leader 2.

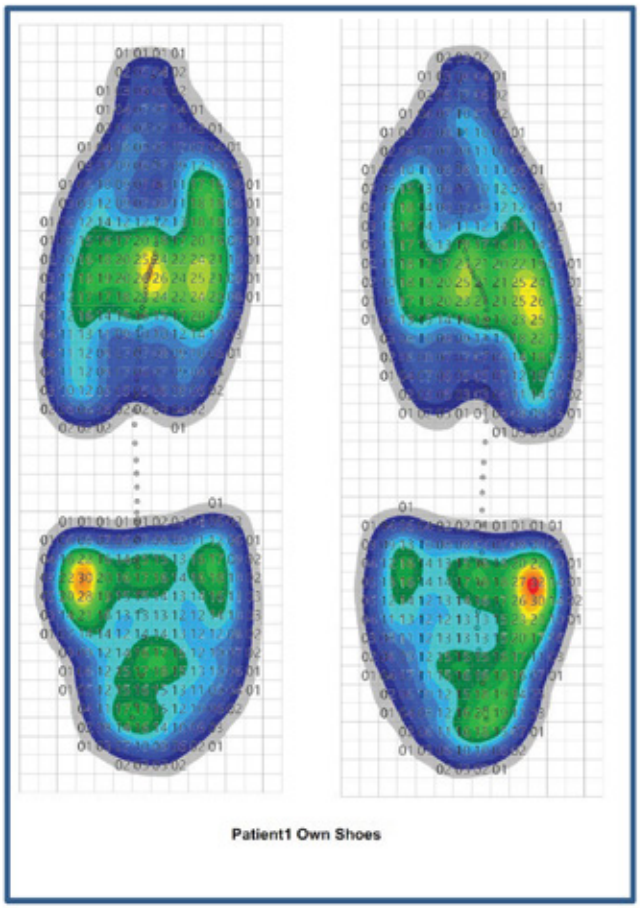
As our test results show the TalarMade Ltd Footshield II has been validated as being more effective at offloading pressure than all other tested examples available at the time of authoring this report.

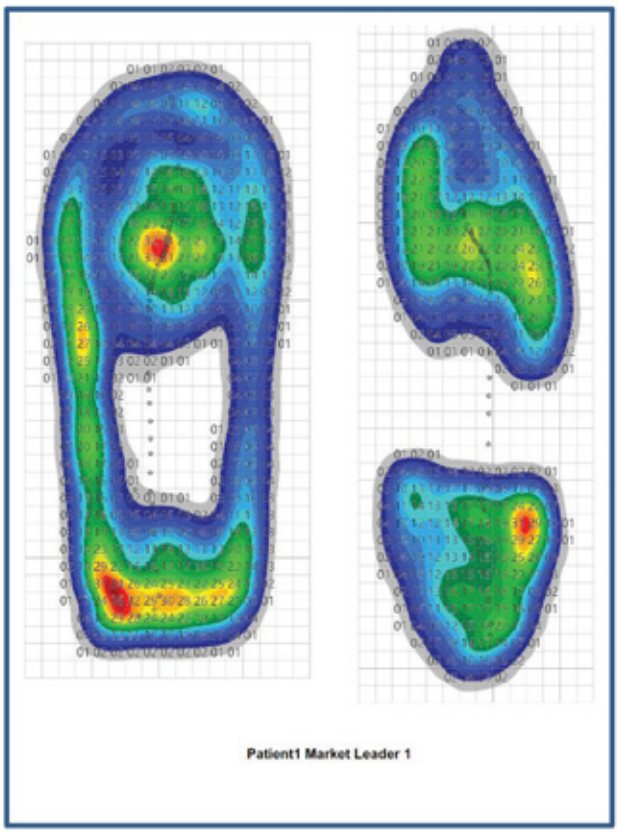
Appendix
The following pages contain a selection of representative and visualised data.

Patient 1 data as Pressure Averaged Maps
Patient 2 data as Pressure Averaged Maps
Independent Evidence
Spreadsheet Data

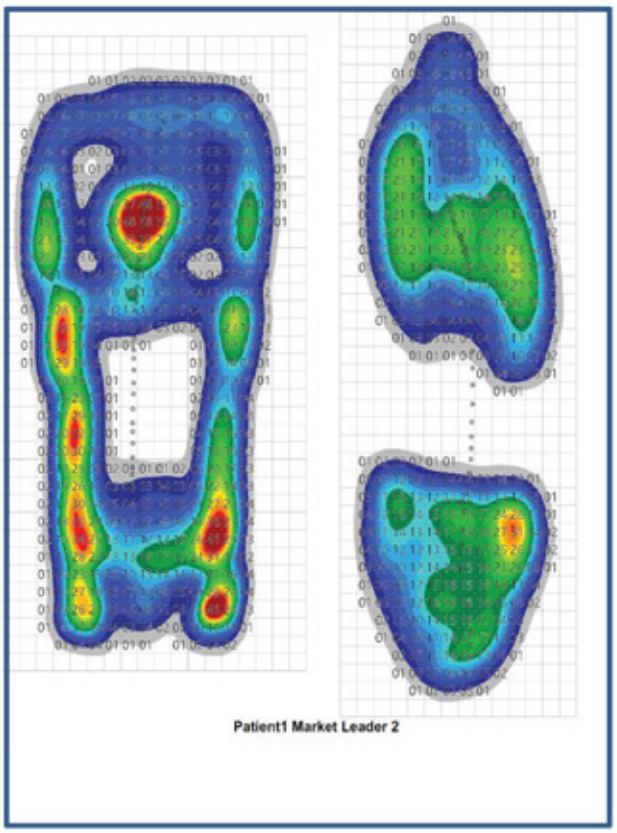
Patient 1 Pressure Maps


Patient1 Barefoot Walking

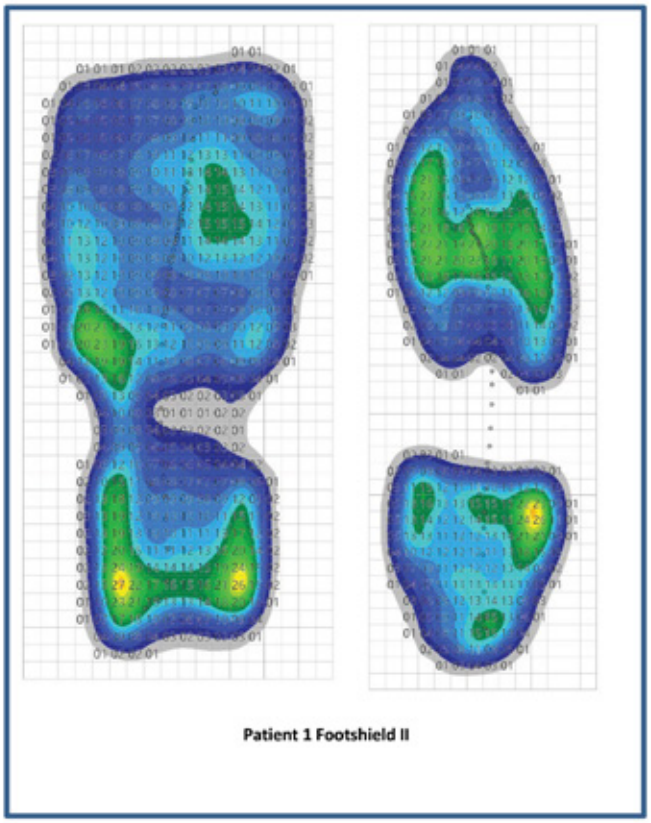

Patient1 Own Shoes



Patient1 Market Leader 1

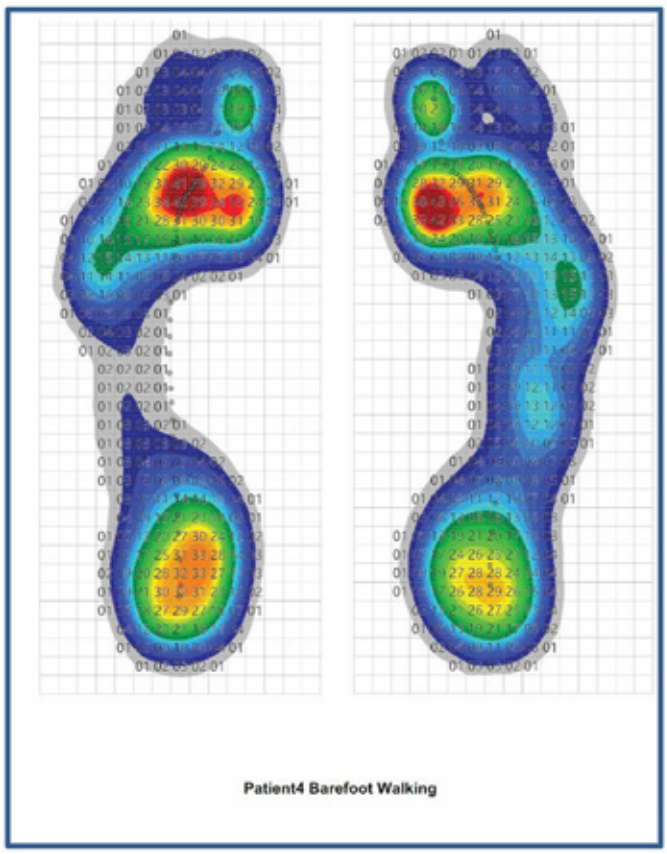


Patient1 Market Leader 2

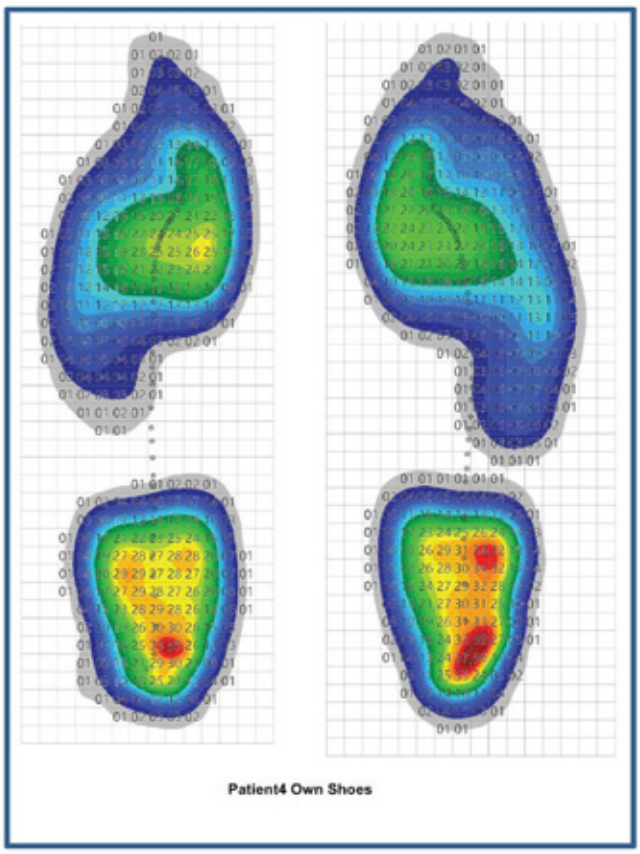


Patient 1 Footshield II

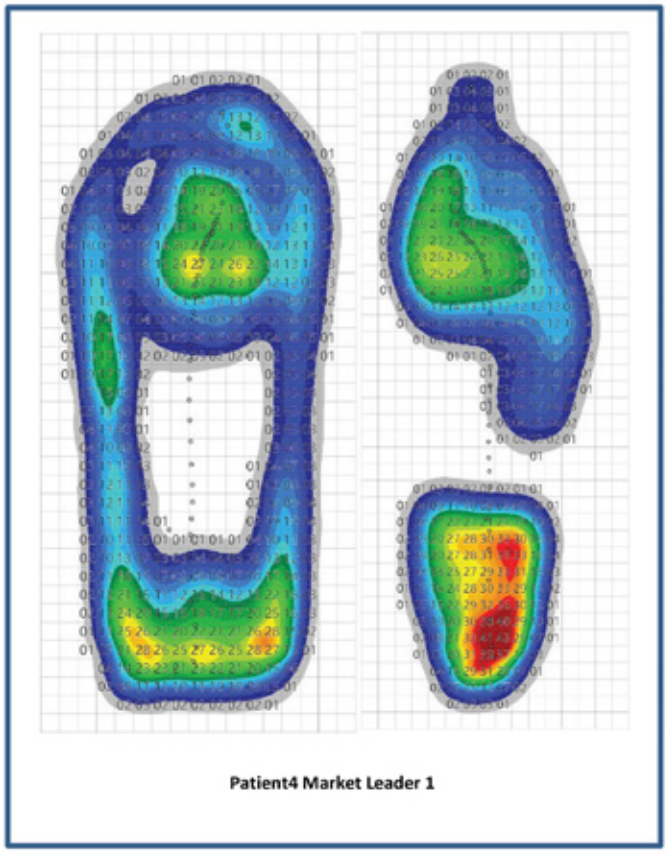
Patient 2 Pressure Maps



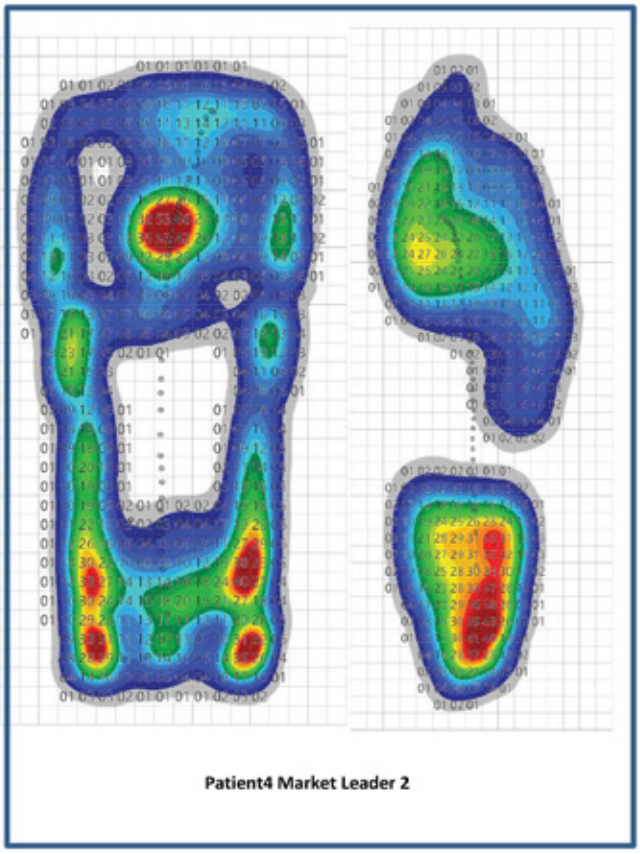
Patient4 Barefoot Walking



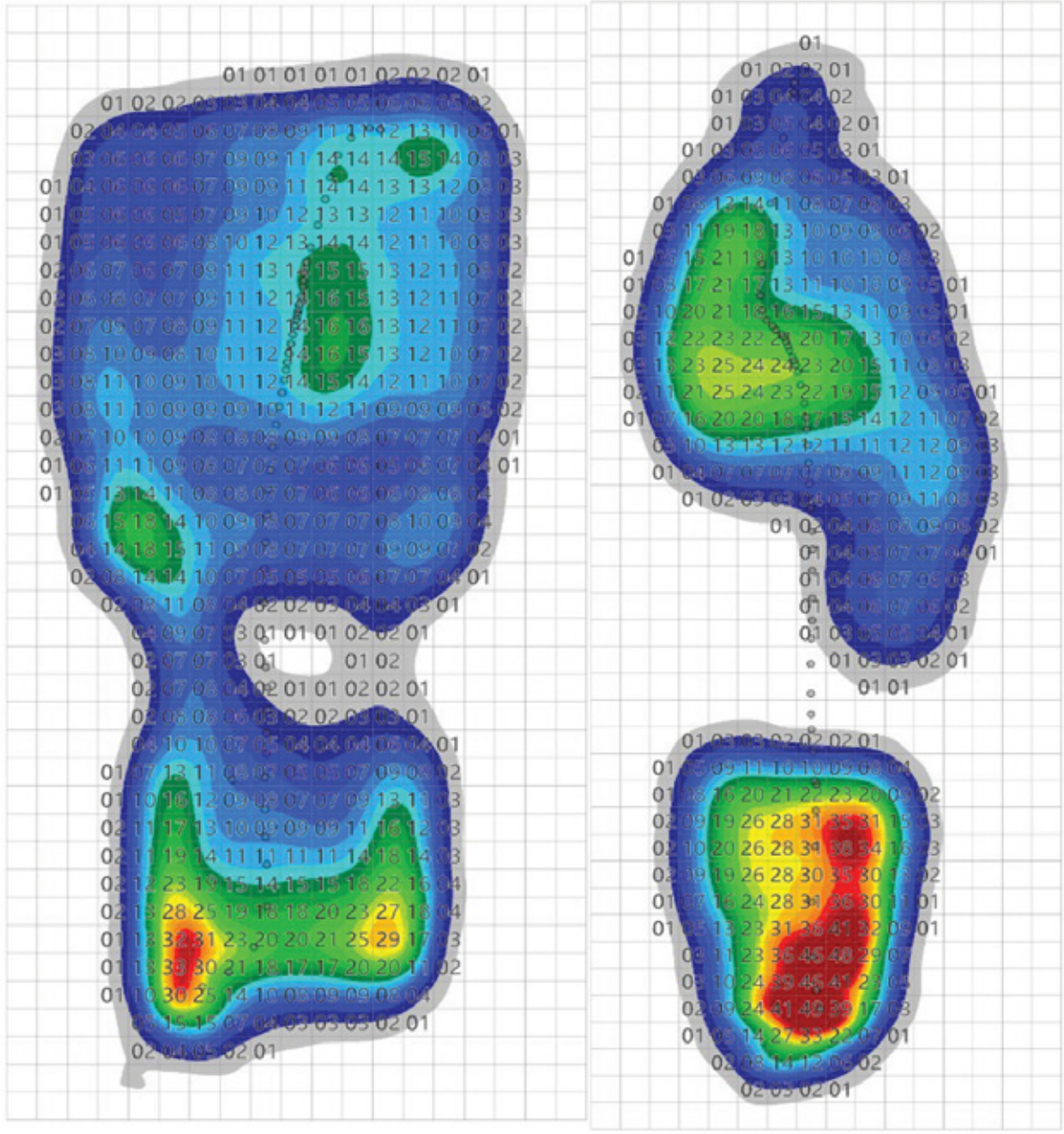
Patient4 Own Shoes



Patient4 Market Leader 1



Patient4 Market Leader 2



Patient4 Footshield II

Independent Evidence

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"Footshield II"

Effect of rocker shoe design features on forefoot plantar pressures in people with and without diabetes.

Chapman JD. Preece S. Braunstein B. Hohne A. Nester CJ. Brueggemann P. Hutchins S.
Ovid MEDLINE(R) 1946 to Present with Daily Update.

Clinical Biomechanics. 28(6):679-85, 2013 Jul.
(Controlled Clinical Trial. Journal Article. Research Support, Non-U.S. Gov't).
UI: 23731579

BACKGROUND:
There is no consensus on the precise rocker shoe outsole design that will optimally reduce plantar pressure in people with diabetes. This study aimed to understand how peak plantar pressure is influenced by systematically varying three design features which characterise a curved rocker shoe: apex angle, apex position and rocker angle.

METHODS:
A total of 12 different rocker shoe designs, spanning a range of each of the three design features, were tested in 24 people with diabetes and 24 healthy participants. Each subject also wore a flexible control shoe. Peak plantar pressure, in four anatomical regions, was recorded for each of the 13 shoes during walking at a controlled speed.

FINDINGS:
There were a number of significant main effects for each of the three design features, however, the precise effect of each feature varied between the different regions. The results demonstrated maximum pressure reduction in the 2nd-4th metatarsal regions (39%) but that lower rocker angles (<20˚ degree) and anterior apex positions (>60% shoe length) should be avoided for this region. The effect of apex angle was most pronounced in the 1st metatarsophalangeal region with a clear decrease in pressure as the apex angle was increased to 100˚ degree.

INTERPRETATION:
We suggest that an outsole design with a 90˚ degree apex angle, apex position at 60% of shoe length and 20˚ degree rocker ankle may achieve an optimal balance for offloading different regions of the forefoot. However, future studies incorporating additional design feature combinations, on high risk patients, are required to make definitive recommendations.

Spreadsheet Data

Raw 2nd/3rd Met Head data gathered by the Zebris System and averaged in Excel.
Full Spreadsheet available.

Average Pressure Readings N/cm²	Average Pressure Readings N/cm2	Average Pressure Readings N/cm2	Average Pressure Readings N/cm2	Average Pressure Readings N/cm2	Average Pressure Readings N/cm2	Average Pressure Readings N/cm2
Barefoot	49	30	19	42	33	36.42857
Wearing own shoes	26	26	16	26	23	23.71429
Market Leader 1	31	23	15	27	23	24.71429
Market Leader 2	58	37	39	53	42	47
TalarMade Footshield	15	13	11	16	16	14.57143

% reduction against barefoot	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Group Average
Wearing own shoes	46.94%	13.33%	15.79%	38.10%	30.30%	28.89%
Market Leader 1	36.73%	23.33%	21.05%	35.71%	30.30%	29.43%
Market Leader 2	-18.37%	-23.33%	-105.26%	-26.19%	-27.27%	-40.09%
TalarMade Footshield	69.39%	56.67%	61.90%	61.90%	51.52%	60.28%

% reduction against own footwear	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Group Average
Market Leader 1	-19.23%	11.54%	6.25%	-3.85%	0.00%	-1.06%
Market Leader 2	-123.08%	-42.31%	-143.75%	-103.85%	-82.61%	-99.12%
TalarMade Footshield	42.31%	50.00%	31.25%	38.46%	30.43%	38.49%

Footshield Pressure reduction % vs Market Leader 1	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Group Average
TalarMade Footshield	51.61%	43.48%	26.67%	40.74%	30.43%	38.59%
Footshield Pressure Reduction % vs Market Leader 2	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Group Average
TalarMade Footshield	74.14%	64.86%	71.79%	69.81%	61.90%	68.50%

We remain at your disposal should you require further information or wish to discuss anything in this submission.

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