



Evaluation of a Pixelated Innersole Designed to Offload Areas of Elevated Pressure on the Sole of At-Risk Feet.

James McGuire DPM, PT, LPed, FAPWHc, James Furmato DPM, PhD., Jesse Borys BS

Temple University School of Podiatric Medicine, Philadelphia, PA.



Background

The Total Contact Cast (TCC) has been recognized as the “gold standard” to treat diabetic foot ulcers due to its superior healing rate and ability to reduce pressures at the site of ulceration (1). Total contact casts have been shown to heal a higher proportion of DFUs and to heal them faster than some types of removable cast boots and shoe-based systems (SBS). Only a very small minority of clinicians who identify themselves as wound experts (1.7%-6%) use total contact casts. Many other clinicians do not have the training or the resources to use total contact casting. In addition many patients have conditions that make the TCC contraindicated or ill-advised. In those cases alternative devices such as the removable cast walker (RCW) or a shoe-based system has to be used. (2),(3)

According to the International Working Group on the Diabetic Foot, when a TCC or other knee-high device is contraindicated or cannot be tolerated, you should consider offloading with a forefoot offloading shoe, cast shoe, or custom-made temporary shoe to heal a neuropathic plantar forefoot ulcer in a patient with diabetes when the patient can be expected to be adherent to wearing them. Because an appropriate foot-device interface is recommended for use in the TCC and knee high devices it is implied that these should also be included in the shoe-based systems (4)

Numerous over the counter and professionally modified off-loading devices have been produced to provide a foot-device interface that would reduce pressure on ulcerated areas of the foot. Few of these have studies with data to show that they demonstrated any degree of pressure reduction or improvements in healing outcomes.(5-8) Only a limited number of studies have been done to look at the offloading capabilities of individual innersoles and less have looked at the comparative effectiveness of foot-device interfaces. (9-13)

Abstract

This study evaluated the effectiveness of the FORS-15 Offloading Innersole® (Saluber, San Zeno, Italy) in reducing pressure under focal areas on the sole of the foot. A simulated pressure site was created under the right first metatarsal head. Normal subjects walked wearing a surgical shoe while pressure was measured under the foot in three conditions: no insole, unmodified insole and insole modified for offloading. The study was able to demonstrate an average 43% reduction in maximum pressure under the first metatarsal head when using the modified insole.

Data

	Peak submetatarsal 1 pressure (kPa)					
	Cond 1	Cond 2	Cond 3	change 1>2	Change 2>3	Change 1>3
S1	165.913	162.7826	130.087	1.9%	20.1%	21.6%
S2	162.7826	128.4638	102.029	21.1%	20.6%	37.3%
S3	121.7391	96.69565	48.34783	20.6%	50.0%	60.3%
S4	74.08696	65.73913	43.13043	11.3%	34.4%	41.8%
S5	55.30435	43.47826	29.56522	21.4%	32.0%	46.5%
S6	59.36232	29.56522	21.91304	50.2%	25.9%	63.1%
S7	65.3913	66.43478	45.21739	-1.6%	31.9%	30.9%
S10	82.43478	18.08696	12.86957	78.1%	28.8%	84.4%
S11	104	99.13043	93.56522	4.7%	5.6%	10.0%
S12	169.3913	142.9565	99.47826	15.6%	30.4%	41.3%
S13	77.91304	34.08696	44.52174	56.3%	-30.6%	42.9%
S14	61.21739	47.65217	38.26087	22.2%	19.7%	37.5%
S15	124.1739	107.1304	66.31884	13.7%	38.1%	46.6%
			mean change	24.3%	23.6%	43.4%
			mean deviation	23%	19%	19%

Results

The average pressure reduction by the insole alone was 24.3% and with the pixels removed 43.4%, reflecting an average additional pressure reduction of 19.1% when the pixels are removed.

Procedures and Data Analysis

After giving consent each subject was examined and the first metatarsal head of the right foot identified and a 1/4 inch thick 1.5 inch circle of skived adhesive felt prepared to apply to the plantar skin over the area. The subjects were then observed in three conditions: barefoot in a standard surgical shoe, barefoot in the surgical shoe with an unmodified insole, and barefoot in the surgical shoe with an insole modified to remove pixels from under the designated areas of high pressure. The subjects were allowed time to acclimate to the off-loading device and then data was collected while subjects walked in the surgical shoes. Dynamic plantar pressures were collected at 100 Hz while subjects walked at self-selected speeds in a straight line. The FScan® in-shoe dynamic pressure measuring system and software (Tekscan, Boston, MA) was used to record pressures ranging from 30 – 1,500 kPa. Pressure insoles were calibrated for each subject to ensure accurate data acquisition. Three gait trials were performed five mid-gait steps identified from each trial for evaluation. Pressure distributions were calculated for a total of 15 steps for each subject. There were consent issues regarding subjects 8,9 so they were eliminated from the data pool. Custom written Matlab (Mathworks Inc, Natick, MA) codes will be used to visualize maximum pressures in ten regions of each foot. Descriptive statistics for each condition were calculated and conditions compared using the Student t-test. No funding was received from any outside source for this study.

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