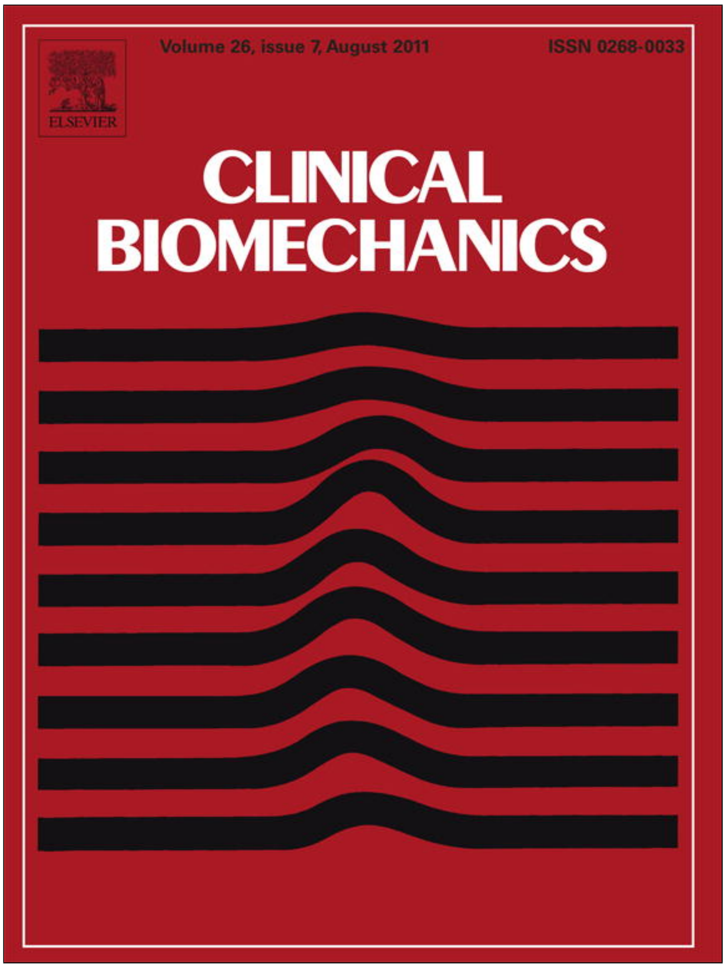
Volume 26, issue 7, August 2011
ISSN 0268-0033
ELSEVIER
CLINICAL
BIOMECHANICS

Clinical Biomechanics 26 (2011) 778–782

Contents lists available at ScienceDirect

Clinical Biomechanics

journal homepage: www.elsevier.com/locate/clinbiomech

Forefoot plantar pressure reduction of off-the-shelf rocker bottom provisional footwear

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ARTICLE INFO

Article history:
Received 8 September 2010
Accepted 16 March 2011

Keywords:
Plantar pressures
Neuropathy
Rocker sole shoe

ABSTRACT

Background: Increased plantar pressures have been shown to be a risk factor in ulceration of the neuropathic foot. Prescriptive footwear is a common medical treatment, yet evidence regarding the efficacy of these prescriptions is underdeveloped. The purpose of this study is to determine the off-loading properties of four provisional shoes; a rocker sole compared to a flat sole shoe with and without the addition of a 1.25 cm plastizote insert.

Methods: Fifteen subjects with peripheral neuropathy and a normal longitudinal arch were recruited to compare four types of provisional (post-operative) footwear. Plantar surface foot pressures were measured while wearing a rocker sole shoe or a flat stiff sole shoe. Both shoes were worn with and without a 1.25 cm plastizote insert. Peak plantar pressures were recorded for the hallux, metatarsal heads (1–5), midfoot, and heel.

Findings: The rocker sole shoe with plastizote had the best off-loading properties. While wearing this footwear, mean peak plantar pressure was 2.8 kg/cm^2 (range: 1.7 to 4.5 kg/cm^2, 50% mean reduction from flat sole shoe without plastizote) and 1.9 kg/cm^2 (range: 0.7 to 3.6 kg/cm^2, 35% mean reduction) at the five metatarsal heads and hallux, respectively.

Interpretation: For patients with a normal longitudinal arch and forefeet, either at risk of developing an ulcer or are healing a forefoot ulcer, a provisional shoe with a rocker sole and plastizote insole provides plantar pressure reduction of the forefoot. However, when results were analyzed for the subjects individually the amount of off-loading varied.

1. Introduction

Foot ulceration caused by peripheral neuropathy is a major public-health problem. An estimated 20 million people in the United States are affected by peripheral neuropathy. It is a common complication of people with diabetes (Paton et al., 2011). As much as 25% of the estimated 23 million people in the U.S. with diabetes will have a foot ulcer in their lifetime (Cavanagh et al., 2005, Pham et al., 2000). Foot ulcers may be caused from trauma or repetitive mechanical loads applied to an insensate foot. Complications from peripheral neuropathy, including lack of sensation, make these foot ulcers difficult to heal and re-ulceration of healed wounds is common (Sacco et al., 2009). Plantar ulcers in the neuropathic patient can be devastating, limiting function and the ability to work. Wound infection can lead to osteomyelitis which can be life threatening and require amputation (Berquist, 2000, Dyck et al., 2010). Increased plantar pressures have been shown to be a major risk factor in ulceration and re-ulceration of the neuropathic foot (Mueller, 1999). Therapeutic footwear to improve off-loading of the ulcerated foot is common in clinical practice; however, the evidence base to support this use is under-developed.

Plantar pressure reduction has been used to measure efficacy of footwear for off-loading properties (Bus et al., 2009). Footwear with custom insoles has been shown to be effective in reducing peak plantar pressure (Bus et al., 2004, Paton et al., 2011). However, there is a need for provisional footwear while these custom solutions are being fabricated for patients or while waiting for enough healing of ulceration to occur before being fitted with custom footwear. To date, the interim footwear that provides the most pressure reduction is the total contact cast (TCC (Cavanagh and Bus, 2010)). However, using this gold standard (TCC) footwear for off-loading is not possible in every situation. Removable footwear is necessary for patients with the presence of superfluous wound discharge, requiring more than one dressing a week, or for patients who are treated with adjunctive wound therapies such as noncontact low-frequency ultrasound (Cavanagh et al., 2005, Kavros and Schenck, 2007, Kavros et al., 2008). TCCs require fabrication and are not an off-the-shelf provisional shoe (Catanzariti et al., 1999). Bus et al. (2009) found that prefabricated forefoot off-loading shoes (FOS) relieved pressure at the forefoot, a region at particular risk of ulceration in the neuropathic

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doi:10.1016/j.clinbiomech.2011.03.009

foot (Bus et al., 2009, Cavanagh et al., 2005, Sacco et al., 2009). Recently, DARCO International Inc. created a post-surgical shoe with a stiff rocker sole. They report a 25% reduction in forefoot plantar pressure with this new design. However, a controlled study has not been done to confirm this statement.

The purpose of our study was to measure the peak plantar pressures of a rocker bottom provisional shoe to determine its off-loading properties of the forefoot. We hypothesized that the provisional rocker bottom shoe would have lower peak plantar pressures of the forefoot compared to a flat sole control shoe. Furthermore, we hypothesized that the addition of a plastizote insert would further reduce the plantar pressures in all regions of the foot.

2. Methods

This study was a repeated measure design. Each subject walked in four different conditions (Fig. 1). Two types of provisional shoes were worn by each subject: 1) a shoe with a stiff rocker bottom sole (DARCO MedSurg™ shoe, DARCO International, Huntington, WV, USA) and 2) a shoe with a flat stiff sole (Classic Post-op shoe, Health Design, Inc., Huntington, WV, USA). The DARCO MedSurg™ shoe has a rocker axis location of 55% of total shoe length measured from the heel. The rocker axis position with respect to the long axis of the shoe (A–P location) is perpendicular. The rocker angle (angle of the front part of the shoe to the ground) is 5°. The height of the shoe (insole of the heel to the ground) is 2.5 cm. These measurements are the details of interest when considering design criteria of a rigid rocker sole and its effect on pressure relief (van Schie et al., 2000). Both of these shoes were worn with and without a plastizote insert (1.25 cm in thickness).

Fifteen subjects were studied. This was a convenience sample of patients from the Department of Orthopedic Surgery and the Vascular Ulcer Wound Healing Clinic at the Mayo Clinic in Rochester, Minnesota. Eligibility criteria included documentation of peripheral neuropathy and a normal medial longitudinal arch. Peripheral neuropathy was determined initially by physical examination with sensory testing nylon filament and vibratory tuning fork of the foot and ankle. This diagnosis was confirmed with electromyography and nerve conduction velocity and followed by Quantitative Sensory Testing (Dyck et al., 2010). A normal medial longitudinal arch was defined as a calcaneal inclination angle of 15 to 38° (Berquist, 2000). Exclusion criteria included a gross abnormality of foot pathology, such as a Charcot deformity. The majority of our subjects were men with diabetes and a history of a forefoot ulcer (Table 1). The study protocol was approved by the Mayo Clinic Institutional Review Board and

Table 1
Subjects' characteristics.

Age (yr)	69 (mean), 55–82 (range)
Men, no. (%)	12 (80)
History of neuropathy, no. (%)	15 (100)
Diabetes mellitus, no. (%)	11 (73)
History of forefoot ulcer, no. (%)	13 (87)
History of partial foot amputation, no. (%)	4 (27)

informed consent was obtained from all participants before initiating test procedures.

Data collection was done at the Mayo Clinic Motion Analysis Laboratory. Plantar surface foot pressures were measured with the F-Scan Mobile Research 5.72 system (Tekscan, Boston, MA, USA). Reliability and validity have been reported elsewhere (Ahroni et al., 1998, Luo et al., 1998, Randolph et al., 2000). The sensors (Tekscan model 3000) were flexible, 0.18 mm thick, and trimmed to the appropriate size. They were adhered to the footwear with double-sided tape. The sensor connectors (0.3 kg each) were attached to the subject with an elasticized Velcro cuff around the calf. Data were collected with a receiver unit (1.0 kg) worn around the waist. Identical nylon stockings were used with each subject to prevent subjects' individual socks from affecting plantar foot pressures. Five sizes of shoes were available for both the flat sole and the rocker sole: women's medium and large and men's medium, large, and extra-large. Shoes were fit to the subjects so that the length of the shoe most closely matched the length of the subject's foot. Toes did not extend past the length of the shoe. In all 15 subjects the apex of the rocker on the DARCO MedSurg™ shoe was proximal to the five metatarsal heads.

Each subject's plantar foot pressures were measured while walking over a level tile-covered surface. The order of testing the four types of footwear was randomized. The subject walked for 20 m with the equipment prior to collecting data. Plantar foot pressures were measured while walking for a ten second interval at a self-selected speed. Foot pressures were measured unilaterally on the foot with the healing or healed wound. For the two subjects without a healing or healed wound, pressures were measured on the foot with the most amount of callus. Averaged peak plantar pressures were obtained in four regions of the foot: 1) hallux, 2) metatarsal heads (1–5), 3) midfoot, and 4) heel. The hallux, the five metatarsal heads, and heel were defined individually for each subject. After data collection, the image of the loaded foot (each stance already averaged) was viewed by the researcher. These images allowed the researcher to

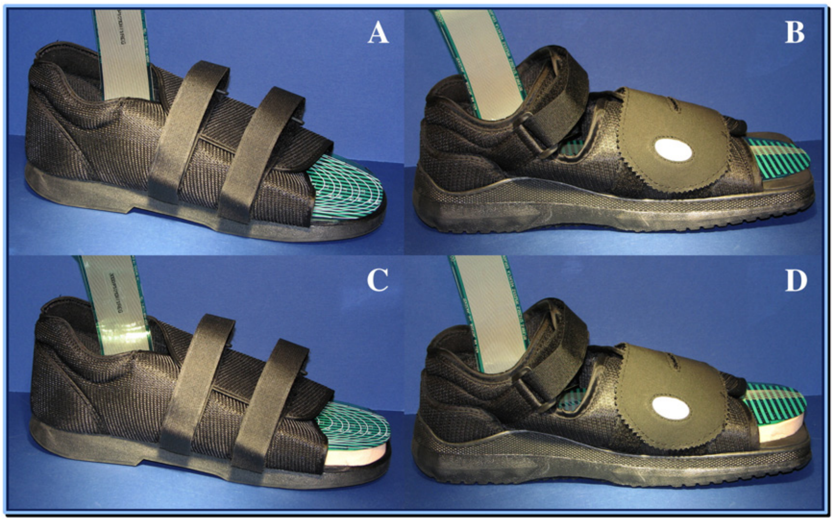

Fig. 1. Four footwear conditions tested: (A) shoe with a flat stiff sole, (B) shoe with a stiff rocker bottom sole, (C) flat sole shoe with 1.25 cm thick plastizote insole, and (D) rocker bottom sole shoe with 1.25 cm thick plastizote insole.

visually see the anatomical landmarks of the hallux, the five metatarsal heads, and the heel. These landmarks were boxed to form an object and within each object the peak pressure was calculated by the software. The midfoot region was the remaining area after the other three regions were defined. The peak plantar pressures were averaged over all gait cycles except the first and last. The software normalized the raw data to percent gait cycle. The maximum pressure was then identified for each foot region. Data for the hallux was not available for two subjects with previous great toe amputations. A two factor repeated-measures ANOVA was performed to test for statistical differences in peak pressures. The independent factors were type of sole and the use of an insert. The dependent variables were peak plantar pressures in the four foot regions. Percent reduction of the DARCO MedSurg™ shoe compared with the shoe with a flat stiff sole (Classic Post-op shoe, Health Design, Inc.) and no plastizote was determined for each subject and each region of that subject's foot. The percent change for each region was averaged between subjects. This same percent reduction was determined for the flat soled shoe with plastizote.

3. Results

The provisional rocker sole shoe reduced peak pressures compared to the flat soled post-op shoe in three regions of the foot (Fig. 2); hallux ($P = 0.02$), metatarsal heads 1–5 ($P < 0.001$), and heel ($P < 0.01$). The midfoot area had lower pressures (than other regions of the foot) in every shoe and there was no difference between shoes ($P = 0.67$). The plastizote insert also provided better off-loading in all four regions of the foot; hallux ($P = 0.01$), metatarsal heads 1–5 ($P < 0.001$), midfoot ($P = 0.01$), and heel ($P < 0.01$). Using both a rocker sole and a plastizote insert had the best off-loading properties in three regions of the foot, although their effects were not additive. Interaction at the hallux, metatarsal heads 1–5, and heel was $P < 0.01$, $P < 0.001$ and $P < 0.05$, respectively. This means that the effect of the two variables (1. sole of the shoe and 2. presence/absence of the plastizote) when used in combination was less than the effect of each variable if added together. Table 2 lists the means of the averaged peak pressures and percent pressure reductions, standard deviations and ranges for each of the four types of footwear at the four regions of the foot.

Although the primary purpose of this study was to determine the off-loading properties of the provisional rocker bottom shoe compared to the flat sole, the plastizote insert had more effect on load than the shape of the sole. In all four regions of the foot the mean peak plantar pressure for the plastizote insert in a flat soled shoe was lower than the rocker bottom sole without the insert. The metatarsal head (1–5) region, the region that received the greatest pressure relief from the interventions, improved from a mean of 6.0 kg/cm^2 in the flat soled shoe to 3.5 kg/cm^2 in the rocker bottom shoe (without plastizote) and 3.1 kg/cm^2 with the addition of the plastizote to a

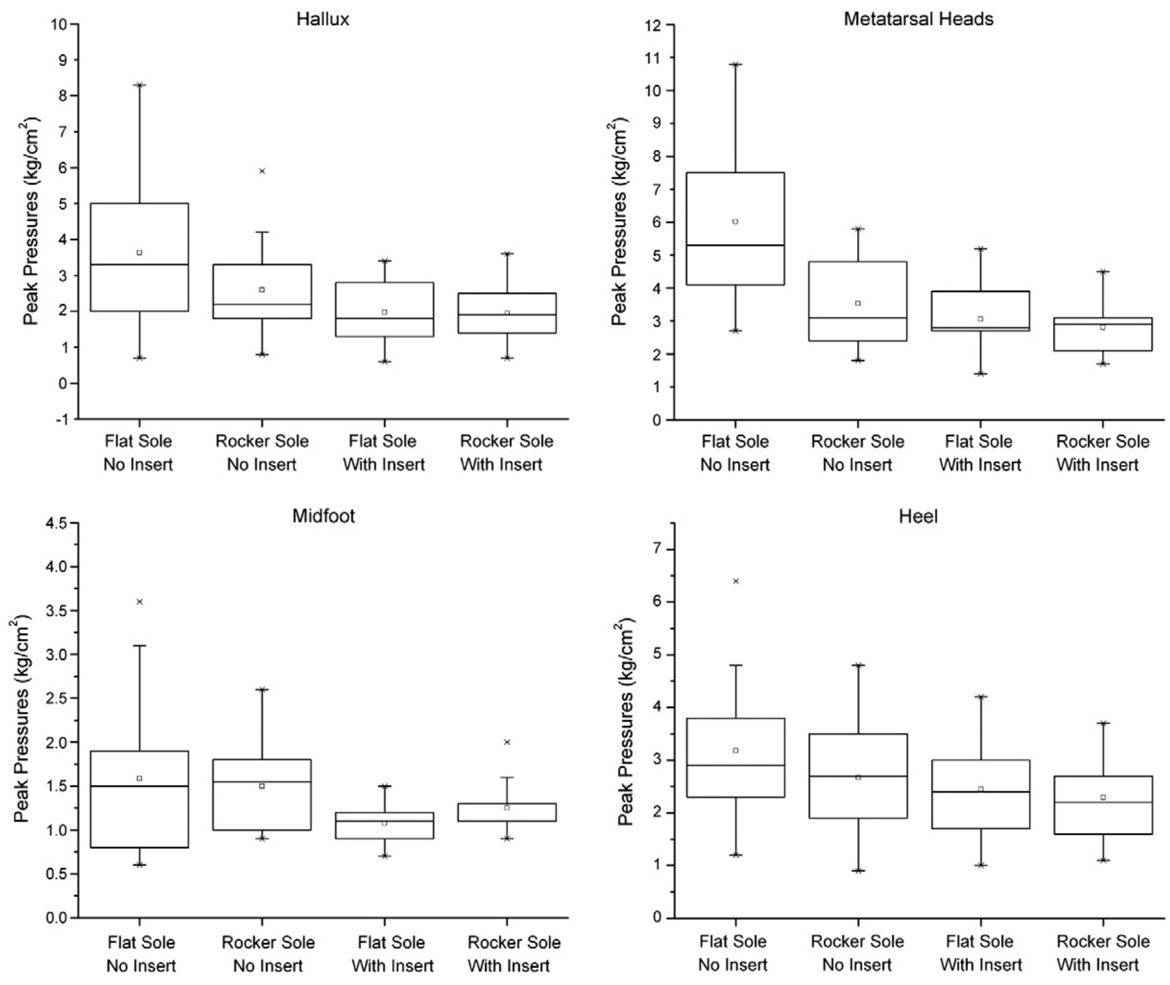

Fig. 2. Box Plot of Plantar Peak Pressures for four types of footwear by region of the foot. The rocker bottom shoe had lower peak pressures than the flat sole shoe at the hallux, metatarsal head and heel regions. Footwear with the plastizote insert had lower peak pressures than footwear without the plastizote in all four regions of the foot. Mean peak pressures were the lowest in the rocker bottom sole shoes with a plastizote insert for three regions of the foot; hallux, metatarsal heads, and heel. Asterisk indicates extrema. Square indicates mean.

Table 2
Mean averaged peak plantar pressures and percent pressure reduction by foot region.

Footwear measured	Flat sole no plastizote				Rocker sole no plastizote				Flat sole with plastizote				Rocker sole with plastizote			
Foot region	Hallux	MT head 1–5	Midfoot	Heel	Hallux	MT head 1–5	Midfoot	Heel	Hallux	MT head 1–5	Midfoot	Heel	Hallux	MT head 1–5	Midfoot	Heel
Mean peak pressure (kg/cm^2)	3.6	6	1.6	3.2	2.6	3.5	1.5	2.7	2	3.1	1.1	2.5	1.9	2.8	1.3	2.3
SD (PP)	2.4	2.5	0.9	1.4	1.4	1.3	0.5	1.0	0.9	1.0	0.3	0.9	0.9	0.7	0.3	0.7
Min PP	0.7	2.7	0.6	1.2	0.8	1.8	0.9	0.9	0.6	1.4	0.7	1	0.7	1.7	0.9	1.1
Max PP	8.3	10.8	3.6	6.4	5.9	5.8	2.6	4.8	3.4	5.2	1.5	4.2	3.6	4.5	2	3.7
Mean% reduction	Reference shoe for % reduction				21	39	−17	14	36	47	17	−12	35	50	−3	23
SD (%R)					19	11	49	14	21	9	36	52	22	12	48	19
Min %R					−14	20	−113	−17	−4	34	−50	−125	0	26	−83	−19
Max %R					48	62	58	27	67	69	61	72	75	71	68	45

Peak pressure (PP).
Percent reduction (%R), negative values indicate an increase in pressure when compared to the reference footwear.
Standard deviation (SD).

flat soled shoe (Fig. 2). The best pressure relief was the use of the rocker bottom shoe with the plastizote insert (mean peak pressure of 2.8 kg/cm^2).

Using the flat soled provisional shoe without plastizote as our baseline measurement, the provisional rocker bottom sole with a plastizote insert reduced peak plantar pressure by an average of 50% (SD 12%) in the region of the five metatarsal heads. The rocker bottom sole with plastizote reduced pressure in the hallux by 35% (SD 22%) and the heel by 23% (SD 19%.) Pressure at the midfoot increased 3% (SD 48%.)

4. Discussion

The provisional rocker bottom sole is intended to off-load the forefoot. Off-loading the forefoot is an important clinical goal for patients with neuropathy who are at risk of developing a foot ulcer or who are healing an ulcer. When worn in combination with a 1.25 cm thick plastizote insert, lower peak pressures were seen at the hallux and the metatarsal head (1–5) region than with a flat sole post-operative shoe.

As expected the forefoot (hallux and metatarsal heads (1–5) regions) did demonstrate lower peak pressures in the rocker bottom shoe than the flat soled shoe. A rocker bottom sole is designed to minimize metatarsal phalangeal joint extension and maximize foot contact area during late stance (Mueller, 1999, Schaff and Cavanagh, 1990, van Schie et al., 2000). Therefore, one might expect to see decreased pressure points at the metatarsal heads and hallux with the other areas of the foot (midfoot and heel) receiving these distributed forces. In fact, other studies measuring the effect of rocker soles on plantar pressures have found pressure reduction of the forefoot and an increase in pressure at the mid and hindfoot (Brown et al., 2004, Schaff and Cavanagh, 1990). This pattern was also seen by Bus et al. (2009) when they compared peak pressures in five forefoot off-loading shoes to a control shoe. They demonstrated load transfers from the forefoot to the midfoot using load transfer algorithms. In contrast, our data did not show increased peak pressures of the midfoot and heel. The midfoot did not demonstrate differences in peak pressures between shoes, and the heel had lower peak pressures in the rocker bottom shoe compared to the flat soled shoe. The reduction in peak plantar pressures at the heel with the use of the rocker sole shoe may be explained by the design of the ankle strap. The location and direction of pull of the ankle strap holds the heel in the shoe better than the flat sole shoe, therefore reducing the amount of pistoning that may occur at heel strike. Table 2 shows percent change between our flat post-operative shoe and the rocker bottom shoe with plastizote. At first glance this table indicates that the midfoot did have pressure reduction by 3%; however, the standard deviation is large (48%) and looking at the individual data shows that the increase or decrease in pressure at the midfoot varied between subjects.

In addition to reducing pressure by decreasing the force, pressure can also be relieved by increasing the area through which the force is applied (Mueller, 1999, Sacco et al., 2009). This was the effect of adding a plastizote insert to the shoes. The subject's foot sunk down further into the softer material of the plastizote and therefore more of the subject's plantar surface was supported. The pressure reduction that occurred as a result of the plastizote was better than that of the shoe alone. One reason that the shape of the sole of the provisional shoe may have had less influence on pressure reduction than the plastizote is that the reference shoe used for comparison had a stiff sole. Theoretically one of the reasons that a rocker sole off-loads the forefoot is that its rigid sole restricts movement at the joints of the foot, particularly the metatarsophalangeal joints (van Schie et al., 2000). Since our baseline shoe had a stiff sole as well, this joint restriction may have also been occurring in our reference shoe. Additionally, our provisional shoe has a relatively small rocker angle of 5° compared to the other studies that have shown efficacy for off-loading the forefoot and tested shoes with rocker angles that ranged from 20 to 30° (Brown et al., 2004, Hutchins et al., 2009, Praet and Louwerens, 2003, Schaff and Cavanagh, 1990, van Schie et al., 2000).

This study was limited to a sample of individuals with neuropathy who have a normal longitudinal arch. These findings should not be generalized to individuals who have foot ulcers secondary to ischemia or deformity of the midfoot such as Charcot Arthropathy. A study that determined the load transfer of forefoot off-loading shoes found that the midfoot received most of the load transferred from the forefoot (Bus et al., 2009). Other studies that examined pressure change with the implementation of a rocker sole also found that pressure increased at the midfoot (Brown et al., 2004, Schaff and Cavanagh, 1990). Therefore, a rocker bottom outsole should not be recommended for individuals with midfoot deformity. Currently there are no commercially available pressure assessment systems that measure shear forces (Mueller, 1999). The pressures measured in this study are those forces that are applied perpendicular to the sensor. Once technology advances to provide a sensor that will also measure shear forces on the foot, there will be improved understanding about how footwear contributes to foot ulcers.

Comparison between studies that examine the efficacy of rocker soled shoes is challenging for several reasons. Readers are cautioned to avoid comparing magnitudes of peak pressures when the equipment and methods used vary between studies (Mueller, 1999). Comparing the difference between percent changes would seemingly solve the problem of variable methods. However, the reference footwear that is measured for baseline data prior to the implementation of the footwear of interest varies. This makes comparison of the percent change difficult. Other differences between studies include the population studied and the characteristics of the rocker sole (description of axis angle/location and the rocker angle). Keeping these limitations in mind, several studies have shown a percent reduction of plantar pressures of the forefoot ranging from 10% to 60%, proving efficacy of rocker soles to provide pressure reduction of the forefoot (Brown et al., 2004, Hutchins et al., 2009, Praet and Louwerens, 2003, Schaff and Cavanagh, 1990, van Schie et al., 2000). Our data showed that the rocker bottom sole with plastizote reduced pressure in the five metatarsal heads by 50% (SD 12%) and the hallux by 35% (SD 22%) when compared with a standard rigid flat soled post-operative shoe.

Consistently found in the literature is the finding that there is variability between individuals. There is not one rocker profile that provides the best off-loading for all subjects (Schaff and Cavanagh, 1990, van Schie et al., 2000). Our data also demonstrate this. Table 2 shows the large standard deviations of mean pressure reductions in many of the footwear/regions tested. That being said, we do want to point out that the best performing footwear (rocker sole with plastizote) did not demonstrate a pressure increase of the forefoot for any of our subjects.

5. Conclusion

The clinical application of this study is specific to a group of patients who are awaiting fabrication of permanent footwear. These patients do not have significant foot deformity requiring more aggressive provisional footwear such as a total contact cast or a Charcot Restraint Orthotic Walker (CROW). For patients with a normal longitudinal arch and whose forefeet are either at risk of developing an ulcer or who are healing a forefoot ulcer, a provisional off-the-shelf shoe with a rocker sole and a 1.25 cm plastizote insole is a better option than the standard flat soled post-operative shoe. Off-loading the foot by limiting pressures during walking is only one important component to addressing the biomechanical elements of ulcer care. Compliance and walking time are also important and should be considered in addition to the off-loading properties of the footwear. In addition, a patient's activity level and foot care routine should be taken into consideration when considering the best footwear for off-loading a neuropathic wound (Lavery et al., 2003).

Author contributions

SJK generated the concept, secured funding, recruited subjects, and wrote the protocol and manuscript; MVS carried out data reduction and data analysis and also drafted the manuscript; KRK was responsible for statistical analysis as well as the writing of the protocol and manuscript; and KCW wrote the protocol.

Conflict of interest

There are no commercial relationships which may lead to a conflict of interest with any of the authors.

Acknowledgments

This work was supported by the Orthopedic Research Review Committee (ORRC) in the Department of Orthopedic Surgery at Mayo Clinic Rochester, MN USA. The authors wish to acknowledge the help of Barbara Iverson (Department of Orthopedic Research, Mayo Clinic, Rochester, MN USA) for subject scheduling, Kari Hammel (Department of Orthopedic Research, Mayo Clinic, Rochester, MN USA) for subject scheduling, creation and editing of graphs, editing and submission of manuscript, Diane Serfling (Department of Orthopedic Research, Mayo Clinic, Rochester, MN USA) for collection of the data, and Kathie Bernhardt (Department of Orthopedic Research, Mayo Clinic, Rochester, MN USA) for commenting on an early draft of the manuscript.

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