

Prospective Evaluation of Leprosy Patients Wearing Insole

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Abstract

The use of custom-made insoles has shown to be effective for the treatment of high plantar pressure peak of patients with neuropathic feet. Objective: To observe the results of the usage of metatarsal plantar support type of insole in leprosy, through tests in gait and static posture with a baropodometric device. Ten patients with leprosy were randomly selected, ageing 25 to 60 years at the leprosy outpatient clinic of Ribeirao Preto Medical School Clinical Hospital. They were asked to stand in a static position and then to walk on the baropodometer (Footwork-ISP). Pressure peaks were observed in 7 predefined plantar areas during standing position, and plantar contact time was observed during gait. Next, a custom-made insole was installed into the patient's footwear, according to the Brazilian Ministry of Health's protocol

The above assessment was redone after 10 months of continuous insole usage. The collected data was statistically analyzed, revealing that the 7 plantar areas did not show significant differences for pressure peaks recorded before and after the use of insoles during standing position. The dynamic analysis, however, showed a significant reduction in plantar contact time, meaning a faster gait of these patients after the use of insoles. We conclude that the metatarsal plantar support type of insoles improve the dynamic balance of patients, but did not modify the foot's pressure distribution.

Keywords: Neuropathic feet; Leprosy; Ulcers; Insoles; Baropodometry

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Introduction

Leprosy is a slow evolution disease caused by the bacillus *Mycobacterium leprae* causing a specific inflammation, which affects the peripheral nervous system with special attention to sensory fibers [1]. Neuropathy due to leprosy presents acute and sub-acute inflammatory processes, depending on the extent of the infection, with different clinical presentations and treatments, also with lepromatous reactions and consequent complex handling [2,3]. Thus, the nerve damage could cause motor and sensitive changes that leads to various degrees of disability. These factors results in interference on social and economical life of the patients, as well as stigma and discrimination against them [4].

The injury of sensory fibers leads to patient's loss of thermal, tactile and pain sensitivity. The injury of autonomic fibers causes alteration of glandular functions, resulting in dry skin and weakness of mucous membranes [2]. Damaged motor peripheral fibers are responsible for the decrease or absence of muscle

response, which can lead to muscle paralysis or atrophy [5].

The most commonly affected nervous branches by leprosy are the ulnar and common peroneal, the latter being responsible for gait in its early stages (dorsiflexion prior to heel contact instance) and during unilateral weight-bearing phase (maintenance of the lateral arch support and stability). The common peroneal nerve injury and plantar sensory deficit can also interfere with body balance control by compromising the feedback of the interaction between ground and feet, thus resulting in foot deformities such as the weakness of dorsal flexors (anterior tibial muscle), and weakness of inverters and everter of the midfoot (posterior tibial and fibular muscle). The fall of the transverse arch of the foot can be observed in a leprotic feet, along with the exposure of plantar metatarsal heads and the onset of claw toes. These deformities are known to cause calluses and plantar ulcers in neuropathic feet, supposedly due to the increase in plantar pressure peaks [6-8]. It has been observed that 32% of leprosy patients present skin ulceration, and the incidence of plantar ulcers specifically for these patients ranges from 20% to 70% [9,10].

The baropodometer is a clinical tool consisting of a polycarbonate board with calibrated pressure sensors that identify sites of plantar overpressure (in kPa) both in static position and gait, and record time of total foot contact (in milliseconds) and contact area (cm) for each step. The results are shown on the computer screen: each activated sensor is labeled with colors according to the pressure recorded, and numeral results are shown alongside the image. This device is well accepted clinically because it is non-invasive and presents relatively low cost to the Health Service [11,12].

The treatment of foot deformities for leprosy patients in Brazil includes the use of customized insoles, handmade according to the alteration in sensitivity and ankle position (protocol of the Brazilian Ministry of Health [13]). Clinically, it has been observed the remission of plantar ulcers using these insoles in patients treated at the National Reference Center for Sanitary Dermatology of the Hospital of Ribeirao Preto Medical School, University of Sao Paulo (CRNDS-HCFMRP-USP), but there are no scientific studies proving its effectiveness regarding the reduction of plantar peak pressures.

Objective

To analyze the influence of the prospective use of metatarsal plantar support type of insole in leprosy, through tests using a baropodometric device during gait and static position.

Methodology

Ten leprosy patients undergoing drug treatment at the leprosy outpatient Clinic of Ribeirao Preto Medical School Clinic with previous history of plantar protective sensory impairment were randomly selected. The patients were submitted to the Semmes-Weinstein sensory test and were considered eligible to the study if didn't respond to the purple monofilament stimuli (10g) at 3 or more plantar sites on each foot [6]. Patients presenting other neurological diseases that could alter plantar sensitivity, such as Diabetes, or presenting orthopedic or neurologic diseases other than leprosy that could affect free gait, or patients wearing assistive walking devices were not included in this study. The volunteers signed a consent form to participate on the study, and were asked to stand barefoot in a static position with arms relaxed and opened eyes for 30 seconds on the baropodometer (Footwork-ISP Informatique®, France). They were then conducted to the walking test on the same device, also barefooted, where they were asked to walk through a path 5 meters long, with the baropodometer positioned halfway from the start position. After these first tests, an insole with metatarsal plantar support (Figure 1a) was tailor made for each foot (as indicated by the Brazilian Ministry of Health), and the baropodometry tests redone after a period of 10 months.

Each image of the foot provided by the baropodometer was divided into 7 plantar areas as shown:

- 1-halux;
- 2-first metatarsal head (1MTH);
- 3-third metatarsal head (3MTH);

- 4-fifth metatarsal head (5MTH);
- 5-midfoot;
- 6-heel;
- 7-total plantar support (TPS).

The peak pressures (kPa) were recorded separately during standing position (Figure 1b) and the plantar contact time (milliseconds-ms) was recorded during gait for each foot. All data were statistically analyzed by the GraphPad® software (paired t-test) to compare the values obtained before and after the usage of the insoles. It is important to consider that all measurements were taken with the subjects barefooted, to observe whether the insoles could influence an adaptation to pressure peak distribution or gait speed after 10 months.

Results

The leprosy patients (6 male and 4 female) were 25 to 60 years old (mean 42, 5±24, 7sd). The analysis of baropodometric data revealed pressure changes before and after the usage of insoles, according to Tables 1 and 2, and Figures 2a and 2b.

The data collected of plantar pressure peaks during standing position showed that halux, 1MTH, 3MTH, 5MTH and heel areas had increased values both for right and left feet, while the midfoot area showed maintenance of the plantar pressure for right and left foot. The data collected from Total Plantar Support showed maintenance of pressure peaks on the left foot while it increased on the right foot of the subjects after a period of 10 months.

Although these findings might be fairly visible on the charts, there was no statistical correlation (p value <0.05) between the data found before and after the usage of insoles for all plantar areas observed during standing position.

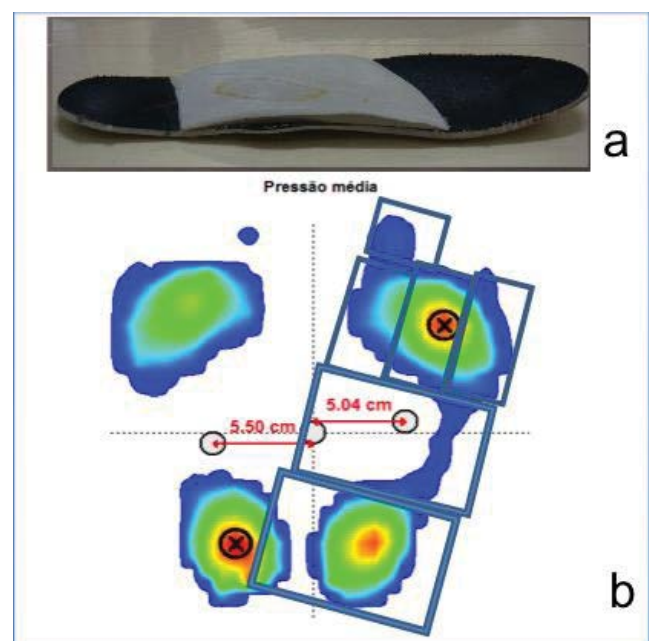


Figure 1 Custom-made insole with plantar metatarsal support; Figure 1b Selection of the foot areas within the Baropodometric impression during standing position.

Table 1 Mean and standard deviation on plantar pressure peaks (kPa) for each area of the foot before and after 10 months wearing insoles.

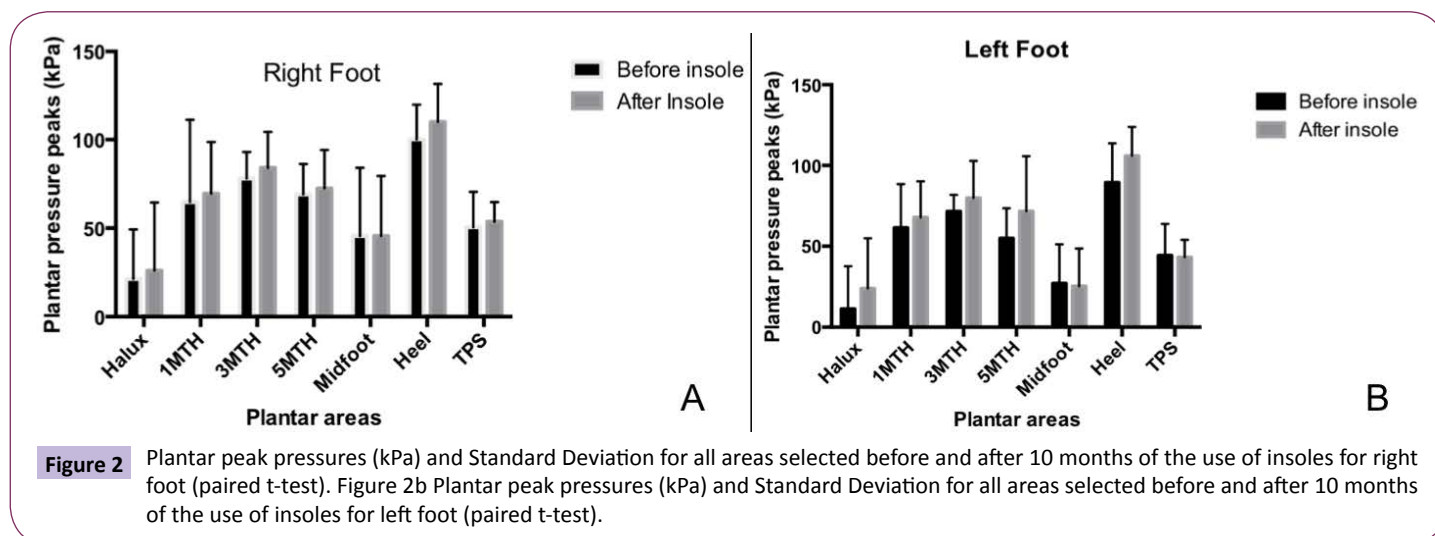
	Right Foot			Left Foot		
	Before Insole (mean ±std)	After Insole (mean±std)	p value	Before Insole (mean ±std)	After Insole (mean±std)	p value
Halux	21,3±27,96	26,1±38,52	0,504	11,3±26,34	23,9±31,02	0,326
1MTH	64,85±46,5	69,5±29,19	0,707	61,4±27,06	67,8±22,34	0,382
3MTH	78±46,5	84,2±20,3	0,211	71,6±10,17	79,8±22,96	0,212
5MTH	69,2±17,16	72,6±21,58	0,701	54,9±18,63	71,7±33,95	0,122
Midfoot	45,5±38,75	45,6±34,02	0,989	27±24,19	25,3±23,31	0,729
Heel	100,2±19,79	110,2±21,52	0,076	89,4±24,25	105,9±17,95	0,116
TPS	50,5±20,10	53,7±11,13	0,650	44,3±19,52	43,2±10,73	0,829

*p<0,05

Table 2 Mean and standard deviation on plantar contact time (ms) during gait for each foot before and after 10 months wearing insoles.

Right Foot			Left Foot		
Before Insole (mean±std)	After Insole (mean±std)	p value	Before Insole (mean±std)	After Insole (mean±std)	p value
1981,3±1320,53	1025222,7	0,048*	1637,5±1142,95	933,6±198,01	0,096

*p<0,05



The data collected during gait, however, showed a significant reduction in Contact Time of the right and left foot, but a statistically significant correlation could only be observed on the right foot after the use of insoles (Figure 3).

Discussion

The patient with leprosy suffers stigma and prejudice on daily basis, even after the development of clinical treatment and expressive remission of its disabling symptoms. Plantar sensory impairment has been a challenge for the patient, who needs daily preventive care as well as multidisciplinary support. Maladapted shoes, uneven pavements, several working hours with no footrest, are factors that worsen neuropathic foot condition and hinder the prevention of plantar ulcers [8]. In this sense, there is an effort of the Public Health Care System in Brazil to adapt shoes and make insoles more fitted to the reality of the patients, but much of these adaptations come from the knowledge of clinical observation, without scientific basis [6,9,13,14].

The use of customized insoles helps reducing 14% or more plantar

pressure peaks and increases the contact area of the diabetic foot to the ground, which is an important issue since the steps for the formation of ulcer in diabetic foot includes neuropathy, foot deformity and trauma [15].

When it comes to patients with leprosy, there is a correlation between plantar ulcers, areas of protective sensory loss, and increased plantar pressure peaks [12]. The use of insoles has been found to reduce pressure peaks while wearing them [11], but nothing has been described showing how the foot might adapt to the modifications the insoles or shoes might impose through time.

The results obtained in this study showed that after 10 months wearing insoles there was no significant change in plantar pressure peaks in all seven areas selected for static analysis, contrary to what was expected. On the other hand, the leprosy patients showed an increase in gait speed. This is an indicative of gain in independence and improved body balance according with [16].

Nerve injury resulting from leprosy occurs heterogeneously in the plantar region, which may lead to anomalous usage of muscle

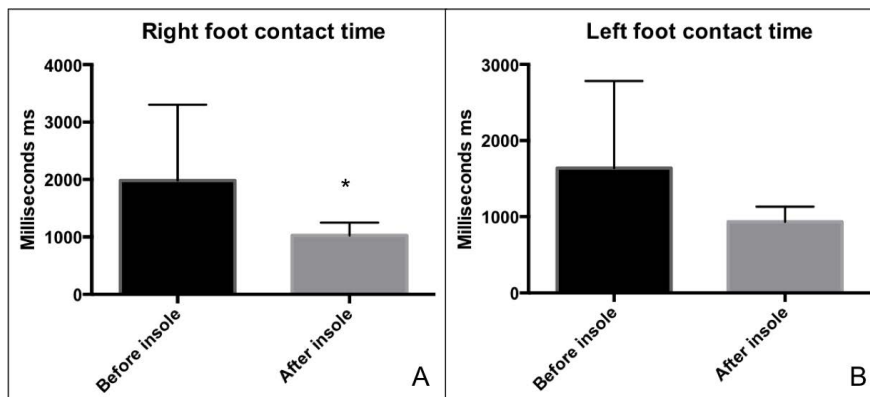


Figure 3 3a Plantar contact time (ms) during gait before and after 10 months of the use of insole on the right foot (paired t-test). 3b Plantar contact time (ms) before and after 10 months of the use of insole on the left foot (paired t-test).

groups to maintain body balance, since the plantar sensory outputs are part of the balance control mechanism, along with eyes and the vestibular system [17,18]. The studies relating body balance control and plantar sensitivity reported an alternate muscle recruitment for maintaining the body in an upright position when there is a change in one or more regulators of the postural control such as eyes, plantar surface or vestibular system. Also, it has been noticed that a faster walking speed leads to more independency to perform chores inside and outside their home. When it comes to daily activities performed by patients with leprosy, it has been proved by the BESTest-balance evaluation that sensory loss on foot and hands could be related to a bad performance in postural control [19,20].

Conclusion

Therefore, it can be inferred by these results that the continuous use of an insole is not enough to generate muscle adaptations in

favor of reducing plantar pressure peaks of the leprosy patient, which corroborates to the importance of the follow up of this patient, even after clinical discharge.

Furthermore, it was found that the continuous use of an insole with metatarsal plantar support reduces the contact time of bony prominences and insensitive areas and might help to prevent and / or cure plantar ulcers as observed in clinical care.

Taken the relevance of these findings, we suggest the continuation of this study with greater attention to the patient's body balance control during gait.

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References

- 1 Aquino DMC, Caldas AdeJ, da Silva AA, Costa JM (2003) Profile of Leprosy Patients in a Hiperendemic Area of Amazonian Maranhao Brazil. *Rev Soc Bras Med Trop* 36: 57-64.
- 2 Britton WJ, Lockwood DN (2004) Leprosy. *Lancet* 363: 1209-1219.
- 3 Marciano LHSC, Garbino JA (1994) Comparação de Técnicas de Monitoração da Neuropatia Hanseniana: Teste de Sensibilidade e Estudo de Condução Nervosa. *Hansen. Int* 19: 5-10.
- 4 Cordeiro TL, Frade MAC (2014) Leprosy: Education as first priority. *J Neurosci Rural Pract* 5: S3-S4.
- 5 Chauhan VS, Pandey SS, Shukla VK (2003) Management of plantar ulcer in hansen's disease. *Int J Low Extrem Wounds* 2: 164-167.
- 6 Brasil, Ministério da Saúde, Secretaria de Políticas de Saúde, Departamento de Atenção Básica (2008) Manual de adaptações de palmilhas e calçados. Ed. MS. Brasília.
- 7 Gomes FG, Frade MAC, Foss NT (2007) Úlceras Cutâneas na hanseníase: perfil clínico-epidemiológico dos pacientes. *An Bras Dermatol* 82: 433-437.
- 8 Brasil, Ministério Da Saúde (2010) Anexo I-Diretrizes para vigilância, atenção e controle da Hanseníase. Available at http://bvsmms.saude.gov.br/bvs/saudelegis/gm/2010/prt3125_07_2010.html
- 9 Lehman LF, Orsini MPB, Fuzikawa PL, Lima RC, Gonçalves SD (2009) Avaliação Neurológica Simplificada. *Belo Horizonte: ALM International* 104: 79 - 103.
- 10 Costa, TS, Sandoval RCB, Coral MHC, Marques JLB, Marques CMG (2001) Análise da Pressão Plantar de Indivíduos Diabéticos com Risco de Ulceração. In: *Memoórias II Congresso Latinoamericano de Ingenieria Biomédica - Habana, Cuba. Artigo 00463.*
- 11 Tang SF, Chen CP, Lin SC, Wu CK, Chen CK, et al. (2015) Reduction of plantar pressures in leprosy patients by using custom made shoes and total contact insoles. *Clin Neurol Neurosurg* 129: S12-S15.
- 12 Cordeiro TL, Frade MA, Barros AR, Foss NT (2014) Baropodometric Evaluations and Sensitivity Alterations in Plantar Ulcer Formation in Leprosy. *Int J Low Extrem Wounds* 13: 110-115.
- 13 Neto HP, Grecco LA, Braun Ferreira LA, Christovão TC, Duarte NdeA, et al. (2015) Clinical analysis and baropodometric evaluation in diagnosis of abnormal foot posture: A clinical trial. *J Bodyw Mov Ther* 19: 429-433.
- 14 Guldemond NA, Leffers P, Schaper NC, Sanders AP, Nieman F, et al. (2007) The effects of forefoot plantar pressure and walking convenience in diabetic patients with neuropathic feet. *Clinical Biomechanics* 22: 81-87.
- 15 Tsung BY, Zhang M, Mak AFT (2004) Effectiveness of insoles on plantar pressure distribution. *Journal of rehabilitation Research & Development* 41: 767-774.
- 16 della Volpe RPT, Ginanneschi F, Spidalieri R, Mazzocchio R, Rossi A (2006) "Changes in coordination of postural control during dynamic stance in chronic low back pain patients." *Gait Posture*. 24(3): 349-55. apud *Balance Manager Systems: Clinical Operation Guide* (2011) Neurocom Int. Clakamas OR p.51
- 17 Bricot B (2004) *Posturologia 3rd edn* São Paulo: Ed. Ícone 270 p.
- 18 Chen H, Nigg BM, Hulliger M, Koning J (1995) Influence of sensory input on plantar pressure distribution. *Clinical Biomechanics* 10: 271-274.
- 19 Mercadante FA (2013) Avaliação para o controle postural em portadores de Haseníase. *Masters Degree Dissertation - University of Sao Paulo. Sao Paulo. p.87*
- 20 Viel E (2004) *A Marcha Humana, a Corrida e o Salto. 1a ed. Bras. Barueri Ed. Manole. p 84-93*

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