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Inter- and intra-examiner reliability of footprint pattern analysis obtained from diabetics using the Harris Mat

Confiabilidade intra e interexaminador da análise por padrões de impressão de plantigrafias de pessoas diabéticas obtidas com o Harris Mat

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Abstract

Introduction: High plantar pressure is a proven risk factor for ulceration among individuals with diabetes mellitus. The Harris and Beath footprinting mat is one of the tools used in screening for foot ulceration risk among these subjects. There are no reports in the literature on the reliability of footprint analysis using print pattern criteria. **Objective:** The aim of this study was to evaluate the inter- and intra-examiner reliability of the analysis of footprint patterns obtained using the Harris and Beath footprinting mat. **Methods:** Footprints were taken from 41 subjects using the footprinting mat. The images were subjected to analysis by three independent examiners. To investigate the intra-examiner reliability, the analysis was repeated by one of the examiners one week later. **Results:** The weighted kappa coefficient was excellent (K_w>0.80) for the inter- and intra-examiner analyses for most of the points studied on both feet. **Conclusions:** The criteria for analyzing footprint patterns obtained using the Harris and Beath footprinting mat presented good reliability and high to excellent inter- and intra-examiner agreement. This method is reliable for analyses involving one or more examiners.
Article registered in the Australian New Zealand Clinical Trials Registry (ANZCTR) under the number ACTRN12609000693224.

Key words: plantar pressure; footprint; reliability; diabetic foot.

Resumo

Introdução: A hiperpressão plantar é um fator de risco comprovado para a ulceração em portadores de diabetes mellitus. O "*Harris and Beath Footprinting Mat*" é um dos instrumentos usados nas avaliações para rastreamento do risco de ulceração nos pés desses pacientes. Não há relatos na literatura sobre estudos da confiabilidade da análise das impressões plantares usando o critério de padrões de impressão. **Objetivo:** O objetivo deste estudo foi avaliar a confiabilidade inter e intraexaminador da análise dos padrões de impressão plantar obtida com o "*Harris and Beath Footprinting Mat*". **Métodos:** As impressões plantares de 41 sujeitos foram obtidas usando o plantígrafo. As imagens foram submetidas à análise de três examinadores independentes. Para verificar a confiabilidade intraexaminador, um dos examinadores repetiu a análise após uma semana. **Resultados:** O coeficiente de Kappa ponderado foi excelente (K_p>0,80) para as análises inter e intraexaminador para a maioria dos pontos estudados em ambos os pés. **Conclusão:** O critério de análise por padrões de impressão plantar obtidas com o "*Harris and Beath Footprinting Mat*" apresentou boa confiabilidade e de alta a excelente concordância para as condições inter e intraexaminador. Esse método é confiável para análises que envolvam um ou mais examinadores.
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Palavras-chave: pressões plantares; impressão plantar; confiabilidade; pé diabético.

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Introduction

Plantar ulcers and lower-limb amputations among individuals with diabetes mellitus (DM) contribute towards the morbidity and mortality caused by this disease. Foot ulceration affects 15% of patients with DM at some point in their lives[1]. Ulcerative foot lesions lead to amputations and represent a substantial proportion of healthcare expenditure for treating patients with DM[2-5]. Early identification of risk factors for ulceration is necessary to prevent injuries to the feet of these subjects. High plantar pressure, combined with insensitivity, is a proven risk factor for ulceration among these patients[6-10]. Evaluation of plantar pressure helps to identify areas with such propensities[11-13]. These evaluations range from physical examination, inspection and simple footprinting methods, to precise measurements using computerized equipment[6].

The Harris and Beath footprinting mat is one of the tools used in screening for the risk of foot ulceration among individuals with DM[14,15]. Based on the footprint configuration, this mat can measure plantar pressures between 0.27 kg/cm^2 and 4.80 kg/cm^2. Thus, it can identify individuals who have high plantar pressure points. In a comparison of footprint impressions between subjects with metatarsalgia and a control group, Silvino, Evanski e Waugh[16] estimated that the sensitivity and specificity of this instrument were, respectively, 0.57 and 0.77. The Harris and Beath footprinting mat is easy to apply in clinical practice and provides low-cost assessment of plantar pressures[17,18]. However, the criteria for footprint analysis are subjective. Silvino, Evanski e Waugh[16] described a criterion that established pressure values in accordance with the print pattern. Nevertheless, there are no reports in the literature that demonstrate reliability analyses on footprinting using such criteria.

Therefore, the aim of this study was to evaluate the intra and inter-rater reliability of footprint patterns analyses obtained using the Harris and Beath footprinting mat, among individuals with DM neuropathy, without active ulcers.

Methods

Subjects

The study was carried out in individuals with DM who participated in educational programs that were conducted at a unit within the National Health System, in Porto Alegre, Rio Grande do Sul (RS), Brazil. To participate, individual had to have a diagnosis of DM, had to be receiving clinical and laboratory care at the Department of Endocrinology of the unit, and had to show loss of foot protective sensitivity due to diabetic neuropathy.

Screening to identify loss of foot protective sensitivity among a sample of 563 patients with DM was carried out. The Semmes-Weinstein 10-gram monofilament, which is a validated tool for screening patients with peripheral diabetic polyneuropathy[19-22], was used. Forty-one individuals with type 2 DM who met the inclusion criteria and voluntarily agreed to participate, were included in the study. Ethical approval for this study was obtained from the Municipal Health Department of Porto Alegre (RS), Brazil, in accordance with protocol number 1279/00. All the volunteers signed the informed consent form.

To characterize the sample, personal, demographic and clinical data and information on the history of ulcers and lower-limb amputations among the participants were collected through interviews and the medical records. Footprinting of feet with active ulcers was not performed.

Footprint recording and analysis

Footprints were obtained using the Harris and Beath footprinting mat (Apex Foot Products Corporation, Englewood, NJ, USA). The examinations were carried out by one of the examiners who had participated in the reliability study. Footprints were taken from both feet, and were obtained barefoot, from the stance phase of a pace[23]. The footprinting mat consisted of two rectangular plates mediated by a rubber sheet that was structured on its underside with squares filled with smaller squares to which water-soluble ink was applied (Figure 1).

This rubber structure made it possible to transform qualitative information from the pressures (imprints produced using ink), into numerical values, as described by Silvino, Evanski e Waugh[16]. A piece of white paper was placed under the rubber in order to register the plantar imprint as the rubber received the weight of the foot.

The natural stride length (comfortable speed) for each patient was measured in order to achieve correct placement of the footprinting mat on the ground. To this end, before undergoing the examination, the participants performed a regular path of five meters, repeating it three times, which also allowed them to become familiarized with the examination.

The footprints were analyzed in accordance with footprinting pattern criteria that were based on the study by Silvino, Evanski e Waugh[16], as shown in Figure 2. The areas evaluated were the first to fifth toes (points 1-5), first to fifth metatarsals (points 6-10) and ankle (point 11) of both feet.

Figure 1. Plantar pressure taking.

 Grau I	 Grau II	 Grau III	 Grau IV
0.27 Kg/cm^2	1.25 Kg/cm^2	2.6 Kg/cm^2	4.80 Kg/cm^2

Figure 2. Print patterns and the respective pressure values.

The examiners were trained previously. The training consisted of familiarization with the test criteria, and then ten independent tests were analyzed by three examiners. The results were compared and disagreements were discussed in order to reach a standardized trial.

Reliability analysis

To evaluate the inter-rater reliability of the footprinting, the examinations were reviewed by three independent examiners. The results were recorded on separate forms to avoid comparison of the data during the analysis.

To assess the intra-rater reliability of the footprinting, one examiner reviewed the examinations on two different occasions with an interval of one week[24].

Statistical analysis

After performing a descriptive analysis on the data, the intra and inter-rater concordance and intra and inter-rater reliability were determined by calculating the Kappa coefficients of agreement, with their respective 95% confidence intervals. The weighted Kappa coefficient (K_w) was used because the data were categorical on an ordinal scale[25]. The SPSS for Windows software (Statistical Package for the Social Sciences), version 13.0 (Chicago, Illinois, USA) was used for descriptive analysis. To calculate the K_w coefficient, the StatXact 6 software (Cytel Software Corporation) was used. K_w values greater than 0.80 were deemed to characterize excellent agreement; values between 0.60 and 0.79, high concordance; values between 0.40 and 0.59, medium concordance; and values below 0.39, low concordance, as described by Landis and Koch[26].

Results

Among the 41 subjects, three underwent footprinting on only one foot. Among the other 38 individuals, footprinting was performed on both feet. The participants' mean age was 63.4 years (±9.73). The mean time elapsed from DM diagnosis was 14.3 years (±8.97). Incidence or recurrence of neuropathic injury was reported by 48.8% of the sample, and 22% had a history of amputation. The K_w intra and inter-rater coefficients (right and left foot) are shown, respectively, in Tables 1, 2 and 3. The results from the intra-rater concordance analysis, with a one-week interval between tests, showed high to excellent agreement. For most of the points studied on both feet, the inter-rater K_w showed rates above 0.80, thus characterizing the existence of significant agreement (high and excellent) among the three observers.

Discussion

The results from this study showed high to excellent concordance for intra and inter-rater footprint pattern analysis. There are no reports in the literature of studies on the reliability of methods for interpreting footprints obtained from the Harris and Beath footprinting mat, for evaluating foot pressures in individuals with DM neuropathy. Studies relating to the footprinting mat have prioritized the search for methods to transform the images into quantitative data by scanning the examinations for further electronic processing[27,28]. This procedure aims to optimize the footprinting reliability analysis. However, its use depends on specific software. In most cases, under clinical conditions, professionals attending DM patients do not have any electronic equipment at their disposal. The criteria for analyzing footprinting patterns that were used in this study depended only on training in order to transform the qualitative

assessment derived from the Harris and Beath footprinting mat, into categories (stages I to IV) that have quantitative equivalence. It is important to remember that this analysis criterion distinguishes values up to 4.80 kg/cm^2. According to Veves et al.[10], plantar foot ulceration in individuals with DM neuropathy occurs at pressure values greater than 12.3 kg/cm^2. Therefore, the Harris and Beath footprinting mat cannot predict the occurrence of ulceration, but it can be considered to be an effective tool for the initial diagnosis of abnormal distribution of plantar pressures, as mentioned by Gomes[29]. Early identification of areas that are potentially vulnerable to ulceration, because of association with insensitivity, favors preventive actions[14,15,22]. This is possibly one more reason why, in addition to the low cost, simplicity and portability of footprinting mats, in comparison with modern computerized baropodometry equipment, the footprinting technique has been kept in the routines that are internationally recommended for assessing patients with DM neuropathy[14,15,17,30].

The analysis criteria of Silvino, Evanski e Waugh[16] provides four degrees of pressure. However, the footprint images are often intermediate between one grade and another, which creates doubt among examiners. To minimize the possibility of error in this study, training was provided for the evaluators and a pilot test was conducted. Through this, assessment standards for these cases were established. This approach may not have been sufficient or it

Table 1. Intra-examiner agreement analysis.

	Right foot		Left foot	
Point	K_w	CI to 95%	K_w	CI to 95%
1	0.64	0.42-0.84	0.69	0.49-0.85
2	0.87	0.76-0.97	0.88	0.74-1.00
3	0.71	0.49-0.87	0.72	0.58-0.87
4	0.85	0.76-0.93	0.77	0.59-0.95
5	0.85	0.72-0.98	0.79	0.59-0.98
6	0.73	0.49-0.81	0.70	0.55-0.85
7	0.68	0.48-0.87	0.68	0.50-0.87
8	0.63	0.37-0.88	0.66	0.48-0.83
9	0.70	0.51-0.89	0.67	0.45-0.88
10	0.88	0.79-0.98	0.80	0.65-0.94
11	0.73	0.53-0.86	0.71	0.54-0.89

K_w=Weighted Kappa coefficient; CI=confidence interval to 95%.

Table 2. Right foot inter-examiners agreement analysis (A, B e C).

Examiners	A-B		A-C		B-C	
Points	K_w	IC to 95%	K_w	CI to 95%	K_w	CI to 95%
1	0.94	{0.84-1.00}	0.94	{0.88-1.00}	0.96	{0.91-1.00}
2	0.95	{0.89-1.00}	0.95	{0.89-1.00}	0.86	{0.75-0.96}
3	0.90	{0.81-1.00}	0.89	{0.80-0.98}	0.91	{0.82-0.99}
4	0.89	{0.79-0.99}	0.92	{0.83-1.00}	0.94	{0.85-1.00}
5	0.92	{0.83-1.00}	0.95	{0.84-1.00}	0.95	{0.83-1.00}
6	0.90	{0.77-1.00}	0.92	{0.84-0.99}	0.77	{0.62-0.92}
7	0.83	{0.69-0.97}	0.89	{0.78-1.00}	0.81	{0.61-1.00}
8	0.87	{0.70-1.00}	0.89	{0.75-1.00}	0.79	{0.59-0.98}
9	0.71	{0.49-0.93}	0.77	{0.58-0.96}	0.64	{0.34-0.95}
10	0.66	{0.41-0.91}	0.84	{0.67-1.00}	0.86	{0.70-1.00}
11	0.84	{0.75-0.94}	0.93	{0.79-1.00}	0.52	{0.24-0.79}

K_w=Weighted Kappa coefficient; CI=confidence interval to 95%.

Table 3. Left foot inter-examiners agreement analysis (A, B e C).

Examiners	A-B		A-C		B-C	
Points	K_w	CI to 95%	K_w	CI to 95%	K_w	CI to 95%
1	0.89	{0.74-1.00}	0.87	{0.74-1.00}	0.84	{0.71-0.98}
2	0.91	{0.81-1.00}	0.97	{0.93-1.00}	0.92	{0.84-0.99}
3	0.92	{0.85-0.99}	0.88	{0.78-0.97}	0.82	{0.70-0.94}
4	0.88	{0.78-0.98}	0.91	{0.83-0.99}	0.80	{0.70-0.91}
5	0.90	{0.82-0.99}	0.86	{0.71-1.00}	0.95	{0.85-1.00}
6	0.80	{0.61-0.99}	0.80	{0.66-0.93}	0.79	{0.66-0.92}
7	0.90	{0.79-0.98}	0.64	{0.33-0.95}	0.84	{0.71-0.97}
8	0.72	{0.47-0.98}	0.83	{0.68-0.98}	0.77	{0.61-0.92}
9	0.76	{0.62-0.90}	0.94	{0.86-1.00}	0.77	{0.61-0.93}
10	0.78	{0.62-0.93}	0.87	{0.79-0.96}	0.85	{0.76-0.95}
11	0.49	{0.21-0.76}	0.83	{0.68-0.98}	0.63	{0.42-0.83}

K_w=Weighted Kappa coefficient; CI=confidence interval to 95%.

may have been a limitation of the analysis method, since there was variability in the observed agreement between the points assessed, especially in relation to the inter-rater conditions. It is suggested that the classification of Silvino, Evanski e Waugh[16] could be subdivided in order to minimize the chances of doubt regarding footprint pattern analysis in future studies.

Within clinical settings, according to the results from this study, it may be inferred that the footprint pattern analysis identified abnormal plantar pressures and could also be used to monitor the distribution of plantar pressures in response to physical therapeutic interventions or to indicate the use of insoles to cushion the pressures.

Conclusions

Footprint pattern analysis on subjects with DM neuropathy, from the Harris and Beath footprinting mat, showed high to excellent agreement under inter and intra-rater conditions. Therefore, this method is reliable for analysis involving one or more examiners.

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