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Published in:
Foot

DOI:
10.1016/j.foot.2023.101990

The Foot 56 (2023) 101990

Contents lists available at ScienceDirect

The Foot

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

Effect of painful Ledderhose disease on dynamic plantar foot pressure distribution during walking: a case-control study

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ARTICLE INFO

Keywords:
Ledderhose disease
Plantar pressure
Walking
Pedobarography

ABSTRACT

Background: Plantar pressure distribution during walking in patients with painful Ledderhose disease is unknown.
Research question: Do patients with painful Ledderhose disease have an altered plantar pressure distribution during walking compared to individuals without foot pathologies? It was hypothesized that plantar pressure is shifted away from the painful nodules.
Methods: Pedobarography data of 41 patients with painful Ledderhose disease (cases, mean age: 54.2 ± 10.4 years) was collected and compared to pedobarography data from 41 individuals without foot pathologies (controls, mean age: 21.7 ± 2.0 years). Peak Pressure (PP), Maximum Mean Pressure (MMP) and Force-Time Integral (FTI) were calculated for eight regions (heel, medial midfoot, lateral midfoot, medial forefoot, central forefoot, lateral forefoot, hallux and other toes) under the soles of the feet. Differences between cases and controls were calculated and analysed by means of linear (mixed models) regression.
Results: Proportional differences in PP, MMP and FTI showed increased values for the cases compared to the controls, especially in the heel, hallux and other toes regions, and decreased values in the medial- and lateral midfoot regions. In naïve regression analysis, being a patient was a predictor for increased- and decreased values for PP, MMP and FTI for several regions. When dependencies in the data were taken into account with linear mixed-model regression analysis, the increased- and decreased values for the patients were most prevalent for FTI at the heel, medial midfoot, hallux and other toes regions.
Significance: In patients with painful Ledderhose disease, during walking, a shift of pressure was found towards the proximal and distal foot regions, while offloading the midfoot regions.

1. Introduction

Ledderhose disease is a benign hyperproliferative disorder of the foot [1]. It is characterized by slow growing subcutaneous nodules, often located on the medial and central bands of the plantar fascia (Fig. 1). The disease can cause symptoms of pain, increased tension of the fascia and pressure sensitivity in the affected foot [2–5]. Pain from foot pathologies, like Ledderhose disease, can have a tremendous negative impact on the ability to perform physical activity that involve standing, walking or running [6].

The plantar fascia is a complex network of fibrous tissues originating from the medial tubercle of the calcaneus and inserting into the phalanges and has strong vertical connections to deeper structures in the foot. It plays an important role during walking. During the different

Abbreviations: FTI, Force-Time Integral; MMP, Maximum Mean Pressure; PP, Peak Pressure; SD, Standard Deviation.

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https://doi.org/10.1016/j.foot.2023.101990
Received 16 January 2023; Received in revised form 23 February 2023; Accepted 27 February 2023
Available online 1 March 2023
0958-2592/

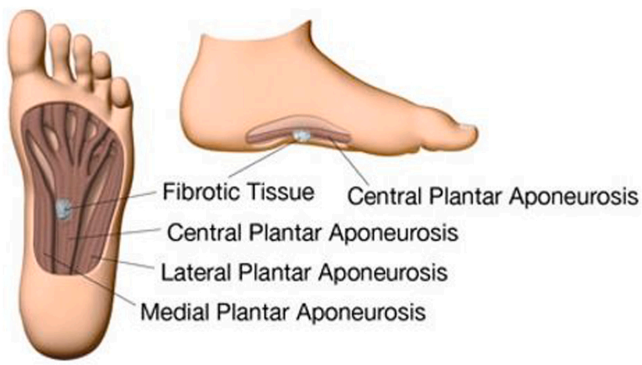

Fig. 1. Plantar fascia with a subcutaneous nodule [26]. Figure used with written approval from Dr. Spilken.

phases of the gait cycle the plantar fascia is subject to length changes as a result of forces applied to it. Pain from foot pathologies, like Ledderhose disease, can influence the way the foot is used and the amount to which the plantar fascia is loaded and therefore disturb the gait pattern [7–13]. The pain is often associated with abnormalities in plantar pressure distribution. These abnormalities can lead to injuries, imbalance and asymmetry in plantar pressure between the affected and unaffected foot, further increasing the risk of plantar injuries [14].

Dynamic plantar foot pressure measurements (pedobarography) can be used to evaluate plantar pressure distribution in patients with different types of foot disorders, both from a clinical and research perspective. The plantar pressure distribution is a kinetic measure which can provide valuable information on the nature of an individual's gait and may help to determine the impact of a disorder on walking. Besides, it can also be used to evaluate the effect of specific interventions, such as insoles, shoe modifications or foot orthoses [15–17]. Different types of plantar foot measurement systems are available: pressure platforms, imaging technologies and in-shoe pressure measurement systems [18]. The latter measures the pressure distribution at the foot-shoe interface and is adopted in both clinical and research field [18,19]. Due to the evolutions in this technology a wide range of in-shoe systems, from simple to very advanced, are available [18]. Overall advantages of this technology are efficiency (flexible and mobile), possibility to measure multiple steps and the possibility to monitor the effect of footwear and footwear adaptations on the mechanisms of the foot [18,20]. The pressure sensing elements in the insoles make it possible to divide the foot in several regions which contributes to the precision of analysis [18]. The accuracy and precision of the devices are important factors to take into account. The system used in this research meets the standards for accuracy and precision [19].

To the best of our knowledge, the exact effect of pain from Ledderhose disease on walking, and especially on plantar pressure distribution during walking, has never been reported before. Insights in potentially altered plantar pressure distribution during the gait cycle in patients with painful Ledderhose disease might offer opportunities for interventions. Therefore, the aim of this study was to explore plantar pressure distribution during walking in patients with painful Ledderhose disease. It was hypothesized that these patients had a different plantar pressure distribution during walking, compared to individuals without foot pathologies. A shift of plantar pressure away from the painful nodules was expected.

2. Methods

2.1. Study design

Dynamic plantar pressure distribution data from patients with painful Ledderhose disease (cases) and individuals without foot pathologies (controls) were compared.

2.2. Cases: patient population

The cases consisted out of patients with painful Ledderhose disease who all participated in the LedRad-study at the department of Radiation Oncology of the coordinating centre (NCT03507010, NL62429.042.17) [21]. The LedRad-study is a prospective multicentre randomized double-blind phase III trial into the effectivity of radiotherapy for Ledderhose disease. Approval for the study was obtained from the central institutional ethical review-board (METc 2017/397). Prior to enrolment, written informed consent was received from each patient. Main criteria for eligibility in the LedRad-study were: age ≥ 18 years, WHO-performance score between 0 and 2, pain score related to Ledderhose disease ≥ 2 (measured with the numeric rating scale (0−10)) and no previous surgery and/or radiotherapy for Ledderhose disease. Pedobarography assessments were part of the LedRad-study at several time points. For the current study, the data from the baseline (prior to treatment) pedobarography assessments were used. A schematic overview of the chronology of this study can be found in Fig. 2.

2.3. Controls: healthy population

A dataset with pedobarography data from individuals without foot pathologies (controls) was available at the department of Rehabilitation Medicine of the coordinating centre of the LedRad-study. This data was collected in previous research, under the same conditions (including the used footwear) and with the same system as with pedobarography assessments for the cases [22,23].

It was known upfront that the mean age of the controls was lower compared to the mean age of the cases. But as the methods applied in both groups were the same, the amount of data available is extensive and it is known, from previous research, that with increasing age no reductions in pressure parameters in the midfoot are expected [24], it was decided that it was valid to use this dataset for the comparison.

2.4. Pedobarography assessment

Flexible PEDAR® insoles (Pedar-X system, Novel Inc., Munich, Germany) were inserted into a standard shoe (Dr. Comfort Athletic Shoe Meghan and Chris, Mequon, WI, USA) to measure in-shoe plantar pressure. All insoles were 1.8 mm thick and consisted of 99 pressure sensors. Calibration of the insoles was performed according to the instructions of the manufacturer. Sampling frequency was set at 100 Hz and data was sent to a computer via Bluetooth® wireless communication. Patients were instructed to walk back and forth in the Motion Lab at their self-selected comfortable walking pace. After each walk it was checked if steps were registered correctly and once five valid walks were obtained the measurement was stopped. The walking speed for each walk was registered with the Nexus Vicon motion analysis system (©Vicon Motion Systems Ltd, UK), with one marker attached to the Pedar-X strap just above the umbilicus.

2.5. Data extraction

For the cases, only the data of the affected feet were analysed. The first four valid walks were selected for data analysis and the fifth was kept as reserve. As twelve steps per foot are recommended for valid and reliable in-shoe plantar pressure data, from each walk three valid steps, preferably from the mid part of a walk, were selected, resulting in 12 steps per foot [25]. Data from the controls was included in the analysis when 12 valid steps could be selected. With Pedar® medical professional software, the foot area was divided into eight anatomical regions (masks): heel, medial midfoot, lateral midfoot, medial forefoot, central forefoot, lateral forefoot, hallux and other toes (Fig. 3). In previous research, where the data of the controls was collected, the foot area was divided into seven anatomical masks. For this study, the midfoot mask was divided into a medial- and lateral midfoot mask, as the

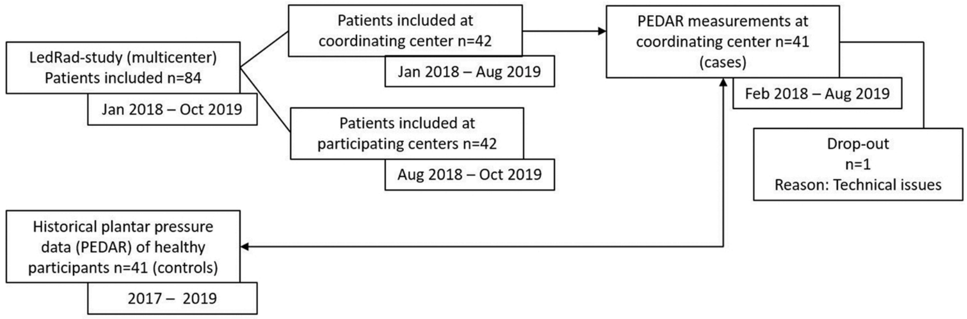

Fig. 2. Schematic overview of the chronology of the study.

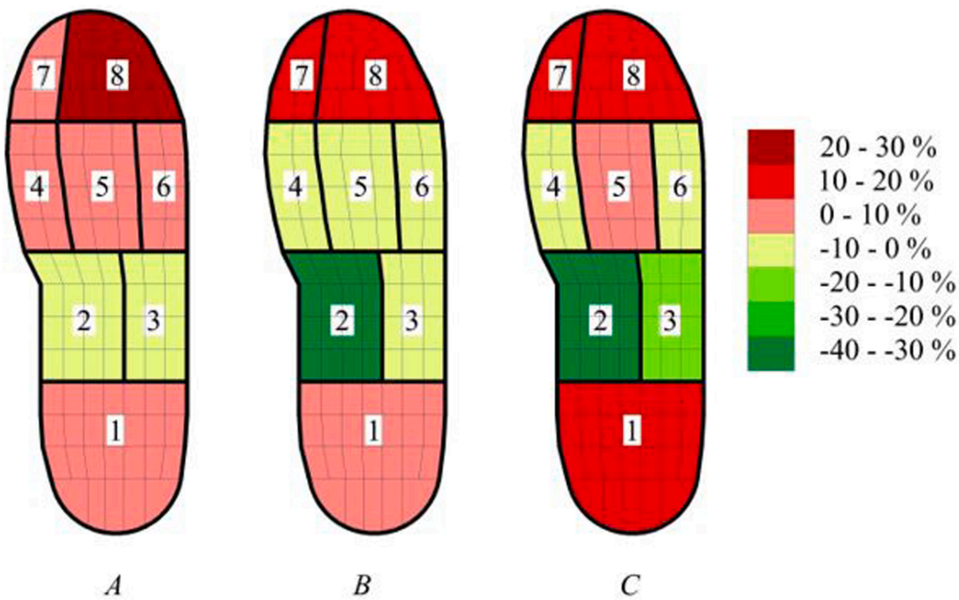

Fig. 3. The 99 sensors of Pedar-X divided into eight masks: 1. Heel, 2. Medial midfoot, 3. Lateral midfoot, 4. Medial forefoot, 5. Central forefoot, 6. Lateral forefoot, 7. Hallux and 8. Other toes. The colours show the proportional differences per mask (relative to individuals without foot pathologies). A: Peak Pressure, B: Maximum Mean Pressure and C: Force Time Integral.

subcutaneous Ledderhose nodules are in general located in the medial midfoot. Matlab (R2018a, MathWorks®, Natick, USA) was used to further process the data. For each step and mask the peak pressure (PP), maximum mean pressure (MMP) and force-time integral (FTI) were determined. PP is the maximum pressure over all individual sensors within a mask and all time frames of each step. MMP is the highest average pressure of all sensors within a mask during one step. FTI also includes time and represents the area under the force-time curve within each mask per step.

2.6. Statistical analysis

For the 12 included steps per subject, and for each mask of a foot, means and standard deviations of PP, MMP and FTI were obtained. Relative changes were calculated by dividing the means of the cases by the means of the controls, resulting in a value above or below 1.0. Proportional differences were derived from the relative changes. Positive values indicate an increase in pressure for the cases compared to the controls, while negative values indicate a decrease in pressure.

Subsequently, regression analyses were performed to assess the effect of group membership (cases versus controls) on the endpoints PP, MMP and FTI. The mean values for PP, MMP and FTI for each mask were used in these analyses (Table 1). In the first step, we assumed that measurements for each foot were independent (naïve analysis) and that there were no confounders. In the event that group (cases) was a significant factor, the potential association was further analysed using a linear mixed-model regression analysis with random intercept to correct for patient-to-patient variance (different feet are part of the same patient) and to check whether age, gender or walking speed were confounders. Statistical analyses were performed using R (version 4.0.5.), with the 'nlme' package (version 3.1–152) for linear mixed effect models. For all testing for differences between the cases and controls, the level of significance was set at $p < 0.05$.

3. Results

The cases consisted of 13 males and 28 females with a mean age of 54.2 (± 10.4 (SD)) years and an average walking speed of 1.32 (± 0.25 (SD)) m/s. The controls consisted of 14 males and 27 females with a mean age of 21.7 (± 2.0 (SD)) years and an average walking speed of 1.47 (± 0.20 (SD)) m/s. All affected feet of the cases (100%) had subcutaneous Ledderhose nodules in the medial midfoot mask while 12% of the affected feet also had nodules in other masks (lateral midfoot, heel, medial- central- or lateral forefoot).

All the proportional differences for PP, MMP and FTI at each mask, are shown in Fig. 3. Largest increases, for the cases compared to the controls, were found for PP in the other toes mask (+20%), for MMP in the hallux and other toes masks (+10% and +13%, respectively) and for

Table 1
Mean values ± SD for Peak Pressure (PP), Maximum Mean Pressure (MMP) and Force Time Integral (FTI) for each mask for the patients with painful Ledderhose disease (cases) and the individuals without foot pathologies (controls). Abbreviations: MF: midfoot, FF: forefoot.

	Cases (n = 41)	Controls (n = 41)	p-value*
	Mean (± SD)	Mean (± SD)	
PP (kPa)			
1. Heel	237.5 (± 32.9)	230.7 (± 40.7)	0.29
2. Medial MF	72.1 (± 34.7)	77.5 (± 25.2)	0.30
3. Lateral MF	93.4 (± 29.7)	94.9 (± 22.6)	0.72
4. Medial FF	202.3 (± 44.2)	190.4 (± 47.4)	0.14
5. Central FF	229.1 (± 42.7)	211.4 (± 37.8)	0.02
6. Lateral FF	163.5 (± 41.7)	158.0 (± 40.0)	0.55
7. Hallux	207.1 (± 68.1)	194.1 (± 53.8)	0.22
8. Other toes	169.9 (± 50.2)	142.1 (± 39.1)	< 0.001
MMP (kPa)			
1. Heel	134.2 (± 22.3)	133.2 (± 23.0)	0.84
2. Medial MF	12.9 (± 10.9)	19.0 (± 8.3)	< 0.001
3. Lateral MF	50.0 (± 19.0)	55.1 (± 18.5)	0.09
4. Medial FF	102.7 (± 35.6)	109.2 (± 29.6)	0.21
5. Central FF	124.8 (± 33.0)	127.5 (± 24.7)	0.45
6. Lateral FF	95.5 (± 28.1)	98.1 (± 30.6)	0.52
7. Hallux	140.1 (± 45.9)	128.0 (± 34.9)	0.07
8. Other toes	83.7 (± 30.6)	73.8 (± 19.7)	0.02
FTI (Ns)			
1. Heel	153.9 (± 33.0)	132.1 (± 31.7)	< 0.001
2. Medial MF	8.5 (± 8.5)	13.3 (± 8.2)	0.001
3. Lateral MF	31.1 (± 17.2)	36.8 (± 14.8)	0.03
4. Medial FF	38.1 (± 15.0)	41.1 (± 15.5)	0.23
5. Central FF	77.9 (± 24.9)	77.3 (± 20.8)	0.94
6. Lateral FF	42.5 (± 16.5)	43.1 (± 15.3)	0.74
7. Hallux	24.4 (± 9.6)	20.7 (± 6.3)	0.005
8. Other toes	38.2 (± 16.8)	33.2 (± 11.3)	0.03

*p-value from naïve linear regression analysis

FTI in the heel, the hallux and the other toes masks (+17%, +18% and +15%, respectively). Largest decreases were found for MMP in the medial midfoot mask (−32%) and for FTI in the medial- and lateral midfoot masks (−36% and −15%, respectively).

Naïve regression analysis showed that being a Ledderhose patient was a predictor for differences in PP, MMP and FTI for several masks. Compared to the controls, cases had higher PP in the central forefoot and in the other toes masks ($p = 0.02$ and $p < 0.001$, respectively), higher MMP in the other toes mask ($p = 0.02$) and lower MMP in the medial midfoot mask ($p < 0.001$), higher FTI in the heel, the hallux and the other toes masks ($p < 0.001$, $p = 0.005$ and $p = 0.03$, respectively) and lower FTI in the medial- and lateral midfoot masks ($p = 0.001$ and $p = 0.03$, respectively).

Compared to the controls, cases had higher PP in the other toes mask ($p = 0.003$) and higher FTI in the heel and the hallux masks ($p = 0.002$ and $p = 0.02$, respectively), when accounting for dependencies in the data with linear mixed-model regression. Conversely, the cases had lower MMP and FTI in the medial midfoot mask ($p = 0.003$ and $p = 0.005$, respectively) compared to the controls.

Age was a confounder for all significant effects of group (cases versus controls) on the values of PP, MMP and FTI, for the specific masks from linear mixed-model regression analysis, but could not be added to the final model as it was highly correlated to variable group (0.82). Gender and walking speed were no confounders.

4. Discussion

To the best of our knowledge, this is the first study to explore the dynamic plantar foot pressure distribution in patients with painful Ledderhose disease during walking. Compared to individuals without foot pathologies we found a shift of pressure (PP, MMP and FTI) for the patients with painful Ledderhose disease towards the proximal and distal foot regions, while offloading the midfoot regions.

This shift of pressure supports our hypothesis that patients with painful Ledderhose disease have a different plantar pressure distribution during walking due to their disease. The Ledderhose nodules are often located in the medial midfoot and from these results we learned that this region is offloaded during walking. These differences are especially evident for the FTI, in which the time component is included and the entire load of each region is evaluated. In PP and MMP, where the duration of the pressure is not incorporated in the parameter, the difference between patients and controls is less evident. For patients with painful Ledderhose disease the load on the entire heel and hallux regions is increased and the load on the entire medial midfoot region is decreased, during walking.

There is only one other study reporting on dynamic pressure distribution in patients with Ledderhose disease [25]. In this study, the differences in pressure distribution during static bipedal standing were investigated between patients with Ledderhose disease ($n = 3$) and healthy individuals ($n = 20$). Like in our study, decreases in maximum- and mean pressures at and around the area with the Ledderhose nodule (s) were found.

Our study has several strengths. Considering the incidence of Ledderhose disease and compared to the other study reporting on dynamic pressure distribution in patients with Ledderhose disease our study consisted of a large patient cohort, not described before. And as the pedobarography measurements were all performed at the same location and under the same conditions the risk of measurement bias is low.

The main limitation of our study is that the cases and controls could not be matched with regard to age and gender, as the pedobarography data of the controls was only available in the dataset collected during previous research. Age appeared to be a confounding factor in the results but was highly correlated to the variable group (patient versus healthy subject). However, as earlier research found that with increasing age no reductions in pressure parameters in the midfoot are expected [24], we conclude that we found some first strong leads that the shift of pressure, we found for the patients in our study, is related to painful Ledderhose disease.

In conclusion, we found that patients with painful Ledderhose disease have a different plantar pressure distribution during walking. The insights gained with this study are helpful in providing clinical interventions, like custom insoles and shoe adaptations, and might be used for evaluation of the effectiveness of treatment, for example radiotherapy.

Brief summary

What is already known.

- Ledderhose disease is a benign hyperproliferative disease
- Over time symptoms can aggravate to become disabling
- The exact effect of Ledderhose disease on plantar pressure distribution during walking is unknown

What this study adds

- First insight in effect of Ledderhose disease on plantar pressure distribution during walking
- Offloading of affected midfoot regions during walking
- Increase of load on heel and hallux regions during walking

Funding

The LedRad-study is supported by a grant of ZonMw (843001809).

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: P. M.N. Werker was a SERB member and is currently a DMC member of Fidia Ltd, Milan, Italy. The other authors declare that they do not have

any known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

We are indebted to all patients within the LedRad study at the UMCG for their willingness to undergo the pedobarography measurements. We thank Chantal Beijersbergen and Thijs Lutjeboer from the department of Rehabilitation Medicine at the UMCG for their support and supervision with the pedobarography measurements at the Motion Lab. We also like to thank Laurens van Kouwenhove, also from the department of Rehabilitation Medicine at the UMCG, with his support for processing the data with Matlab.

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