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ORIGINAL PAPER

Off-loading strategies in diabetic foot syndrome–evaluation of different devices

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Abstract
Introduction Diabetic foot syndrome is one of the most dreaded complications in diabetes mellitus. The purpose of this study was to assess the value of different offloading devices compared to walking in barefoot condition and in normal shoes both in healthy subjects and in patients with diabetes and neuropathy.
Methods Twenty patients with diabetes and polyneuropathy and ten healthy probands were included. Pedobarographic examination was performed in barefoot condition, with sneakers, postoperative shoes, Aircast® Diabetic Pneumatic Walker™ and VACO®diaped. In the diabetic group, a total contact cast was additionally tested.
Results The most effective reduction of force was achieved by TCC (75%) and VACOdiaped (64.3%) with the VACO®diaped resulting in the most homogeneous distribution of forces all over the foot.
Discussion/Conclusion A customized device like the TCC is still the most proven offloading device. However, a removable cast walker being based on vacuum pads and a cushioning sole, provides better results concerning force distribution.

Keywords Diabetic foot syndrome · Off-loading strategies · Orthosis · TCC

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Introduction

Diabetes mellitus is one of the most common diseases worldwide and is associated with the risk of developing severe comorbidities and complications [1]. In 2014 the global prevalence of diabetes was estimated to be 8.5% among adults aged 18+ years [2]. It is supposed that 50% of all diabetic patients who have suffered the disease for more than 20 years develop peripheral neuropathy. This is one of the most important risk factors for the diabetic foot syndrome, which leads to high morbidity, reduced quality of life and high costs for healthcare [3, 4]. The prevalence of foot ulceration in the general diabetic population is stated with 4–10% [5].

Non-weight bearing strategies in terms of bed rest or use of wheelchair seem to be most effective in acute ulcer treatment but restricted by patients' compliance, quality of life and mobility [6–8]. As alternative treatment options, offloading orthotic devices are used to mitigate pressure at an area of high vertical or shear stress [9]. Different offloading modalities exist like post-operative shoes, felt padding, half-shoes, cast-shoes and walkers [10], as well as two-shell unloading casts. Total contact cast (TCC) seems to be the gold standard in the United States and some western countries to relieve plantar pressure from the ulcer [11]. In their systematic review de Oliveira and Moore describe the TCC as the most effective device to achieve ulcer healing [12]. The disadvantages of the TCC are time-consuming application, learning curve, lack of qualification of auxiliary staff, no assess to the wound on a daily base, contraindication in soft tissue infections or osteomyelitis and impaired activities of daily living [9, 12]. It is thus not surprising that a US survey showed that this therapy, considered as the gold standard, is used by merely 1.7% of centres for treatment of plantar diabetic foot ulcer [9]. In case of plantar ulcers post-operative shoes gained popularity to reduce plantar pressure in the forefoot region [13]. An alternative option of care is the commercially available removable cast walker (RCW). Although this device is claimed to be equivalent to the TCC, you can find divergent study results in literature. In summary, there is only weak evidence for the effectiveness of offloading devices for diabetes-related plantar neuropathic foot ulcers [14, 15].

The aim of our study was to assess the value of four different offloading devices (TCC, post-operative shoe, vacuum cushioned RCW, air cushioned RCW) in patients with diabetes and neuropathy. We compared these results with walking in barefoot condition and in normal shoes.

We hypothesized that

– diabetic neuropathy alters the pedobarographic outcome compared to a healthy probands group when using the same devices
– the TCC still provides the best off-loading in the group of patients with diabetic neuropathy.

Materials and methods

Subjects

In this study we recruited 30 probands, 20 patients (group A) with diabetes mellitus and peripheral neuropathy and ten age-matched healthy probands as control group (group B), passing the same study protocol except for TCC.

Inclusion criteria for group A were the long-term presence of diabetes mellitus, a reduction of the vibration sense (<6/8 using a 128 Hz tuning fork) and/or no detection of application of the Semmes-Weinstein 5.07 monofilament wire, which exerts 10 g of force. The presence of plantar callosities was essential but no ulceration (Armstrong classification Grade 0). Inclusion criteria for group B were men or women between the age of 50 and 65 without any systemic disease and physiologic gait pattern. Exclusion criteria for both groups were the use of walking aids, former musculoskeletal surgery, neurological diseases, vestibular deficiencies or any other systemic disease, which could influence gait pattern. Patients not willing to participate in the study were excluded as well. Patients and probands provided informed consent to the study protocol that was approved by the local ethics committee (Ethic Committee Approv. No 10-101-0089).

Pedobarography

Plantar pressure distribution was measured with a resistive sensor F-Scan in-shoe system (100 Hz, SCAN 3000 Tekscan Inc., South Boston/USA). The F-Scan insole is a very thin disposable force-sensing resistor insole (0.15 mm) with a maximum of 1260 elements. The density of the sensors is 4 sensors/square centimeter. The insole can be trimmed to fit various shoe sizes [16]. Good reliability was shown in previous studies [17–19].

Tested devices and test procedure

The different test conditions comprised barefoot walking, walking with standard shoes and walking with different orthosis, which are routinely used in diabetic foot syndrome:

- postoperative shoe: orthosis “Hannover” (Fior & Gentz, Lueneburg/Germany (Fig. 1).
- air-cushioned RCW: AIRCAST® Diabetic Pneumatic Walker™ (Ormed GmbH, Freiburg/Germany) (Fig. 2).
- vacuum-cushioned RCW: VACO®diaped (OPED GmbH, Valley/Germany) (Fig. 3).
- Total Contact Cast (in the diabetic group) (products by Lohmann & Rauscher GmbH & Co. KG, Neuwied/Germany).
- standard shoe: “Cascadia 4“(Brooks Sports, Inc., Seattle, USA).
- Barefoot walking condition: simulated by fixing the sensor sole with a thin cotton sock.

Methods

Pedobarographic examination was performed with sensor insoles in barefoot condition, with sneakers, post-operative shoes, Aircast® Diabetic Pneumatic Walker™, VACO®diaped and TCC. Control group passed through the same test protocol except TCC. The order of the different devices was randomized.

Fig. 1 **a**, **b** postoperative shoe

Fig. 2 Aircast ® Diabetic Pneumatic Walker™

After an adaption phase (50 metres) patients had to walk a distance of about 10 metres, recording was performed only in one direction. In total, we recorded four sequences for each patient for each device. Patients were asked to walk in comfortable walking speed to eliminate a potential bias by determining the speed and to guarantee a real-life scenario. Data of first and last recorded step were discarded. For recording the software Foot-Scan Research 5.24 (Tekscan Inc., South Boston/USA) was used. The foot was divided into three regions: forefoot, midfoot, hindfoot. Hindfoot was defined as the region of the heel, forefoot as the area from metatarsal heads I–V to the toes and midfoot as the region in between. In consideration of Nagel's study protocol [13] following parameters were determined: contact area (CA), contact time (CT), maximum force (MF), force–time integral (FTI) and peak pressure (PP) as the highest local load within the region.

Statistics

All statistical analyses were performed with the use of PASW Statistics 18.0.3 (SPSS Inc. Chicago, Illinois USA). The Kolmogorow-Smirnov-test for samples was used to evaluate normal distribution. Subsequent to the descriptive statistics, a variance analysis (ANOVA) for adjusting the differences in average was conducted in both groups using post hoc Tamhane-T2. The Levene's test was conducted for both anthropometric data and pedobarographic parameter. The significance level was set at $p \leq .05$.

Results

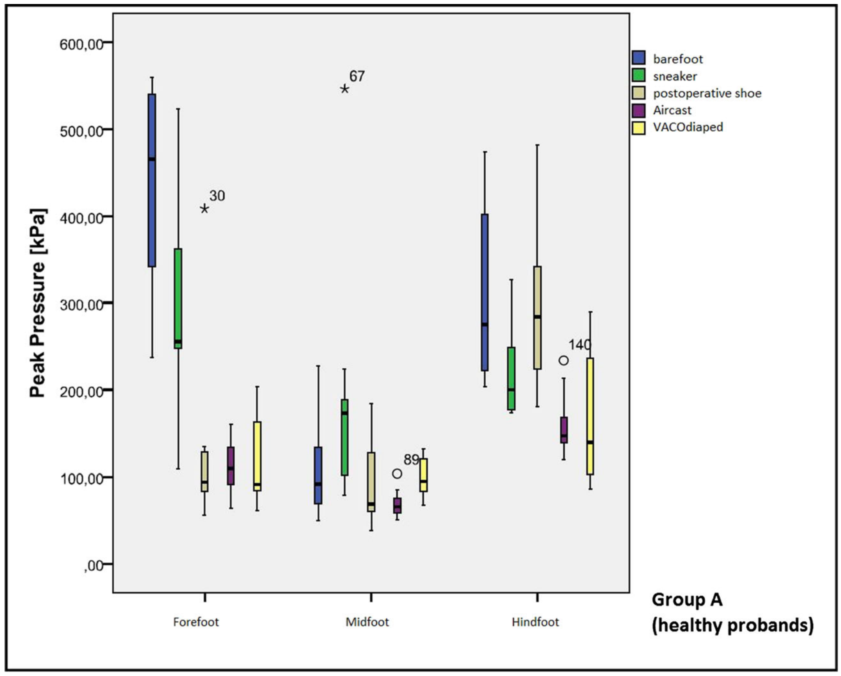
Twenty patients suffering from diabetes mellitus type II (group A) and ten healthy probands (group B), serving as control group, were included. Demographic data are presented in Table 1.

The different walking conditions revealed an influence on the contact time of the three different regions of the foot during rollover (Table 2). In both groups, the Aircast was the only device with a statistically significant difference in contact time of the forefoot compared to barefoot walking and walking with sneakers. The greatest effect was demonstrated in both study groups regarding the hind foot. There was no significant difference of contact time of the hind foot when walking in barefoot condition or with sneaker. However, compared to these two walking conditions every other device caused a significant prolonged contact time of the hind foot.

Contact area of the three regions of the foot showed differences during rollover between healthy probands and patients with diabetic polyneuropathy (Table 3). In group A we could detect statistically significant differences only in the forefoot region when comparing the post-operative shoe with the other walking conditions. In group B the sneaker showed the greatest contact area in the forefoot, followed by the Aircast. The post-operative shoe (53 cm^2) and the TCC (58.9 cm^2) had the smallest contact area.

Fig. 3 VACO®diaped

Fig. 4 Boxplot of peak pressure in group A



Maximum force was significantly reduced in the forefoot of healthy probands and patients with diabetic neuropathy during walking with all devices compared to barefoot walking and walking with sneakers. In group B, the post-operative shoe showed a reduction of 82% of maximum force and Aircast and VACOdiaped showed a reduction of 52 and 64%, respectively.

The effect of the different orthosis in group A was different. All orthosis revealed a significant decrease of maximum force in the forefoot compared with barefoot condition or walking with sneakers. Compared to group B the post-operative shoe showed a decrease of only 59% and was in the same range with the Aircast (59%) and the VACOdiaped (64%). The TCC showed a reduction of 75% of maximum force.

Concerning the maximum force of the midfoot the use of sneakers led to an increase in both cohorts, the post-operative shoe showed a decrease in group B and an increase in group A. The use of Aircast showed no differences in maximum force of the midfoot compared to walking in barefoot condition, the VACOdiaped showed an increase, which was not significant. The TCC had almost the same value as barefoot condition.

Table 1 Groups A and B demographic data

$N = 30$		Group A DN ($n = 20$)	Group B HP ($n = 10$)
Sex	Male (n [%])	19 (95%)	3 (30%)
	Female (n [%])	1 (5%)	7 (70%)
Age (m ± sd)		61.4 ± 5.10	55.2 ± 4.32
BMI (med [Q1, Q3])		3131.82 (28.1, 34.52)	28.06 (26.1, 30.5)

DN patients with diabetic neuropathy, *HP* healthy probands

Concerning the hindfoot, the VACOdiaped was the only orthosis that achieved a significant decrease of maximum force in group B. In group A, all orthosis except the post-operative shoe had a significant lower maximum force in the hindfoot region (Table 4).

In regards to the force-time integral of the forefoot region of group A all orthosis and the TCC managed to decrease the values significantly up to 64%. In group B only the post-operative shoe showed a significant reduction of 85% in the forefoot region. Midfoot showed no significant differences in this group and the post-operative shoe led to a significant increase of force-time integral in the hindfoot. In group A the post-operative shoe and the VACOdiaped showed a significant increase in the midfoot. Concerningthe hindfoot no significant differences between all orthosis and barefoot walking could be detected (Table 5).

Plantar peak pressure of the forefoot could be significantly reduced with the three orthosis in both groups. The TCC showed the same effect in group A. In the midfoot region, the only statistically relevant differences could be detected between the higher peak pressure of the VACOdiaped compared to the Aircast in group B and the increase of peak pressure in group A when walking with sneakers instead of walking barefoot. In both groups, both Aircast and VACOdiaped had a significant decrease of peak pressure compared to barefoot walking (Table 6, Figs. 4 and 5).

Discussion

Interdisciplinary care approach in the treatment of diabetic foot ulcer is essential [20]. Besides adequate wound

Table 2 Contact time [ms]

	Forefoot	Midfoot	Hindfoot
Healthy probands			
Barefoot	607.6 ± 69.3*(1)	443.3 ± 72.9*(5,7)	460.6 ± 87.1*(10,11,12)
Sneaker	597.6 ± 52.3*(2)	548.8 ± 92.6*(8)	521.1 ± 82.6*(13,14,15)
Postoperative shoe	499.8 ± 123.7*(3,4)	515.1 ± 121.1*(6,9)	658.1 ± 69.1*(12,13)
Aircast	738.3 ± 69.2*(1,2,3)	676 ± 90.3*(5,6)	717.5 ± 102.2*(10,14)
VACO®diaped	671.4 ± 97.2*(4)	690.4 ± 74.7*(7,8,9)	712.6 ± 80*(11,15)
Patients with diabetic neuropathy			
Barefoot	737.6 ± 74*(a)	542 ± 107.7*(c,d,e,f)	580.2 ± 109.3*(j,k,l)
Sneaker	728.3 ± 84.4*(b)	631.7 ± 101.9*(g,h,i)	656.9 ± 109.9*(m,n,o,p)
Postoperative shoe	714.1 ± 132.8	679.9 ± 148.8*(c)	777.6 ± 110.7*(j,m,q)
Aircast	826.9 ± 101.1*(a,b)	747.8 ± 109.7*(d,g)	843.5 ± 113.9*(k,n)
VACO®diaped	794.3 ± 83.2	774.3 ± 85.4*(e,h)	811.8 ± 115.4*(l,o)
Total contact cast	831.1 ± 126.4	769.6 ± 92.4*(f,,i)	913.8 ± 140.1*(m,p,q)

Items with an asterisk present a significant difference. The same numbers or letters in brackets flesh out the pair of devices, in which the significant difference was detected, e.g. significant difference in healthy probands between barefoot walking (1) and Aircast walking (1) concerning contact time, illustrated by superscript (1)

management, treatment of infection and control of comorbidities [21], off-loading is the most important tool in ulcer healing. Although there exist different orthotic devices, there is lack of data comparing their effectiveness concerning off-loading in healthy probands and patients with diabetic neuropathy. In accordance with Chakraborty et al. it is important to differentiate between "unweighting the foot" which means that there is no weight on the foot and "off-loading the foot" which is described as rebalancing the weight on the foot/leg, with the patient still weight-bearing [22]. Off-loading is the most important method to redistribute pressure in order to reduce force on the site of the pressure sore [10].

Table 3 Contact area [cm^2]

	Forefoot	Midfoot	Hindfoot
Healthy probands			
Barefoot	67.7 ± 8.1*(1)	29 ± 15.7	38.7 ± 9.5
Sneaker	74.9 ± 7*(2)	39.4 ± 10.9	45.4 ± 9.4
Postoperative shoe	36.3 ± 4.1*(1,2, 3,4)	29.7 ± 20.8	41 ± 7.3
Aircast	77.4 ± 30.2*(3)	31.8 ± 8.9	43.8 ± 7.5
VACO®diaped	67.1 ± 12.9*(4)	41.7 ± 11.8	40.7 ± 7.3
Patients with diabetic neuropathy			
Barefoot	70.5 ± 12.5*(a,b)	26.9 ± 10.6*(g,h)	43.8 ± 6.8
Sneaker	84.8 ± 13.1*(a,c,d,e)	40.8 ± 8.2*(g)	46.5 ± 8.2
Postoperative shoe	53 ± 15.4*(b,c,f)	31.9 ± 10.1	45.1 ± 7.5
Aircast	73.6 ± 18.7*(f)	33.4 ± 10.8	46.6 ± 7.5
VACO®diaped	67.3 ± 18.1*(d)	40.7 ± 8.6*(h)	43.6 ± 9.3
Total contact cast	58.9 ± 20.6*(e)	31.9 ± 10.7	45.6 ± 7.4

Items with an asterisk present a significant difference. The same numbers or letters in brackets flesh out the pair of devices, in which the significant difference was detected

Therefore, the aim of our study was to evaluate the pressure relief of the most common orthosis, both in healthy probands with physiological sensibility and patients with verified diabetic neuropathy.

> Our first hypothesis was: Diabetic neuropathy alters the pedobarographic outcome compared to a healthy probands group when using the same devices.

In relation to the data from all devices tested we could demonstrate that the effectiveness of the post-operative shoe was lesser in the group of the diabetic probands. Furthermore, contact area, maximal force and force time integral were significantly elevated in the diabetes group ($p \leq 0.05$).

The forefoot region is of particular interest in diabetic foot syndrome, being the area with the most frequent incidence of pressure sores. As a matter of fact, we supposed, that patients with neuropathy and the consequent loss of superficial and deep sensibility develop gait patterns with a stamping, unsteady and insecure gait. This would lead to an inadequate use of the post-operative shoe. The decreased peak pressure in the hindfoot region when using the postoperative shoe in the group with diabetic neuropathy supported this hypothesis. The other orthosis that had been tested did not show similar results so that a negative influence of diabetic neuropathy on their efficacy could not be proven.

> Our second hypothesis was: The TCC still provides the best off-loading in the group of patients with diabetic neuropathy.

All orthosis showed a statistically significant increase in contact time in mid- and hindfoot region compared to the barefoot walking condition. However, this result must be

Table 4 Maximum force [N]

	Forefoot	Midfoot	Hindfoot
Healthy probands			
Barefoot	707.7 ± 166.7*(1,2,3)	105.4 ± 60.9	455.9 ± 133.3*(11)
Sneaker	621.3 ± 173.8*(4,5,6)	171.9 ± 72.5*(8)	410 ± 84.3*(12)
Postoperative shoe	125.7 ± 48.6*(1,4,7)	73.5 ± 42.6*(8,9)	552.2 ± 155.7*(10,13)
Aircast	337.2 ± 108*(2,5,7)	86.6 ± 36.6	334.1 ± 79*(10)
VACO®diaped	258.1 ± 122.9*(3,6)	135.9 ± 44.2*(9)	237.4 ± 135.8*(11,12,13)
Patients with diabetic neuropathy			
Barefoot	773.5 ± 148.9*(a,b,c,d,e)	100.6 ± 55.6*(k,l)	548.9 ± 111.5*(p,q,r,s)
Sneaker	586.6 ± 162.6*(a,f,g,h,i)	169.1 ± 46.2*(k,m,n)	395.6 ± 108.3*(p,t,u)
Postoperative shoe	314.7 ± 164.8*(b,f)	163.3 ± 67.6*(l,o)	526 ± 114*(t,v,w,x)
Aircast	316 ± 120.3*(c,g,j)	94.9 ± 37.5*(m,o)	350.2 ± 97.2*(q,v)
VACO®diaped	276.4 ± 111.6*(d,h)	175 ± 161.8	280.4 ± 95.8*(r,u,w)
Total contact cast	193.5 ± 111,1*(e,i,j)	101.2 ± 76,2*(n)	362.9 ± 135,7*(s,x)

Items with an asterisk present a significant difference. The same numbers or letters in brackets flesh out the pair of devices, in which the significant difference was detected

attributed to the lower velocity when walking with restraining orthoses. Choosing an individual free walking speed was one of the study's pillars as a prescribed speed—even in probands with neuropathy—would generate incalculable consequences on gait patterns [23]. Plotnik et al. reported about slowed gait related effects on asymmetry of gait [24]. However, the condition of walking with an orthosis inevitably leads to a slower gait speed influencing especially the parameter contact time.

The differences in contact area, however, are to be considered as an immediate effect of the orthoses and their different mechanisms of action. Regarding the postoperative shoe the reduction of contact area in the forefoot region is significantly higher compared with VACOdiaped and Aircast. However, the principles of VACOdiaped, Aircast and TCC ensure a decrease of force and pressure by enlargement of the contact area. Assessing the anatomic conditions of the human foot the midfoot area offers the greatest potential for raising the magnitude of the loaded area. In relation to our results, the VACOdiaped showed significantly superior results in increasing midfoot's contact area compared with barefoot walking condition and the other devices.

Relevant issues for proving the effectiveness of orthotic treatment in diabetic foot syndrome are especially the reduction of maximum force, peak pressure and force time integral at the predilection sites of the forefoot. All tested devices showed a significant decrease concerning the above mentioned parameters, thus demonstrating their efficacy.

In regards to the forefoot the TCC was the most effective device. The VACOdiaped achieved the most homogeneous distribution of forces among the entire sole.

Raspovic and Landorf list elevated peak pressure as a significant risk factor for ulceration [10]. Summarizing all orthotic devices, peak pressure was most affected by the VACOdiaped. Similar to the results of maximum force, the VACOdiaped presented the most homogeneous distribution of peak pressure among the sole with peak pressure in forefoot and hindfoot being lower than those of the other devices.

The most notable change concerning force-time integral in the forefoot was found with the TCC. Increased contact area and contact time in the midfoot region consequently led to an increase of force-time integral in the midfoot region for all tested

Table 5 Force-time-integral [Ns]

	Forefoot	Midfoot	Hindfoot
Healthy probands			
Barefoot	206.3 ± 117.4*(1)	37.6 ± 36.6	103.2 ± 29.8*(4)
Sneaker	144.9 ± 37.8*(2)	51.1 ± 27.3	97.9 ± 28.3*(5)
Postoperative shoe	30.7 ± 18.2*(1,2,3)	27 ± 19.2	234.1 ± 82.6*(4,5,6)
Aircast	130.4 ± 53.4*(3)	30.1 ± 18.9	142.7 ± 45.6
VACO®diaped	94.1 ± 61.2	53.1 ± 19.7	92.5 ± 58.6*(6)
Patients with diabetic neuropathy			
Barefoot	218.4 ± 49.1*(a,b,c,d)	27.3 ± 20.1*(h,i,j)	168.4 ± 80.1
Sneaker	178.6 ± 89.5*(e,f,g)	58.1 ± 27.4*(h,k)	137 ± 66.6*(n,o)
Postoperative shoe	93.5 ± 46.6*(a,e)	55.6 ± 27.1*(i,l)	220.5 ± 55.9*(n,p)
Aircast	121.9 ± 56*(b)	36.1 ± 21.1	181.7 ± 92
VACO®diaped	96.6 ± 50.3*(c,f)	59.8 ± 28.6*(j,m)	132.5 ± 69.1*(p,q)
Total contact cast	79.4 ± 52.1*(d,g)	32.9 ± 15.9*(k,l,m)	227.3 ± 89.2*(o,q)

Items with an asterisk present a significant difference. The same numbers or letters in brackets flesh out the pair of devices, in which the significant difference was detected

Table 6 Peak pressure [kPa]

	Forefoot	Midfoot	Hindfoot
Healthy probands			
Barefoot	438.4 ± 113.5*(1,2,3)	105,9 ± 52,8	308,7 ± 100,9*(8,10)
Sneaker	295.4 ± 112.6*(4,5,6)	192.2 ± 133.1	217.5 ± 50.5
Postoperative shoe	124.5 ± 103.2*(1,4)	87.4 ± 46.4	302.3 ± 100.9*(9,11)
Aircast	111.9 ± 29.1*(2,5)	68.9 ± 16.7*(7)	160.3 ± 36.4*(8,9)
VACO®diaped	117.2 ± 48.8*(3,6)	98.41 ± 23.3*(7)	171.3 ± 75.1*(10,11)
Patients with diabetic neuropathy			
Barefoot	491.6 ± 208.3*(a,b,c,d,e)	95.3 ± 35.7*(g)	322.2 ± 108.8*(h,i,j)
Sneaker	301.8 ± 134.7*(a,f)	148.4 ± 51.9*(g)	193.6 ± 68.9*(h)
Postoperative shoe	229.5 ± 251.8*(b)	165.3 ± 167.3	243 ± 46.7*(k11)
Aircast	181.6 ± 225.4*(c)	92.5 ± 110.8	187.2 ± 65.5*(i,l)
VACO®diaped	126.8 ± 62.9*(d,f)	104.5 ± 70	177.3 ± 66.3*(j,k,m)
Total contact cast	185.7 ± 179.1*(e)	115.7 ± 172.8	287.9 ± 115.4*(l,m)

Items with an asterisk present a significant difference. The same numbers or letters in brackets flesh out the pair of devices, in which the significant difference was detected

orthoses. The results in the hindfoot diverged. The VACOdiaped presented the most homogeneous distribution along the foot.

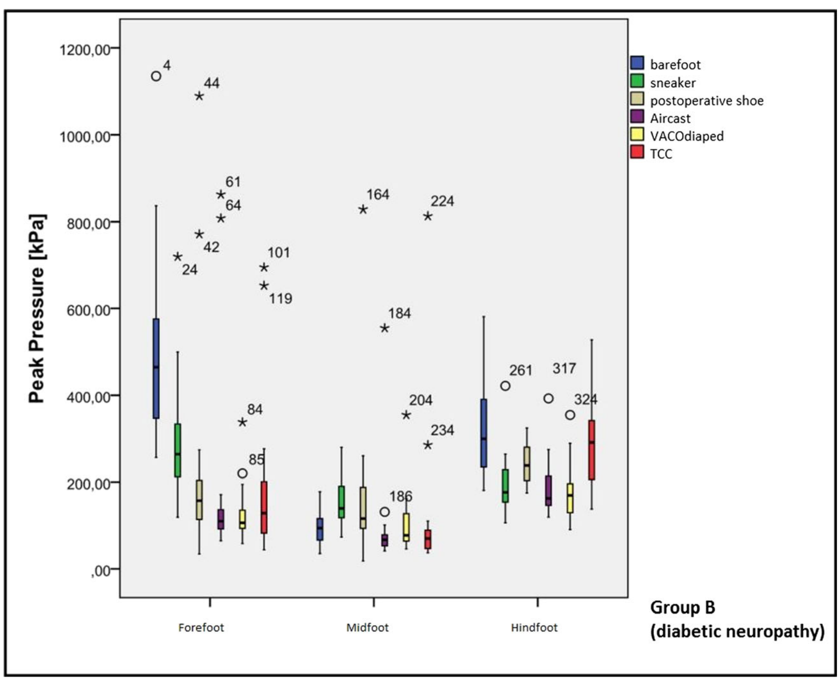
Accordingly, it can therefore be concluded that the VACOdiaped was the orthosis with the least impairment of gait patterns, with the greatest reduction of peak force in the forefoot and with an adequate reduction of the other measured parameters. The most inhomogeneous results revealed the post-operative shoe. The TCC showed the clearest decrease of maximal force and force-time integral in the forefoot. The Aircast revealed results in between.

What consequences can be drawn with regard to clinical routine? Basically, all four orthoses could prove their functionality. The results of the VACOdiaped regarding peak pressure, maximum force and force-time integral as well as the homogeneous distribution of the measurement parameters were superior compared to the other devices tested. The negative influence on neuropathy on the use of the post-operative shoe seems to be underestimated, yet.

Limitations of the study

The study group is small with 20/10 participants. Due to financial reasons, we could not evaluate the total contact cast in the healthy group. Furthermore, we focused on the evaluation of the most commonly used orthosis and devices. The TCC is not a standardized device. There are several different types existing, the differences mainly concerning production and material, but also manual dexterity is an important consideration. It also must be mentioned, that it is not possible to measure shear forces with the standard pedobarography systems. In regards to the

Fig. 5 Box plot of peak pressure in group B



differences between the healthy and the diabetic group, the measurement of postural stability would have been an additional tool to quantify the influence of each orthotic device on postural stability and the risk of fall. This study has to be regarded as a baseline study as it is not possible to predict clinical outcome, which is influenced by many other factors. Especially in patients with diabetes, compliance is a major concern. Our study was just a test in a laboratory. In daily life, limited compliance could be a major problem when using the removable orthosis, on the other hand the wound accessibility is restricted by using a TCC. Consequently, an individualized therapy for each patient bearing in mind the compliance, the location of ulcer and co-morbidities, is still the best to optimize outcome.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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Ethical approval The study protocol was approved by the local ethics committee (University of Regensburg, Ethic Committee Approv. No 10-101-0089)

Informed consent Informed consent was obtained from all individual participants included in the study

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