The efficacy of the VACO®Diaped+ diabetic foot system in reducing plantar forefoot pressures in diabetic neuropathic patients

Summary

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Plantar foot ulcers are a significant burden in patients with diabetes mellitus which may lead to infection and eventually amputation if not adequately treated. The VACO®Diaped+ system is specifically designed as treatment option for offloading plantar diabetic foot ulcers. The system comprises a vacuum cushion, which can be remodeled instantly to accommodate for structural deformity of the patients' foot, a dampening insole and a roller bottom outsole configuration with the goal to reduce plantar forefoot pressures. However, little is known about the biomechanical efficacy of this device. The purpose of this study was therefore to determine the pressure-relieving effect of the VACO®Diaped+ system in the plantar forefoot of diabetic neuropathic patients in comparison with a forefoot offloading shoe and a control shoe condition.

Fifteen diabetic neuropathic subjects (14 male, 1 female) at high risk for plantar ulceration (neuropathy and foot deformity) were included and underwent in-shoe dynamic plantar pressure assessment in five different footwear conditions: VACO®Diaped+ system with custom molded vacuum insole and a roller outsole (RollMold), VACO®Diaped+ system with custom molded vacuum insole and a flat outsole (FlatMold), VACO®Diaped+ system with flat vacuum insole and a roller outsole (RollFlat), Forefoot Offloading Shoe (FOS, Rattenhuber Talus), and Pulman control shoe (Control). The RollMold condition was the standard VACO®Diaped+ condition. The other two were tested to assess the specific effects of (1) outsole configuration (RollMold vs. FlatMold) and (2) custom molding of the vacuum insole (RollMold vs. RollFlat). After initial assessment of comfortable walking speed in the RollMold condition, walking speed was standardized between footwear conditions. All test shoes were worn on the right foot, and the patients’ own shoe on the left foot. Peak pressures, pressure-time integrals (PTI), and force-time integrals (FTI) were calculated from the pressure readings for 6 different foot regions: heel, midfoot, first metatarsal head, 2nd-5th metatarsal heads, hallux and lateral toes. Additionally, perceived comfort of walking was compared between footwear conditions using a 0 to 10 point VAS score.

Forefoot peak pressures and PTIs were significantly lower in all four footwear intervention conditions when compared with the control shoe (see Figure, P<0.05)). The FOS condition

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showed the lowest 2\textsuperscript{nd} to 5\textsuperscript{th} metatarsal head peak pressures, with significant differences compared with the VACO®Diaped+ conditions. No significant differences between the FOS and the VACO®Diaped+ conditions were found at the first metatarsal head, hallux and toes. PTIs and FTIs were not significantly different between FOS and VACO®Diaped+ conditions in any of the six foot regions. Pressure results between each of the three VACO®Diaped+ conditions were very similar with no significant differences found. Perceived comfort of walking was lowest in the FOS (score 3.4) and highest in the FlatMold condition (7.4). The molded VACO®Diaped+ conditions (RollMold and FlatMold) scored significantly higher for perceived comfort than the FOS.

The data showed that the VACO®Diaped+ system offloads the forefoot of at-risk patients better than a control shoe and is comparable to the FOS at the medial forefoot and toe regions. Characteristic features of the VACO®Diaped+, such as the instant vacuum cushion and roller outsole did not prove beneficial in pressure reduction. Patients perceive the VACO®Diaped+ as more comfortable to walk in compared with the FOS. In conclusion, the pressure results in combination with the findings on perceived comfort of walking makes the VACO®Diaped+ system a useful alternative option for the FOS for offloading the plantar forefoot in diabetic patients. Clinical studies will have to prove if the VACO®Diaped+ system is effective in healing plantar diabetic forefoot ulcers.

Figure. Peak pressures shown per region and per condition for the right foot (study foot). Data are shown as mean values in kPa with 1 standard deviation error bars. Brackets denote significant differences (P<0.05), $: significantly different compared to all other conditions, #: significantly different compared to all VACO®Diaped+ conditions.

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The efficacy of a removable vacuum-cushioned cast replacement system in reducing plantar forefoot pressures in diabetic patients

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1. Introduction

Foot ulcers are a significant burden in patients with diabetes mellitus. These ulcers may lead to infection and eventually amputation if not adequately treated (Boulton et al., 2004). Excessive mechanical pressure on the foot causing trauma which is not recognized by the patient due to loss of protective sensation is a major risk factor for the development of foot ulcers, in particular on the plantar surface (Veyes et al., 1992). Reducing these excessive pressures (named ‘offloading’) is the most important component of treatment of these neuropathic plantar foot ulcers. Different devices are used for this purpose in clinical practice. The total contact cast (TCC) is the best described offloading modality and has proven to be highly effective in reducing plantar foot pressures (Baumhauer et al., 1997; Beuker et al., 2005; Lavery et al., 1996) and in healing neuropathic plantar foot ulcers (Armstrong et al., 2001). However, the use of the TCC requires trained casting personnel and sufficient time for application and re-application of the cast. Furthermore, complications may occur with the use of the TCC and patient acceptance is not always high. For these reasons, the use of the TCC for ulcer treatment is limited in many centers as data from a recent US survey shows (Wu et al., 2008).

As alternatives for casting, prefabricated devices are commonly used in clinical practice. These devices include below-the-knee systems such as removable walking braces and ankle-high devices such as half shoes and forefoot offloading shoes. All these devices have been shown to be effective in reducing plantar foot pressures (Beuker et al., 2005; Bus et al., 2009; Fleischli et al., 1997; Lavery et al., 1996), and many have also been shown to be effective in...
healing plantar diabetic foot ulcers (Armstrong et al., 2005; Chantelau et al., 1993; Katz et al., 2005). The data from these studies also show that ankle-high devices do not reduce pressure to the same level as below-the-knee devices but have the advantage that they are lighter in weight and do not immobilize the ankle joint, which facilitates walking, prevents muscle atrophy with long term use, and improves patient acceptance.

A new prefabricated ankle-high vacuum-cushioned cast replacement system (VCRS) has been designed for treatment of plantar forefoot ulcers in diabetic patients. This system comprises a vacuum cushion (bean bag) in conjunction with a roller walking sole. The vacuum cushion can be remodeled instantly to accommodate for structural abnormalities or changes in the shape of the patients’ foot. Furthermore, the system features a lightweight stable lattice frame structure in which the foot and lower leg are placed to provide stability. The VCRS is a removable device which can be reapplied instantly for wound control purposes and it requires only limited instruction to apply. Currently, no scientific evidence exists for the efficacy of the VCRS in reducing pressures underneath the forefoot in diabetic patients. Therefore, the purpose of this study was to assess the plantar forefoot offloading efficacy of the VCRS in neuropathic diabetic patients at risk for plantar ulceration and compare this with a footoffloading shoe (FOS) and a control shoe condition. Furthermore, we aimed to assess the specific contribution of the instantly moldable vacuum cushion and the roller outsole of the VCRS in offloading the forefoot as well as perceived walking comfort using this system. We hypothesized that the VCRS would be more effective than the control shoe and similarly effective as the FOS in reducing plantar forefoot pressures in diabetic patients. Furthermore, we anticipated a significant contribution of the custom molded vacuum cushion and roller outsole in the forefoot offloading effect of the VCRS together with a higher walking comfort in the VCRS than in the FOS.

2. Methods

2.1. Study design

This study was conducted using a repeated measures study design in which five different footwear conditions were tested in each patient during one single test session.

2.2. Subjects

Fifteen diabetic patients at high risk for developing plantar foot ulcers were recruited from our outpatient diabetic foot clinic and participated in this study. All patients had loss of protective sensation due to peripheral neuropathy as confirmed by the inability to sense a 10 g monofilament on the plantar hallux, first metatarsal head, or fifth metatarsal head (Apelqvist et al., 2008) or a vibration perception threshold above 25 V measured at the dorsal hallux using a Bio-thesiometer (Bio-Medical Instrument Company, Newbury, OH, USA) (Pham et al., 2000). All patients had one or more foot deformities, including claw/hammer toe deformity, hallux valgus, hallux rigidus, prominent metatarsal heads, pes cavus, or pes planus. Patients with a current foot ulcer, midfoot Charcot neuro-osteoarthopathy, equines deformity, lower extremity amputations or the inability to walk unaided were excluded from the study. All patients gave their written informed consent prior to the study, which was approved by the medical ethics committee of the University of Amsterdam Medical Center.

2.3. Footwear

Five different footwear conditions were tested in this study, including three VCRS conditions (VACO®Diaped Plus, OPED, Valley, Germany, www.oped.de), a footoffloading shoe (FOS) and a control shoe (Fig. 1). Besides the standard VCRS condition, two modified VCRS conditions were tested to assess the biomechanical efficacy of the roller walking sole and to test the efficacy of the instant custom molding of the vacuum cushion. In the standard VCRS condition, the vacuum cushion was custom molded and a roller outsole was attached to the system (RollMold). In the first modified VCRS condition, the vacuum cushion was custom molded and a flat outsole was attached to the system (FlatMold). In the second modified VCRS condition, a flat surface vacuum cushion was created and a roller outsole was attached to the system (RollFlat). Custom molding of the vacuum cushion in the RollMold and FlatMold conditions was achieved by manually shaping the air filled bean bag into a flat cushion, then inserting the cushion into the system, subsequently having the patient walk a few steps while wearing the system, and finally drawing the air out of the cushion with a vacuum pump to fixate the instantly customized

Fig. 1. (A) The components of the VCRS, including a vacuum cushion filled with small plastic balls which is inserted into a soft cover, a lightweight lattice frame structure, a dual density cushioning insole, a detachable roller walking sole, and a small vacuum pump to extract the air from the cushion. (B) VCRS with roller outsole and custom molded vacuum cushion (RollMold). (C) VCRS with flat outsole and custom molded vacuum cushion (FlatMold). (D) VCRS with roller outsole and flat surface vacuum cushion (RollFlat). (E) Pullman control shoe and (F) Rattenhuber Talus footoffloading shoe.

cushion. For the RollFlat condition, the air was drawn from the cushion directly after manually shaping the cushion into a flat surface providing a rigid non-customized vacuum device. For each patient a new VCRS was used. The VCRS was available in two sizes: standard and small. All but one subject used the standard size device.

A FOS was used as comparison condition because the FOS is also an ankle-high device, which is frequently used in clinical practice as treatment modality for plantar diabetic foot ulcers. Furthermore, the FOS shows good efficacy in relieving forefoot pressures in the diabetic foot (Bus et al., 2009; Fleischli et al., 1997). The FOS (Rattenhuber Talus II, www.rattenhuber.de) consisted of a rocker-bottom negative heel outsole configuration. A 13-mm dual density flat inlay was placed inside the FOS. The control shoe was a Pulman shoe (www.fld.fr) with flexible outsole and flat insole.

Each test shoe was worn on the right foot without socks, while the patients’ own footwear was worn on the left foot in each of the five footwear conditions. This footwear consisted mostly of custom-made orthopedic footwear.

2.4. Procedures

At the start of the test session, data on health history, neuropathic status, and foot deformities were recorded. Table 1 provides a summary of baseline patient characteristics. After this baseline assessment, each of the five different footwear conditions was tested in a random order with the patient repeatedly walking along a 12 m walkway in the gait laboratory. Walking speed was measured using photocells positioned at a 6 m distance from each other halfway along the walkway (Tag-Heuer, Switzerland). Each patient was tested at a self-chosen walking speed which was determined prior to each measurement session in the RollMold VCRS condition by averaging the speed from three walking trials. Walking speed was then standardized between walking trials within each footwear condition (maximum variation 10%) and between footwear conditions (maximum mean difference 5%). Before the actual pressure measurements in each device took place, patients walked several times across the laboratory to become accustomed to wearing the device.

In-shoe dynamic plantar foot pressures were recorded using the Pedar-X system (Novel, Munich, Germany). The Pedar system comprises a matrix of 99 sensors in 2-mm thick capacitance based flexible insoles which were placed between the foot and the insoles of the shoe and sampled at 50 Hz. The Pedar insoles were available in five different sizes to accommodate different foot sizes of the tested patients. A minimum of 20 midgait steps per foot were collected in four walking trials. Directly after testing each footwear condition patients scored their perceived walking comfort by drawing a vertical line on a 10 cm visual analogue scale (VAS), where the far left of the scale denoted ‘lowest possible comfort’ and the far right ‘highest possible comfort’.

2.5. Data analysis

In-shoe pressure data was analyzed with Novel software. Peak pressure pictures of both feet were divided by an automated masking procedure into six anatomical regions: heel, midfoot, first metatarsal head, second-to-fifth metatarsal heads, hallux and lesser toes. For each region, the peak pressure, pressure–time integral, force–time integral (synonymous for force impulse or load), contact time, and average peak pressure were calculated. The last two parameters were only calculated to explain potential differences between peak pressure and pressure–time integral results at specific regions. The force–time integral data was used to define load transfer diagrams with which the mechanisms of action of the intervention footwear with respect to the control shoe could be determined. These load transfer diagrams were slightly adapted from previously reported diagrams (Bus et al., 2004). For this purpose, the regional load impulses in the VCRS and FOS conditions were normalized to the total load impulse in the control shoe condition. Based on the regional load differences between the offloading and control footwear, load transfer was then calculated from regions where load was reduced to regions where load was increased by means of the offloading footwear. Load transfer calculations started with the toe regions and ended with the heel region. The VAS score for perceived walking comfort was determined by measuring the distance from the far left of the scale to the vertical line drawn by the patient using a ruler.

All pressure, walking speed, and comfort data were statistically analyzed using repeated measures analysis of variance (ANOVA). Bonferroni post-hoc analysis, including Bonferroni corrected confidence intervals, was used for multiple pairwise comparisons between the different footwear conditions. Separate analyses were conducted for comparing the standard VCRS with the FOS and control shoe (primary comparison) and for comparing the two modified VCRS conditions (FlatMold and RollFlat) with the standard VCRS condition (RollMold) (secondary comparison). This separation was done to increase focus and to avoid comparisons between conditions that we did not consider relevant and would only increase the number of pairwise comparisons and the risk for a type 1 error. For both analyses, three footwear conditions were chosen for the within-subject variable factor. A $P < 0.05$ was considered statistically significant in all analyses. For all statistical analyses SPSS version 14.0 (SPSS Inc., Illinois, Chicago, USA) was used.

### Table 1

Baseline patient characteristics. Data are expressed as mean (SD) or number (N). Data for vibration perception threshold and foot deformity are shown for the right foot (=study foot).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (SD) or N</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of subjects</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>58.9 (7.9)</td>
<td>39–74</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>178.4 (7.5)</td>
<td>169–199</td>
</tr>
<tr>
<td>Body mass (kg)</td>
<td>100.8 (25.4)</td>
<td>62–155</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>31.4 (6.4)</td>
<td>20.7–39.5</td>
</tr>
<tr>
<td>Male/Female</td>
<td>14 (1)</td>
<td></td>
</tr>
<tr>
<td>Diabetes duration (yrs)</td>
<td>21.0 (14.3)</td>
<td>6.5–41.0</td>
</tr>
<tr>
<td>DM type 1/2</td>
<td>6/9</td>
<td></td>
</tr>
<tr>
<td>Vibration perception threshold (V)</td>
<td>39.1 (12.1)</td>
<td>10–50 (=max.)</td>
</tr>
</tbody>
</table>

**Foot deformity:**
- Claw/hammer toes: 5
- Hallux valgus: 2
- Hallux rigidus: 3
- Prominent metatarsal heads: 6
- Pes cavus: 5
- Pes planus: 4
- Shoe size (European): 42.9 (2.0) 39–47
head and a 26% difference at the second-to-fifth metatarsal heads. In contrast, hallux peak pressure was significantly lower by 24% in the VCRS than in the FOS. No significant differences in peak pressure were found between the VCRS and FOS in the other foot regions. When comparing peak pressures between the standard and the modified VCRS conditions, relatively small differences were found overall. In the standard VCRS condition (RollMold), peak pressure was significantly lower by 9% at the first metatarsal head and by 10% at metatarsal head 2–5 when compared with the VCRS condition with flat outsole (FlatMold). No other significant differences were found.

In all forefoot regions (including toes) pressure–time integrals were significantly lower in the VCRS and FOS conditions when compared with control shoe. Percentage differences were between 45% and 49% for the metatarsal head regions and between 37% and 56% for the toe regions. Midfoot pressure–time integral was significantly higher in the VCRS and FOS when compared with the control shoe. In the heel, pressure–time integral was significantly lower in the VCRS than in control. None of the foot regions showed significant differences in pressure–time integrals between the VCRS and FOS, except for the hallux in which pressure–time integral was significantly lower in the VCRS by 31%. When comparing pressure–time integrals between the standard VCRS and the modified VCRS conditions, relatively small differences were found overall. In the standard VCRS condition (RollMold), the only significant difference found was at the metatarsal head 2–5 region with significantly lower pressure–time integral in the RollMold than in the FlatMold VCRS condition.

Contact time at the first metatarsal head was on average 657 ms in the FOS compared with 598 ms in the VCRS. At the second-to-fifth metatarsal heads, contact times were 684 ms and 677 ms in the FOS and VCRS, respectively. Average peak pressure at the first metatarsal head was on average 92.5 kPa in the FOS and 92.8 kPa in the VCRS. At metatarsal head 2–5 average peak pressures were 90.6 kPa and 92.4 kPa in the FOS and VCRS, respectively.

Inter-regional transfer of load through the action of the offloading footwear, calculated using the load transfer diagrams, is shown in Fig. 2 for the standard VCRS and FOS conditions. The largest load transfers were present between the metatarsal heads and midfoot. The portion of force impulse present in the forefoot (including toes) which was transferred proximally was 53% for the VCRS (RollMold) and 36% in the FOS. The diagrams also showed a transfer of load of ~20 N s from the heel to the midfoot.

For the left foot, which was fitted with the patients’ own shoe in each of the five test conditions, pressure results were comparable between VCRS, FOS and control shoe. The only significant differ-

<table>
<thead>
<tr>
<th>Variable</th>
<th>Footwear condition</th>
<th>VCRS (RollMold)</th>
<th>VCRS (FlatMold)</th>
<th>VCRS (RollFlat)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking speed (m/s)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>%^e</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Control shoe</td>
<td>1.18 (0.17)</td>
<td>1.16 (0.17)</td>
<td>−31</td>
<td>1.18 (0.18)</td>
</tr>
<tr>
<td>FOS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pressure (kPa)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heel</td>
<td>322 (107)b,c</td>
<td>221 (40)b</td>
<td>−31</td>
<td>216 (40)a</td>
</tr>
<tr>
<td>Midfoot</td>
<td>107 (41)</td>
<td>123 (24)</td>
<td>+15</td>
<td>138 (36)a</td>
</tr>
<tr>
<td>Metatarsal head 1</td>
<td>330 (71)b,c</td>
<td>145 (23)</td>
<td>−56</td>
<td>183 (39)b,d</td>
</tr>
<tr>
<td>Metatarsal head 2–5</td>
<td>344 (75)b,c</td>
<td>140 (19)</td>
<td>−59</td>
<td>190 (35)b,d</td>
</tr>
<tr>
<td>Hallux</td>
<td>235 (107)b,c</td>
<td>176 (72)b,c</td>
<td>−25</td>
<td>133 (59)ab</td>
</tr>
<tr>
<td>Lesser toes</td>
<td>274 (82)b,c</td>
<td>161 (45)</td>
<td>−41</td>
<td>163 (54)ab</td>
</tr>
<tr>
<td>Pressure–time integral (kPa s)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heel</td>
<td>86.6 (22.8)b</td>
<td>72.9 (18.3)</td>
<td>−17</td>
<td>69.8 (11.5)b</td>
</tr>
<tr>
<td>Midfoot</td>
<td>42.5 (23.5)</td>
<td>66.5 (17.8)</td>
<td>+42</td>
<td>68.1 (27.7)</td>
</tr>
<tr>
<td>Metatarsal head 1</td>
<td>110.3 (38.1)b,c</td>
<td>60.8 (14.0)b</td>
<td>−45</td>
<td>56.0 (16.7)b</td>
</tr>
<tr>
<td>Metatarsal head 2–5</td>
<td>119.9 (35.8)b,c</td>
<td>62.2 (12.0)b,c</td>
<td>−48</td>
<td>62.7 (14.6)b,d</td>
</tr>
<tr>
<td>Hallux</td>
<td>51.3 (25.7)b,c</td>
<td>32.4 (16.6)b,c</td>
<td>−37</td>
<td>22.5 (13.2)b</td>
</tr>
<tr>
<td>Lesser toes</td>
<td>84.5 (26.3)b,c</td>
<td>47.7 (9.7)b</td>
<td>−44</td>
<td>38.2 (15.5)b</td>
</tr>
<tr>
<td>Perceived walking comfort</td>
<td>5.5 (2.0)b</td>
<td>3.4 (2.5)b,c</td>
<td>−66</td>
<td>6.6 (1.6)b</td>
</tr>
</tbody>
</table>

^a Significantly different to control shoe at P < 0.05.
^b Significantly different to FOS P < 0.05.
^c Significantly different to VCRS (RollMold) at P < 0.05.
^d Significantly different to VCRS (FlatMold) at P < 0.05.
^e Percentage difference compared with control shoe condition.

ences found were lower peak pressures and pressure–time integrals at metatarsal heads 2–5 in the FOS and VCRS when compared with the control shoe. For perceived walking comfort, large variations between the tested footwear conditions were found (Table 2). Both the standard VCRS (VAS score 6.6) and control shoe (VAS score 5.5) scored significantly higher than the FOS (VAS score 3.4). Between the standard VCRS condition and both modified VCRS conditions, no significant differences in VAS scores were found.

4. Discussion

The results of the study show that the VCRS was effective in relieving forefoot pressures in the neuropathic diabetic patients tested. Between 41% and 56% relief in peak pressure and pressure–time integral were found when compared with the control shoe condition. The VCRS was less effective than the FOS in reducing peak pressure at the metatarsal heads, but more effective in relieving the hallux region. Furthermore, the results showed that the offloading contribution of the instant custom molding was negligible and the contribution of the roller outsole configuration was small (maximum 10% difference found between the modified and standard VCRS conditions). For the left foot, which was fitted with the patients’ own shoes, no relevant differences were found between the conditions. This shows that pressure transfer effects to the contralateral foot were not present.

When compared with reported results on other commonly used offloading devices, the VCRS was less effective than a TCC (~80% forefoot pressure relief) or removable walking brace (~70% forefoot pressure relief) but more effective than a healing sandal or post-operative shoe (~20% pressure relief) (Fleischli et al., 1997). The differences with the TCC and walking braces may be explained by the fact that in these below-the-knee devices significant amounts of load are carried by the lower leg providing extra pressure relief at the foot compared with ankle-high devices such as the VCRS. The offloading efficacy measured in the VCRS was comparable to that found in a cast shoe (Beuker et al., 2005), a device which has been reported to be efficacious in healing plantar neuropathic forefoot ulcers (Hissink et al., 2000). Whether the pressure reductions found in the VCRS are sufficient to promote healing of plantar forefoot ulcers in diabetic patients remains to be investigated in future clinical studies.

The more effective relief of metatarsal head peak pressure in the FOS compared with the VCRS may be explained by the contribution of the negative heel rocker-bottom outsole configuration of the FOS which shifts weight-bearing proximally during stance and limits active dorsiflexion of the toes; the VCRS does not incorporate these design features. However, when considering the integral of peak pressure at the metatarsal heads, the beneficial effect of the FOS in relation to the VCRS was lost. This result is difficult to explain. In general, contact time and average peak pressure are the two factors that define the pressure–time integral. The results showed that contact time at the first metatarsal head was 10% longer in the FOS than in the VCRS and that average peak pressure was not different between conditions. The difference in contact time may be responsible for leveling the values on pressure–time integral between these conditions, despite differences in peak pressure. The longer contact times measured in the FOS may be an effect of the differences in roll-over mechanisms between these two devices. However, at metatarsal head 2–5, a difference between footwear conditions was not present for contact time nor for average peak pressure so that it remains to be identified what caused the contrasting results in peak pressure and pressure–time integral at this region. The more effective offloading of the hallux in the VCRS compared with the FOS may be associated with the observation that several patients walking in the FOS tip the shoe against the ground in terminal stance which may have created some localized pressure at this region.

The mechanisms of action of the VCRS and the FOS were defined by assessing inter-regional load redistribution in comparison with the control shoe condition using adapted versions of previously defined load transfer diagrams (Bus et al., 2004). These diagrams showed a substantial transfer of load from the forefoot to the midfoot, both in the VCRS (53% of total forefoot load) and in the FOS (36%). They also showed a transfer of load from the heel to the midfoot. These results clearly demonstrate that the midfoot is the primary target location for load redistribution in these offloading devices. But despite these high concentrations of load at the midfoot, a concomitantly large increase in peak pressure was not found, probably because pressures were well distributed over a large midfoot contact area. These results suggest that pressures can be safely redistributed to this region of the foot without necessarily increasing the risk for ulceration. This principle of action may be given more consideration in the future designs of offloading footwear for the diabetic foot which is not complicated with midfoot deformity.

Two modified VCRS conditions were tested in order to specifically assess the offloading efficacy of the instant custom molding interface and the detachable roller outsole. As the results showed, the instant custom molding of the vacuum cushion did not seem to contribute to the offloading efficacy of the VCRS, with only small differences in peak pressure and pressure–time integral found between the molded (RollMold) and flat surface (RollFlat) vacuum cushion conditions of the VCRS. This may be related to the fact that the instant molding process merely accommodates the foot surface (through total contact) but does not correct it, something that is normally achieved using a metatarsal pad or bar, or a medial arch support, which have been shown to be effective pressure-reducing modalities for the diabetic foot (Bus et al., 2004; Guldemond et al., 2007). The VCRS with roller outsole (RollMold) offloaded the metatarsal heads significantly better than the VCRS with flat outsole (FlatMold). Although the differences found were relatively small, this provides support for the use of a roller outsole configuration which reduces active dorsiflexion of the toes and, therefore, forefoot contribution in foot propulsion. However, forefoot offloading using the roller outsole may still have been sub-optimal, considering the fact that all participating subjects with European shoe size 39–47 (14 out of 15) wore the same size VCRS. This clearly increases the variability of the roller pivot point location relative to the metatarsal heads, which has an optimum location directly proximal to the heads (van Schie et al., 2000). These results suggest that improvements in this design of the VCRS are indicated.

Perceived comfort of walking was scored significantly better in the VCRS (VAS score 6.6) than in the FOS (VAS score 3.4), and also better, although not significantly, in the VCRS than in control shoe (VAS 5.5). The difference found in VAS scores between the VCRS and the FOS are suggested to be due to the fact that the VCRS, unlike the FOS, does not incorporate a negative heel rocker-bottom outsole configuration, a construction feature patients normally do not have in their shoes and, hence, may be felt as uneasy to walk in. The low VAS score in the FOS confirms earlier findings on walking comfort in different FOS models (Bus et al., 2009). We would suggest that perceived walking comfort may affect adherence to treatment, which by itself is important for promoting ulcer healing with removable devices. Therefore, the results suggest that this may be less of a factor in the VCRS than in the FOS.

In the chosen experimental setup of this study, each subject was given only a brief period (i.e. several walking trials) to become accustomed to wearing each offloading device. This brief habituation period may have prevented the assessment of robust walking comfort ratings in the tested footwear. Furthermore, in this study
only normal pressures were measured. We acknowledge the potential contribution of shear pressures in causing plantar foot ulcers, and we therefore suggest that such measures should be incorporated in future studies as soon as equipment is capable of measuring these shear pressure components.

5. Conclusions

This study was performed to assess the offloading efficacy, mechanisms of offloading and the perceived walking comfort of a new prefabricated vacuum-cushioned cast replacement system in diabetic patients at risk for plantar foot ulceration. The use of the VCRS resulted in a substantial pressure relief in the forefoot when compared to a control shoe condition. In comparison with a FOS, the VCRS was less effective in relieving peak pressures at the metatarsal heads, similarly effective in reducing pressure–time integrals at these regions, and more effective in relieving peak pressures and pressure–time integrals at the hallux. The mechanism of offloading with the VCRS seems the transfer of substantial amounts of load from the forefoot to the midfoot. The exact design features responsible for foot offloading in the VCRS are difficult to determine based on the data obtained since the instant custom molding of the vacuum cushion did not seem to contribute significantly to forefoot pressure relief. Perceived walking comfort was scored significantly higher in the VCRS than the FOS, and this result may improve adherence to treatment. Based on the combined pressure and comfort results, the VCRS may be a useful alternative for the FOS in offloading the plantar forefoot in diabetic patients. However, whether the VCRS is effective in healing diabetic plantar forefoot ulcers remains to be investigated in a prospective clinical trial.

Conflict of Interest

The authors declare that there is no conflict of interest.

Acknowledgements

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Vacuum cushioned removable cast walkers reduce foot loading in patients with diabetes mellitus

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**1. Introduction**

Diabetes mellitus is one of the most frequent diseases worldwide. More than 180 million patients suffer from diabetes according to data from the World Health Organization (WHO; http://www.who.int/mediacentre/factsheets). Furthermore, the WHO anticipates that the number of diabetic patients will more than double by 2030. Diabetic neuropathy damages the nerves of almost 50% of diabetic patients and is a major cause for the diabetic foot syndrome that leads to high morbidity, reduced quality of life and high health-care costs [1,2]. Foot ulceration is a major complication in patients with diabetes mellitus [3] and 15–25% of diabetic patients develop foot ulcers during their lifetime [4–6].

High plantar pressures during the roll-over process combined with peripheral neuropathy are believed to increase the risk for plantar ulceration [7]. An association between neuropathy and high plantar pressures has been reported [8,9]. Therefore, reducing pressure from the region of diabetic foot ulcers is a major part of the ulcer prevention management [5].

In diabetic patients, a redistribution of plantar pressure, which prevents high local pressures has been achieved with custom-made orthotic insoles [10–12]. A load transfer from the highly loaded forefoot to the midfoot region was demonstrated [13]. The contact area increased in the midfoot with the vacuum orthoses. Maximum force and peak pressures showed a significant decrease under the rearfoot and forefoot and increased in the midfoot area during walking with both vacuum orthoses. The high-cut vacuum orthosis revealed equal pressure relief under the forefoot and significantly lower rearfoot pressures compared to the post-operative shoe.

Conclusions: The vacuum orthoses demonstrated a comparable pressure-relieving efficacy under the forefoot to post-operative shoes. Using vacuum orthosis significantly benefited re-distribution of plantar pressure and the roll-over process. Clinical significance of the pressure-relieving efficacy could not be confirmed in this investigation and has to be addressed in further studies.

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to reduce high local pressures is the removable cast walker. This device is claimed to provide similar pressure relief to total contact casts. Removable cast walkers can be removed and reapplied directly and therefore allow wound control, adaptation to foot/wound status and improved hygiene of the patient. In some studies total contact casting demonstrated shorter healing times for foot ulcers in comparison to removable cast walkers and therapeutic footwear [15,16]. However, reviews of studies concerning wound healing in diabetes patients provided little evidence for greater efficacy of total contact casts in wound healing in comparison to other offloading techniques [14,17].

The aim of this study was to investigate the effects of commercially available cast walkers with vacuum cushioning to decrease plantar foot loading in patients with diabetes. We measured plantar pressure distribution during walking in a standard shoe, a post-operative shoe and in two designs of vacuum orthoses to detect changes in foot loading. The vacuum orthoses provide individual support by adapting the insole to the foot shape based on a vacuum cushion in combination with a dampening insole.

2. Methods

2.1. Subjects

The study included 20 patients (13 females, 7 males) with diabetes mellitus type I (4) or II (16). The mean age was 56.4 ± 15.7 years with a range from 18 to 74 years. The body mass index varied between 19 and 41 kg/m² with a mean value of 29 ± 6.8 kg/m². The disease duration was 12.8 ± 12.1 years (range: 2–58 years). The patients’ feet had plantar calllosities but no ulcerations. Exclusion criteria were the use of walking aids and other systemic diseases, such as rheumatoid arthritis or Parkinson’s disease. All patients gave informed consent to participate in the study.

2.2. Shoes and vacuum orthoses

The vacuum orthoses (Oped GmbH, Valley, Germany) are removable cast walkers using vacuum pads in conjunction with a cushioning dual-density insole and a rocker bottom sole (Fig. 1c and d). The vacuum pads were similar in both orthoses and consisted of a bag filled with Styrofoam ‘beans’ of about 1 mm of diameter. These pads conform to the individual shape of the plantar surface after walking a few steps with the orthoses. The individual shape of the bean bag was conserved by removing the air between the beans thus creating a vacuum. This is meant to provide strict movement restriction to the ankle joint. The orthosis can be fixed on the patients’ shank and foot with an additional strap to improve the wearing comfort. The DARCO® Light was the third orthosis used in this study (Fig. 1b). This post-operative shoe was constructed to unload the whole forefoot region and to allow load transfer only in the midfoot and rearfoot regions. The subjects wore each orthosis on the right foot. On the left foot they wore an off-the-shelf shoe to replicate the usual application situation and ensure comparable conditions for all subjects. Reference measurements were conducted while wearing a pair of these off-the-shelf shoes. They were wide in shape and are usually recommended for people with foot problems (Fig. 1a).

2.3. Pedobarography

The pedobarography measurements were performed in a 25-m corridor. Plantar pressure distribution was measured with capacitive sensor insoles with 99 sensors (Pedar-X, sampling rate 50 Hz, Novel GmbH, Munich, Germany). Good reliability has been previously demonstrated with this method [18,19]. The patients performed two trials of walking in each condition in a randomized testing order. They were asked to walk at a comfortable speed. At least 15 steps of each walking condition were selected for further data analysis. After determining the mean values of the 15 steps the foot was subdivided with standard software (Database Pro-M, Novel GmbH, Munich, Germany) in three areas of interest: rearfoot, midfoot and forefoot. The following parameters were determined: contact area (CA), contact time (CT), maximum force (MF), force–time integral (FTI), i.e., the product of the amplitude and duration of force application as the overall effect loading effect in a region and peak pressure (PP) as the highest local load within the region. Furthermore, the gait line as an indicator for the roll-over process was analyzed. The gait line consists of the center of pressure of every recorded frame and is suggested to reveal information about gait velocity and locomotor capability [20,21].

2.4. Statistical analysis

Statistical analysis was undertaken using SPSS for Windows 13.0 (SPSS Inc., Chicago, IL, USA). Non-parametric tests were used after testing for normal distribution with the Kolmogorow–Smirnov-test. Friedman tests were used to investigate general differences between walking with orthoses and standard shoes (p < 0.05). The paired Wilcoxon signed-rank test was then conducted (p < 0.0083 after Bonferroni correction).

3. Results

The results revealed significant differences in the plantar pressure patterns between the four walking conditions (Table 1). No significant differences were found in contact times. This confirmed comparable gait dynamics without significant differences in walking velocity between the four walking conditions.

3.1. Contact area

The contact area of the foot during the roll-over process differed between the off-the-shelf shoe and the three orthoses (Fig. 2). Thus, an increase of contact area up to 45.1% (p < 0.006) could be seen in the midfoot in both vacuum orthoses and also for the whole foot compared to the control condition. The post-operative shoe revealed an increase of 29.1% (p < 0.000) in the midfoot region. Comparing orthoses revealed higher contact areas in the midfoot for the VACOdiaped-Plus®.

3.2. Maximum force and force–time integral

Maximum force and force–time integral revealed significant differences in foot loading for the off-the-shelf shoe with respect to the three orthoses in every foot region. Maximum force was significantly reduced in the forefoot during walking with both vacuum orthoses by 36.8% and 38%, respectively (p < 0.001). The post-operative shoe showed a reduction of 44.8% (p < 0.001) in the forefoot region. The orthoses significantly increased the maximum force in the midfoot region. The VACOdiaped-Plus® provided the most pronounced effect (+47.6%, p < 0.001). The force–time integrals showed a similar effect as the maximum force in these foot regions. Under the rearfoot the post-operative shoe revealed a decreased maximum force but an increased force–time integral. The vacuum orthoses showed a decrease of maximum force and...
minimum change in the force–time integrals in the rearfoot. The VACOdiaped revealed significantly lower maximum forces in the all foot regions than the VACOdiaped-Plus$^1$.

### 3.3. Peak pressure

Plantar peak pressures were significantly altered during walking with the three orthoses (Figs. 2 and 3). Peak pressures were elevated under the midfoot whereas a significant decrease of plantar pressures could be seen under the rearfoot and forefoot, i.e. the sites where ulcers predominantly occur. The VACOdiaped$^1$ and the post-operative shoe revealed similar pressure reduction in the forefoot whereas the rearfoot pressures were significantly higher while walking in the post-operative shoe compared to the two vacuum orthoses. The VACOdiaped-Plus$^1$ showed significantly higher peak pressures under the forefoot as compared to the VACOdiaped$^1$ and the post-operative shoe (Figs. 2 and 3). Furthermore, the VACOdiaped revealed significantly lower peak pressures in the rearfoot region than the VACOdiaped-Plus$^1$.

### Table 1

Results of plantar pressure measurements (MW ± S.D.) for all subjects ($n = 20$) and conditions.

<table>
<thead>
<tr>
<th></th>
<th>Off-the-shelf footwear (OSF)</th>
<th>Post-operative shoe (POS)</th>
<th>VACOdiaped (high-cut)</th>
<th>VACOdiaped-Plus (low-cut)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contact area [cm²]</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Rearfoot$^{1,2,3,5}$</td>
<td>28.4 ± 4.5</td>
<td>28.8 ± 3.9</td>
<td>27.3 ± 5.4</td>
<td>28.3 ± 4.9</td>
</tr>
<tr>
<td>Midfoot$^{1,2,3,4,5}$</td>
<td>36.6 ± 8.6</td>
<td>47.3 ± 9.4</td>
<td>50.6 ± 9.1</td>
<td>53.1 ± 8.1</td>
</tr>
<tr>
<td>Forefoot$^3$</td>
<td>68.6 ± 9.0</td>
<td>63.4 ± 8.6</td>
<td>63.3 ± 12.3</td>
<td>66.0 ± 13.2</td>
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<tr>
<td><strong>Contact time [ms]</strong></td>
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<td></td>
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<td></td>
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<tr>
<td>Rearfoot</td>
<td>714.2 ± 210.0</td>
<td>724.0 ± 118.9</td>
<td>753.5 ± 158.6</td>
<td>677.2 ± 130.5</td>
</tr>
<tr>
<td>Midfoot</td>
<td>731.6 ± 192.7</td>
<td>721.5 ± 120.1</td>
<td>761.9 ± 132.3</td>
<td>723.4 ± 122.4</td>
</tr>
<tr>
<td>Forefoot</td>
<td>757.9 ± 180.2</td>
<td>725.8 ± 116.0</td>
<td>755.0 ± 118.0</td>
<td>725.2 ± 114.3</td>
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<tr>
<td><strong>Force–time integral [N s]</strong></td>
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<tr>
<td>Rearfoot$^{1,2,3,4,5}$</td>
<td>142.8 ± 38.4</td>
<td>180.4 ± 54.4</td>
<td>141.3 ± 54.5</td>
<td>131.8 ± 42.7</td>
</tr>
<tr>
<td>Midfoot$^{1,2,3,4,5}$</td>
<td>101.7 ± 65.9</td>
<td>148.7 ± 83.3</td>
<td>176.7 ± 75.9</td>
<td>195.2 ± 83.7</td>
</tr>
<tr>
<td>Forefoot$^{1,2,3}$</td>
<td>321.9 ± 107.4</td>
<td>198.4 ± 66.6</td>
<td>199.5 ± 86.6</td>
<td>203.4 ± 75.9</td>
</tr>
<tr>
<td><strong>Maximum force [N]</strong></td>
<td></td>
<td></td>
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<tr>
<td>Rearfoot$^{1,2,3,4,5,6}$</td>
<td>528.2 ± 123.1</td>
<td>458.8 ± 126.8</td>
<td>320.9 ± 92.9</td>
<td>385.2 ± 98.9</td>
</tr>
<tr>
<td>Midfoot$^{1,2,3,4,5,6}$</td>
<td>272.5 ± 140.0</td>
<td>314.3 ± 140.4</td>
<td>340.3 ± 130.3</td>
<td>402.3 ± 148.4</td>
</tr>
<tr>
<td>Forefoot$^{1,2,3,4,5,6}$</td>
<td>890.3 ± 191.5</td>
<td>491.0 ± 117.8</td>
<td>516.8 ± 189.0</td>
<td>615.8 ± 205.1</td>
</tr>
<tr>
<td><strong>Peak pressure [kPa]</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rearfoot$^{1,2,3,4,5}$</td>
<td>306.7 ± 67.4</td>
<td>224.4 ± 57.1</td>
<td>176.2 ± 34.1</td>
<td>194.4 ± 38.3</td>
</tr>
<tr>
<td>Midfoot$^{1,2,4,5}$</td>
<td>154.0 ± 58.8</td>
<td>117.4 ± 33.4</td>
<td>121.3 ± 28.8</td>
<td>146.8 ± 38.5</td>
</tr>
<tr>
<td>Forefoot$^{1,2,3,4,5}$</td>
<td>420.5 ± 99.3</td>
<td>153.4 ± 39.9</td>
<td>160.9 ± 50.2</td>
<td>191.8 ± 54.2</td>
</tr>
</tbody>
</table>

$^1$Significant difference between the OSF and the POS ($p < 0.0083$); $^2$Significant difference between the OSF and the high-cut vacuum orthosis ($p < 0.0083$); $^3$Significant difference between the OSF and the low-cut vacuum orthosis ($p < 0.0083$); $^4$Significant difference between the POS and the high-cut vacuum orthosis ($p < 0.0083$); $^5$Significant difference between the POS and the low-cut vacuum orthosis ($p < 0.0083$); $^6$Significant difference between the two vacuum orthosis ($p < 0.0083$).

Fig. 2. Plantar pressure distribution of a 24-year-old female patient during walking with the four-shoe conditions.
3.4. Gait line

The gait line showed remarkable differences between the four walking conditions. The gait line of the off-the-shelf shoe started in the center of the rearfoot and ended in the distal part of the forefoot (Fig. 4). The vacuum orthoses showed a gait line from the distal part of the rearfoot to the center of the forefoot. The gait line while walking in the post-operative shoe showed a similar starting point as the off-the-shelf shoe but ended before reaching the center of the forefoot.

4. Discussion

The aim of this study was to investigate pressure-relieving effects of vacuum orthoses in patients with diabetes mellitus. The vacuum orthoses proved to be as effective in redistributing plantar pressures as cushioning orthotic insoles [10,11]. The same redistribution pattern could be seen with an increased midfoot loading and a pressure relief in the rearfoot and forefoot regions [13].

This more evenly distributed plantar pressure pattern is an advantage in comparison to the post-operative shoe that showed significantly higher peak pressures under the rearfoot while revealing the same pressure relief under the forefoot as the high-cut vacuum orthosis. The combination of moulding the plantar surface and using a rocker bottom sole in the vacuum orthoses therefore lead to a highly efficient pressure relief under the whole foot. The efficacy of midfoot rockers for pressure relief in diabetic patients has been demonstrated by Drerup et al. [13]. Furthermore, the rigid frame structure of the high-cut vacuum orthosis immobilized the upper ankle joint. This seemed to provide additional pressure relief in comparison to the low-cut vacuum orthosis as shown in significantly lower peak pressures and maximum forces under the forefoot region. In that case the load may have partly been carried by the rigid frame structure of the high-cut vacuum orthosis. Another explanation could be a pronounced load transfer in the midfoot region due to restricted push-off efficacy under the forefoot.

The assessment of the roll-over process of the foot using the gait line revealed remarkable differences between the three orthoses. The two vacuum orthoses indicated a more physiological pattern in the push-off phase in comparison to the post-operative shoe. The shortened gait line of the post-operative shoe suggested an early termination of the roll-over process of the foot whereas the subjects executed an almost complete roll-over process while wearing the vacuum orthoses. This could lead to a more comfortable gait and a better compliance.

The comparison to total contact casts is difficult due to only few studies measuring the pressure re-distribution capacity of total contact casts. Studies investigating the efficacy of total contact casts mainly described the healing rate or healing time of foot ulcers [14,15,22]. However, Armstrong and Stacpoole-Shea reported a significantly better relief of plantar pressure under the heel in total contact casts compared to removable cast walkers [23]. The efficacy of removable cast walkers in healing rate and healing time of foot ulceration was improved by fixing them on the patients’ foot and shank not allowing self-removal of the cast walker [24]. The high-cut vacuum orthosis includes the option to be used as a non-removable cast walker. Therefore, this orthosis might be equally as effective in wound treatment as total contact casts.

4.1. Limitations of the study

There was no total contact cast included in this study, although it is the gold standard in the treatment of plantar ulcers in diabetic patients. The aim of this study was to evaluate the pressure-relieving efficacy of the two vacuum orthoses in diabetic patients without acute ulcers and therefore it was not possible to apply a total contact cast to the subjects for a pressure measurement in this study. Furthermore, the literature review showed that the efficacy of total contact casts is mainly evaluated in clinical studies.
concerning healing rates of acute ulcers. The clinical efficacy of the vacuum orthoses has to be proven in clinical trials with the total contact cast as competitor. The study population demonstrated a wide distribution of age and body weight and this may have influenced their gait. The statistical analysis with Wilcoxon signed-rank tests includes comparison of the four conditions within the same person. This seems to be the appropriate way to obtain valid results in such a heterogeneous group.

5. Conclusion

In summary, the vacuum orthoses proved to be good alternatives to typically used post-operative shoes in diabetic patients. They revealed the same pressure relief in the foot region but demonstrated advantages in the re-distribution of plantar pressure and the roll-over process. Clinical trials including healing rates of acute ulcers would have to demonstrate the clinical efficacy of the vacuum orthosis. In these studies the total contact cast, which is the gold standard in the treatment of plantar foot ulcers, would have to be used as the criterion for comparison.

Conflict of interest

The authors state that there is no financial or other conflict of interest.

Acknowledgement

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References

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Plantar ulcerations are a frequent complication for patients with diabetes mellitus [1] and restrict the quality of life for the patients involved [2]. In particular, high plantar pressure loads as a component of the diabetic foot syndrome are described as a cause of this symptom [3]. A successful treatment of plantar ulcerations should aim at effectively relieving pressure on the area involved [3]. The objective of this investigation was to examine the possible relief mechanisms of various therapeutic shoe models. Two models of a vacuum orthosis, designed to relieve plantar pressure for diabetics with plantar ulcerations, were examined in comparison with a forefoot-relief/wedge shoe and a “health shoe”.

**INTRODUCTION**

For 20 patients with diabetes mellitus (56.4±15.7 years) a plantar pressure distribution measurement was performed using capacitive measuring soles (Pedar-X, Novel GmbH, Munich) (Fig. 2a), as they each walked a length of 20 meters wearing a “health shoe”, a wedge shoe and two vacuum orthoses. The vacuum orthoses (VACOdiaped and VACOdiaped Plus, OPED GmbH, Valley) consisted of an orthosis shell, the inner shoe with vacuum cushions and a rocker bottom sole. The VACOdiaped stood out here through a high and stable shaft (Fig. 1). The load was determined in three areas of the foot, the forefoot, midfoot and hindfoot (Fig. 2b), using established parameters of pressure distribution measurement (maximum force, pulse, peak pressure) and then compared for the different products.

**OBJECTIVE OF STUDY**

Investigation of the pressure relief mechanisms of the VACOdiaped vacuum orthoses in comparison with a wedge shoe and a “health shoe” for patients with diabetes mellitus

**METHODS**

For 20 patients with diabetes mellitus (56.4±15.7 years) a plantar pressure distribution measurement was performed using capacitive measuring soles (Pedar-X, Novel GmbH, Munich) (Fig. 2a), as they each walked a length of 20 meters wearing a “health shoe”, a wedge shoe and two vacuum orthoses. The vacuum orthoses (VACOdiaped and VACOdiaped Plus, OPED GmbH, Valley) consisted of an orthosis shell, the inner shoe with vacuum cushions and a rocker bottom sole. The VACOdiaped stood out here through a high and stable shaft (Fig. 1). The load was determined in three areas of the foot, the forefoot, midfoot and hindfoot (Fig. 2b), using established parameters of pressure distribution measurement (maximum force, pulse, peak pressure) and then compared for the different products.
Compared with the “health shoe”, the two vacuum orthoses and the wedge shoe significantly reduced the plantar pressure loads in the hindfoot and forefoot. At the same time an increase in the foot load in the midfoot area was demonstrated, which was associated with an increase in the contact area in this region. Compared with the wedge shoe (Fig. 3 a+b), both vacuum orthoses achieved a larger contact area and higher loading in the midfoot, as well as a significantly lower pressure load in the hindfoot. Regarding comfort, the VACOdiaped Plus attained similarly high ratings as the “health shoe” that had achieved the highest rating. The VACOdiaped (high rise boot) and the wedge shoe were rated significantly lower in regard to comfort.

RESULTS

The vacuum orthoses, utilizing vacuum cushions, produce an even pressure distribution under the entire foot, avoiding pressure peaks. The VACOdiaped achieved a relief of the forefoot comparable to the wedge shoe. Pressure loads in the wedge shoe shifted to the hindfoot, which can be dangerous for patients with diabetes who are prone to ulcerations. The VACOdiaped Plus, with its shorter shaft, does not achieve the same forefoot relief as the VACOdiaped and the wedge shoe; however, patients felt it to be considerably more comfortable. To summarize, it can be stated that the two vacuum orthoses can achieve a more even pressure distribution, as well as an effective pressure relief, and are thus suited to avoid pressure peaks.

DISCUSSION

The vacuum orthoses, utilizing vacuum cushions, produce an even pressure distribution under the entire foot, avoiding pressure peaks. The VACOdiaped achieved a relief of the forefoot comparable to the wedge shoe. Pressure loads in the wedge shoe shifted to the hindfoot, which can be dangerous for patients with diabetes who are prone to ulcerations. The VACOdiaped Plus, with its shorter shaft, does not achieve the same forefoot relief as the VACOdiaped and the wedge shoe; however, patients felt it to be considerably more comfortable. To summarize, it can be stated that the two vacuum orthoses can achieve a more even pressure distribution, as well as an effective pressure relief, and are thus suited to avoid pressure peaks.

CONCLUSIONS

- The vacuum orthoses achieve an effective relief, in accordance with their objectives
- In contrast to the wedge shoe, no significant increase in load in other foot areas were seen with the orthoses; an even pressure distribution under the entire foot is attained
- The vacuum orthoses allow for a staged treatment:
  - VACOdiaped Plus: for prevention and for less severe cases
  - VACOdiaped: for more severe cases

LITERATURE


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Statement on the use of the VACOdiaped to relieve pressure in diabetic foot syndrome

1. Definition of diabetic foot syndrome:
   In diabetes patients, every lesion in the foot and distal lower leg area is categorized as diabetic foot syndrome (DFS). In the majority of cases, the origin of the lesion is a neuropathy, possibly in combination with, and rarely caused solely by, an arterial occlusive disease. In a broader sense, Charcot foot can also be classified under diabetic foot syndrome. If not properly treated, there is a risk of serious follow-up illness, down to sepsis and/or loss of limb. Pressure-relieving measures are a fundamental basis of therapy, along with optimizing the metabolism and a structured wound-dressing, as well as ensuring sufficient blood circulation.

2. Pressure-relief systems:
   There is a variety of different pressure relief systems on the market. So-called forefoot and heel relief shoes should not be used if there is concurrent neuropathy and loss of sensitivity, since stress is generally put on the wound during the walking process. In classic bandage shoes, there is no significant relief of pressure - pressure can only be avoided with shoes that are not too narrow. An individually produced total contact cast (TTC, with and without padding) and if necessary, individually produced one- or two-cast orthoses (e.g. molded resin orthosis according to a construction method of the company Zieger) are still considered to be the gold standard of pressure relief. These systems demonstrate a high potential for pressure relief, but are expensive to produce and are not available at all times and at every location.
   The use of a VACOdiaped pressure relief system has proven itself as an alternative in clinical care. In our own pressure measurements, a considerably better pressure relief was demonstrated, especially in the area of the toes and forefoot, in comparison to the brace shoe, and an equally effective pressure relief in comparison to the TCC. The application is simple and safe, and can generally be handled easily by nursing staff or by the patient. As in all pressure relief systems, if neuropathy and/or peripheral arterial occlusive disease are diagnosed, you must be very careful of any lesions and pressure marks. There are currently not enough studies on the decision of the need for anticoagulation in joint-stiffening pressure relief systems to be able to make decisions on their necessity, and to be the subject of discussion.
3. Possible indications for the use of a VACOdiaped:
From clinical experience and from the result of comparative pressure measurements between a brace shoe, a total contact cast and the VACOdiaped, the following possible indications for a VACOdiaped were revealed:

1.) Plantar forefoot lesions, especially in the area of the metatarsal bone, for pressure relief with and without signs of infection.
2.) Condition after amputation in the region of the toes and forefoot up to the Chopart line, for pressure relief in the scar region and the prevention of shearing forces.
3.) With sufficient clinical experience and selected patients, a therapy for acute Charcot foot can also be undertaken in the VACOdiaped, there are currently insufficient data concerning this. In the period from 6/08 - 6/09, some 40 patients with a Charcot in Levin stage 1 were treated, in most cases medical provision with the VacoDiaped was considered to be sufficient until a final shoe was introduced.
4.) In particular situations, and after an individual decision of a physician, lesions of other types on the metatarsal to the heel, or in the distal lower leg area, can be treated with the VACOdiaped, especially if no suitable alternative is available. As with all pressure relief systems, however, the pressure relief in this area is less effective than in the forefoot area.

4. Contraindications:
4.1 All pressure relief systems have an increased risk for patients with an unstable gait, and in certain cases, the benefit of a pressure relief must be weighed up against the danger of falling.
4.2 In particular with pressure relief systems that extend beyond the ankle, sufficient perfusion must be ensured. For critical ischemia, this may result in a further decline in perfusion through pressure in the lower legs area. In this case, these systems should not be used. An alternative could be the use of a VacoDiaped plus with a low shaft, although currently we do not yet have any own measured values with respect to pressure relief.
4.3 The VACOdiaped can, with limitations, be adjusted to the foot shape by distorting it using hot air. For major deformations and very large and wide foot shapes, it is possible that a VACOdiaped may not be suitable, but this must be decided on the basis of individual cases. The patient/family/nursing staff must take an active involvement to avoid the possibility of the device being wrongly fitted. If it is wrongly fitted (e.g. a missing vacuum or if the vacuum cushion has been forgotten) the risk of pressure points can be increased. The physician must also make the decision based on individual cases, in case the need arises.

5. Final comment:
The current state of research into pressure relief systems is generally unsatisfactory. One of the fundamental problems in the effectiveness of all pressure relief systems appears to be acceptance by the patient. Many pressure relief systems are not worn sufficiently, so that often closed systems are recommended; the consequence of this is that inspections of the wound are inadequate, so that their use, particularly where there are infected wounds, must be assessed as being critical. From our experience, the VACOdiaped is well accepted by patients, and is correspondingly worn regularly. Controlled studies in accordance with the criteria of the EBM do not exist yet, especially no comparative studies between different pressure relief systems, so that evaluations overall are based on clinical experience. The treatment of patients with diabetic foot syndrome should be reserved for institutions that can demonstrate adequate knowledge and experience in the treatment of DFS (e.g. certification by the DDG / Fuß-AG).
Examples for Treatment with VACO®diaped

After 12 Weeks

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