Effectiveness Testing of the Relief Insert® Walker Lower Leg / Foot Orthosis

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Summary

This study aimed to compare two ankle-foot orthoses (AFO) with respect to their immobilizing function. The investigation focused on the Relief Insert® Walker AFO (DARCO (Europe) GmbH, Raisting, Germany) and a comparator model already listed in the Medical Aids Directory of the German statutory health insurers. Examination of 22 healthy subjects (mean age 34 ± 10 years) showed that both the maximum dorsal extension and the range of motion at the upper ankle joint for the Relief Insert® Walker (RIW) were significantly lower as compared to the comparator model.

The bending and torsional loads in numerous ranges produced varying results for the two orthotic devices. In some cases, the comparator showed lower bending or torsional loads, in others, the walker manufactured by DARCO did.

Both orthotic devices ensure that the medical aid is securely affixed to the foot. The comparator achieves this using the heel and forefoot area, whereas the RIW primarily makes use of the midfoot and forefoot area.

Introduction

In this study, two different lower leg/foot orthoses were investigated with regard to their secure fixation on the foot, their immobilizing effect on the forefoot and the changes in angle of the ankle joint. This study was carried out by the Laboratory for Biomechanics of the University of Applied Sciences Münster and vebitosolution GmbH, commissioned by DARCO (Europe) GmbH of Raisting, Germany. The manufacturer, DARCO (Europe) GmbH, is working towards having its new product – the Relief Insert® Walker Lower Leg/Foot Orthosis (RIW) – be included in the Medical Aids Directory of the German Statutory Health Insurance Funds (GKV). Among other things, the following properties are required in order for a medical aid to be categorized in the intended Product Group 23 of medical splints/orthoses indicated for immobilization of the lower leg and foot in a defined position:

- Relief/protection of injured anatomical structures
- Prevention of unhealthy movements throughout the entire treatment area
- Immobilization of the lower leg/foot region in a defined position
- Secure fixation of the orthotic device to the foot.

Secure fixation to the foot was verified by means of pressure measurement using pressure distribution insoles (manufactured by T&T medilogic Medizintechnik GmbH). To assess the effects of mechanical relief on the foot and immobilization of the forefoot joints, the bending and torsional moments at the foot in the shoe were analyzed using the vebitosCIENCE measurement system (vebitosolution GmbH, Steinfurt, Germany). The changes in angle at the upper ankle joint were measured to assess the immobilization of the lower leg/foot region. The Zebris CMS ultrasound (Zebris Medical GmbH, Isny, Germany) was employed to carry out this investigation. To evaluate the measurement values of the RIW, they were compared to a competitor's walker boot that already has a directory number in the medical aid category.

Methodology

Walker conditions investigated

During the measurements, the respective orthotic device was worn on the right foot. On the left foot, the subject wore a neutral shoe (Samba, adidas AG, Herzogenaurach, Germany) with height compensation. Figure 1 shows the RIW. The RIW consists of the Relief Dual® Foot Relief Shoe and a plastic splint, as well as an optional relief contour soft bed insole (not used in this study). The comparator model (not shown) that was also investigated is a walker boot with a short shaft, consisting of a main body and a front shell fastened by means of straps.

Measurement systems

The medilogic soles (T&T medilogic Medizintechnik GmbH, Schönefeld, Germany) were employed to assess the devices' secure fixation to the foot at a measurement frequency of 60 Hz. The bending and torsional loads were recorded and analyzed with the vebitosCIENCE measuring system (vebitosolution GmbH) at the heel, first and fifth metatarsophalangeal joints (MTP I and MTP V) and first and fifth distal interphalangeal joints (DIP I and DIP V) at a measurement frequency of 200 Hz.
of the daily walking distance (OR 0.91), but the main effect was the regular wearing (>80 percent) of effective shoes, reducing the peak pressure to < 200 kPa (OR 0.45).

Conclusions
The authors conclude from their data that calluses, dermatorrhapsia and blisters are highly significant for the prediction which patients develop a foot ulcer. The regular wearing of effective shoes on the other hand reduced the risk of an ulcer recurrence by about 50 percent. These data show that well manufactured footbeds are an effective measure for recurrence prophylaxis of neuropathic plantar ulcers. A regular screening for non-ulcerative skin lesions has a high sensitivity to recognize patients with an extraordinary risk for an ulcer and to take the corresponding shoe-technical and podiatric measures.

Commentary
This extraordinarily important study by the group of Sicco Bus quantified for the first time risks for the occurrence of ulcer recurrences under consideration of many demographic and disease-specific factors. Additionally also the treatment with shoes, the pressure load and first of all the wearing of effective shoes were considered. Also in this study it was shown that plantar ulcer recurrences are extremely frequent and that they occur not long after the healing of the previous ulcer. Furthermore this study proves that effective shoes and the treatment of non-ulcerative skin lesions are effective measures to reduce this strong risk for our patients.

Also it is shown here that such a high risk group needs foot exams much more frequently than what is done nowadays and that a tight connection to a specialized outpatient clinic is decisive for the reduction of the rate of ulcer recurrences.

Maximilian Spraul

References

Assessing Patients Adherence to Costumized Diabetic Insoles
By Wolfgang Best
Background: International guidelines strongly recommend the use of customized diabetic footwear and insoles for people with diabetes at risk for diabetic foot problems in order to reduce the mechanical stress by redistributing pressure to the plantar tissue. Recent studies suggest that adherence to footwear and insoles which offload the foot is associated with the prevention and healing of diabetic foot ulcers. However, little is known about the long-term course of adherence in patients at risk for diabetic foot problems.

Method: In this study a temperature sensor was incorporated into the specialized footwear of patients with type 2 diabetes after their first plantar ulceration. The wearing time was monitored by measuring the temperature inside the footwear every 15 minutes. 26 patients with a mean observation time of 135.5 days could be analyzed.

Results: Mean wearing time of diabetic footwear was between 4.2 and 5.6 h/day. But data analysis showed, that on 51% of the days patients did not wear their footwear at all. A closer look at the data revealed that adherence to the footwear dropped after a couple of weeks. Men achieved a mean time of adherence of 30.5 weeks, while women only achieved 14 weeks. The mean time of adherence was 27.5 weeks.

Conclusions: The results suggest that the overall wearing time was rather low as patients have only worn their footwear for about 4 hours a day and did not put it on at all on more than 50% of the days. As footwear can only help reduce stress on tissue when it is worn, the authors conclude that the long term effect of diabetic footwear can be questioned. However, no reulceration occurred during the observation period.

Commentary:
This study shows that adherence is not an "add on" but should be in the center of attention when providing specialized footwear for people with diabetic foot problems. Further investigations should also focus on reasons for adherence and non-adherence. Achieving better adherence is a challenge. Education on the importance of adequate footwear that incorporates personal perceptions, values and experiences of the patients will play an important role in this task.

Reference:

Prof. Maximilian Spraul is an expert in diabetes. He is head physician at the Medical Clinic in Rheine/Germany and is a member of the Diabetic Foot Study Group. Wolfgang Best is editor of foot & shoe.
bending and torsional load was defined as zero for freely suspended, unloaded feet (in the orthotic device). When measuring with vebitoSCIENCE and Medilogic, each of the insoles was inserted into the shoe directly under the foot. The soles were connected by cables to a data transmission unit worn at the hip on a belt. From there, the data was wirelessly transmitted to a computer. The changes in angle at the upper ankle joint were recorded with the Zebris CMS ultrasound (Zebris Medical GmbH, Isny, Germany) at a measuring frequency of 100 Hz. This system is based on the transit time measurement of ultrasonic pulses. To record the changes in angle of the upper ankle joint during gait over time, three single markers were used and the sagittal plane angle formed between them. Figure 2 shows the placement of the markers and the evaluated angle. The angle was defined as zero in the upright position.

22 healthy subjects without foot deformities or acute injuries of the lower musculoskeletal system were examined. The subjects were aged between 22 and 50 years (34 ± 10 years) and had an average BMI of 25 ± 2 kg/m². Of the 22 participants, 11 were female and 11 male. One test subject had to be excluded from further analysis due to measurement errors. The test subjects were informed about the procedure prior to the start of the measurement and gave their written consent to participate in the study as well as to the anonymized disclosure and publication of measured results. Subsequently, all relevant data on the subjects and their health history were collected by means of a questionnaire.

**Measurement procedure**

The measurements were taken during gait on a treadmill. The orthotic devices and the measuring systems were used in randomized order. The vebitoSCIENCE and zebris measurements were carried out simultaneously. In each case, 30 consecutive double steps were recorded at a self-selected walking speed. The measurements were carried out on a slat-belt treadmill. The test persons were allowed to choose a comfortable walking speed during the first measurement. For each additional measurement, the subjects had to maintain this speed. For each shoe condition examined for the first time, the walking time was five minutes. When measuring in the same shoe with the other measuring system, the walking time was two minutes.

**Data preparation and evaluation**

The recorded steps were standardized to 100 percent of the gait cycle and then averaged. The incremental detection for this was carried out manually for the bending and torsional data, as well as for the angle curve of the upper ankle joint. Figure 3 shows a schematic plot of the bending and torsional loads on MTP I as they can occur during gait. The x-axis describes the time in the gait cycle as a percentage, whereby the time zero percent corresponds to the moment of heel strike. The y-axis shows the load in Nmm that occurs at the corresponding time. Negative values correspond to loading in terms of plantarflexion or internal rotation, positive values to loading in terms of dorsiflexion or external rotation. The expression of the corresponding loading direction can be very well described by the respective maximum. The total load range results from the difference between the two extreme values. If a step contains loading in the direction of plantarflexion and dorsal extension, or in the direction of internal and external rotation, it is called an alternating load. The reference axis for the direction of rotation of the torsion in the forefoot is the foot center axis; for torsion at the heel, it is the center axis of the body (Figure 4). The upper ankle joint angle can both decrease and increase during gait. Starting from the neutral, upright position, positive values correspond to a dorsal extension movement and negative values to a plantar-
flexion movement. Here too, maximum plantarflexion, maximum dorsiflexion and range were evaluated. Figure 5 shows a typical curve for the ankle angle during gait. To determine how securely the shoe was affixed to the foot, the plantar pressure distribution was measured. The percentage of the gait cycle at which there is contact between the sole of the foot and the respective orthotic device was investigated. The software used allowed for separate calculation of an average step for the forefoot, midfoot and heel area. It was assumed that if at least one pressure value greater than or equal to 0.025 Nmm exists, there is contact between the foot and the shoe. For each foot region, the contact time was determined as a percentage over the gait cycle. The individual parameters of all measuring systems were analyzed for differences (p<0.05) by means of two-factorial mixed ANOVA or, if the Kolmogorov-Smirnov test did not show a normal distribution, by means of the Wilcoxon signed-rank test. The two factors were the different walkers and gender. Only the differences between the walkers are shown.

Results
Influence of orthotic devices on forefoot joints and heel
In the following, the bending and torsional loads for each measuring area where significant differences occurred are shown. Each graph shows the average curve across all subjects, in each case for both orthotic devices, as well as the respective positive and negative standard deviation. The orange curve shows the results of the comparator, the purple curve the results of the Relief Insert Walker. Figure 6 shows the bending load on MTP I. The maximum dorsal extension was significantly lower in RIW than in the comparator. The comparator

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2 Jacqueline Penny, Gangankyrse. Urban und Fischer Verlag Munich. 2003
7 Mean curve of the torsional load at MTP I across subjects for both walker conditions. The full line corresponds to the mean value; the dashed line indicates the standard deviation. Positive values: internal rotation; negative values: external rotation.

8 Mean curve of the bending load at MTP V across subjects for both walker conditions. The full line corresponds to the mean value; the dashed line indicates the standard deviation. Positive values: dorsiflexion; negative values: plantarflexion.

9 Average torsional load progression at MTP V across subjects for both walker conditions. The full line corresponds to the mean value; the dashed line indicates the standard deviation. Positive values: external rotation; negative values: internal rotation.

10 Mean curve of the bending load at DIP I across subjects for both walker conditions. The full line corresponds to the mean value; the dashed line indicates the standard deviation. Positive values: dorsiflexion; negative values: plantarflexion.

11 Mean curve of the bending load at DIP V across subjects for both walker conditions. The full line corresponds to the mean value; the dashed line indicates the standard deviation. Positive values: dorsiflexion; negative values: plantarflexion.

The model shows a significantly lower alternating load. Figure 7 shows the torsional load on MTP I. Strikingly here is that the load is generally very low under both conditions and significantly lower than it would be under standard conditions (barefoot shoe). Moreover, very different curves are produced under both conditions. While—in the case of the comparator—the torsional load at the beginning of the gait cycle corresponds to an internal rotational load and external rotation does not occur until the end of the stance phase, the RIW shows external rotation throughout the gait cycle. The maximum external rotational moment is significantly higher in the RIW than in the comparator. The curve of the bending load on MTP V is also fundamentally different for the two AFO. In this case, the RIW first shows a plantarflexion load and, at the end of the stance phase, a dorsiflexion. The comparator consistently shows dorsiflexion. Versus the comparator, in the RIW, maximum plantarflexion is significantly higher while maximum dorsiflexion is significantly lower (Figure 8). Figure 9 plots the mean torsional load at MTP V. Both orthotic devices show similar basic curves; however, the range of the torsional load and the torsional alternating load on MTP I are higher in the RIW than its comparator. Furthermore, whereas the curve of the bending load at DIP I is basically similar for both walkers, the maximum bending load and range in this foot area are higher for the RIW than for the comparator (Figure 10). There were no detectable differences between the devices in the torsional moments at DIP I. The bending loads on DIP V (Figure 11) again showed marked differences between the study conditions. Overall, the bending load in the RIW was very low, as it was close to zero over the entire gait cycle. The maximum dorsiflexion load in the RIW was significantly higher, the maximum plantarflexion significantly lower.

Kerkhoff, Pelkenkamp. Norm Data for bending and torsional loads of the foot in shoes including the effect of gender. ISB 2015 in Glasgow.
than that of the comparator. The torsional load on DIP V shows no significant differences between the two conditions. Figure 12 shows the mean bending load curves at the heel. The maximum bending load in the direction of dorsiflexion is significantly lower in the RIW than in the comparator. The same applied to the range and the bending alternating load. The maximum bending load in terms of plantarflexion was slightly increased in the RIW. The torsional alternating load on the heel (Figure 13) was significantly reduced in the RIW.

Influence of the orthotic devices on the upper ankle joint angle

Figure 14 shows the change in angle of the upper ankle joint. The basic curve under both conditions hardly differed and also corresponded to the known curve described in the literature (Figure 5). Both the dorsiflexion maximum and the range of motion were lower for the two orthotic devices than those reported in the literature. Both parameters are significantly lower in the RIW as compared to the comparator model.

Influence of orthotic devices on fixation to the foot

The results of the plantar pressure measurement to assess the secure fixation of the orthotic device to the foot are presented in Figure 15. The * indicates significant differences. Whereas the comparator model allows for more secure fixation at the heel (longer contact time between shoe and foot region), the RIW achieves this in the midfoot area.

Discussion

The investigation of the bending and torsional loads in the forefoot joints and at the heel showed that the dorsal extension load in the RIW is lower at the MTPs than in the comparator. On the other hand, torsional load was slightly increased. However, due to the stiff material of the orthotic devices and the available space for the foot, torsional loads were generally severely limited as compared to the load values described in the literature. These torsional limitations were not as severe in the RIW as in the comparator. The reduced bending and torsional loading in the heel area of the RIW is an indicator for its greater rigidity. The greater restriction of dorsiflexion motion at the MTPs in the insert can be attributed to the better roll-off function. If the shoe rolls off more easily, it is not necessary to considerably increase the dorsal angle in the movement. This was also evident in the evaluation of the ankle angle. Here, the RIW had a significantly lower maximum dorsiflexion angle. It can be assumed that the better roll-off function leads to a reduced effort of the plantar flexors that, in turn, reduces the pressure load in the ankle joint. The comparator model has a
12 Mean curve of the bending load at the heel across subjects for both shoe conditions. The full line corresponds to the mean value; the dashed line indicates the standard deviation. Positive values: external rotation; negative values: internal rotation.

13 Mean curve of the torsional load at the heel across subjects for both shoe conditions. The full line corresponds to the mean value; the dashed line indicates the standard deviation. Positive values: external rotation; negative values: internal rotation.

14 Mean curve of the angle of the upper ankle joint in both walker conditions. The full line corresponds to the mean value; the dashed line indicates the standard deviation. Positive values: dorsiflexion; negative values: plantarflexion.

15 Contact times between the foot region and the orthotic device, based on the percentage of double-step duration (DSD). The * indicate a significant difference.

shorter shaft than the RIW and therefore a shorter lever arm for dorsal and plantarflexion loads. A shorter lever arm with the same force would result in a lower torque load and thus in less movement in the upper ankle joint. However, since the comparator model has a relatively flexible front shell, the positive effects of the shorter shaft on the movement in the upper ankle joint are overcompensated. This explains the significantly higher range of the upper ankle joint angle in the comparator model. Both AFO models demonstrate secure fixation to the foot, i.e. a long contact time between the foot and the orthotic device. The RIW shows a significantly longer contact time in the midfoot area, while the comparator model shows a much longer contact time in the heel area. The differences in these regions can be explained by the respective structures of the orthotic devices. The RIW has a cutout in the cushioning inlay in the heel area to ensure a good fit of the inlay to the foot. In the midfoot area, however, the inlay is intact, thus ensuring a very long contact time between foot and shoe. The comparator model has a heel wedge underneath the insole, which results in a longer contact time in the heel area. In summary, both walker models ensure a secure fixation of the orthotic device to the foot. Both orthotic devices reduce movement in the upper ankle joint as compared to the literature data, whereby the RIW restricts range and dorsiflexion to a greater extent than the comparator model. At the distal interphalangeal joint of the hallux, the comparator model shows a lower bending load. At the MTPs, DIP V and heel, on the other hand, the RIW shows a greater reduction in dorsiflexion loads.

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