Foot loading with an ankle-foot orthosis: the accuracy of an integrated physical strain trainer

Johannes Pauser · Andreas Jendrissek ·
Matthias Brem · Kolja Gelse · Bernd Swoboda ·
Hans-Dieter Carl

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Abstract

Purpose To investigate the value of a built-in physical strain trainer for the monitoring of partial weight bearing with an ankle-foot orthosis.

Methods 12 healthy volunteers were asked to perform three trials. Plantar peak pressure values from normal gait (trial one) were defined as 100% (baseline). The following trials were performed with the Vacoped[®] dynamic vacuum ankle orthosis worn in a neutral position with full weight bearing (trial two) and a restriction to 10% body weight (BW) (trial three), as monitored with an integrated physical strain trainer. Peak plantar pressure values were obtained using the pedar[®] X system.

Results Peak pressure values were statistically significantly reduced wearing the Vacoped[®] shoe with full weight bearing for the hindfoot to 68% of the baseline (normal gait) and for the midfoot and forefoot to 83% and 60%, respectively. Limited weight bearing with 10% BW as controlled by physical strain trainer further reduced plantar peak pressure values for the hindfoot to 19%, for the midfoot to 43% of the baseline and the forefoot to 22% of the baseline.

Conclusions The Vacoped[®] vacuum ankle orthosis significantly reduces plantar peak pressure. The integrated physical strain trainer seems unsuitable to monitor a limitation to 10% BW adequately for the total foot. The concept of controlling partial weight bearing with the hindfoot-addressing device within the orthosis seems debatable but may be useful when the hindfoot in particular must be off-loaded.

Introduction

The follow-up treatment of foot and ankle injuries like Achilles tendon rupture, ankle fractures or arthrodeses frequently requires orthotic devices such as casts or dynamic orthoses. This strategy is based on previous evidence that partial weight bearing is beneficial in several ways. A positive effect of early limited weight bearing in the treatment of tibial fractures has been described [1]. In addition, enchondral ossification depends upon the amounts of strain and overloading can lead to delayed healing or non-union [2].

There is, however, some data from previous studies that partial weight bearing is carried out inaccurately by patients. A study of healthy volunteers and patients described an exertion of 27–35% of body weight (BW) more than required when partial weight bearing is tested using bathroom scales [3]. A further report stated that even young patients were unable to follow weight bearing restrictions after autologous chondrocyte implantation [4]. A visual control of weight bearing has been described as being invalid to assess partial weight bearing [5]. Thus, there is a need to monitor limited weight bearing of the lower limb.

Several computer-based auditory biofeedback soles have been developed and validated for this purpose [6, 7], but the high costs and technical expenditure still limit their routine clinical use. As an alternative to electronic devices, physical strain trainers are available. One of these non-electronic trainers has recently been combined with a dynamic vacuum orthosis in order to monitor weight bearing. Based on the previous evidence that such a physical strain trainer may lead to an inaccurate reduction of foot loading [8], our study was conducted to investigate the use of such a combination for the monitoring of partial weight bearing. The hypothesis behind our work was that a physical strain trainer is not useful to monitor foot loading in a dynamic vacuum orthoses.

J. Pauser · A. Jendrissek · M. Brem · K. Gelse · B. Swoboda ·
H.-D. Carl (✉)
Division of Orthopedic Rheumatology,
Friedrich-Alexander-University of Erlangen-Nuremberg,
Erlangen, Germany
e-mail: hansdietercarl@yahoo.de

Methods

Twelve healthy volunteers (eight men and four women, mean age 35 ± 5 years, mean BMI 29.5 ± 3.2 kg/m²) with no history of foot complaints were recruited from the hospital staff and asked to participate. A total of three trials were performed. Walking speed was kept constant for each volunteer and inter-individual differences between volunteers were accepted. During the first trial, the volunteers were asked to walk with their normal gait in sports shoes without any orthotic devices to assess their baseline values, defined as 100%. The second trial was performed with full weight bearing with the Vacoped® dynamic vacuum ankle orthosis (OPED Inc., Framingham, MA, USA) (Fig. 1) worn on the right leg. The size of the orthosis was adjusted individually. It consists of two covers to be fixed with straps and an adjustable vacuum cushion. Its removable polyurethane sole has about 40 shore density. The ankle joint can either be immobilized in fixed angles from 15 degrees dorsiflexion to 30 degrees plantarflexion or mobilized

in various ranges of motion. We used a fixed neutral position of the ankle joint for our measurements.

A third trial with limited weight bearing of 10% BW was conducted with the Vacoped® shoe and an integrated physical strain trainer. The combination of the two devices is commercially available. The physical strain trainer consists of a divided heel pad with insertable signal springs that is placed under the heel (Fig. 1) and gives an audible and mechanical feedback when the pre-defined strain limit is crossed. The volunteers were made familiar with limited weight bearing with a bathroom scale by an experienced physiotherapist. Adequate limitation of weight bearing was defined as the absence of an audible or mechanical feedback from the strain trainer for all steps. A levelling shoe was applied for all measurements with the Vacoped® shoe to adjust limb length. No crutches were used for the trials with normal gait and full weight bearing with the Vacoped® shoe. Limited weight bearing was performed with two individually adjusted crutches.

Fig. 1 The Vacoped® vacuum ankle orthosis with two hemispheric covers and a vacuum cushion. There are insertable metal springs to be placed under the heel for the monitoring of partial weight bearing

Pedobarographic data were obtained using the Pedar® X system (Novel Inc., Munich, Germany), consisting of insoles holding 99 capacitive sensors that capture dynamic in-shoe pressure and force information in a frequency of 50 Hz. The size of the sole was adjusted individually. Peak pressure values (highest values during trial under foot) were obtained for the right foot from 15 left and right steps. The following foot portions were defined for data analysis: heel (0–15% of total insole length), hindfoot (16–30% of total insole length), midfoot (31–60% of total insole length) and forefoot (61–100% total insole length). The Novel Multiprojects-ip® software package (Novel Inc., Munich, Germany) was used to calculate means, medians and standard deviations. Data were then transferred to Prism® 5 software (GraphPad Software Inc., San Diego, USA). Paired medians were compared with the two-tailed non-parametric Wilcoxon matched-pairs signed rank test; *p*-values of less than 0.05 were regarded as statistically significant. No adjustments for multiple comparisons were made. Our local IRB was contacted and approved the conduct of the study with no requirements.

Results

All results are summarized in Table 1 and illustrated in Fig. 2. In detail, peak pressure values in mass-produced shoes and insoles were 251 ± 50 kPa (252 kPa) (mean $\pm$ SD; median) under the hindfoot, 136 ± 34 kPa (125 kPa) under the midfoot and 302 ± 93 kPa (289 kPa) under the forefoot.

Wearing the Vacoped® shoe with full weight bearing led to a statistically significant reduction of hindfoot peak pressure values to 167 ± 41 kPa (172 kPa) or 68% of the baseline (normal gait) ($p=0.0093$). Midfoot peak pressure with full weight bearing applying the vacuum ankle orthosis was 109 ± 29 kPa (104 kPa) which equals a statistically significant reduction to 83% of the baseline ($p=0.0005$). Forefoot peak pressure under such conditions was 164 ± 46 kPa (174 kPa) or a remaining 60% of the baseline ($p=0.0042$).

Limited weight bearing with the vacuum ankle orthoses as controlled by a physical strain trainer with a restriction to

10% BW resulted in hindfoot peak pressure values of 57 ± 31 kPa (47 kPa) or 19% of the baseline value (normal gait), which was a statistically significant reduction compared both to normal gait (baseline; $p=0.0005$) and full weight bearing ($p=0.0005$). Midfoot peak pressure with limited weight bearing was 54 ± 32 kPa (54 kPa) or 43% of the baseline value, equal to a statistically significant reduction compared to normal gait values ($p=0.0025$) and full weight bearing ($p=0.002$). In addition, forefoot peak pressure with limited weight bearing was 98 ± 98 kPa (63 kPa) or 22% of the baseline and thus statistically significantly reduced compared to normal gait ($p=0.0042$) and also compared to full weight bearing ($p=0.0342$).

Discussion

Reduction of foot loading

Our results show that partial weight bearing with 10% BW reduces plantar pressure in the Vacoped® orthosis to 20% of normal gait for the hindfoot and forefoot, and to 40% of normal gait for the midfoot. Given that such an extent of plantar pressure reduction is sufficient to protect the hindfoot and forefoot, our results do not prove our hypothesis. Our findings however point towards a less marked reduction of peak pressure for the midfoot, suggesting that the midfoot is not sufficiently protected. As a consequence in clinical practice, the Vacoped® orthosis seems suitable for off-loading the hindfoot and forefoot, as it may be required after calcaneal and talar fractures, hindfoot arthrodeses or metatarsal fractures. Taking into account that patients tend to put more weight on the limb than they are intended to, it seems quite surprising that the idea of “partial weight bearing with 10% BW” is nonetheless successful in clinical practice. As midfoot load remains 40% of normal gait even with a limitation to 10% BW, the Vacoped® orthosis may not be reliable enough for off-loading midfoot disorders such as tarsal fractures or arthrodeses. If physicians demand a greater plantar pressure reduction than the Vacoped® orthosis offers, be it noncompliant patients or critical conditions such as highly instable fractures, complete weight relief seems to become necessary.

Table 1 Assessment of peak plantar pressure with the Vacoped® vacuum ankle orthoses and its relation to normal gait

Peak pressure (kPa)	Hindfoot	Midfoot	Forefoot
Normal gait (baseline)	251 ± 50 (252)	136 ± 34 (125)	302 ± 93 (289)
Vacoped® full weight bearing	167 ± 41 (172) 68%	109 ± 29 (104) 83%	164 ± 46 (174) 60%
Vacoped® limited weight bearing (10% BW)	57 ± 31 (47) 19%	54 ± 32 (54) 43%	98 ± 98 (63) 22%

Results from peak plantar pressure assessments (kPa) are listed as absolute values: mean $\pm$ standard deviation (median) for different foot regions under varied conditions: Normal gait (baseline) and with the Vacoped® vacuum ankle orthoses (OPED Inc., Framingham, MA, USA) under full weight bearing and a limitation to 10% body weight. Median values are expressed as percentage referred to normal gait (baseline)

Fig. 2 Plantar peak pressure values (kPa) were assessed during normal gait (*black columns*) and in Vacoped® vacuum ankle orthoses (OPED Inc., Framingham, MA, USA) with full weight bearing (*grey columns*) and a limitation to 10% BW (*white columns*). * $p < 0.05$

We consider future studies necessary to investigate if our theoretical findings with healthy volunteers can be confirmed with patients in postoperative care.

With regard to limited weight bearing as controlled by the physical strain trainer, our findings are in line with previous measurements of peak plantar pressure with 10% BW, as a remaining 48% peak pressure of normal gait for the total foot as has been described earlier [9]. Thus it remains in doubt that the concept of monitoring foot loading with the hindfoot-addressing device is suitable. We agree with others that such a device may be preferably applied in cases when the hindfoot in particular must be off-loaded [8].

There also seems to be an “intrinsic mechanism” of the Vacoped® orthosis that reduces plantar pressure values of normal gait up to 60% of the baseline (forefoot) even with full weight bearing. We speculate that this effect is due to the design of the orthosis with a low density plastazote heel, the midfoot roll and the cushioned cotton.

Pedobarography

We decided to use dynamic pedobarography to assess foot loading because it has been established as a useful technique for clinical research [10–19]. Dynamic pedobarography can be applied either with platform-based devices or sensor-loaded insoles. Sensor loaded insoles are useful to record forces at the foot–sole interface, whereas platform-based systems measure forces at the foot–ground interface. We chose sensor-loaded insoles for our pedobarographic

measurements because such a system seems closer to real life, collecting data from a series of steps from both right and left feet. Moreover, insole systems are more mobile and flexible enough to be used for different conditions such as walking, running or stair climbing.

Strain training

For the monitoring of partial weight bearing, mechanical strain trainers such as the PBS® (PBS®, Sicuro Inc, Gunzach, Germany) or various computer-based auditory biofeedback soles have been developed [6, 7]. Computer-based biofeedback strain trainers have been proven to increase the compliance in patients intended to reduce weight bearing [6]. The principle of biofeedback has been described to be more efficient than physiotherapy for gait rehabilitation [19]. However, until now such devices have not been in routine clinical use, probably due to the technical expenditure and high cost. Assuming that a physical strain trainer is equally reliable its use is beneficial because it is cheaper and easy to use.

Study limitations

We clearly recognize the limitations of our study. Firstly, we performed our trials with healthy volunteers and not with patients. However, we believe that such an approach is justified to avoid jeopardizing patients who require an accurate limitation of weight bearing. Secondly, we did not gather kinematic data of the ankle, knee and hip angles of movement to observe

in which position the subject placed the limb to support it. Altered biomechanics of the limb may play a role in the change of foot loading, although our pedobarographic data do not allow that conclusion. Further studies on limb kinematics may explain in more detail the results obtained with pedobarography. Nonetheless we assume that a strain trainer must guarantee accurate control of weight bearing no matter how gait kinematics are altered postoperatively. Thus we focussed on foot loading characteristics regardless of any changes in gait patterns, which is a topic to be addressed in further studies.

Conclusions

The Vacoped® vacuum ankle orthosis (OPED Inc., Framingham, MA, USA) with an integrated physical strain trainer may be preferably applied for off-loading the hindfoot and forefoot, but it seems unsuitable to monitor a limitation to 10% BW adequately for the midfoot. As such the concept of controlling partial weight bearing for the total foot with the hindfoot-addressing device remains in doubt.

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