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LOW EFFECTIVENESS OF PRESCRIBED PARTIAL WEIGHT BEARING

Continuous recording of vertical loads using a new pressure-sensitive insole

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To enable objective measurements of weight bearing in hip replacement patients a portable instrument set-up with an on-line registering pressure-sensitive insole was developed. Six men and 9 women, median age 58 (48–67) years, who had been operated on with a cementless or hybrid hip arthroplasty were studied. All patients were independent and functional. A physiotherapist instructed the patients to use crutches in order to support 30% of their body weight. The patients then walked a standardized distance with crutches over five different types of terrain: level, uphill, downhill, upstairs and downstairs. The trial was repeated once. In both men and women most of the steps taken resulted in a load of >30% of body weight. None of the patients managed to comply with the directive, even though five of them thought they did. The type of terrain had no significant influence on the pattern of load. Our findings indicate that the effectiveness of prescribing limited weight bearing is questionable.

Key words: weight bearing, insole, rehabilitation, biomechanics, gait analysis, hip prosthesis, osteoarthritis, force plate, activity.

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INTRODUCTION

Several studies have indicated that the loosening process of total joints starts early and within the first 1–2 years after operation (1–4). Poor primary fixation has been suggested to be one of the important causes of failure of cemented prostheses (2, 5, 6). It has also been stated that patients with cementless prostheses should be protected from high torsional loads until bony fixation of the implant has taken place (7–9). Loizeau et al. (10) measured energy loss in both the operated and the non-operated limb 3.8 ± 2.5 years after total hip replacement (THR), using a laboratory system based on video image and force plate analysis. Their observations suggested that orthopaedic problems can often be expected to occur from the contralateral hip. Wykman and Olsson (11) showed that bilaterally disabled patients did not gain optimal function on either side until THR was done on both legs. Long et al. (12) used video cameras, force plate and electromyography equipment to demonstrate persisting weakness of the operated hip >2 years after surgery. They considered that this weakness could jeopardize the implant–fixation interface and recommended a prolonged exercise regime. Using an instrumented femoral hip prosthesis Hodge et al. (13) recorded increasing contact pressures between the acetabular cartilage and the prosthesis up to 12–18 months after surgery, when no further functional improvement occurred. They too indicated that the traditional postoperative management and protocols for rehabilitation might not be optimally standardized.

To what extent the postoperative rehabilitation phase can influence the integration process of a hip prosthesis and the incidence of later clinical loosening is not clear. Bergmann et al. (14) highlighted three important mechanical parameters which should be evaluated further: the average peak loads during routine activities, the long-term average of the joint loads and extreme peak loads during occasional activities.

In principle there are two ways to measure the ground reaction force in patients, using either a force-sensitive plate on the ground or an in-shoe pressure-sensitive insole. Gait laboratories usually use force plates based on piezoelectric technology, such as Kistler plates (15–17). The most commonly used in-shoe sensing systems currently on the market employ force-sensitive resistor (FSR) technology, such as the F-Scan. These systems require continuous calibration and are therefore best suited to the laboratory setting (18, 19). Although recordings of patient activity during recovery after hip surgery have been scarce, the development of new instrumentation, which could measure certain activities of daily living for a large patient pool, would have the potential to increase the amount of knowledge in this field.

We have developed a new pressure-sensitive insole based on well-documented strain gauge technology (20), with non-relevant sensitivity to moisture, surface conditions and temperature (18). Our study had two aims. The first was to evaluate a new insole designed to measure long-term ground reaction forces away from the laboratory. The second aim was to determine the effectiveness of instructions concerning partial weight bearing on different types of terrain, when postoperative pain no longer served as protection.

PATIENTS AND METHODS

Six men and nine women (median age 58 years; range 48–67 years) who had been operated on with a cementless or hybrid hip arthroplasty were studied. Median time between the operation and the study was 4 years

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and 2 months (range 1 year and 9 months to 8 years and 6 months). Our main concern was to choose patients with a good or excellent clinical result. We therefore selected patients who had been followed using radiostereometry and the Harris hip score. The Harris hip score was originally described in 1969 (21). This scoring system and the one described by d'Aubigné and Postel (22) are those most commonly used to evaluate the results after total hip arthroplasty. The last follow-up had been done 1, 2, 5 or 7 years after the operation. All patients had stable implants, with no or minimal pain which did not influence their level of activity. This corresponds to a Harris pain score $\geq$40, which also requires that the patient should not be taking any analgesics. All patients could walk at least 1–2 km without any aids. None of the patients had any upper-extremity symptoms. During the first 2 months after operation all the patients had been prescribed partial weight bearing using two crutches.

An instrumental set-up including a force plate, measuring insoles, four amplifiers, one multichannel datalogger and a PC with an analysis software program was designed. The force plate was made of solid metal and rested on two s-type load cells based on Wheatstone bridge strain gauges. The load cells were calibrated over the range 0–250 kg before the study and were additionally calibrated each morning from 0 to 30 kg during the study to ensure linearity and stability. The effect of the position of force application on the plate was checked and found to be negligible (<10 N). The pressure-sensitive insoles were also based on strain gauge technology. Each insole was equipped with two load cells that were placed along the centreline of the pressure pathway in order to optimize the measured ground reaction force for each individual. The cells were placed underneath the calcaneus and the two medial metatarsal heads. The integrated analogue signals from the plate and insole were recorded on a portable AAC-2 logger (INTAB interface Teknik AB) via four channels of an A-D converter. Data were later analysed on a PC using EasyView v3 software (INTAB interface Teknik AB). The sampling rate on all channels was set to 250 Hz.

The calibration procedure followed a defined routine. Having tried the correct shoe size and insole the patients were asked to stand on the force plate and perform a rotational movement. The patients then walked repeatedly over the force plate in order to give $\geq$10 valid recordings. Finally the sensitivity of the sensors was individually set to obtain recordings from the insole and force plate that were as equal as possible.

A physiotherapist (PT) instructed or reminded the patients how to use two crutches to support 30% of their body weight. The patients practised closely with the PT until the assignment was fully comprehended and well performed. The patients were then instructed to walk with crutches a standardized distance of 58.4 m over five different types of terrain in the following sequence: uphill (7° inclination); level; upstairs (step height = 14 cm); downstairs; level; downhill. The patients were asked to choose a comfortable speed according to their own performance. This routine was executed twice with a few minutes of rest in between in order to avoid exhaustion. Our intention was to study how well the patients could reproduce their method of not putting weight on the extremity. This information was judged to be of importance in order to obtain preliminary information about sampling time and sample size in future studies. The patients obtained no further instructions between the two trials. Two crutches were used during both trials. All patients wore the same type of training shoes throughout the study. Between trials the patients were asked if they thought they had managed to stay within the instructed partial load limit or not. They were also asked if they had felt any discomfort or pain during the trial.

The data were analysed according to gender, terrain and the two identical distances walked. The parameters investigated were ground reaction force and free walking speed. The ground reaction force registered by the insole was presented in 10% intervals of each individual's body weight (e.g. 40–50% BW). The median (PF_{median}) and maximum ($PF_{maximum}$) peak forces were consequently defined as the 10% intervals of BW where the median and maximum ground reaction forces were found. The number of steps taken above the chosen threshold (which was set to 30% of total BW) is referred to as steps above threshold. The mean value of two observations for each of the five types of terrain was computed in all 15 patients. The Mann–Whitney *u*-test, non-parametric correlation (Spearman's rho) and the Friedman test were used to analyse the results.

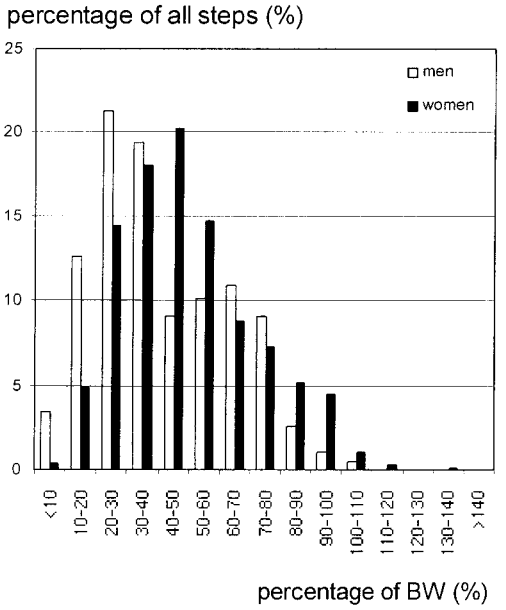

Fig. 1. Distribution of the peak forces in men and women on all types of terrain. The median peak force (PF_{median}) was 30–40% of BW in men and 40–50% of BW in women (mean values of two trials/patient).

RESULTS

None of the patients experienced discomfort or reported any pain. None of the patients managed to comply with the directive, although five of them thought they did. In both men and women most of the steps taken corresponded to a load of >30% BW (mean, median and range = 63%, 64% and 0–100% of steps, respectively for men and 80%, 96% and 0–100% of steps, respectively for women; Fig. 1). The loading patterns tended to be rather similar for each individual patient regardless of the

Table I. *Correlation coefficients and p-values between the median peak forces (PF_{median}) recorded for different types of terrain*

	Level		Uphill		Downhill		Upstairs	
	r	*p*	*r*	*p*	*r*	*p*	*r*	*p*
Downstairs	0.61	0.016	0.43	0.106	0.81	<0.0005	0.78	0.001
Upstairs	0.66	0.007	0.72	0.002	0.96	<0.0005		
Downhill	0.76	0.001	0.72	0.002				
Uphill	0.80	<0.0005						

Table II. *Variation of the median peak force (PF_{median}) and peak force range (PF_{range}) for men and women on the different types of terrain as a percentage of BW*

	Level			Uphill			Downhill			Upstairs			Downstairs		
	Med.	Min.	Max.	Med.	Min.	Max.	Med.	Min.	Max.	Med.	Min.	Max.	Med.	Min.	Max.
Men	30–40	< 10	100–110	30–40	10–20	80–90	30–40	10–20	70–80	30–40	< 10	100–110	30–40	10–20	70–80
Women	40–50	< 10	110–120	40–50	10–20	110–120	40–50	< 10	130–140	30–40	< 10	100–110	40–50	10–20	90–100

terrain, as reflected by a comparatively high correlation between the values obtained from the different types of terrain ($r = 0.43$–0.96, $p < 0.0005$–0.10, Spearman's rho; Table I). There was, however, a considerable inter-individual variability. The individual PF_{median} varied between 10–20% and 90–100% BW with 1–3 patients in each interval (overall PF_{median} = 40–50% BW). The type of terrain had no significant influence on the pattern of load ($p = 0.2$, Friedman test; Table II). The median peak force (PF_{median}) did not differ between men and women for any of the different types of terrain ($p = 0.15$–0.86; all grounds: $p = 0.27$, Mann–Whitney test).

The walking speed differed depending on the terrain ($p < 0.0005$, Friedman test) but did not differ between men and women ($p \geq 0.4$, Mann–Whitney test). The highest walking speed was recorded when the patients went uphill (median: 0.8 m/s, range 0.5–1.1 m/s). The speed decreased when walking

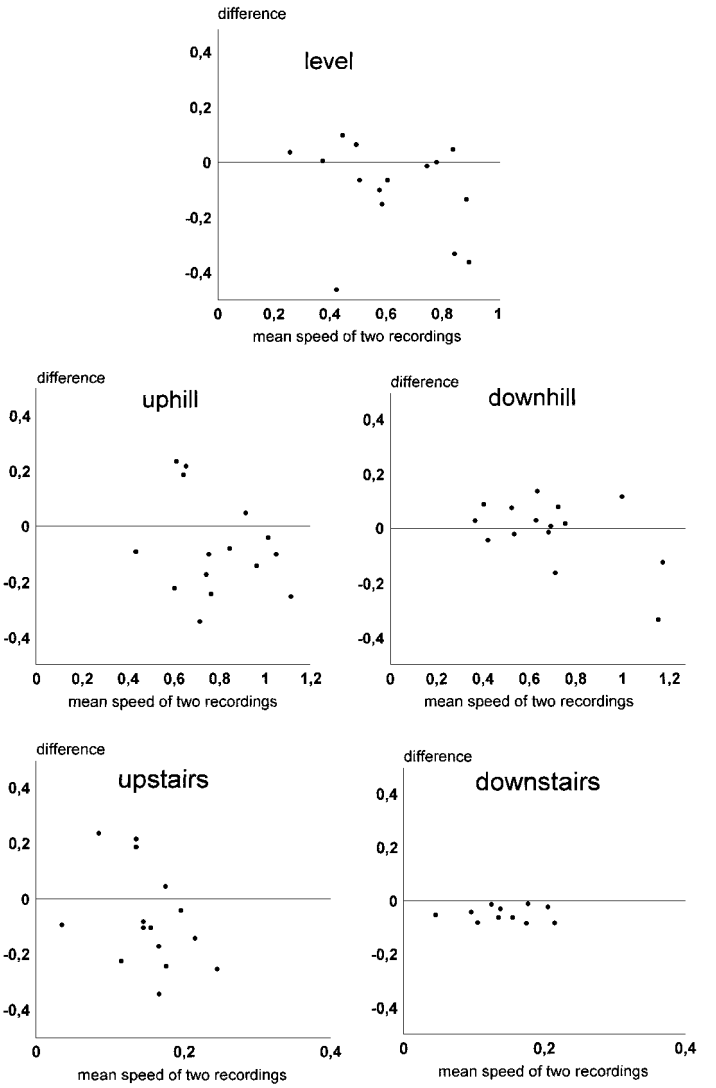

Fig. 2. Difference in walking speed (m/s) on the five types of terrain plotted against the mean value for the two recordings.

downhill (0.7 m/s, 0.4–1.2 m/s) and on level ground (0.6 m/s, 0.3–0.9 m/s). The slowest speed (0.2 m/s, 0.1–0.2 m/s) was recorded when the patients walked up- or downstairs. There was no correlation between the PF_{median} values for the different types of terrain and the corresponding walking speeds ($r \leq 0.42$, $p \geq 0.12$, Spearman's rho).

Reproducibility

When the trial was repeated for each patient the PF_{median} value remained the same in 30 of 75 observations. In 36 of the observations the PF_{median} value was located in the interval immediately above or below that recorded in the first trial. In nine of the observations the PF_{median} values were displaced by two or three intervals at the second measurement. The correlation between the walking speeds recorded during the first and second trials varied between 0.66 and 0.87 (upstairs, downstairs; $p \leq 0.005$, Spearman's rho). The variability (CV) of the walking speed expressed as 1 SD/mean value of each activity varied between 18% (downhill, downstairs) and 28% (level, upstairs). The measurement agreement plotted according to Bland and Altman (23) showed that the difference between the two repeated measurements was most pronounced when walking upstairs or on level ground (Fig. 2).

DISCUSSION

Most studies of functional recovery after hip surgery concern short-term gait analyses conducted within laboratories, emphasizing each individual's locomotion in detail. We have studied the ability to simply follow a prescribed partial weight bearing instruction over various types of terrain. To enable studies outside the laboratory and over longer time periods our prototype model was based on insoles employing strain gauge technology. Even though they take up more space compared with the more frequently used FSR sensors, measurements made using strain gauges are more repeatable over time (18, 19). We did not use any scientific procedures to optimize the number or placement of sensors in the insole. Katoh et al. (24) have shown that the centre of pressure differs when using different types of footwear, and we tried to address this by optimizing the insole for each patient.

One advantage of our system is that it enables long-term collection of motion data from each patient in his or her home environment. This is made possible as data are continuously calculated and sorted into intervals of BW. Many patients can also be analysed simultaneously. The obvious disadvantage of our system is the lack of any monitoring by camera or personal observation in order to witness the true events behind the recordings.

Angles cannot be calculated unless the patient participates in a conventional motion analysis in a laboratory. The ground reaction force is always approximated to a vertical load. This in-shoe sensing system cannot compete with those systems using FSR-based insoles, where the aim is to measure the relative plantar pressure.

After a THA pain is usually reduced substantially after 2–3 weeks (8). In clinical practice patients may be advised to use reduced weight bearing for several weeks or months. Our patients had practised reduced weight bearing for a period of 2 months. A PT instructed them again before walking the standardized distance and they were continuously supervised during the trial. Despite this they did not manage to stay within the prescribed weight bearing limits when they were continuously observed. In addition many of them misjudged their ability to follow the instructions. This finding strongly suggests that prescription of reduced weight bearing can be expected to be only fairly well adhered to at best, at least as long as the activity is not limited because of pain. If the intention is to ensure reduced weight bearing for longer periods it is probably necessary to use some type of feedback device, which provides a warning when load levels have passed a predetermined threshold for a predefined time period or for a certain number of steps. Avoidance of a gradual change to normal loading and occasional extreme loads might otherwise be very difficult or impossible for a number of patients. Prescription of reduced weight bearing might at least make the patient aware that they should reduce their level of activity.

The repeatability was acceptable in this study and probably reflects the overall tendency that each patient selects a particular walking pattern. The lack of correlation between loading patterns and walking speed using the median values for each patient would support this theory. There might, however, be a correlation between speed and loading pattern for each individual, but this was not analysed in this study.

Knowledge of the amount of weight bearing has many important applications in orthopaedics. With the exception of the fixation of implants, the healing process of fractures, maintenance or restitution of bone stock or bone mineral density and overuse injuries to the musculoskeletal system can be related to the level of activity. In order to be able to monitor the activity level in these cases the development of an easy-to-use portable system is desirable. In this study we have shown that such a system can be used, but further studies regarding patient compliance and long-term reliability are required.

Accomplishment of reduced weight bearing is not without consequences. Many activities of daily living will be influenced. Sooner or later many patients complain of secondary symptoms of the upper extremities, often in terms of numbness and pain. It is therefore pertinent to more precisely evaluate the true efficiency of this therapy. To accomplish this not only the activity, but also the effect of this activity or inactivity, has to be measurable with a reasonably high resolution.

CONCLUSION

In 15 patients we have shown that the prescribed reduction of weight bearing could not be followed in any case. Further more, one-third of the patients were not aware of their inability to follow the instructions. Further studies of patients' ability to follow instructions of reduced weight bearing, combined with

accurate measurements of implant fixation and bone turnover, are required in order to more precisely delineate the efficacy and indications for this treatment.

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