Gait & Posture 61 (2018) 306–310

Contents lists available at ScienceDirect

Gait & Posture

journal homepage: www.elsevier.com/locate/gaitpost

Full length article

Real-time visual biofeedback to improve therapy compliance after total hip arthroplasty: A pilot randomized controlled trial

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ARTICLE INFO

Keywords:
SensiStep
Gait monitoring
Biofeedback
Rehabilitation
Total hip arthroplasty

ABSTRACT

Background: Previous studies have shown limited therapy compliance in weight-bearing in patients following total hip arthroplasty.

Research question: The purpose of this pilot RCT is to determine the immediate and late effect of real-time, visual biofeedback on weight-bearing during rehabilitation after THA in elderly.

Methods: 24 participants who underwent THA were randomized to either the control or the intervention group. The intervention group received real-time, visual biofeedback on weight-bearing during training with the physical therapist during hospitalization and at twelve weeks follow up.

Results: Without biofeedback, therapy compliance was limited. Significant improvement in peak load was found in the intervention group in the early postoperative phase. In contrast to the control group, the peak load at twelve weeks was significantly higher in the intervention group compared to the pre-operative peak load, indicating a lasting effect of early biofeedback. Other gait parameters were not significantly different in the early postoperative phase. In the intervention group a longer walking distance was observed and the use of walking aids was reduced at twelve weeks.

Significance: Biofeedback systems could be promising to improve outcomes and reduce costs in future rehabilitation programs after THA.

1. Introduction

Total hip arthroplasty (THA) is a common and effective procedure in the treatment of coxarthrosis [1,2]. The demand for this procedure is still growing due to the ageing population worldwide [3]. To optimise the treatment and to decrease growing healthcare costs, many improvements have been made in surgical techniques to ensure rapid recovery in the early postoperative phase [4]. Although a meticulous surgical technique for THA is important, rapid recovery also depends on interventions performed in the early postoperative phase [5]. Early, full weight-bearing has positive effects on general coordination and muscle strength [5,6] and prevents complications, such as osteoporosis, bedsores and pneumonia [7]. Previous studies have already shown that early, full weight-bearing is safe and does not increase the incidence of postoperative complications [5,7]. The absence of an evidence-based, worldwide guideline on rehabilitation after THA is, in this light, remarkable.

In addition, currently used protocols and technologies during rehabilitation are outdated or of limited value. Clinical mobility scores are commonly used to observe the progress of individuals in a rehabilitation setting. The most frequently used Harris Hip Score, however, possesses ceiling effects and has potential clinician bias [8]. Moreover, using a score hardly offers the opportunity to give adequate feedback to the patient or the physician, which makes it difficult to improve gait. Bathroom scales and vocal instructions are often used as guiding techniques to improve weight-bearing, but their information is lost in the dynamic situation. This leads to limited therapy compliance, as previously shown in both healthy volunteers and patients [9–12]. Biofeedback systems offer the opportunity to measure weight-bearing in the dynamic situation [13]. In this context, the use of biofeedback systems is promising, especially when real-time feedback is given.

Biofeedback systems were already used to improve gait symmetry after THA [14,15]. Although gait symmetry is important, far less studies have been performed on weight-bearing of the affected limb. Some studies have reported positive effects if partial weight-bearing was allowed [16–18]. However, since early, full weight-bearing has beneficial effects on healing outcome, the aim of this pilot RCT (randomized controlled trial) was to investigate the therapy compliance of patients

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https://doi.org/10.1016/j.gaitpost.2018.01.038
Received 5 January 2018; Received in revised form 24 January 2018; Accepted 29 January 2018
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with unrestricted weight-bearing following THA. In addition, it was determined whether real-time, visual feedback improved full weight-bearing in the early postoperative phase.

2. Patients and methods

2.1. Inclusion and exclusion criteria

Patients aged between 60 and 85 years who underwent THA for treatment of primary coxarthrosis were eligible for inclusion in this study. Patients with impaired mobility prior to surgery due to causes other than coxarthrosis were excluded, as well as patients with post-traumatic coxarthrosis. Patients with impaired cognition, either pre-existent or post-operative, were also excluded. Informed consent was obtained for all patients. This research protocol was approved by the local Ethics Committee (approval number 14-559/D) of our institution, a university medical center with full orthopaedic facilities, including a resident program.

2.2. Operative procedure

All participants underwent THA by a senior orthopaedic surgeon. The systems used were an Exceed/Taperloc (n = 4), a Mallory/Taperloc (n = 2), an Exceed/Stanmore (n = 14) and an Advantage/Stanmore (n = 1). A standardized protocol for surgery was followed. In short, the participants were operated in full lateral position, secured with positioning devices to ensure complete stability. After draping and under antibiotic prophylaxis, a lateral (n = 6) or posterolateral (n = 18) approach was used to visualise and dislocate the hip joint. The femoral head was removed by sawing through the collum femoris. Then the acetabulum was prepared and gentamicin loaded cement was used for fixation of the acetabulum cup. The intramedullary canal of the proximal femur was prepared and gentamicin loaded cement was used for fixation of the steel. Following insertion of the correct size of the head, the hip joint was reduced and stability and function were tested to ensure a proper end result. Post-operatively, all participants were allowed full weight-bearing. Early mobilisation of the participants was ensured by physical therapists dedicated to the orthopaedic ward within 24 h after surgery.

2.3. Biofeedback system

Weight-bearing was measured in the clinical setting using an ambulatory biofeedback system (SensiStep, Evalan BV, Amsterdam, The Netherlands). In short, SensiStep consists of an in-sole sensor, which registers axial loading on the affected extremity accurately and continuously during gait. In addition to ambulatory force measurements, SensiStep is able to provide real-time, visual feedback about weight-bearing to both the patient and the healthcare professional via a bracelet and/or tablet as shown in Fig. 1 [19]. The SensiStep system was previously validated in static and dynamic situations [20].

2.4. Study protocol

Patients that fulfilled inclusion criteria were asked to participate in this study. After informed consent was obtained, the participants were randomized into two different groups by block randomization and an allocation ratio of 1:1. Group 1 received real-time, visual feedback on weight-bearing via the SensiStep tablet. In group 2, weight-bearing was measured using SensiStep, but neither the participants nor the physical therapist had insight to the data. The participants in both groups were asked to walk 30 m in a straight line with SensiStep. Measurements were obtained at pre-defined moments: before the operation, daily after surgery during admission in the hospital and 12 weeks post-operatively at the outpatient follow-up. The post-operative measurements were repeated up to a maximum of five days after surgery, depending on the

Fig. 1. The different parts of the SensiStep system [19]. The force sensor was placed inside the sole of the custom-made sandals. Real-time, visual biofeedback was shown to both the participant and the healthcare professional via the tablet as a green bar (i.e. target weight) and grey step curves (actual weight). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

length of stay in the hospital. Primary outcome parameters were (1) average peak load, (2) average loading rate and (3) average cadence. The secondary outcome parameters (1) Visual Analogue Scale (VAS) pain score (cm), (2) walking distance, (3) duration of usage of walking aids and (4) pain medication, were assessed via questionnaires at 12 weeks follow-up.

2.5. Data processing and statistical analysis

All raw data were encrypted and stored on a secured Web Portal. The raw data were analysed with MATLAB 2014a. Specific Matlab routines were developed to convert the raw data into the parameters of interest. Data was corrected for the position of the sensor [21]. The average peak load is shown in percentage bodyweight (%BW), the average loading rate in kilogram per second (kg/s) and the average cadence in number of steps per second (steps/s). Statistical significance of the SensiStep parameters was determined using multiple T tests with the Holm-Sidak method. A Chi-square test was used to determine statistical difference of the mobility scores. All data are shown as means with ranges and significance was set at $\alpha = 0.05$.

3. Results

Between May 2015 and May 2016, a total of 96 patients underwent THA. Of these, 81 underwent the procedure for treatment of primary coxarthrosis. A total of 57 patients were excluded due to either age (21), comorbidities (24), lack of informed consent (8), adverse events (2) or technical failure of the biofeedback system (2). A total of 24 participants were randomized into two groups of twelve participants. Group 1 (6♂, 6♀) had a mean age of 70.5 years (range: 61–83 years), average weight of 78.3 kg (range: 45–117) and received real-time, visual feedback from SensiStep. Group 2 (6♂, 6♀) had a mean age of 72.8 years (range: 61–84 years), average weight of 84.3 kg (range: 70–120) and did not received feedback from SensiStep.

The length of hospital stay after surgery was respectively 3.1 (2–5) and 3.7 (2–5) days for group 1 and 2 (P = .144). Pre-operatively, the participants showed an average peak load of 64.0 (38.4–99.0) %BW in group 1 and 55.0 (21.7–89.1) %BW in group 2 (P = .241). In all early postoperative days (days 1–4), significantly higher average peak loads were found in group 1, as shown in Fig. 2 and Table 1. No significant differences were found in loading rate or cadence for both groups in the early postoperative phase (Figs. 3 and 4 and Table 1). Compared to the pre-operative peak load, group 1 showed a significant improvement at twelve weeks follow up: respectively 64.0 (38.4–99.0) %BW vs 77.1 (57.3–104.0) %BW (P = .047). In group 2 an increase in peak load from pre-operative to 12 weeks was also seen, but this difference was not significant: respectively (55.0 (21.7–89.1) %BW vs 68.4 (48.2–91.9) %

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