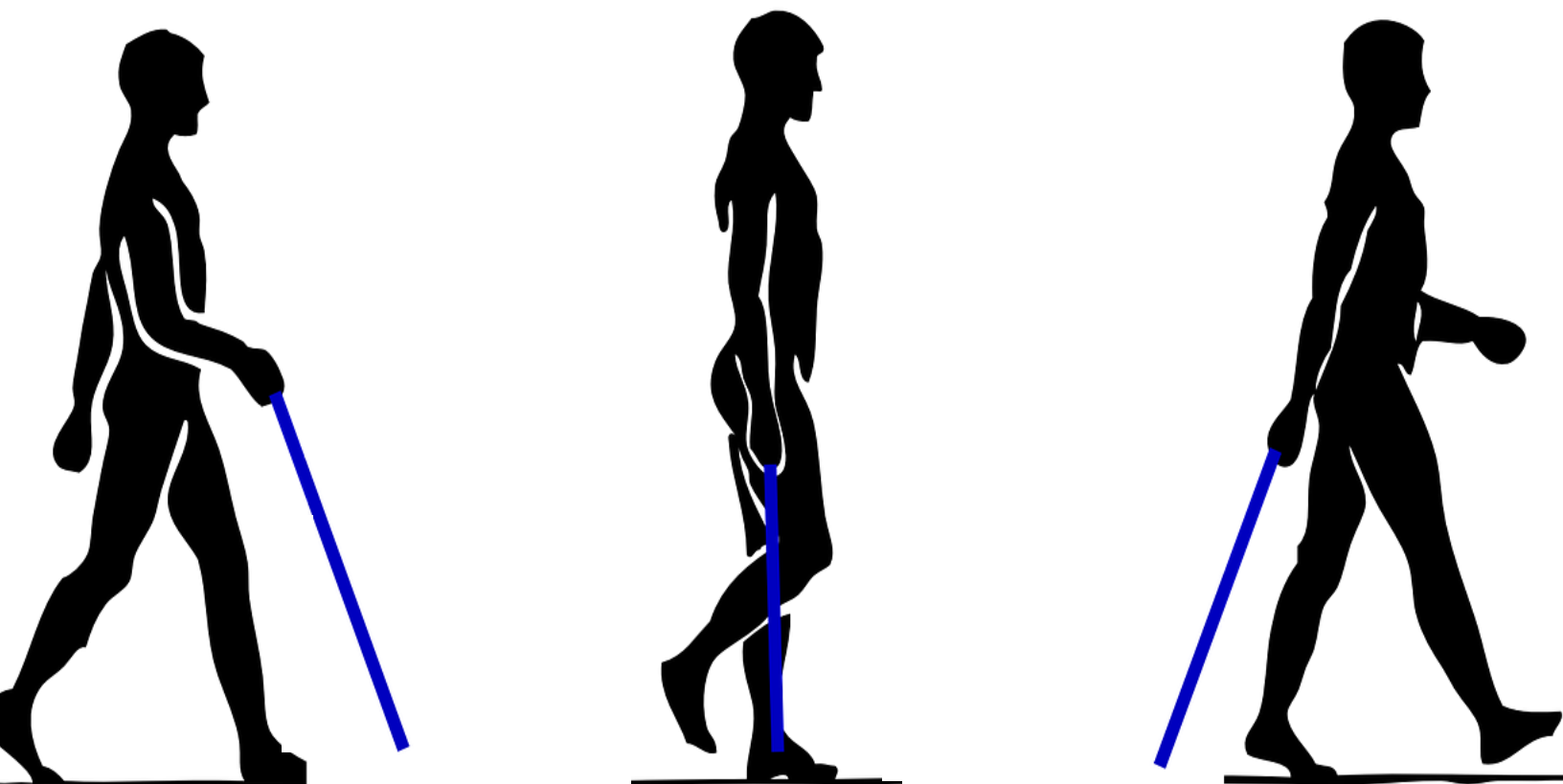


# FLEX CEUs



## Total Hip Replacement Recovery Considerations



# Does an early home-based progressive resistance training program improve function following total hip replacement? Results of a randomized controlled study

## Abstract

**Background:** In-hospital progressive resistance training (PRT) has been shown to be an effective method of rehabilitation following hip surgery. The aim of this study was to assess whether a home-based PRT program would be beneficial in improving patients' muscle strength and physical function compared to standard rehabilitation.

**Methods:** Subjects ( $n = 49$ ) either received home-based PRT rehabilitation ( $n = 25$ ) or standard rehabilitation ( $n = 24$ ) in a prospective single blinded randomized trial carried out over a two-year period. The primary outcome measure was the maximal voluntary contraction of the operated leg quadriceps (MVCOLQ) with secondary measures of outcome being the sit to stand score (ST), timed up and go (TUG), stair climb performance (SCP), the 6 min walk test (6MWT), and lean mass of the operated leg (LM).

**Results:** Twenty-six patients completed follow up at 1 year ( $n = 13$  per group) for the final comparative analysis. All the outcome measures showed marked progressive improvements from the baseline measures at 9–12 months post op (Estimated effect (std error);  $p$  value)- MVCOLQ 26.50 (8.71) N  $p = 0.001$ ; ST 1.37 (0.33)  $p = 0.0001$ ; TUG  $-1.44$  (0.45)  $p = 0.0001$ ; SCP  $-3.41$  (0.80)  $p = 0.0001$ ; 6MWT 45.61 (6.10)  $p = 0.0001$ ; LM 20 (204)g  $p = 0.326$  following surgery for both groups. Overall, there was no significant effect for participation in the exercise regime compared with standard care for all outcomes assessed.

**Conclusions:** Overall, this study demonstrated that there is no significant difference between the two groups for participation in the home-based PRT exercise programme when compared to standard care for all outcomes.

**Trial registration:** ISRCTN 1309951. Registered February 2011.

**Keywords:** Progressive resistance training, Home based rehabilitation, Total hip replacement

## Background

Centre-based progressive resistance training (PRT) regimes for post- total hip replacement (THR) patients have been shown to improve objective measures of physical performance (e.g. 30 % higher sit to stand score, 30 % higher gait speed and 28 % higher stair climb performance [1]), but unfortunately require patients to exercise under supervision making program delivery expensive [2].

Addressing these issues has led to the assessment of home-based rehabilitation programs; also shown to be effective in improving function post-THR. However, at the time the current study was commenced, the two home-based interventions available in the literature featured programs initiated between 4 and 48 months following THR, with neither assessing the retention of benefits at follow up [3, 4]. Jan et al. [3] demonstrated improvement in the hip muscle strength of the operated side (~20 %), as well as improvement in walking speed (~24 %) after a 12-week program commenced between 18 and 48 months following surgery. Similarly, Trudelle-Jackson and Smith [4] showed an improvement

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in hip flexor and extensor strength (41 and 48 % respectively) for patients undergoing an exercise intervention compared to standard regimes after an 8 week program that included PRT, with the intervention commenced at least 4 months post-THR. A possible alternative to the centre-based programmes would be a home-based rehabilitation program that features PRT, and commences in the immediate post-surgical period with longer follow up. Thus the aim of this study was to perform a pilot study as proof of concept, assessing whether an inexpensive home-based PRT program with weekly supervision in the early post-operative phase after total hip replacement surgery was beneficial in improving muscle strength and physical function relative to standard rehabilitation at up to 1 year follow up.

## Methods

This was a prospective single blinded randomized trial carried out from April 2010 to March 2012. Patients undergoing elective THR surgery for osteoarthritis were recruited after local NHS Research Ethics (North West Wales) Committee approval (Ref 09/WNo01/52), and trial registration (ISRCTN13019951; registered February 2011). All participating patients gave their informed consent.

Patients considered for this study were on the inpatient waiting list for THR at Ysbyty Gwynedd Hospital, Bangor, UK. They were eligible for participation if they had unilateral hip osteoarthritis requiring THR via a posterior approach with a 26 mm, 28 mm, or 32 mm femoral head, with the joint affected being the only severely arthritic joint, and no evidence of inflammatory arthropathy. The exclusion criteria were dementia, neurological impairment, cancer or other muscle wasting illness, unstable chronic or terminal illness, or any co-morbid disease that contraindicated resistance training. A Consolidated Standards of Reporting Trials (CONSORT) diagram [5] for patients recruited into the study after informed consent is shown in Fig. 1. A single patient acted as a pilot for the exercise intervention before subsequent one to one sequential individual randomization with stratification for age and gender [6] was performed for the other 49 study recruits. An offsite researcher performed randomization with the subsequent results only made available to physiotherapists in contact with the patients in the immediate post-operative period, with the assessor (TO) blinded to the results of randomization till the end of the study. A total of 25 patients were randomized to the home-based PRT group with 24 randomized to the standard rehabilitation (SR, control) group.

## Outcome measures

The primary outcome measure for this study was the maximal voluntary contraction (MVC) of the operated leg quadriceps (MVCOLQ; in Newtons (N)). The secondary

outcome measures were the sit to stand score in 30 s (ST), other objective measures of function such as: timed up and go (TUG), stair climb performance (SCP) and the 6 min walk test (6MWT), as well as the lean mass of the operated leg as assessed by dual energy X-ray absorptiometry (DEXA) scanning. Assessments of the primary and secondary outcome measures were performed pre-operatively, and at 6 weeks, 6 months and 9–12 months post-operatively by the first author (TO). All data was collected at the laboratories of the School of Sports, Health and Exercise Science, at Bangor University, Bangor, UK. The lean mass of the operated leg was assessed at 6 weeks and 9–12 months post-operatively.

## The outcome measures are described below

### *Maximal voluntary contraction of the operated leg quadriceps (MVCOLQ; in Newtons (N))*

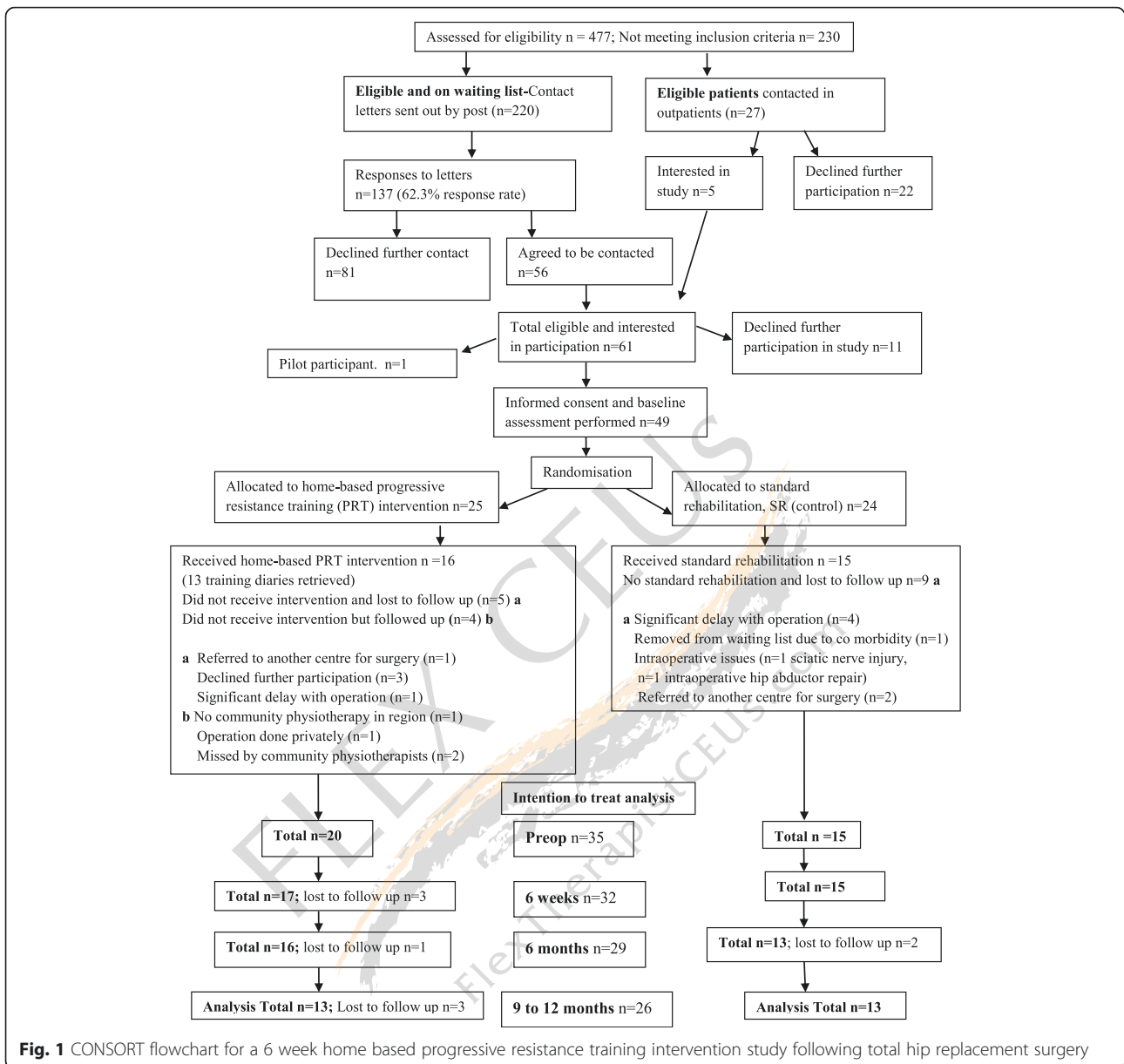
This primary outcome measurement was made using a handheld isokinetic dynamometer (CSD300, Chatillon-Ametek, Largo, FL, USA), which has been shown to have high test/retest reliability (0.97,  $p < 0.001$ ; [7]). For the assessment, subjects sat on a medical table with arms across their chest. The curved push attachment of the dynamometer was positioned over the tibia just proximal to the 2 malleoli, and the subjects were instructed to attempt to straighten the leg forcefully. Following 2 sub-maximal familiarization trials, subjects were asked to exert force maximally for about 5 s on 3 further occasions. Between all 5 trials, a 1-min rest was observed. Peak force produced during each of the 3 maximal trials was recorded with the best score noted.

### *Sit to stand in 30 s (ST) score*

This is the maximal number of times the subject was able to rise, with arms crossed over their chest, from a standardized chair (seat height 43 cm) in 30 s, and is a test designed to reflect the ability to perform activities of daily living (ADLs; [8]). A moderately high correlation exists between ST performance and maximum weight-adjusted leg-press performance for both men and women ( $r = 0.78$  and  $0.71$ , respectively) supporting the criterion-related validity of the sit to stand test as a measure of lower body strength [8]. Construct (or discriminant) validity of the chair-stand has been demonstrated by the test's ability to detect differences between various age and physical activity level groups [8]. This test has an intra class correlation coefficient of 0.80 [9].

### *Timed up and go (TUG) in seconds (s)*

The time taken in seconds for subjects to rise from a standard armchair, walk at a safe and comfortable pace to a cone 8 ft away, and return to a sitting position (back against the chair). Test-retest reliability estimates of 0.75 (type 2, 1 intraclass correlation coefficient (ICC))



for patients awaiting hip or knee replacement surgery have been demonstrated.

#### Stair Climb performance (SCP)

The time taken to ascend 14 standard steps of 20 cm height each in a usual manner and at a comfortable pace. The SCP has test-retest reliability (ICC) of 0.90.

#### Six-minute walk test (6MWT)

The distance covered (metres) in a level corridor over a 6-min period. Originally conceived as an outcome measure for patients with respiratory problems. It has been shown to have high reproducibility in different patient populations. It has the advantage of being reflective of

patients' ability to perform activities of daily living. It has a test-retest reliability estimate (ICC) of 0.94.

#### Lean mass of the operated leg

Whole body DEXA was performed using a pencil-beam scanner (QDR1500, Hologic, Bedford, Massachusetts) to determine total and regional (left and right arm, left and right leg, trunk, head) lean fat and bone mass. The lean mass value in grams for the operated leg of the subjects assessed whether the home-based PRT intervention increased muscle mass in the involved leg compared to standard rehabilitation (SR; control). A calibration standard was scanned daily, and measurement accuracy was measured by scanning a water/oil phantom of known

proportions (41 % fat) monthly. The coefficient of variation of repeated measurements using the DEXA is between 1–3 % [10].

After informed consent, baseline preoperative assessment, and subsequent THR, patients in the study were randomized to either a home-based PRT intervention or SR (control) for the immediate (6 week) post operative period. These interventions are described below:

#### **Prescribed home-based PRT exercise intervention**

This was devised by convening a discussion group of hospital and community physiotherapists ( $n = 5$ ; all with more than 5 years experience of treating patients following THR). For patients randomized to home-based PRT, the exercises to be performed at home were demonstrated to them as inpatients by the attending physiotherapist on post-operative day 2. On discharge home, a qualified physiotherapist saw them and initiated the PRT regime between post-operative days 4 to 7. The exercises performed were: sit to stand, block stepping, stair climbing, walking, sitting knee extension against resistance, and lateral weight transfer exercises. Ankle weights and foam blocks were used as inexpensive and adjustable forms of equipment to increase resistance for the knee extension and stepping exercises, respectively. Patients in the intervention group were instructed to perform a range of repetitions (0–3, 4–6, 7–10) depending on their initial physiotherapy assessment and then to progress, when able to, to achieve progressive overload, i.e. the addition of increased resistance over time (the decision to progress was reviewed and facilitated by weekly physiotherapy visits during each of the 6 exercise intervention weeks). Subjects were encouraged to exercise at least 5 times a week. The physiotherapists determined the progression subjectively based on the ability of the patient. This was a pragmatic trial and the attending physiotherapist did their best to assess the patients in terms of ability to enable progression to occur.

Training volume (multiplying the number of repetitions performed/day by the number of days) was monitored using a simple training diary with compliance assessed as a measure of practice ratio i.e. number of days the subjects actually carried out the program multiplied by the program duration in days (5 days a week for 6 weeks, i.e. 30 days).

#### **Standard rehabilitation, SR (control)**

The SR (control) group received routine inpatient and/or outpatient physiotherapy as provided by the local physiotherapy service. The standard rehabilitation provided in this study typically involved home-based functional non-PRT exercises that was geared towards getting the patients safely mobile. These included weight bearing (performed against gravity) and functional (without

external loading) exercises, as well as bed-based (e.g. buttock squeezes, leg sliding and straight leg raise)/bridging (targeting core abdominal muscles as well as lower back and hip)/postural exercises (focusing on strengthening muscles which have become overstretched and weak).

#### **Statistical analysis**

Based on the assumption that the exercise intervention would lead to a 15 % increase in the muscle strength (MVCOLQ) of the home-based PRT group relative to the SR (control) group [1], with an alpha value of 0.05 and power of 0.8, it was determined that 10 experimental subjects and 10 controls would be needed to demonstrate a significant effect. The target of a total of 50 participants (25 per group) was set to allow for potential dropouts during the follow up period (9–12 months post-THR).

A mixed model repeated measures ANOVA was performed with the primary and secondary outcome measures as dependent variables. The null model to fit the grand mean for the outcome variables was run first, and then an unconditional model with no predictors was used to determine whether a model with varying intercepts was suitable as well as determining the variance in the outcome measures between subjects. After the addition of time-point indexing to assess whether the pattern of linear change over time varies, additional predictors (group randomization (fixed, between-subjects effects)) and the effect of the follow up time period (random, within-subjects effects) were added to the model to attempt to explain any overall change over time. An interaction term of randomization group and time was then added to the model and if this was not significant, it was removed from the final model applied. A  $p$  value  $<0.05$  was considered statistically significant. SPSS version 18 (SPSS for Windows v18, Rel. 30.07.2009. Chicago: SPSS Inc) was used for all analysis.

#### **Results**

Of a total of 49 patients recruited to this study, a total of 14 were lost to follow up preoperatively due to a variety of reasons; see CONSORT diagram (Fig. 1). Thirty-five patients were therefore included in the analysis (Demographic data for the eligible and recruited cohort ( $n = 49$ ) is described in Table 1. Three patients were lost to follow up at each of the review time points with 26 patients completing 9–12 month final follow-up (final follow-up rate of 74.28 % (26/35)).

The values for the primary and secondary outcome variables preoperatively and at 9–12 month follow-up for the home-based PRT and SR (control) groups appear in Table 2. There were no statistically significant differences between the randomized groups preoperatively (Table 1).

**Table 1** Baseline demographic characteristics, and preoperative outcome measures for total hip replacement surgery rehabilitation trial participants

Characteristic/outcome measure	Home-based, progressive resistance training (PRT) group ( <i>n</i> = 25)	Standard rehabilitation (control) group ( <i>n</i> = 24)
Age in years (mean (SD))	65.15 (9.06)	66.33 (11.02)
Sex- Males ( <i>n</i> )	10	14
Sex- Females ( <i>n</i> )	15	10
Weight (kg)	78.88 (19.17)	81.46 (16.43)
Height (m)	1.67 (0.10)	1.66 (0.09)
BMI	28.04 (5.79)	29.44 (5.25)
Maximal Voluntary Contraction Operated Leg Quadriceps (N)	167.38 (77.04)	182.13 (73.05) <i>p</i> = 0.497
Sit to stand (ST) number performed in 30 s	8.92 (4.69)	8.20 (4.18) <i>p</i> = 0.574
Stair Climb Performance (SCP) in seconds (s)	14.70 (8.67)	18.13 (9.94) <i>p</i> = 0.204
Timed up and go test (TUG) in seconds (s)	13.35 (10.05)	12.06 (6.02) <i>p</i> = 0.589
Six Minute Walk Test (6MWT) in metres (m)	259.71 (116.57)	236.96 (108.69) <i>p</i> = 0.480

Thirteen patients who completed the home-based PRT exercise program returned exercise diaries (Fig. 1), with the average training volume over each of the 6 weeks shown in Fig. 2. There was a gradual increase in the calculated training volume from (mean (SD)) 583 (409) repetitions.days in week 1 to 687 (478) repetitions.days in week 6.

The average compliance to the prescribed program was 125 % (i.e. on average, the home-based PRT subjects completed 37.5 training days rather than the minimal requirement of 30 days), indicating that for the patients from whom training records were retrieved, the intervention was well tolerated.

An intention to treat analysis was performed (Fig. 1) and the mixed model repeated measures ANOVA output data for both the absolute values for the primary and secondary outcomes, as well as the change from baseline values for these measures, is incorporated into Table 2.

#### Absolute values of the outcome measures

All the outcome measures (both primary and secondary) showed marked progressive improvements from the baseline measures in terms of absolute values following surgery for both groups. There was no effect of treatment, i.e. no differences between the home-based PRT or standard physiotherapy (control) groups, on the absolute values for any of the outcomes (MVCOLQ, sit to stand (ST) score, and lean mass of the operated leg) at any stage over the 9–12 month period of investigation.

#### Changes in outcome variables from preoperative values

Improvement in 2 of the secondary outcome variables (SCP and 6MWT) at the 9–12 month post-surgery follow-up was observed for patients in the SR (control) group relative to the home-based PRT patients (Table 2).

#### Effect of training volume on change in outcomes (dose response)

The training volumes (dose) were determined for the 13 study participants who completed exercise diaries. The only significant correlation identified was between volume and the change from baseline for the ST score, with an R-value of 0.639 (*p* = 0.019) at 6 weeks, 0.646 (*p* = 0.023) at 6 months, and 0.855 (0.002) at 9–12 months follow up. This indicates that higher training volume was associated with greater improvement in performance of the ST test, our surrogate measure of lower body function.

The median training volume was 4398 repetitions.days. Patients with higher values than this were classified as high training volume participants (HTVP, *n* = 7) whilst those with lower values were classified as low training volume participants (LTVP, *n* = 6). There was a significant effect at 9–12 months for being in the HTVP group compared to the LTVP for improvement in the ST test (mean (SD), 4.83 (2.04) increased repetitions vs. 1.50 (1.00), *p* = 0.010). There was also a significant effect at 9–12 months in the change from baseline values for the MVCOLQ, with the HTVP showing a mean improvement of 121 (84.63) Newtons (N) relative to a reduction of 5.33 (54.12) N in the LTVP (*p* = 0.034). There were no effects of training volume on the other primary and secondary outcome variables.

The compliance scores from the exercise diaries obtained combined with the analysis of training volume in the home-based PRT group indicate that the regime was well tolerated and in those patients who had high training volumes, significantly better improvements in two of the three principal outcomes were achieved and sustained for up to 9–12 months post-operatively.

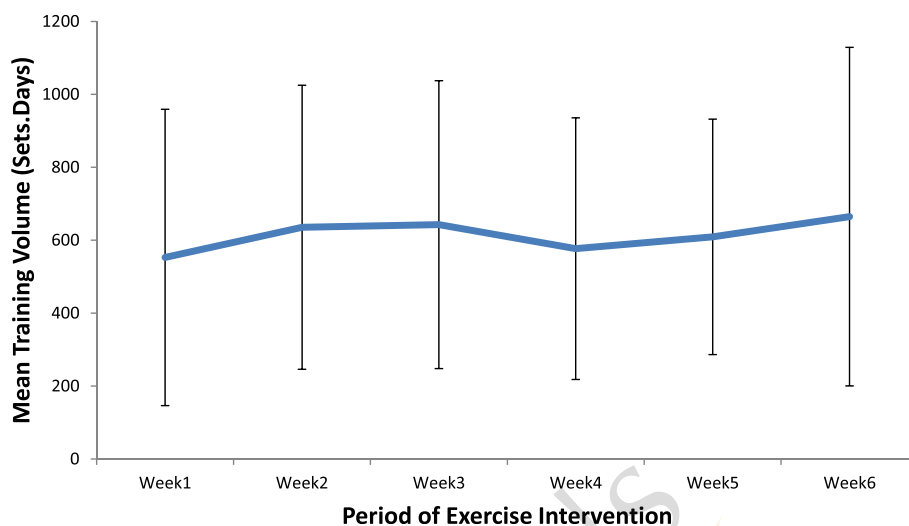
**Table 2** Absolute and change values (mean (SD)), and mixed model ANOVA results at final follow up for primary and secondary outcome measures for home-based progressive resistance training (PRT) and standard rehabilitation (control) groups preoperatively following total hip replacement surgery

	Preoperative <sup>a</sup>		9-12 months postoperatively		Change values (Difference between 9-12 months and baseline)		Mixed model ANOVA for change from baseline values effect (std. error)	
	Home-based PRT <i>n</i> = 20	Standard rehabilitation (control) <i>n</i> = 15	Home-based PRT <i>n</i> = 13	Standard rehabilitation (control) <i>n</i> = 13	Home-based PRT <i>n</i> = 13	Standard rehabilitation (control) <i>n</i> = 13	Effect of Treatment SR > PRT	Effect of Time
Primary Outcome								
MVCOLQ (N)	172.30 (85.10)	174.20 (70.30)	247.40 (85.10)	240.3 (87.4)	58.31 (95.43)	56.08 (61.66)	10.38 (23.72) <i>p</i> = 0.065	26.50 (8.71) <i>p</i> = 0.001 <sup>b</sup>
Secondary Outcomes (Exploratory analysis)								
ST	9.30 (4.74)	8.26 (4.80)	13.21 (5.46)	14.16 (5.47)	3.64 (2.73)	4.75 (4.04)	1.43 (1.19) <i>p</i> = 0.239	1.37 (0.33) <i>p</i> = 0.0001 <sup>b</sup>
Lean mass in grams (g) of the operated leg	8265 (2326)	7601 (1989)	8769 (2109)	7889 (2226)	200.15 (800.58)	194.08 (586.98)	280 (419) <i>p</i> = 0.508	20 (204) <i>p</i> = 0.326
TUG (s)	13.47 (11.06)	12.14 (6.90)	8.64 (3.23)	7.06 (1.31)	-3.74 (5.37)	-2.68 (2.35)	0.09 (2.64) <i>p</i> = 0.972	-1.44 (0.45) <i>p</i> = 0.0001
SCP (s)	13.74 (7.49)	17.80 (10.99)	8.32 (4.45)	7.64 (2.70)	-6.69 (5.08)	-7.71 (6.99)	-5.67 (2.61) <i>p</i> = 0.038 <sup>b</sup>	-3.41 (0.80) <i>p</i> = 0.0001 <sup>b</sup>
6MWT (m)	269.80 (115.0)	238.7 (110.5)	352.4 (109.3)	376.5 (49.9)	84.52 (52.41)	120.91 (88.59)	86.39 (27.94) <i>p</i> = 0.004 <sup>b</sup>	45.61 (6.10) <i>p</i> = 0.0001

Key: MVCOLQ Maximal voluntary contraction of the operated leg quadriceps, ST Sit to stand, number of repetitions in 30 s, TUG Timed up and go test in seconds (s), 6MWT Six minute walk test in metres (m), SCP Stair Climb performance in seconds (s)

<sup>a</sup>No statistically significant differences between groups

<sup>b</sup>Statistically significant



**Fig. 2** Mean Training Volume versus Period of Exercise Intervention in patients undertaking a home based progressive resistance training regime after total hip replacement

## Discussion

This study shows that a home-based PRT program is just as efficacious as standard rehabilitation for improving quadriceps maximum voluntary contraction, sit to stand reps, skeletal muscle mass in the operated leg as well as timed up and go, in the year following total hip replacement surgery.

The SR (control) group showed greater improvement at final follow up in two objective measures of physical function, SCP and the 6MWT, relative to home-based PRT patients. All the measures assessed (except the lean mass of the operated leg) improved significantly over time for both treatment groups, which would be expected in this patient population as THR provides good pain relief and patients tend to become more physically active following surgery [11].

The home-based PRT intervention appears well tolerated, with the participants for whom exercise diaries were retrieved showing compliance rates on average of 125 % (i.e. 25 % more than the recommended minimum). There was a significant dose response for training, with significant differences observed between HTVP and LTVP in terms of the amount of improvement at 1 year in ST performance, and MVCOLQ. Compliance as a self-report measure is however a limitation to the study as it was impossible to accurately monitor how much the patients did in terms of the exercise prescription.

A study by Mikkelsen et al. [12]; published after this study was undertaken, also compared a home-based, intensified, early postoperative regime (12 weeks duration) after THR to standard rehabilitation. Consistent with our findings, they also found no differences between groups at their final follow up point (12 weeks). Again, like us, these investigators noted the expected improvement from baseline values in both groups following THR, and the

prescribed resistance training regime was well accepted by patients on the basis of pain, compliance, and patient satisfaction [12]. The authors suggest that the lack of a significant benefit for the regime may be that participants' additional training activities could not be controlled for. They also suggest that perhaps not all post-operative THR patients can perform exercises effectively without supervision [12].

Home-based interventions in the literature that have demonstrated a beneficial effect on restoration of muscle strength and objective function following THR have all been conducted some time after surgery i.e. 4 to 12 months [4] and at least 1.5 years [3]. Whilst the improvements in the objective measures of physical function assessed in these studies were significantly better in the exercise intervention groups than the controls (routine rehabilitation protocols), a significant level of impairment still persisted in these patients when final function was compared to a population of community dwelling age- and sex-matched adults without hip osteoarthritis.

The centre-based rehabilitation intervention conducted by Suetta et al. [1] was able to restore objective functional parameters such as "normal" gait speed (from 1.10 m/s ( $\pm 0.50$ ) to 1.43 m/s ( $\pm 0.60$ )) following 12 weeks resistance training in patients immediately post-THR. As the follow up periods for the centre-based PRT studies in the literature do extend beyond the time frame of the interventions assessed, it remains to be seen whether the substantial functional improvements observed are maintained over a longer period.

For the 6MWT, the values obtained in our study after 9–12 months for the home-based PRT and SR (control) groups were 352 ( $\pm 109$ ) m and 377 ( $\pm 50$ ) m, respectively, which again is considerably lower than that for healthy



community dwelling match adults without hip osteoarthritis (~527 m, [13]). This implies an average functional deficit in the present study population at final follow up of around 30 %; the same proportional deficit as for gait speed. Once again, this compares poorly to the improvement elicited by the centre-based rehabilitation intervention of Galea et al. [2] in which the values obtained after an 8 week PRT intervention was 427 m (an average deficit of 23 % from the normal value). These results suggest that centre-based regimes are able to produce better functional improvements.

There was a significant difference in the change from preoperative values at 12 months in 2 of the secondary outcome measures (SCP, 6MWT) in favour of the SR (control) group. This may be explained by the variability that exists in standard practice across the UK, with the regimes prescribed highly dependent on local resource allocation as well as physiotherapists' preference. It demonstrates that a home-based PRT programme is just as effective but not better than pre-existing standard rehabilitation regimes.

The only home-based regimes in the literature that have improved functional outcome were performed between 6 months and 4 years after THR and were either for a short duration (8 weeks) with progressive resistance training [4] or for a long duration (12 weeks) [3]. The longer home-based higher intensity regime (12 weeks, (12)) performed on THR patients in the early post-operative period by Mikkelsen et al. [12] also provided no additional benefit to patients. The latter result in conjunction with ours appears to suggest that centre-based PRT regimes may be more effective in conferring a functional advantage in the early period following THR perhaps due to the additional supervision and the higher training intensity that is achievable. Additionally, the early period of surgical recovery (limb swelling, pain) may be more restrictive on patients in terms of performing training tasks effectively in the home setting. Undertaking an effective home-based intervention in this population may require the provision of trained home exercise specialists. This would ensure that patients under supervision to in the post-operative period might complete sufficiently intense regimes. This may only be effective in the post-recovery phase (>4 months) after THR and it may be appropriate to only target patients who have expectations of additional functional gain.

A limitation of this study is the final follow up rate of ~75 % ( $n = 26$ ) for the number of patients included in the final analysis. Table 1 demonstrates that for the number of recruited and eligible patients ( $n = 49$ ), there is no significant difference in patient characteristics or the baseline assessment of the functional outcomes utilized. The high attrition rate in terms of final analyzed patients means that there is limited generalizability for the results obtained. A further A limitation of the study is that the participants' additional (not study related) exercise

activities (especially relevant for the patients randomized to the SR (control) group) could not be controlled for during the duration of the 6-week intervention period. Another limitation that may have led to the home-based PRT regime not being more effective than standard rehabilitation include the fact that the community physiotherapists who administered the program were also involved in looking after the patients randomised to the SR (control) group. This may have led to some modification of prescription behaviour in dealing with the control group, in terms of adjustment of exercises prescribed (i.e. inclusion of some of the PRT exercises). Additionally, our home-based PRT regime concentrated mainly on training the quadriceps, whilst, most of the studies in the literature involved a variety of exercises which included weight bearing progressive resistance working on hip flexors, extensors, and abductors in a variety of positions [3, 4].

## Conclusions

This study demonstrates that home-based PRT is feasible and well tolerated for patients immediately following THR surgery, and that it is as effective, but not better than standard rehabilitation in improving physical function.

## Ethics statement

This study was approved by the NHS Research Ethics (North West Wales) Committee (Ref 09/WNo01/52) in January 2010. Informed consent was obtained from all participants.

## Abbreviations

6MWT: six minute walk test; ADLs: activities of daily living; ANOVA: analysis of variance; BMI: body mass index; CI: confidence interval; CONSORT: consolidated standards of reporting trials; DEXA: dual energy X-ray absorptiometry; HTVP: high training volume participants; ICC: intra class correlation coefficient; LTVP: low training volume participants; MVC: maximal voluntary contraction; MVCOLQ: Maximal voluntary contraction of operated leg quadriceps; N: Newtons; NFAT: nuclear factor of activated T cells; NHS: national health service; NICE: national institute for health and clinical excellence; NJR: national joint registry; NWORTH: North Wales organisation for randomised trials in health; PRT: progressive resistance training; ROM: range of movement; RT-PCR: reverse transcriptase polymerase chain reaction; SCP: stair climb performance; SD: standard deviation; SR: standard rehabilitation; ST: sit to stand (number of repetitions); THR: total hip replacement; TO: Tosan Okoro, corresponding author; TUG: timed up and go test (seconds).

# Improvement of walking speed and gait symmetry in older patients after hip arthroplasty: a prospective cohort study

## Abstract

**Background:** Retraining walking in patients after hip or knee arthroplasty is an important component of rehabilitation especially in older persons whose social interactions are influenced by their level of mobility. The objective of this study was to test the effect of an intensive inpatient rehabilitation program on walking speed and gait symmetry in patients after hip arthroplasty (THA) using inertial sensor technology.

**Methods:** Twenty-nine patients undergoing a 4-week inpatient rehabilitation program following THA and 30 age-matched healthy subjects participated in this study. Walking speed and gait symmetry parameters were measured using inertial sensor device for standardized walking trials (2\*20.3 m in a gym) at their self-selected normal and fast walking speeds on postoperative days 15, 21, and 27 in patients and in a single session in control subjects. Walking speed was measured using timing lights. Gait symmetry was determined using autocorrelation calculation of the cranio-caudal (CC) acceleration signals from an inertial sensor placed at the lower spine.

**Results:** Walking speed and gait symmetry improved from postoperative days 15–27 (speed, female: 3.2 and 4.5 m/s; male: 4.2 and 5.2 m/s; autocorrelation, female: 0.77 and 0.81; male: 0.70 and 0.79;  $P < 0.001$  for all). After the 4-week rehabilitation program, walking speed and gait symmetry were still lower than those in control subjects (speed, female 4.5 m/s vs. 5.7 m/s; male: 5.2 m/s vs. 5.3 m/s; autocorrelation, female: 0.81 vs. 0.88; male: 0.79 vs. 0.90;  $P < 0.001$  for all).

**Conclusions:** While patients with THA improved their walking capacity during a 4-week inpatient rehabilitation program, subsequent intensive gait training is warranted for achieving normal gait symmetry. Inertial sensor technology may be a useful tool for evaluating the rehabilitation process during the post-inpatient period.

**Keywords:** Gait symmetry, Total hip endoprotheses, Inertial sensor, Gait training

## Background

Changes in ambulatory kinematics and kinetics are commonly observed in patients with asymptomatic, moderate and severe osteoarthritis [1] and include changes in stance phase, walking speed, joint moments and joint angular velocities compared to healthy subjects [1, 2]. In particular, the more severe their disease assessed by clinical scores such as Kellgren-Lawrence grade, the slower patients walk [1, 3]. Moreover, several parameters including loading rate and joint angles have

been proposed for gait asymmetry assessment in persons with hip osteoarthritis [4] although these authors have raised concern regarding reliability of these parameters. Retraining walking is a major focus of rehabilitation in patients after hip or knee arthroplasty (THA or TKA) especially in older persons whose social interactions are influenced by their level of mobility. Common therapy programs are aimed at improving muscle strength and neuromuscular activation patterns.

Natural gait is characterized by nearly symmetric movement patterns of the lower extremities: able-bodied persons show minimal laterality with only subtle differences between the dominant and non-dominant leg. However, severe gait asymmetries have been observed in

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patients with hemiplegia [3], Parkinson's disease [5–7], leg length discrepancies [8] and in lower extremity amputees [9]. While achieving gait symmetry is an important aspect of rehabilitation after lower limb surgery to avoid long-term unilateral loading, to date the required level of symmetry is unknown and is typically clinically evaluated by a patient's level of pain or discomfort due to their asymmetric gait. Further, diagnoses based on standard clinical methods are subjective and influenced by the physician's and patient's perception [10].

Inertial motion devices represent an alternative to laboratory based instrumented gait analysis for objective gait assessments: inertial motion systems are easy to use and over the last decade have become smaller and less expensive, and hence have been increasingly used for many clinical applications including activity monitoring [11] and gait analysis [12, 13]. The stance and stride phases of human walking and running can be reliably calculated from acceleration signals [13]. In particular, the calculation of autocorrelation of the cranio-caudal acceleration signal is a valid method for quantifying gait symmetry in healthy subjects [12]. To date, only few studies [12, 14, 15] have examined symmetry aspects of gait in patients with hip or knee osteoarthritis using these simple devices and showed that these devices are valid for assessing symmetry parameters in these populations [12, 16]. Moreover, these parameters may differ between men and women as the interplay of gait mechanics, pain, and disability differs between men and women with osteoarthritis [17].

The objective of this study was to evaluate the rehabilitation progress in subjects after THA during a 4-week inpatient rehabilitation period using inertial sensor technology. We hypothesized that walking speed and gait symmetry at three different stages of the rehabilitation period incrementally approach values of a reference group of healthy subjects and that a persons sex may influence changes in these parameters.

## Methods

Twenty-nine patients and 30 age-matched healthy subjects (Table 1) participated in this prospective cohort study after providing written informed consent. This

study was approved by the official ethics committee of the Medical University Clinic Tübingen (Germany) and followed the principles of the Declaration of Helsinki.

The THA group comprised patients who were in an inpatient rehabilitation clinic immediately after THA. All subjects in the THA group (15 men, 14 women) received a total hip endoprosthesis because of hip osteoarthritis progression with anterior and medial surgical approaches prior to their clinic stay (12 left hips, 17 right hips). Six patients had already received THA on the opposite hip (3 left hips, 3 right hips) at least 1 year prior and were completely pain and symptom free on the contralateral side. Patients were recruited from gait training courses integrated into the clinic's rehabilitation program and asked to participate in a gait analysis during their stay in the clinic. The inpatient rehabilitation program comprised 4 weeks of daily training with physiotherapy (5 sessions/week), lymph drainage or massage (3 sessions/week), water exercise (3 sessions/week after wound healing), activity of daily living training (2 sessions/week) and patient education on osteoarthritis and prosthesis (3 sessions). The inclusion criterion for patients was permission from their physician to walk without walking aids and to fully load their operated leg.

A reference group (RG; 16 male and 14 female subjects) aged 50 years or older with similar anthropometrical data were recruited from training courses at the local university clinic. The courses are especially designed for elderly people aimed at improving their physical fitness. Only volunteers without orthopedic disorders at the lower extremities were included.

All subjects were asked to walk on a 20.3-m level walkway at a self-selected preferred walking speed (*normal*). In a second trial, subjects were asked to walk at a fast self-selected speed (*fast*). The individual walking speed was recorded for a 2-m section at the midsection of the walkway using two pairs of photo cells (Alge Timing, Lustenau, Austria). Subjects walked down the track and returned after a short break of 3–5 s. The verbal instructions for both subject groups were identical. Subjects wore their own walking shoes (high-heeled shoes were not allowed) and were asked to use the same pair of shoes for all testing sessions.

Patients with THA performed three test sessions with a minimum of 6 days between each session. The first test day (TD1) was scheduled as soon as the patients felt able to complete the task and when the physician and physiotherapist gave their permission. The first test day was on average (mean (1SD)) 15 (3.5) days post-operatively. The subsequent test days were 21 (3.6) days (TD2) and 27 (3.6) days (TD3) post-operatively. All patients received standard therapy after surgery, and therapists aim at achieving a

**Table 1** Anthropometric data of the participants of this study

	Sex	N	Age [years]		Weight [kg]		Height [m]		BMI [kg/m <sup>2</sup> ]	
			Mean	SD	Mean	SD	Mean	SD	Mean	SD
THA	female	14	67.8	6.3	70.6	14.3	1.68	.05	24.9	4.9
	male	15	63.6	7.9	89.4	15.7	1.78	.09	28.1	4.1
RG	female	14	68.0	6.5	67.1	10.0	1.78	.05	25.4	3.4
	male	16	65.9	9.7	86.9	16.6	1.78	.06	27.9	5.2

THA total hip arthroplasty, RG reference group, BMI body mass index, SD standard deviation

subjective symmetric gait pattern. Reference subjects completed only one test session because these subjects did not complete any specific training.

### Equipment

Gait analysis was conducted using an inertial sensor unit recording acceleration and gyroscopic signals (Humotion, Münster, Germany). A three-dimensional accelerometer and three orthogonally aligned gyroscopic sensors were integrated into the inertial sensor unit. The system was mounted inside an aluminum box ( $75 \times 70 \times 10 \text{ mm}^3$ ) and weighed 30 g. Using an elastic belt, the box was secured to the lower part of the dorsal spine at level L4-L5 by the same examiner in each session. This fixation ensured that the measuring axes of the inertial sensor unit closely matched the cardinal body axes. The three acceleration signals represented the medio-lateral, cranio-caudal and anterior-posterior directions, respectively. These axes were also the rotational axes of the gyroscopes. The cranio-caudal acceleration signal was used to detect heel contact, and the medio-lateral acceleration and the medio-lateral gyroscope signals were used to detect left or right foot contact. Two calibration files were recorded while the subjects were (A) standing still in an upright position and (B) leaning their trunk forward to a maximum hip flexion of about  $30^\circ$ . By flexing the hip, the movement orientation of the sensor can be identified from the acceleration signal. Both positions were necessary for offset correction and coordinate transformation to correct for possible orientation errors of the sensor. The vector pointing from the sensor location in the upright position to its position in the forward lean position defined the forward direction regardless of the position of the sensors, and the other two directions were defined orthogonal to this axis. The sensor coordinate system is transformed to match the vertical axis, and hence the calculations are not affected by small deviations in sensor placement on the body.

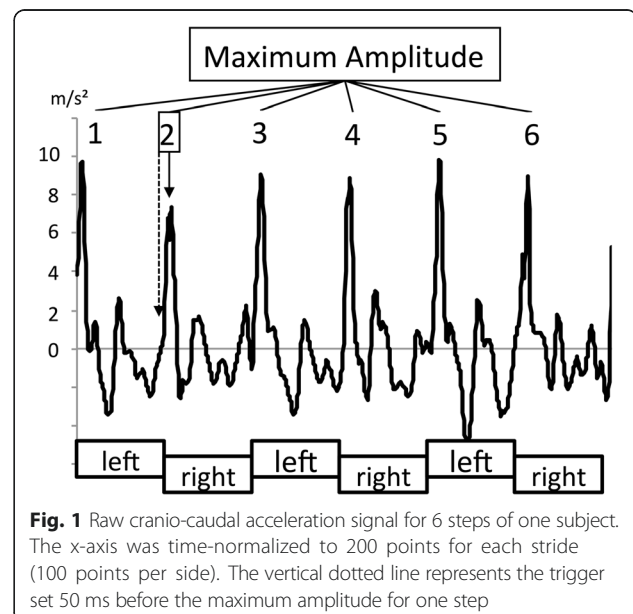
All signals were recorded at 100 Hz and stored on a chip within the inertial sensor unit. The maximal acquisition time of the inertial sensor was specified by the manufacturer as 24 h and thus did not limit measuring time. Prior to the first measurement, a data file containing relevant patient data was established on the PC-system and on the inertial sensor. Data acquisition began automatically after disconnecting the inertial sensor from the PC-system. After finishing the walking task, the sensor was reconnected to the PC and the stored signals were automatically transferred to the PC for further analysis. All signals were stored in ASCII-format and then imported into a MATLAB 7.1 routine (MathWorks, Germany) for further analyzing.

### Signal processing

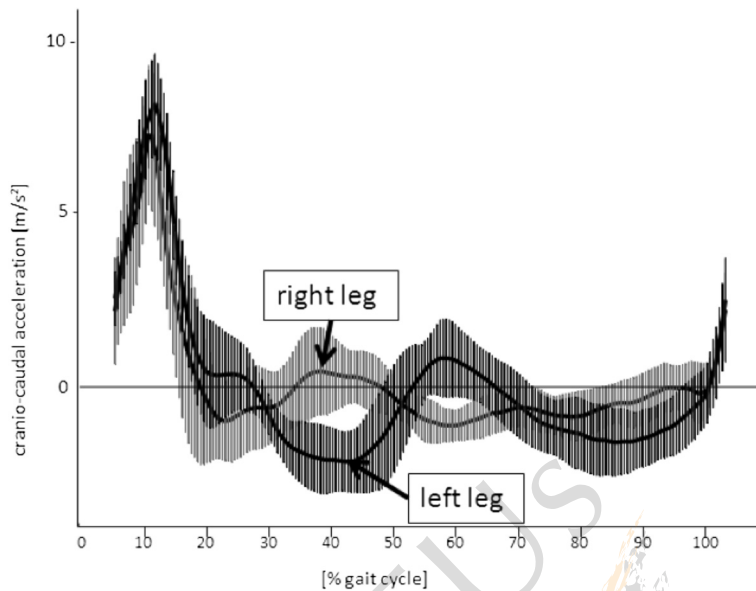
As shown by Auvinet et al. [13] comparing video-based methods with acceleration signals during gait, heel contact is represented by a small peak in the ascending part of the cranio-caudal acceleration signal. While the peak representing foot flat phase is easily detectable, the small peak in the ascending part cannot be easily detected by an automated routine. Our own pilot studies using the inertial sensor unit with synchronized pressure sensitive insoles (Belamed, Germany) confirmed this observation (unpublished data). However, subsequent autocorrelation calculations do not depend on the exact definition of a specific event. To automatically detect heel contact, we selected the maximum peak of the cranio-caudal signal as a trigger with a constant negative delay of 50 ms (Fig. 1), which was used to define individual steps. Because the signal at the beginning and at the end of each measurement was influenced by the subjects accelerating to achieve the desired walking speed, the first and last four steps were eliminated. The acceleration signal for the remaining middle ten strides (ten steps per side) was normalized to 2000 data points so that each step was represented by 100 data points (Fig. 2). All 2000 data points were used for computing autocorrelations.

### Parameter calculation

Calculating autocorrelation coefficients has been proposed as valid method for estimating gait symmetry [18–20]. Autocorrelation describes the correlation of a function or signal with itself at an earlier time point. Analyzing a cyclic signal such as a gait pattern produces autocorrelation coefficients with peak values when similar phases overlap. For a time series of the acceleration



**Fig. 1** Raw cranio-caudal acceleration signal for 6 steps of one subject. The x-axis was time-normalized to 200 points for each stride (100 points per side). The vertical dotted line represents the trigger set 50 ms before the maximum amplitude for one step



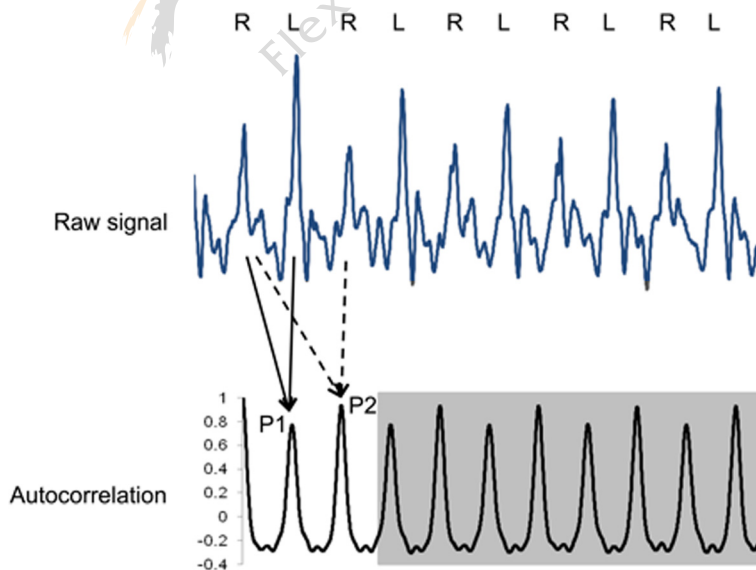
**Fig. 2** Normalized mean (1SD) cranio-caudal acceleration data for one exemplary patient with THA for the *right* and *left* legs (10 steps per side)

signal during walking, the first dominant peak (P1) represents a phase shift equal to one step, and the second dominant peak (P2) represent a phase shift equal to one stride. P1 values represent the regularity of neighboring steps and is low if contralateral steps are asymmetric. P2 values represent the regularity of the ipsilateral steps (Fig. 3). P2 values are typically higher than P1 values because ipsilateral steps are more similar than contralateral steps. As recommended by Moe-Nilssen [18], we calculated P1 and P2 from the cranio-caudal signal, and the

symmetry index was calculated as the ratio of P1 and P2 (P1/P2).

#### Statistic analysis

All statistical analyses were performed using SPSS version 16.0 (IBM Corporation, Somers, NY). A linear mixed model with factors test day (within subjects) and sex and group (between subjects) was used to identify changes in walking speed and gait asymmetry between test days and between groups. Data are presented as



**Fig. 3** Raw signal (*top*) and computed autocorrelation (*bottom*) for one exemplary trial. P1 represents the regularity between neighboring steps of opposite sides and P2 the regularity between neighboring steps of the same leg

group mean values with standard deviations (SD) with test day (TD1, TD2, TD3) as within-subject factors and group (THA, reference) and sex (male, female) as between-subject factors. Independent Student's t-tests and Least Significant Difference (LSD) tests were used for posthoc analyses. Bonferroni adjustments were applied to posthoc analyses to account for multiple comparisons. The level of significance for all statistical tests was set a priori to  $P < 0.05$ .

## Results

### Walking speed

The linear mixed model revealed significant main effects for test day, sex and group for walking speed ( $P < .001$  for all). Walking speed increased from TD1 to TD3 in patients with THA ( $P < 0.05$ ; Table 2). While female patients with THA walked slower than age-matched female reference subjects for both speed conditions, male patients with THA walked significantly slower than age-matched male reference subjects only at TD1 and TD2 but not at TD3.

In female patients with THA, normal walking speed increased from TD1 to TD2 ( $P = 0.001$ ) and from TD1 to TD3 ( $P < 0.001$ ; Table 2). Fast walking speed significantly increased from TD1 to TD2 to TD3 ( $P < 0.03$  for all). In male THA patients, normal and fast walking speeds significantly increased from TD1 to TD2 to TD3 ( $P < 0.03$  for all; Table 2).

In general, female patients with THA walked slower than male patients. The largest difference in normal or fast walking speed between sexes was 23 % at TD1. At TD2 and TD3 these differences were between 10 and 15 % (all  $P < .05$ ).

### Gait asymmetry

The linear mixed model revealed significant main effects for test day, sex and group for autocorrelation coefficients for P1 ( $P < .028$  for all). Although the autocorrelation coefficients for P1 increased from TD1 to TD3 in patients with THA, the autocorrelation coefficients for P1 on all test days and at both walking speeds were significantly lower in patients with THA than in the reference subjects ( $P \leq 0.036$  for all). The autocorrelation coefficients for P1 differed between sexes ( $P = 0.028$ ) and test days ( $P = 0.021$ ). The increase in the autocorrelation coefficients for P1 in patients with THA was only significant for male patients at normal and fast walking speed between TD1 and TD3 ( $P = 0.004$ ) and between TD2 and TD3 ( $P = 0.030$ ). There was no interaction between sex and test day ( $P = .458$ ).

The autocorrelation coefficients for P2, representing the correlation between ipsilateral steps, did not differ significantly between test days, sexes, or between patients with THA or reference subjects ( $P > 0.050$ ; Table 2).

The linear mixed model revealed significant main effects for test day, sex and group for symmetry index ( $P < .039$  for all). The symmetry indices in patients

**Table 2** Mean (1 standard deviation) walking speed and autocorrelation coefficients P1 and P2. The MEAN value represents the average of values at normal and fast walking speeds

Parameter	Sex	Walking speed	TD1		TD2		TD3		Reference group	
			Mean	SD	Mean	SD	Mean	SD	Mean	SD
Walking speed [m/s]	female	normal	2.77	.67	3.75	.54	4.09	.53	5.06	.78
		fast	3.62	.77	4.50	.69	4.83	.70	6.27	.82
	male	normal	3.63	.84	4.20	.47	4.62	.40	4.69	.64
		fast	4.68	.76	5.30	.46	5.75	.52	5.83	.84
Autocorrelation coefficient P1	female	normal	.7738	.0659	.7962	.0883	.8143	.0824	.8828	.0647
		fast	.7604	.0980	.7848	.0988	.8064	.0891	.8771	.0863
		MEAN	.7671	.0820	.7905	.0936	.8104	.0858	.8800	.0755
	male	normal	.6704	.1190	.7350	.1260	.7886	.1246	.9031	.0613
		fast	.7214	.1166	.7597	.1125	.7963	.1037	.8882	.0639
		MEAN	.6959	.1178	.7474	.1193	.7925	.1142	.8957	.0626
Autocorrelation coefficient P2	female	normal	.9007	.0604	.9002	.0669	.9120	.0577	.9094	.0680
		fast	.8983	.0776	.8904	.1005	.9003	.0757	.9054	.0888
		MEAN	.8995	.0690	.8953	.0837	.9061	.0667	.9074	.0784
	male	normal	.8969	.0673	.9174	.0538	.9190	.0564	.9166	.0700
		fast	.9144	.0485	.9198	.0466	.9223	.0572	.9337	.0510
		MEAN	.9056	.0579	.9186	.0502	.9206	.0568	.9251	.0605

P1 first dominant peak of the acceleration signal, P2 second dominant peak of the acceleration signal, SD standard deviation

with THA on all test days at both walking speeds were significantly lower than in the reference group ( $P \leq 0.001$ ; Fig. 4). The symmetry index differed between sexes ( $P = 0.003$ ) and test days ( $P = 0.039$ ). In male patients with THA, the symmetry index increased from TD1 to TD2 to TD3 at both walking speeds (TD3 vs. TD1:  $P < 0.001$ ; TD3 vs. TD2:  $P = 0.020$ ). The symmetry indices in female patients with THA were higher than those for male patients on all test days at normal walking speed (TD1:  $P = 0.019$ ; TD2:  $P = 0.007$ ; TD3:  $P = 0.214$ ) and at fast walking speed (TD1:  $P = 0.025$ ; TD2:  $P = 0.022$ ; TD3:  $P = 0.268$ ). There was no increase in symmetry index over time in female patients with THA.

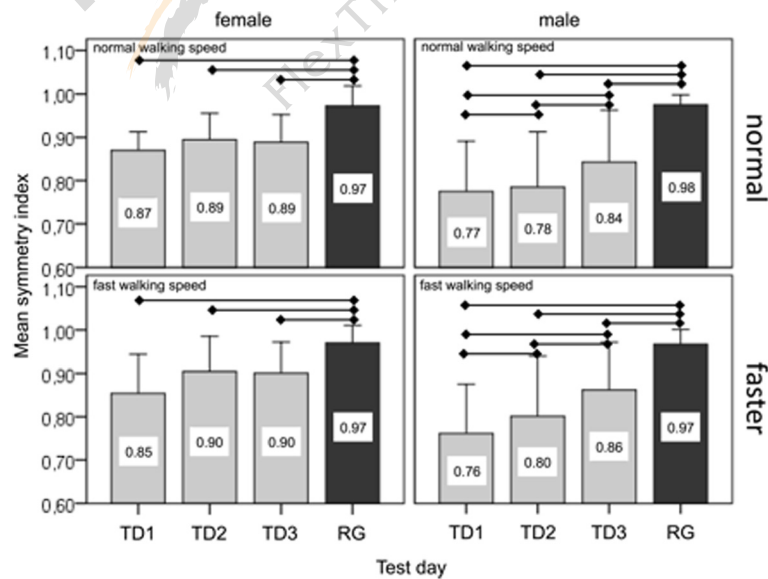
### Discussion

The purpose of this study was to evaluate the rehabilitation progress in subjects after THA during an inpatient rehabilitation period using inertial sensor technology. We found that patients with THA had a clear improvement in walking speed after an intensive inpatient rehabilitation period for an average of 27 days. The inertial sensor data showed that asymmetries in a gait cycle decreased over the rehabilitation period. However, especially female patients did not achieve walking speeds of a reference group within the observed rehabilitation period.

Walking speed is an important gait parameter: faster walking speeds reflect greater mobility and capacity to perform daily activities. The walking speeds for the reference group in our study were comparable to those reported by Moe-Nilssen [20] for physically fit subjects with a mean age of 73 years who walked at a preferred

walking speed of 3.45 km/h and a maximum speed of 5.32 km/h. Although the instructions given to the subjects were similar in both studies, our reference group walked slightly faster at both the normal and the fast walking speeds. One possible reason for this discrepancy is that our reference subjects were about 5 years younger than those in Moe-Nilssen's study. In addition, we recruited our reference subjects from training courses and hence these subjects may have had a better individual physical fitness levels.

Male and female patients with THA showed a significant increase in walking speed at both walking speed conditions throughout the rehabilitation period, which was expected after intensive inpatient clinical rehabilitation [21]. In fact at TD3, there was no significant difference in walking speed between male patients with THA and the male reference subjects. In contrast, female patients with THA did not walk as fast as female reference subjects. One possible explanation for this discrepancy is the older age of female patients with THA compared to that of the reference subjects. Auvinet et al. [13] have previously reported decreasing walking speeds with increasing age. Further, psychological reasons may be responsible for differences at fast walking speeds in male compared with female patients with THA: male patients might be more confident and less afraid of pain or injury. In a recent study evaluating strength and motor performance in older female and male subjects (>65 years), female subjects had lower muscle strength and motor performance than male subjects even after correcting for lean muscle mass [22]. Thus, it is possible that female patients



**Fig. 4** Mean (1SD) symmetry index on three post-THA test days for female and male patients for normal and fast walking speeds. Black bars represent the reference group. TD1—15-days post-THA; TD2—21-days post-THA; TD3—27-days post-THA; THA—total hip arthroplasty. Horizontal bars represent significant differences ( $P < 0.05$ )

walk slower than their healthy peers to increase their perceived safety as shown in stroke patients [23, 24]. Furthermore female subjects may walk slower than their peers to avoid higher loading of the joints and muscular system. However, when asked to walk faster, female patients in our study were able to comply and reached speeds similar to those in female reference subjects (Table 2). These results are relevant for rehabilitation and we propose that the underlying impairments such as lower muscle strength and motor performance should be addressed in sex specific rehabilitation programs to facilitate faster comfortable walking speed although this requires additional study. In the context of training adaptation, a certain level of stimulus to the muscular and neuronal systems is required for improving performance and the training stimuli are greater at higher speeds.

Autocorrelation methods are good measures of symmetry or asymmetry in gait patterns [18]. In our study, only the cranio-caudal acceleration signal was used to evaluate symmetry in gait patterns. The resulting parameters P1 and symmetry index for male and female patients with THA did not reach the values of the reference group even after an intensive rehabilitation program. This result contradicts the results for walking speed. While gait symmetry parameters improved throughout the inpatient rehabilitation phase, there was still a deficit at TD3 compared to the reference group. The patient training courses comprised daily strength, mobility, flexibility and coordination training. We conclude that while this intensive training program of around 27 days improved gait symmetry in patients, this period might still be too short to achieve symmetry values of healthy, age-matched reference subjects. Results of a recent study [25] on total knee arthroplasty showed that while walking speed improved a 6-week rehabilitation program was not sufficient to achieve pre-operative values. Moreover, patients with hip osteoarthritis suffer from significant muscle strength loss and altered muscle activity [26], and it is not to be expected that these deficits would be reversed after a 4-week program.

One possible strategy for avoiding pain during gait—especially in the lower extremities—is asymmetric loading, which may expose the unaffected or less affected leg to higher ambulatory loads. When a movement is learned or has attained a high level of automation, “re-setting” this pattern becomes difficult [27]. An “incorrect” adaptation may develop over a long period of time. Gait patterns specific to patients with THA presumably developed long before hip replacement with their osteoarthritic changes. Therefore, establishing a new motor program by relearning may require longer training periods and longer periods of inpatient rehabilitation than the program presented in this study. Future studies should evaluate whether a longer follow-up period after

the actual treatment will completely restore symmetric gait patterns. It is important to remember, however, that a certain asymmetry can be present even in healthy subjects [8].

Specifically designed gait training programs represent one possibility to help patients achieve a symmetric gait pattern. Experienced therapists generally provide feedback on gait asymmetry in routine rehabilitation, and patients become more conscious of their movement patterns in therapy sessions. However, when unobserved, patients may return to their previous asymmetric gait, possibly because they are unaware of these subtle deviations. Using technical devices for monitoring gait could possibly minimize this deficit during unobserved periods. Systems based on inertial technology are becoming smaller, lighter and less expensive, and may hence become increasingly feasible for routine clinical use as previously suggested [12, 16].

As with most studies involving rehabilitation programs, the limitations of this study include the possibility of differences between patients by the specific exercises performed. Although we tried to standardize the program as much as possible in this inpatient rehabilitation program, there are always slight differences in the therapist-patient interaction. Six of the patients had previously received THA on their opposite hip. However, all of these patients had received their contralateral hip THA more than 1 year prior and were pain and symptom free. It is possible that asymmetry in this subsample may be a result of decreased performance on the original side or of improvements in the operated side. However, such developments would rather increase than decrease discrepancies to healthy subjects. Because these patients were pain and symptom free in the opposite side, we decided to include these patients. Moreover, in patients with unilateral THA, changes in gait asymmetry may also be caused by changes in mainly the operated or those in the contralateral limb. It is possible that assessing gait asymmetry may have influenced the motivation of our patients to perform well. Hence, the outcome in these patients may not be directly transferrable to other cohorts undergoing inpatient rehabilitation programs without additional assessments. In this study, we focused primarily on gait symmetry. However, it is well known that specific joint mechanics plays an important role in the outcome of THA, and hence should be considered in future outcome studies.

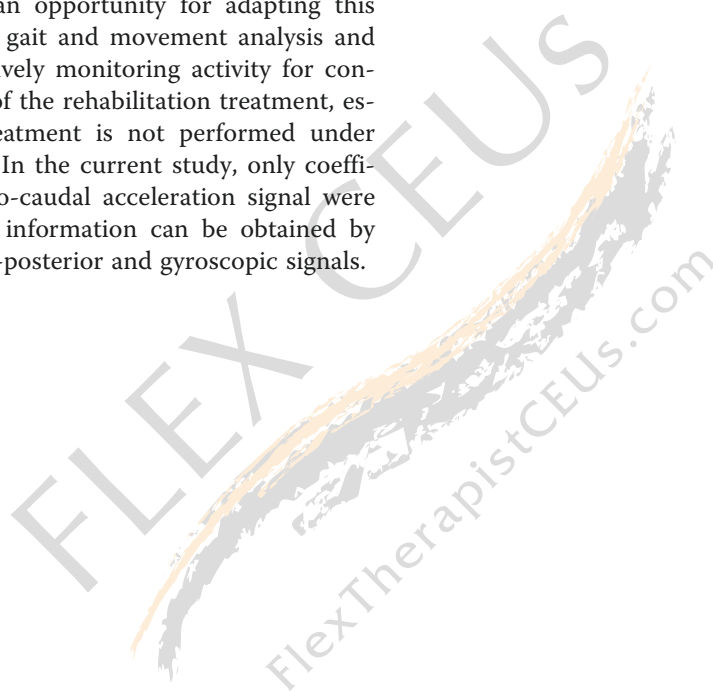
## Conclusion

Walking speed is a key parameter for determining rehabilitation progress and success and a prerequisite for regaining mobility after surgery especially for older persons. Hence, patients strive to regain a walking speed



that enables them to engage in activities of daily living. Gait symmetry is another discriminative parameter of gait quality. As shown in this study, both walking speed and symmetry parameters improved during the rehabilitation period in patients following THA. However, deficits in walking speed and symmetry in patients with THA were still apparent compared to reference group suggesting a need for ongoing rehabilitation. It remains unclear if patients with THA can achieve walking speeds comparable to those in healthy subjects.

Using inertial sensor technology for assessing gait symmetry was simple and easy to evaluate, and subject compliance was high. From a methodological point of view, light-weight and small design of inertial sensor technology provides an opportunity for adapting this technology for use in gait and movement analysis and possibilities for effectively monitoring activity for controlling the outcome of the rehabilitation treatment, especially when the treatment is not performed under therapist supervision. In the current study, only coefficients from the cranio-caudal acceleration signal were analyzed, but further information can be obtained by analyzing the anterior-posterior and gyroscopic signals.



# Pain and Function Recovery Trajectories following Revision Hip Arthroplasty: Short-Term Changes and Comparison with Primary Hip Arthroplasty in the ADAPT Cohort Study

## Abstract

### Background and Purpose

Patients report similar or better pain and function before revision hip arthroplasty than before primary arthroplasty but worse results are reported after revision surgery than after primary surgery. The trajectory of post-operative recovery during the first months and any differences by type of surgery have received little attention. We explored the trajectories of change in pain and function after revision hip arthroplasty to 12-months post-operatively and compare them with those observed after primary hip arthroplasty.

### Methods

This study is a prospective cohort study of patients undergoing primary (n = 80 with 92% for an indication of osteoarthritis) and revision (n = 43) hip arthroplasties. WOMAC pain and function scores and walking speed were collected pre-operatively, at 3 and 12-months post-operatively. Multilevel regression models were used to chart and compare the trajectories of change (0–3 months and 3–12 months) between types of surgery.

### Results

The improvements in pain and function following revision arthroplasty occurred within the first 3-months with no evidence of further change beyond this initial period. While the pattern of recovery was similar to the one observed after primary arthroplasty, improvements in the first 3-months were smaller after revision compared to primary arthroplasty. Patients listed for revision surgery reported lower pre-operative pain levels but similar post-operative levels compared to those undergoing primary surgery. At 12-months post-operation patients who underwent a revision arthroplasty had not reached the same level of function achieved by those who underwent primary arthroplasty.

## Conclusion

The post-operative improvements in pain and function are larger following primary hip arthroplasty than following revision hip arthroplasty. Irrespective of surgery type, most of the improvements occur in the first three post-operative months. More research is required to identify whether the recovery following revision surgery could be improved with specific post-operative interventions.

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## Introduction

The volume of primary hip arthroplasties rose by approximately 26% between 2010 and 2015 [1, 2]. Over 88,000 primary total hip arthroplasties are performed per year in England and Wales [2]. These figures will continue to rise due to increases in obesity and an aging community [3]. The revision burden is approximately 11% and over 9,500 revision hip arthroplasties were performed in England and Wales in 2015 [1, 2].

Both primary and revision hip arthroplasty have been shown to improve patient-reported pain and function for the majority of patients [4–8]. While patients tend to have similar [5, 6, 8] or better [7] pain and function prior to revision arthroplasty than prior to primary arthroplasty, patients who undergo primary surgery report better post-operative outcomes than those who undergo revision surgery [5–7].

Typically, the outcome of both primary and revision is reported at 12-months or more after surgery [6–8]. The pattern of recovery trajectories within the first 12-months after surgery, and differences between primary and revision surgery in this period have received little attention. Pain and function have previously been reported not to improve further after 6-months following revision arthroplasty [9, 10]. In the absence of assessment prior to 6-months in these studies the pattern of improvement in the first months post-operation requires further investigation.

Evidence from the ADAPT cohort study suggests that in primary hip arthroplasty, the improvement in patient-reported pain and function post-operation plateaus at 3-months [11]. It is not currently clear if the pattern of recovery following revision hip arthroplasty is similar or if the complexity, extent of surgery and surgical trauma leads to a different pattern.

To describe and explore potential disparities in the degree and pattern of post-operative recovery following revision hip arthroplasty, we analysed data collected pre-operatively, at 3- and 12-months post-operation from the ADAPT prospective cohort study. Specifically our research aims were 1. to describe the early trajectories of pain and function after revision hip arthroplasty, 2. compare these trajectories with those observed after primary hip arthroplasty and 3. compare the post-operative outcomes achieved after these two types of surgery. We also investigated whether the pattern of recovery was similar when function is objectively assessed with standardised performance tests compared to patient-reported outcome measures.”

## Materials and Methods

This study followed the STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) guidelines for reporting observational studies in epidemiology (Appendix A in [S1 File](#)).

## Study design

ADAPT is a single-centre UK prospective cohort study including patients undergoing hip or knee arthroplasty (UKCRN ID 8311). National Health Service Research Ethics Committee

approval was granted for the study (09/H0102/72) and all patients provided informed, written consent.

Detailed information on study design, patient recruitment, inclusion-exclusion criteria, and assessment methods are provided in the published study protocol [12]. Briefly, between February 2010 and November 2011, patients waiting for hip or knee arthroplasty at a high-volume elective orthopaedic centre were invited to participate in the study. Approximately 250 patients were recruited to ensure a sufficient number of patients to perform meaningful data analysis. Patients were due to undergo a range of primary and revision arthroplasty procedures (primary total knee arthroplasty, unicompartmental knee arthroplasty, patellofemoral arthroplasty, revision total knee arthroplasty, primary total hip arthroplasty, primary hip resurfacing or revision total hip arthroplasty) so that functional measures could be investigated across a range of patients with diverse indications for surgery and degrees of functional impairment. The majority of patients listed for primary arthroplasty had an indication of osteoarthritis. Exclusion criteria included an inability to provide written informed consent, to complete English language questionnaires (not all the questionnaires we used have been translated or validated for use in other languages), participation to another study, and severe functional limitations which would prevent completion of a performance test. In particular, patients using wheelchairs were excluded.

This analysis was restricted to patients who underwent primary total, resurfacing or revision hip arthroplasty.

## Data collection

Assessments were conducted before surgery (median 19 days) and then at 3 and 12-months after surgery. At each post-operative assessment time, participants completed a postal questionnaire.

## Participant and surgical characteristics

Data on gender, age, living arrangement, level of education, working status and number of joints affected by arthritis were collected in the pre-operative questionnaire. The indication for surgery, type of surgery, surgical approach, height and weight were extracted from participants' medical records.

Patients undergoing primary arthroplasty had a total hip replacement ( $n = 74$ ) or hip resurfacing ( $n = 6$ ). Osteoarthritis was the indication for surgery in 92% of primary cases. Patients undergoing revision arthroplasty had revision of a total hip arthroplasty (86%,  $n = 37$ ), hip resurfacing (9%,  $n = 4$ ), or hemiarthroplasty (5%,  $n = 2$ ). The most common indication for revision arthroplasty was aseptic loosening (67%,  $n = 29$ ); the remaining indications were pain (9%,  $n = 4$ ), aseptic lymphocyte-dominated vasculitis-associated lesion (9%,  $n = 4$ ) and other reasons (11%,  $n = 6$ ). Primary (87%,  $n = 70$ ) and revision arthroplasties (98%,  $n = 42$ ) were mostly commonly performed via a posterior surgical approach.

## Patient-reported measures

Self-reported pain and function were assessed using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) function and pain sub-scales [13]. The WOMAC-function measure consists of 17 questions assessing the extent of functional limitation when performing a range of daily activities. WOMAC-pain consists of five questions assessing pain during walking, using stairs, in bed, sitting or lying. Each sub-score ranges from 0–100 (worst to best). The WOMAC score has good psychometric properties with test-retest reliability above 0.8 for the physical function subscale and above 0.7 for the pain subscale [14].

## Performance test

An objective measure of function was obtained using a timed walk test [15]. Participants were timed and supervised by a research nurse as they walked a 20 metres straight distance on level ground at their normal, comfortable speed. Speed (metres per second) was derived by dividing the distance walked by the time required to complete the task. The test-retest reliability of the 20 metres has been showed to be high ( $> 0.9$ ) [16, 17].

## Statistical analysis

Three random intercept and slope linear regression models, one for each studied outcome (WOMAC-pain, WOMAC-function and walking speed), were used to investigate the pattern of post-operative changes following revision hip arthroplasty (aim 1) and compare the changes with those following primary hip arthroplasty (aim 2). This approach accounts for repeated and unequal numbers of measurements per participant while producing estimations valid under the missing at random assumption [18]. In this modelling framework, all available pre- and post-operative assessments of the outcome of interest were modelled. The outcomes were standardised (using the pre-operative mean and standard deviation of the score of interest) to produce estimates comparable across models. Those outcomes were regressed on an intercept (mean of standardised outcome on day of surgery at the sample mean age), age (centred at 65.2, the overall sample mean age) and two time splines (with random effect on their associated effects): one spline (a line between two points) for the “short-term change” occurring between the pre-operative assessment and the second assessment (3-months post-operative) and another spline for the “long-term change” occurring between the two post-operative assessments (3 and 12-months). Changes between assessment points were modelled rather than the actual scores achieved at 3- or 12-months. This was because the distributions of the scores were strongly skewed but the changes were normally distributed and could be analysed with the model framework presented above (as evidenced by the residuals plots). These models were stratified by primary/revision status to produce estimates specific to each type of surgery. Comparisons of the short- and long-term changes by surgery type were performed using their fixed effects and contrasts.

The equation structure of these models is described in more details in appendix B in [S1 File](#) with the code used to compute them.

The short- and long-term changes were also plotted by surgery type. For this purpose, the random intercept and slope linear model framework described above was re-run unadjusted for age on the unstandardised outcomes of pain and function. The fixed effects associated with the intercepts, and time splines of the primary and revision arthroplasty equations were used to produce the mean changes and their 95%CI.

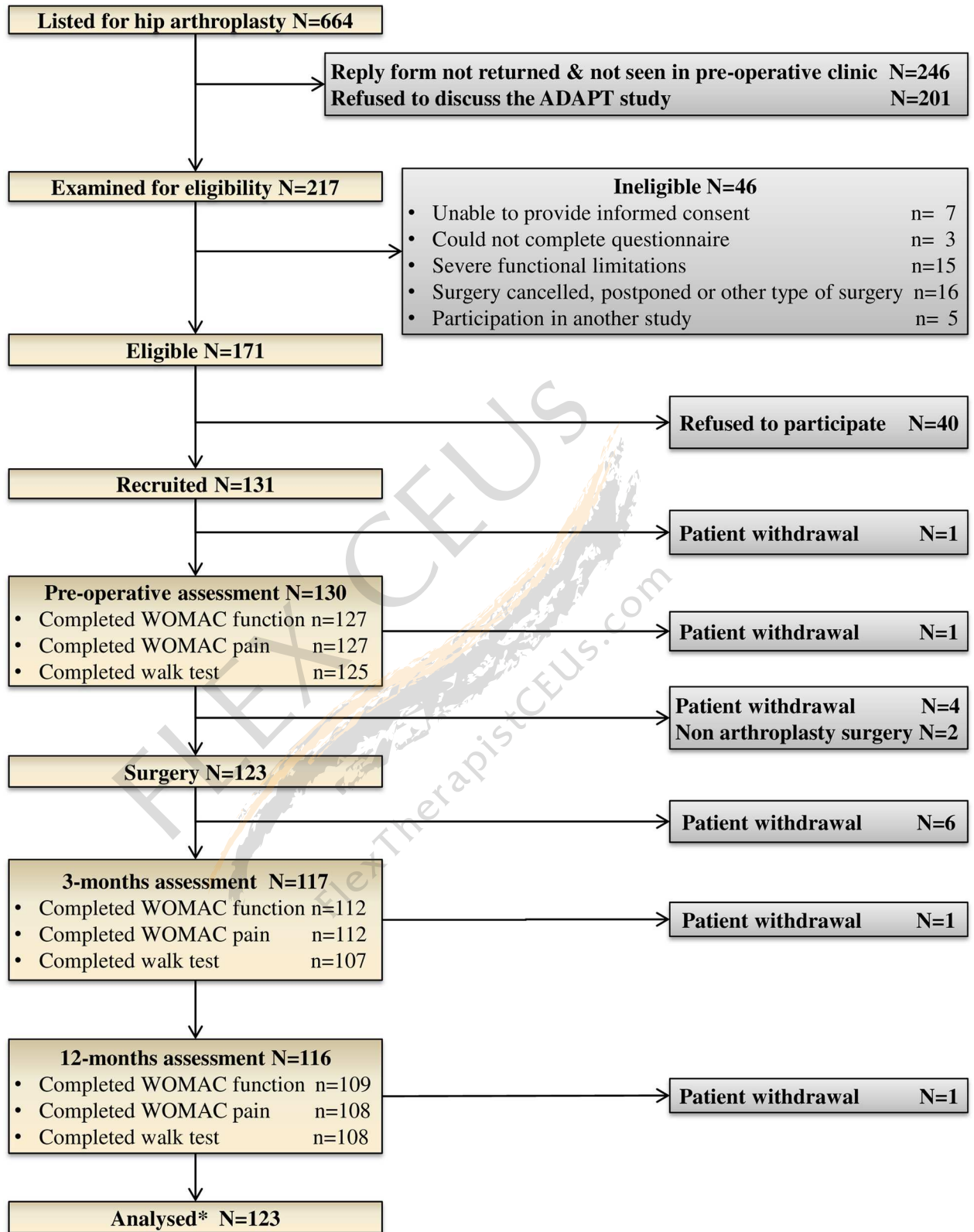
Finally, the post-operative outcomes achieved at 3- and 12-months post-operatively were compared by surgery type (aim 3). As explained, the actual post-operative outcomes were strongly skewed and could not be investigated within the regression framework. Mann-Whitney tests were used for this purpose.

All models were fitted using Stata SE 13.1 (StataCorp LP, College Station, Texas, USA) and MLwiN v2.31 using Stata runmlwin command [19]. A p-value of  $<0.05$  was considered as evidence of statistical significance.

## Results

### Sample description

Overall, 664 patients were identified on the waiting list for primary or revision hip arthroplasty (Fig 1). A total of 447 patients were not approached or refused to discuss the study. Forty-six



\*Patients who underwent surgery, with at least one pre- or post-surgery assessment

Fig 1. Flow diagram of recruitment and participation.

patients were also ineligible among which 15 were wheelchair users including two with severe balance issue. A total of 171 patients were eligible and 131 agreed to take part (77%). Eight patients did not subsequently undergo hip arthroplasty and therefore 123 patients were included in the final analysis. Of these patients 80 had a primary and 43 had a revision hip arthroplasty.

All these 123 participants had at least one assessment (pre-operative, 3 and/or 12-months) for any of the investigated measures (WOMAC-pain, WOMAC-function scores or walking speed) and were considered in the analyses. A description of the available number of assessments at each data collection points is provided in Table 1. The percentage of participants with complete information on WOMAC-pain, WOMAC-function scores and walking speed at 12-months post-operation was comparable between type of surgery (89% and 84% for primary and revision arthroplasty respectively).

The characteristics of the cohort are shown in Table 2. The mean age was 65 years (SD 11) and 66 years (SD 11) respectively for participants who underwent a primary and revision arthroplasty respectively. The median body mass index was 26 kg/m<sup>2</sup> (Interquartile range (IQR) 24–29) and 28 (24–28) respectively.

### Pain and function trajectories after revision arthroplasty

Revision hip arthroplasty lead to a significant improvement in both pain and function (Fig 2). Changes in pain and function occurred within the first 3-months post-operation (WOMAC-pain,  $p < 0.0001$ ; WOMAC-function,  $p < 0.0001$ ; Walking speed,  $p < 0.0001$ ; S1 Table). No evidence of further improvement in pain or function was found between 3 and 12-months

**Table 1. Pain and function by assessment period and revision/primary profile.**

N = 123	Pre-operative			3-months			12-months		
	Total	Primary	Revision	Total	Primary	Revision	Total	Primary	Revision
<b>WOMAC Pain</b>	121	78	43	112	76	36	108	71	37
missing, n =	2	2	0	11	4	7	15	9	6
%	98.4	64.5	35.5	91.1	67.9	32.1	87.8	65.7	34.3
Median	55	55	60	95	95	95	100	100	95
Interquartile range <sup>a</sup>	[35, 70]	[30, 70]	[50, 75]	[80, 100]	[85, 100]	[73, 100]	[85, 100]	[90, 100]	[80, 100]
p-value <sup>b</sup>	0.031			0.479			0.268		
<b>WOMAC function</b>	121	78	43	112	76	36	109	71	38
missing, n =	2	2	0	11	4	7	14	9	5
%	98.4	64.5	35.5	91.1	67.9	32.1	88.6	65.1	34.9
Median	56	54	62	90	90	89	94	96	93
Interquartile range <sup>a</sup>	[38, 71]	[38, 71]	[41, 75]	[81, 96]	[81, 96]	[79, 96]	[84, 99]	[87, 100]	[76, 97]
p-value <sup>b</sup>	0.165			0.678			0.015		
<b>Walking-speed<sup>c</sup></b>	118	77	41	107	74	33	108	72	36
missing, n =	5	3	2	16	6	10	15	8	7
%	95.9	65.3	34.8	87	69.2	30.8	87.8	66.7	33.3
Median	0.91	0.91	0.83	1.11	1.11	1.05	1.18	1.18	1.11
Interquartile range <sup>a</sup>	[0.71, 1.11]	[0.71, 1.11]	[0.67, 1.11]	[0.91, 1.25]	[0.95, 1.25]	[0.91, 1.18]	[0.95, 1.33]	[1.03, 1.38]	[0.87, 1.18]
p-value <sup>b</sup>	0.464			0.343			0.004		

a First and third quartiles: 25<sup>th</sup> and 75<sup>th</sup> percentiles

b Mann-Whitney test to compare median scores by primary/revision profile.

c Walking-speed expressed in metres per second: 20 metres / Completion-time

**Table 2. Participant characteristics.**

		N = 123		Primary n = 80		Revision n = 43	
			%		%		%
<b>Sex</b>	Men	61	49.6	38	47.5	23	53.5
	Women	62	50.4	42	52.5	20	46.5
<b>Number of other joints with OA</b>	None	25	20.3	20	25.0	5	11.6
	One joint	29	23.6	22	27.4	7	16.3
	Two joints	22	17.9	13	16.3	9	20.9
	3 joints	18	14.6	8	10.0	10	23.3
	> = 4 joints	22	17.9	13	16.3	9	20.9
	Unknown	7	5.7	4	5.0	3	7.0
<b>Living alone</b>	Living with someone	90	73.2	59	73.7	31	72.1
	Living alone	30	24.4	18	22.5	12	27.9
	Unknown	3	2.4	3	3.8	0	0.0
<b>Education</b>	Normal school leaving age	66	53.7	41	51.2	25	58.1
	College	26	21.1	20	25.0	6	14.0
	University	28	22.8	16	20.0	12	27.9
	Unknown	3	2.4	3	3.8	0	0.0
	Full time	55	44.7	34	42.5	21	48.8
<b>Working status</b>	Retired	60	48.8	38	47.5	22	51.2
	Unemployed	7	5.7	7	8.7	0	0.0
	Unknown	1	0.8	1	1.3	0	0.0

doi:10.1371/journal.pone.0164839.t002

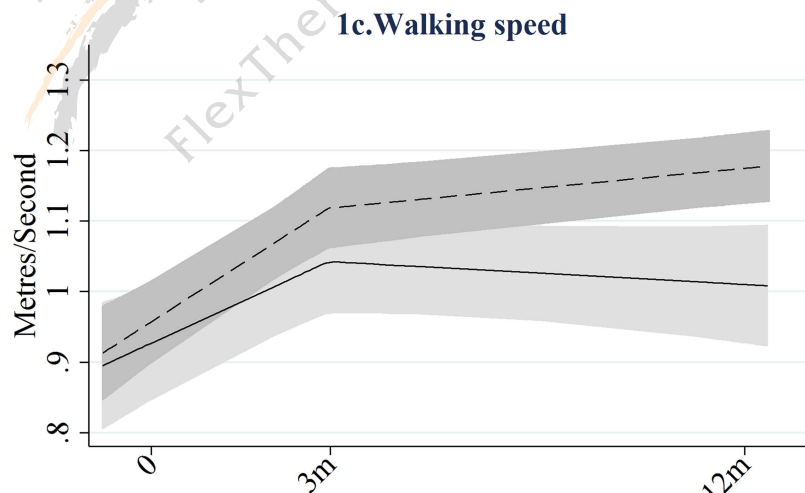
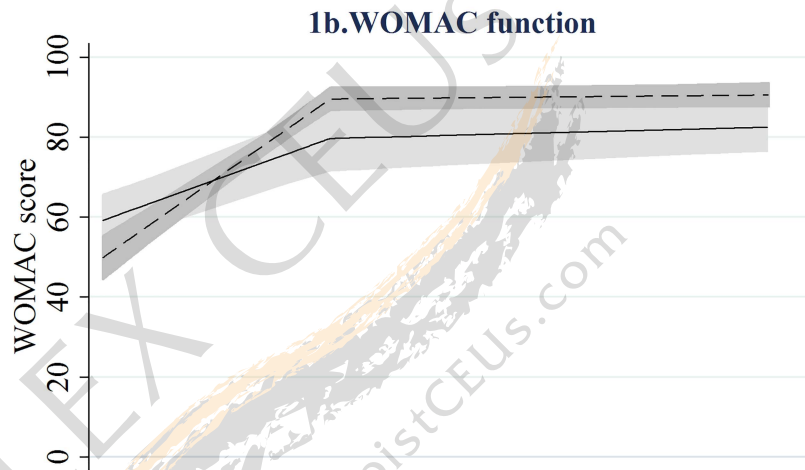
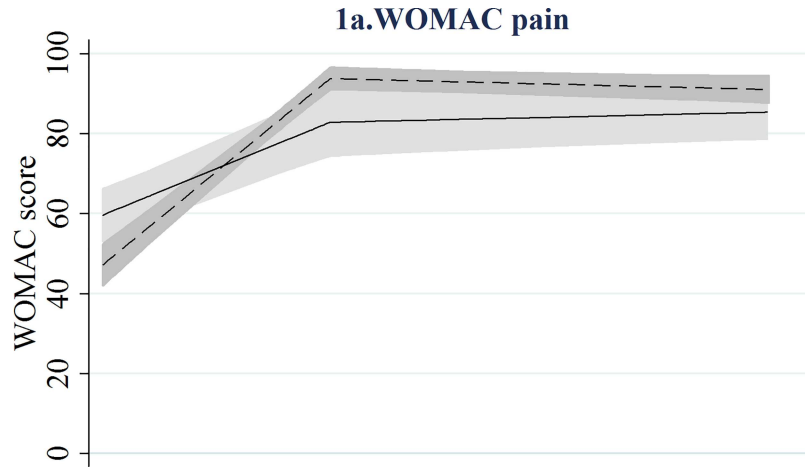
(S1 Table). Pain and function trajectories after primary arthroplasty are reported in Fig 2 and S1 Table and have been previously described [11]. Changes mainly occur within the first 3-months following surgery and there is no evidence of further changes after 3-months with the exception of the walking speed which continued to marginally improved between 3 and 12-months ( $p = 0.005$ ).

### Comparisons between revision and primary arthroplasty

Pre-operatively, the level of pain reported by participants listed for primary surgery was worse than for those listed for revision surgery (median 55 vs. 66,  $p = 0.031$ , Table 1). However greater short-term improvements in WOMAC-pain (Fig 2A) were assessed during the first 3-months following primary arthroplasty compare to the changes found after revision arthroplasty ( $p < 0.0001$ , S1 Table). No evidence of change was found between 3 and 12-months for either type of surgery. As a result there was no more significant difference at 3 ( $p = 0.479$ , Table 1) or 12-months ( $p = 0.268$ , Table 1). Pre-operatively, the median WOMAC-function scores were not different between those that underwent primary and revision hip arthroplasty (Table 1). The mean short-term change in the WOMAC-function score (Fig 2B) following revision arthroplasty was smaller than that following primary arthroplasty ( $p < 0.001$ , S1 Table). No evidence of long-term change (between 3 and 12-months) was observed for either type of surgery. At 12-months post-operation, the median WOMAC-function score was higher after primary surgery than after revision surgery (96 vs 93,  $p = 0.015$ , Table 1).

The walking speed was comparable pre-operatively for participants who subsequently underwent primary and revision arthroplasty ( $p = 0.464$ , Table 1). The trajectory of recovery exhibited by the walking speed differed between patients with revision and primary arthroplasty (Fig 2C). The speed improved to a similar extent during the first 3-months following both types of surgery. However, the improvement continued after 3-months for primary





Time of assessment(days from surgery)

Revision — Primary - - - 95%CI █

**Fig 2. Mean trajectories<sup>a</sup> for WOMAC-pain, WOMAC-function and walking speed (Unstandardised outcomes) by revision/primary surgery.** The mean trajectories are derived using the fixed effects terms of the linear mixed models stratified on primary-revision profile and regressing each outcome on the time of assessment parameterised as two linear splines.

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arthroplasty ( $p = 0.005$ , [S1 Table](#)) but not for revision arthroplasty ( $p = 0.300$ , [S1 Table](#)). Participants who had undergone revision arthroplasty reported a slower walking speed at 12-months post-operatively than those who had undergone primary ( $p = 0.004$ ; [Table 1](#)).

## Discussion

Investigation of the early outcome trajectories after revision hip arthroplasty has revealed that the improvements in pain and function were mainly observed within the first 3 post-operative months with no evidence of further change beyond this initial period. The comparisons of these trajectories with those observed after primary hip arthroplasty have shown that while pain or function recovery was plateauing before six-months for both surgery types, the extent of improvements was different with smaller short-term changes after revision arthroplasty than after primary arthroplasty. Comparisons of the achieved post-operative outcomes reveal that patients who underwent revision surgery reported less pre-operative pain than those who underwent primary surgery but due to the difference in the extent of post-operative changes this advantage was not sustained post-operatively. While function was comparable pre-operatively, at 12-months post-operation patients who underwent revision arthroplasty had not reached the level of function achieved by those who underwent primary arthroplasty. Finally, some difference in the pattern of recovery was observed when function was objectively assessed. Contrary to patient-reported function, minor but statistically significant improvements in walking-speed was observed between 3 and 12-months after primary arthroplasty and this long-term changes were not observed after revision surgery.

The observed effectiveness of revision hip arthroplasty to improve patient-reported pain and function is consistent with the existing evidence [9, 20–25]. The few studies measuring outcomes prior to 12 months post-operation report that changes in outcomes following revision hip arthroplasty plateau at 6-months post-operation [9, 10]. None of these studies has measured pain or function at 3-months post-operation and the current study filled this gap. This “plateau” was reached at least 3-months earlier than previously shown and was lower than the one observed after primary arthroplasty. This suggests that the higher complexity or degree of trauma related to revision surgery as compared to primary surgery limits the extent of the recovery but does not increase the time taken to recover: patients undergoing revision arthroplasty will improve but should not expect to achieve outcomes as high as those reached after their primary surgery.

The differential between the degree of improvement following revision and/or the outcome level reached post-operatively compared to primary surgery have also been shown but only in the post-operative period starting 12 months or more after surgery [4–8, 25–28]. In this respect, the current findings fill another gap in the literature.

There is limited evidence on the improvement in objective function following revision hip arthroplasty but the findings are in agreement with ours [20]. Aghayev et al. demonstrated the benefit of revision hip arthroplasty on the ability to walk, reporting an improvement in the percentage of their patients unable to walk for more than 30 minutes 12-months after surgery from 65% pre-operatively to 50% 12-months after surgery. Similar to our observations, the improvement was less than that observed following primary surgery.

The strengths of this study are the availability of patient reported outcomes measured at 3-months post-operation in addition to objective function assessment with a performance test. Using an objective measurement allows us to ascertain that the lack of functional improvement beyond 3-months among the patients who underwent a revision surgery is not due to the inherent ceiling effect associated with using a score-bounded patient-reported outcome such as the WOMAC score [29–32]: the lack of long-term improvement was also observed when function was measured with the walking speed, an objective tool that may be less subject to ceiling-effect. Moreover, among patients undergoing primary surgery, the mean long-term improvement of objective function was significant but small compared to the short-term mean improvement (0.02 vs 0.15, Table 2), confirming that most of the functional changes, whether objectively or subjectively measured, occur before the 3-month post-operative time point.

This study is not without limitations. The findings were obtained on patients from a single-centre orthopaedic unit limiting their external validity. The modest sample size restricted our ability to adjust for factors known to be associated with post-operative outcomes such as gender, mental health and co-morbidities [26, 33, 34]. However, our findings were adjusted for age. A larger sample would nevertheless have been required to adjust for additional confounding factors, in particular type or indication for surgery. As all patients undergoing revision surgery and 93% of those undergoing primary surgery received a total hip replacement, our comparisons between revision and primary arthroplasty are more generalizable to patients undergoing total joint replacement. The remaining 7% (n = 6) of patients undergoing primary arthroplasty were listed for resurfacing surgery. While they exhibit comparable pre- and post-operative functional outcomes their pain at 12 months post-operation was worse than for those listed for primary total arthroplasty (Medians: 75 vs 100; p-values = 0.03). The group of patients undergoing revision surgery was modest in size (n = 43) but relatively homogeneous with 86% being revision of a primary total arthroplasty rather than after a previous revision. A larger revision group would have allowed the stratification of the analysis by indication for surgery. The post-operative outcomes following revision arthroplasty have been shown to be influenced by the indication for surgery [22, 35] and therefore our findings are more reflective of those revised for aseptic loosening (>67% of the revised participants). No information on the pre- and post-operative treatment received by the participants was available. They were offered standard care as provided at the treating centre. This comprised a pre-operative educational class focusing on preparation for surgery and the hospital stay, and post-operative outpatient physiotherapy on a needs basis. Finally, the inclusion of additional assessment points prior to 3-months would have allowed more detailed investigation of the very early recovery trajectories. We considered that additional assessment points would have represented an excess burden for participants with a probability of increased levels of attrition in the cohort.

## Conclusions

Patients undergoing revision hip arthroplasty should be informed that the expected improvement following such surgery will be less marked than that expected and experienced for primary surgery and the majority of their improvement will occur in the first 3 post-operative months.

More research is now required to identify whether specific in-patient and post-discharge rehabilitation tailored towards patients undergoing revision arthroplasty would improve or achieve equivalent outcomes to primary surgery and whether patients who are achieving limited improvements at 3-months post-operative would benefit from longer or more intensive rehabilitation. This will become all the more important with the increasing volume of revision surgery and the high expectations of patients who aspire to a disease-free and active life [36–38].



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