TITLE: Unrestricted Weight-Bearing after Hip Arthroplasty or Hip Fracture Surgery

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CONTEXT AND POLICY ISSUES:

Total Hip Arthroplasty:

Total hip arthroplasty (THA) generally involves replacing the ball-like head of the femur with a ceramic or metal prosthesis which articulates with a cup-like socket inserted into the pelvis. These components can be implanted with or without the use of bone cement. Since cement fixation can lead to osteolysis, a dissolution of bone, its use has declined in recent years and cementless techniques are now the preferred method. According to data captured by the Canadian Joint Replacement Registry, in fiscal year (FY) 2004-2005, the most common fixation method used for hip arthroplasty was cementless (62%) followed by hybrid (26%, cementless cup with cemented femoral component) and cemented (3%). Implants can loosen, wear out, dislocate or break and may require revision surgery with replacement of part or all of the implants. Because revision surgeries tend to be less successful and more dangerous than the primary surgery, they are undesirable. Canadian Joint Replacement Registry data for FY 2004-2005 indicated the most common causes for revision of hip arthroplasty as aseptic loosening (54%), osteolysis (28%), polyethylene wear (24%), and instability (16%) (more than one cause is possible). However, many surgeons feel that properly implanted prostheses of modern design and materials will last more than 20 years.

In Canada between FY 1994-1995 and 2004-2005, the number of hospitalizations for THA has increased from 16,525 to 25,124 while the average length of stay of primary and revision hip arthroplasty has decreased from 14 to 9 days. Protocols detailing activity and weight-bearing
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**Health Technology Inquiry Service (HTIS)**

(WB) restrictions as well as type and duration of exercise are widely used after THA, but they are generally based on clinical experience and orthopaedic preference rather than empirical evidence. The maximum amount of WB allowed is prescribed by the surgeon and is given in percentage body weight or in kilogram load. For example, full WB means the patient is allowed to place all of their body weight on the operated lower extremity while partial WB of 50% means no more than half of body weight should be transmitted to the operated lower extremity. WB restrictions can be influenced by the type of implant, quality of fixation, degree of bone integrity, presence of trochanteric osteotomy or femoral fracture, and the strength of periarticular soft tissue structures. When comparing 34 European and USA primary THA protocols published between 1991 and 2002, Viliani et al found the most variable aspect concerned walking and WB. Twenty protocols initiated walking on the first to third day after surgery while 14 protocols started on day 4-10. With respect to WB on cemented or hybrid THA, 11 of the 34 protocols initiated full WB on the first day after surgery, 11 protocols within 2-3 weeks after surgery, and in the remaining 12 protocols it was at the surgeon’s discretion. In regards to WB on cementless THA, one protocol initiated full WB on the first day after surgery, one protocol within the first week, and the remaining 32 within 6-12 weeks. The rationale for the cautious approach in cementless procedures is prevention of early migration of the femoral component and compromise of solid bone ingrowth, but compliance with WB restrictions has been questioned. Using a valid and reliable insole pressure system, Hurkmans et al demonstrated difficulty in complying with partial WB instructions of 10% and 50% WB in patients who underwent THA with a trochanteric osteotomy. For example, when measured at home two weeks after discharge, 69.2% of patients prescribed a target load of 10% body weight had a mean peak load above 20% body weight. Although only 6.2% of patients prescribed a target load of 50% body weight had a mean peak load above 60% body weight, an average of 17.4% of steps had a peak load greater than 60% body weight and loads up to 90-95% body weight were observed. Finally, advancements in surgical technique may further accelerate rehabilitation. Berger et al prospectively documented the outcomes of 100 primary cementless THAs using a minimally invasive technique in which no muscle or tendon was cut and the joint capsule incised but not removed. All patients underwent an accelerated rehabilitation protocol which included WB as tolerated on the day of surgery and no hip precaution emphasis. Some of the astonishing outcomes included all patients being safely discharged to home within 23 hours of surgery; a mean of 6 days to resume driving; a mean of 8 days to return to work; and a mean of 9 days to walk independently without an assistive device. In addition, as of three months after surgery, there were no hospital readmissions for any reason, no reoperations, no dislocations, no infections, and no evidence of subsidence or loosening of the femoral component. Although the patients were selected based on inclusion criteria, 62% of all patients operated on during the time of the study would have been eligible attesting to the potential widespread applicability of the procedure. In Canada during FY 2004-2005, the use of a minimally invasive surgical approach was reported in 12% of hip replacements.

**Hip Fractures:**

Hip fractures are fractures of the proximal end of the femur which can occur within the hip joint or just distal to it. The majority of hip fractures occur in the elderly with an average age of 80 years, and the usual cause is a simple fall reflecting the loss of skeletal strength from osteoporosis. Currently, the majority of hip fractures are treated surgically. The fracture is either internally fixated with an implant, such as the dynamic hip screw, or a hemiarthroplasty is performed. Hemiarthroplasty refers to replacement of the femoral head and is most often performed to repair displaced fractures of the femoral neck. Hip fracture patients will experience pain, disability and an excess mortality of 12-20% in the first year after fracture.
In Canada, hip fractures are frequent and costly. Using hospital discharge data and Statistics Canada’s population growth estimates, Papadimitropoulos et al.\textsuperscript{14} estimated an incidence of 23,375 proximal femoral fractures in Canadians aged 65 years or older in FY 1993-1994, and projected an incidence of 88,124 in 2041 as a consequence of growth in the elderly population and projected mean survival. Proximal femoral fractures accounted for a total of 465,000 acute care patient days in FY 1993-1994 and are projected to account for 1.8 million patient days in 2041. Using a prospective cohort study in Ontario, Canada, Wiktorowicz et al.\textsuperscript{13} estimated the average one year cost of hip fracture in patients aged 50 years or older as $26,527 CAN (95% confidence interval (CI): $24,564-$28,490). Costs included initial hospitalization, rehospitalization, rehabilitation, chronic care, home care, long-term care, and informal care. Despite their high incidence and cost, the literature regarding rehabilitation after proximal hip fracture surgery is characterized as heterogeneous with respect to content, timing, and setting.\textsuperscript{12}

Considering the rise in frequency of THA and proximal hip fractures expected with an aging population and the potential advantages of unrestricted WB, such as reduced stress on the upper extremities and non-operated lower extremity, reduction in energy expenditures while walking, increased muscular strength around the surgically treated hip,\textsuperscript{10} improved functional recovery and reduced bone mineral density loss,\textsuperscript{9} full WB may prove to be both therapeutic and cost-effective. This HTIS critically reviews the empirical evidence regarding the efficacy and safety of unrestricted WB after THA or hip fracture surgery.

**RESEARCH QUESTION:**

What is the clinical efficacy and safety of unrestricted WB after hip arthroplasty and hip fracture surgery?

**METHODS:**

A limited literature search was conducted on key health technology assessment resources, including PubMed, OVID Embase, OVID CINAHL, The Cochrane Library (Issue 2, 2007), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international HTA agencies, and a focused Internet search. Results include articles published between 2002 and the present, and are limited to English language publications only. Internet links are provided, where available.

**SUMMARY OF FINDINGS:**

No health technology assessments were identified.

**Systematic Reviews or Meta-analyses**

One Cochrane systematic review,\textsuperscript{12} published in 2007, evaluated the effects of different mobilization strategies implemented at any stage during rehabilitation after hip fracture surgery in adults. Within this systematic review there was only one randomized controlled trial (RCT) examining the issue of WB. The trial compared WB started at 2 weeks versus 12 weeks after surgery in 273 patients with a displaced intracapsular fracture undergoing closed reduction and internal fixation with a sliding nail plate. Those who initiated WB at 2 weeks did not have a higher mortality rate at one year (relative risk (RR)=0.74, 95%CI: 0.43, 1.29) or three years (RR=0.97, 95%CI: 0.58, 1.61) and did not have a higher failure of fixation rate at one year (RR=1.06, 95%CI: 0.56, 2.03) or three years (RR=0.96, 95%CI: 0.49, 1.89). Avascular necrosis was marginally less in the early WB group at 1 year (RR=0.28, 95%CI: 0.08, 0.99) but not at
three years (RR=0.69, 95%CI: 0.33,1.42). At one year, infections of the hip requiring further surgical treatment were reported in 2 of 141 early WB patients and 3 of 132 delayed WB patients (no statistical tests presented, reviewer estimates: RR=0.62, 95%CI: 0.11, 3.68). Finally, when examining all adverse outcomes simultaneously, the early WB group was not at elevated risk at one (RR=0.79, 95%CI: 0.56, 1.10) or three years (RR=0.96, 95%CI: 0.73, 1.25). Methodological limitations included lack of information regarding the randomization process, baseline characteristics of patients, content and comparability of post-surgical care programs, compliance and blinding of outcome assessors; inadequate follow-up of all patients (only 175 of 273 patients were included in the 3 year follow-up); and lack of intention to treat analysis. Most importantly, Handoll and Sherrington questioned the relevance of this dated study because the surgical technique is generally no longer used and the mobilization intervention is not consistent with the current recommended practice of mobilizing patients as soon as practical after surgery.

Guidelines

One guideline, released by the New Zealand Guidelines Group in 2003, was identified. It specifically addressed acute management and immediate rehabilitation after hip fracture amongst people aged 65 years and older. The guideline was based on a critical, systematic review of the grey and published medical literature by a multidisciplinary group and was supplemented, when necessary, by consensus opinion of experts. Based on expert opinion, it was recommended that patients be mobilized, WB as tolerated with assistance, as soon as possible on the first or second day after hip surgery.15

Randomized Controlled Trials

Four RCT7-10 were identified and are discussed in order of publication date starting with the most recent. Ström et al7 compared unrestricted WB plus intensive physiotherapy (n=17) with partial WB of 15 kilograms for three months plus basic unsupervised home exercises (n=19) in elective cementless THA patients (mean age 54.4 years and 53% female). According to the authors, a load of 15 kilograms on the operated lower extremity would equate, approximately, to the weight of the lower extremity. Intensive physiotherapy included a home exercise program, hydrotherapy, stationary cycling, and gym-based strength training with special emphasis on hip abduction and extension. After three months, the partial WB group were allowed unrestricted WB and the training was individually based for both groups. Outcomes, measured one week pre-operatively and up to 12 months post-operatively, included: leg loading in kilograms measured with sole sensors during walking; isometric hip abductor strength in kilograms measured with a dynamometer; the distance between the medial malleoli at full passive abduction as a measure of range of motion; and the Merle-d’ Aubigné clinical score which examines pain, walking ability, and range of motion. As expected, the unrestricted WB group demonstrated significantly greater mean loading of the operated leg relative to the partial WB group at 1 week (mean (sd), 39.0 (16.6) kg vs 25.8 (10.8) kg, p=0.009) and 3 months (70.0 (14.5) kg vs 31.7 (14.9) kg, p=0.001). At 6 and 12 months, no significant difference in leg loading existed between groups or between legs within groups. No significant between group differences were noted over time in strength testing, distance between medial malleoli, or clinical scores. With respect to adverse events, one patient in the unrestricted WB plus intense physiotherapy group (group status deciphered through Ström et al.6) died from pulmonary embolus at 15 days after surgery. Limitations included small sample size; lack of information regarding inclusion/exclusion criteria, blinded outcome measures, compliance and intention to treat analysis; the relatively short duration of follow-up; and the inability to disentangle the impact of WB and exercise.
In a related publication, Ström et al. examined the impact of unrestricted WB plus intensive physiotherapy on the early migration pattern of cementless femoral components in THA. The intervention has been previously described and includes at least some of the participants in Ström et al. Briefly, 29 patients, younger than 65 years of age, were randomly assigned to unrestricted WB plus intensive physiotherapy (n=16) or three months of restricted WB plus basic unsupervised home exercises (n=13). Exclusion criteria included patient weight greater than 100 kilograms, concomitant disease of the musculoskeletal system, or any history of drug abuse. The primary outcome was translations and rotations of the femoral component in three different planes as measured with radiostereometry analysis (RSA) one hour (baseline measure), 1 day, 1 week, and 1, 3 and 12 months after surgery. The groups did not substantially differ in translations or rotations in any of the three planes at any of the time periods. There also appeared to be no statistically significant differences between groups over time except for anteroposterior translation at three months (mean (sd), 0.13 (0.38) mm vs –0.09 (0.12) mm, p<0.05) which was considered minor and no longer significant at one year (0.04 (0.45) mm vs –0.03 (0.16) mm, p>0.05). The unrestricted WB plus intensive physiotherapy group demonstrated a statistically significant degree of subsidence, sinking of the femoral component, (mean change score (sd)= -1.01 (1.61) mm, p=0.04) and retroversion (1.79 (3.22) degrees, p=0.02) at 1 year relative to baseline. One femoral implant in the unrestricted WB plus intensive physiotherapy group subsided continuously over time and required revision surgery 1.5 years after the original THA. Adverse events included one patient in the unrestricted WB plus intensive physiotherapy group dying from a pulmonary embolus 15 days after surgery. Despite the lack of substantial, statistically significant differences between groups, the authors expressed concerns. First, the unrestricted WB plus intense physiotherapy group had femoral components which tended to subside and retrovert slightly more than the partial WB plus home therapy group; second, the mean subsidence at one year in the unrestricted WB plus intense physiotherapy group reached values previously shown to predict early or midterm revision; and last, there was loosening of one femoral component, which required revision, in the unrestricted WB plus intense physiotherapy group. Limitations were as per Ström et al. except that outcome measures were blinded. In addition, discrepancies were noted between text and table estimates.

Bodén and Adolphson also examined the impact of unrestricted WB on hydroxyapatite-coated cementless THA in patients younger than 65 years of age suffering unilateral primary arthrosis. Patients were randomly assigned to unrestricted WB (n=12) or protected WB for three months (n=11). The unrestricted WB group received auditory feedback, through a soul sensor, which encouraged WB during their inpatient stay. These patients also had a home exercise program which instructed them to carry full weight on the operated lower extremity for 6 seconds with support for balance only and to walk with one crutch or without external support when possible. The protected WB group received auditory feedback to discourage WB greater than 10% of body weight and were encouraged to use the soul sensor device in addition to two crutches when walking for three months after surgery. They were also given a home exercise program. Outcomes, measured up to two years after surgery, included clinical assessment with the Harris hip score which ranges from 0 (worse) to 100 (best) and measures pain, function, hip range of motion and leg-length differences; radiographs for the evaluation of implant migration and femoral remodelling; and dual-energy x-ray absorptiometry for the evaluation of bone mineral density. Inclusion criteria were good general health, good bone quality, and no previous hormonal therapy, other medication or illness known to affect bone metabolism. Median Harris hip scores did not significantly differ between groups at 2 years (medians, unrestricted 98 vs protected 99, p=0.7). No femoral component migrated more than 2 millimeters (subsidence≥5 mm) and radiographic signs of bone remodelling were similar across both groups at 2 years. In 3 out of 7 zones around the femoral implant, the median percentage decline in bone mineral density in the operated lower extremity relative to contra-lateral lower extremity was statistically
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significantly greater in the protected WB group at 3 months. At two years, a statistically significant difference remained in 1 out of 7 zones (median percentage decline, -12.5% vs -27.5% estimated from figure 4 in article, p<0.05). The authors concluded that there were no adverse effects of immediate unrestricted WB and a positive effect on bone mineral density. Limitations included small sample size; incomplete information regarding the blinding of outcome measures, compliance, and home exercise program content; and short duration of follow-up.

Finally, Unver et al.\(^\text{10}\) randomly assigned 51 patients with hip joint osteoarthritis to immediate full WB (n=24) and partial WB for 6 weeks (n=27) after cementless primary THA using the thrust plate prosthesis, a femoral prosthesis implanted within the metaphysis of the proximal femur and secured to the lateral cortex of the femur with a plate and two screws. According to biomechanical experiments, this prosthesis produces a force transfer which mimics the non-prosthetic state better than conventional femoral components. Inclusion criteria included patients younger than 65 years who failed to respond to conservative therapy and were experiencing severe pain and limitation of hip movements restricting daily activities. Exclusion criteria included arthritis in other joints requiring treatment, neurological or medical conditions impeding ambulation, or revision hip prosthesis. Although both groups received an accelerated rehabilitation program it varied by group with certain exercises initiated earlier in the full WB group. Primary outcomes, measured pre-operatively and up to 1 year after surgery, included the Harris hip score as a measure of function; manual strength testing of the hip musculature (gluteus maximus and medius); hip range of motion measured with a goniometer; the six minute walk test as a measure of functional capacity; and radiographs to assess stability. The full WB group could transfer from bed to chair/toilet significantly earlier (mean (sd), 4.5 (1.5) days vs 6.3 (2.1) days, p=0.04), had a significantly shorter length of stay (11.6 (2.7) days vs 15.2 (3.5) days, p=0.001), and could walk significantly farther as of discharge (290.0 (145.2) metres vs 164.1 (134.8) metres, p=0.001). Three months after surgery no statistically significant differences existed in hip range of motion, but the full WB group demonstrated significantly stronger gluteus medius (mean (sd) manual muscle grade, 4.1 (0.5) vs 3.6 (0.7), p=0.002) and maximus (4.3 (0.7) vs 3.9 (0.6), p=0.004), significantly longer six minute walk scores (215.8 (52.5) metres vs 182.5 (58.2) metres, p=0.023), significantly shorter duration of crutch use (7.2 (1.2) weeks vs 12.0 (1.5) weeks, p=0.000), and significantly greater Harris hip score (89.3 (4.6) vs 81.4 (9.3), p=0.000). Furthermore, none of the patients showed signs of clinical or radiographic loosening at three months or 1 year and Harris hip score did not significantly differ between groups at 1 year. Limitations included small sample size; lack of information regarding allocation concealment, the meaning of partial WB and compliance; short duration of follow-up; the inability to disentangle the impact of WB and exercise; and it is unclear whether those patients who had both hips replaced contributed twice as much data violating the statistical assumption of independence of observations (3 patients in the partial WB group and 6 patients in the full WB group had both hips operated on).

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

THA and hip fracture surgery are frequently performed in Canada and their frequency is expected to rise as a consequence of growth in the elderly population and projected mean survival.\(^\text{3,14}\) Unfortunately, there is a lack of standard, evidence-based, post-surgical mobilization protocols, particularly with respect to the timing and extent of WB after surgery.\(^\text{6,12}\) Four small RCT\(^\text{7-10}\) have presented preliminary evidence to suggest that unrestricted WB after cementless THA in relatively younger, healthier, select patient groups may not increase the occurrence of adverse outcomes and may actually facilitate functional recovery. Nonetheless, caution is required. All of these RCT were small, followed patients for a relatively short period of time, and confounded the effect of WB by varying exercise programs across groups. Additional
methodological limitations included lack of information regarding inclusion/exclusion criteria, allocation concealment, blinding of outcome measures, intention to treat analysis, and compliance. Furthermore, although not statistically significant, Ström et al. expressed concern regarding the greater mean subsidence and retroversion and the loosening of one femoral component in the unrestricted WB plus intense physiotherapy group. With respect to unrestricted WB after hip fracture surgery, no recent, relevant RCT was identified, but expert consensus recommends that patients be mobilized, WB as tolerated with assistance, as soon as possible on the first or second day after hip surgery. Larger, well conducted RCT with longer periods of follow-up, well described interventions (not confounded by other factors), and standard comprehensive reliable and valid outcome measures are required to definitively determine the efficacy and safety of unrestricted WB in THA and hip fracture surgery patients. Although hip range of motion and strength, and longer term outcomes such as clinical scores, bone mineral density, and implant stability are important, Unver et al. demonstrated statistically significant short-term functional (transferring and walking) and length of stay differences. Such outcomes capture early functional and cost-effectiveness outcomes important to patients and healthcare funders, respectively, and should be considered in future studies.

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