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**Osteoarthritis Year in Review: Rehabilitation and Outcomes**

Aileen M. Davis, PhD

Division of Health Care and Outcomes Research, Toronto Western Research Institute,
University Health Network and Department of Rehabilitation Science
and Institute of Health Policy, Management and Evaluation,
University of Toronto, Toronto, Canada

Corresponding Author:
Aileen M. Davis, PhD
MP-11, Room 322
Toronto Western Research Institute
399 Bathurst Street
Toronto, ON Canada M5T 2S8
Email: adavis@uhnresearch.ca
Telephone: 416-603-5543
Fax: 416-603-6822
Abstract

Purpose:
This review highlights seminal publications of rehabilitation interventions and outcomes in osteoarthritis (OA) of the hip or knee.

Methods:
Medline, CINAHL, and Embase databases from September 2010 through August 2011 were searched using the key words ‘osteoarthritis’, rehabilitation, physical therapy, exercise, and outcome(s), limited to human and English. Rehabilitation intervention studies were included if they were randomized trials (RCT), systematic reviews or meta-analyses. Studies of surgical interventions were excluded unless they included evaluation of a rehabilitation intervention. Outcome studies were included if they contributed methodologically to advancing outcome measurement. Reviews of measurement properties of outcomes were excluded. Eight publications were selected and reviewed that relate to interventions evaluating manual therapy in hip or knee OA, tele-rehabilitation and performance and participation measures as outcomes.

Results:

Interventions: One systematic review of hip and knee OA, one meta-analysis of knee OA provide limited support for the benefit of manual therapy with exercise for improving pain and function to a lesser extent in the short term (three months). Study quality overall was low.

One high quality RCT in knee replacement of usual outpatient physiotherapy versus internet-based tele-rehabilitation based on a non-inferiority analysis demonstrated comparable outcomes on WOMAC pain and function and performance measures.

Outcomes: Three studies demonstrated that observed performance measures such as timed walk tests and stair-climbing and timed-up-and-go measure concepts differ from self-report of
difficulty with physical function. Additionally, two studies showed differential times of recovery following TKR.

Two studies evaluated participation. One demonstrated the conceptual distinction of activity limitations and participation and a second re-analyzed trial data from knee OA studies. In one study, there were larger effects in combined activity/participation than for activity alone for arthroscopic lavage compared to intraarticular steroid and, in a second study, the effect was larger for activity with an advanced pharmacy intervention whereas the physiotherapy intervention demonstrated a larger effect for activity/participation.

**Conclusions:** Interventions of manual therapy for hip and knee OA provided limited evidence of effectiveness. These studies are of limited quality due to lack of blinding and disclosure of co-intervention. Tele-rehabilitation may be a viable option to improve access to rehabilitation post joint replacement for those in rural and remote areas.

Data continue to support the need to include performance measures as well as patient-reported outcomes in evaluating outcomes in OA. Additionally, measures of participation should be considered as core outcomes.

**Key words:** osteoarthritis, hip, knee, interventions, outcome, review
Introduction

Rehabilitation has been defined as “an active process by which those disabled by injury or disease… realize their optimal physical, mental and social potential…”\(^1\). Rehabilitation is a complex process that includes a combination of treatment interventions such as temperature and light-based modalities, tissue manipulation, exercise, education, etc. It is an essential component of management of osteoarthritis (OA) for improving symptoms and maximizing function and life participation and, despite the challenge in defining the intervention, there is an ongoing need to evaluate effectiveness and efficacy of rehabilitation interventions. This evaluation also requires that the outcomes are conceptually appropriate, efficient and responsive. This review highlights seminal publications of rehabilitation interventions and outcomes in OA of the hip or knee since the 2010 meeting of the Osteoarthritis Research Society International, OARSI.

Methods

A literature search of peer-reviewed articles was conducted from September 2010 to August 2011 in Medline, CINAHL and Embase using the search terms osteoarthritis, rehabilitation, exercise, therapy, outcome, limited to English and human. The titles and abstracts of the identified 464 citations were reviewed to identify those related to rehabilitation interventions and outcomes. Intervention studies were included that related to hip and knee OA including meta-analyses and systematic reviews. Outcome studies were included if they advanced the concepts of outcome being measured. Studies were excluded if they reported outcomes following surgical intervention without comparison of rehabilitation interventions; were cohort studies of predictors of outcome; or, were reviews of the measurement properties of outcome measures. The full paper was reviewed when a decision could not be made related to
exclusion based on the abstract. Although 35 of the intervention studies included exercise, given the large body of literature spanning a number of years demonstrating the benefits of exercise and physical activity in managing OA, the literature from the past year that continues to reinforce these findings were not reviewed for this paper. Eight articles were ultimately selected for this review that the author considered had potential impact for management and future research in rehabilitation and outcomes related to OA. The articles forming this review are grouped thematically: Interventions including manual therapy and technology; and, Outcome including performance measures and participation and are summarized in Table 1.

Results

Rehabilitation Interventions

Manual Therapy

One meta-analysis and a systematic review of manual therapy in the treatment of hip and knee OA were identified.

Manual therapy includes specific hands-on techniques such as, although not limited to, manipulation and mobilization. Manipulation and mobilization are defined as a ‘continuum’ of skilled passive movements to joints and/or related soft tissues that are applied at varying speeds and amplitudes, that may include a small-amplitude/high velocity therapeutic movement (manipulation) with the intent to restore optimal motion, function, and/or to reduce pain.

In knee OA, Jansen et al, evaluated 1) the effect of strength training alone, exercise therapy alone (strength, ROM and aerobic) and exercise with mobilization on pain and function; and, 2) the effect of the interventions relative to each other. From January 1990 to December
2008, the authors identified 12 intervention versus control trials. The individual studies used variable definitions of knee OA including the American College of Rheumatology criteria, radiographic evidence of OA, and pain and stiffness in those aged greater than 55 years referred by a primary care physician. In five studies manual therapy was compared to a no intervention control, in six to an education control and one study included comparison with therapeutic ultrasound. No studies directly compared strength training or exercise alone versus manual therapy and exercise. The outcomes were pain and function based on self-report, most often using the Western Ontario McMaster Universities’ (WOMAC) Osteoarthritis questionnaire, evaluated up to three months post treatment. Mixed effects meta-regression methods were used for analysis with pooling by intervention type. For pain, the overall effect size was 0.38 (95% CI: 0.22 to 0.54) for strengthening, 0.34 (95% CI: 0.19 to 0.49) for exercise alone and 0.69 (95% CI: 0.41 to 0.97) for exercise and manual therapy. For function, the overall effect size was 0.37 (95% CI: 0.15 to 0.59) for strengthening, 0.25 (95% CI: 0.04 to 0.46) for exercise alone and 0.39 (95% CI: 0.01 to 0.77) for exercise and manual therapy. These results suggest that exercise and manual therapy may have a larger effect in relieving pain as compared to strengthening or exercise alone in the short-term. However, it should be noted that there is overlap of the confidence intervals. The effect size for strengthening alone and exercise and manual therapy on function is more similar and the confidence interval for the effect size of exercise and manual therapy is very wide.

This study must be interpreted cautiously as the interventions could not be compared directly. Additionally, the individual studies had small sample sizes, limited length of follow-up and were of limited quality. Only one used a blinded assessor, co-intervention was only reported in two and only five used an intention-to-treat analysis.
French et al\textsuperscript{4} conducted a systematic review of hip (1 study)\textsuperscript{5} and knee OA (3 studies)\textsuperscript{6-8} in which manual therapy alone was compared to various interventions. Studies from January 1996 to October 2009 were included if the study was a randomized trial including participants with a clinical or radiographic diagnosis of hip or knee OA; the intervention included manual therapy alone compared to a no intervention or alternate intervention control; and, the outcomes were pain and function. Due to heterogeneity, the studies could not be combined and the results of each individual study were reported. It should be noted that these studies were unique from those included in Jansen et al described above\textsuperscript{3}.

For the hip OA study\textsuperscript{5}, patients were randomized to nine treatments of manual therapy (muscle stretching, traction and high velocity thrust manipulation) over five weeks (n=53) or an exercise program of stretching, strengthening, joint mobility, pain relief and walking plus a home program (n=50). The results at 29 week follow-up favoured those treated with manual therapy based on VAS rest pain (ES=0.48; 95\% CI: 0.08, 0.87), VAS walking pain (ES=0.48; 95\% CI: 0.09, 0.87), Harris Hip Score (ES=0.85; 95\% CI: 0.45, 1.25), and the 80 metre walk test (ES=0.40; 95\% CI: 0.01, 0.79). There were no group differences for the SF-36 bodily pain, function or role-physical subscales. This overall was a well-conducted study with group comparability at baseline, blinding of assessments, avoidance of co-intervention and intention-to-treat analysis.

The three knee OA studies had short-term follow-up (< 16 weeks). Tucker et al\textsuperscript{6}, randomized people to eight treatments of manual therapy (low-amplitude, high velocity thrust in direction of motion restrictions) over three weeks (n=30) or Meloxicam, one 7.5 mg tablet per day for three weeks (n=30). There were no group differences for pain as measured by a numeric pain rating scale or VAS or for function as measured by the Patient Specific Functional Scale (all
ES ≤ 0.20 with 95% CI including zero). This study had several methodological limitations in that there was no blinding, there were baseline group differences, it was unclear if co-intervention occurred and there was no intention-to-treat analysis. Perlman et al evaluated an eight week intervention of a full body Swedish massage therapy protocol (one hour twice per week in weeks one to four and then a once weekly session) (n=34) versus eight weeks of usual care (pain medication, exercise, hot/cold therapy) (n=34)\(^7\). The massage group had significantly improved pain and function as compared to the usual care group as measured by pain VAS (ES=0.86; 95% CI: 0.37, 1.36), WOMAC pain (ES=0.94; 95% CI: 0.44, 1.44), WOMAC-PF (ES=0.60; 95% CI: 0.11, 1.08), and 50 foot walk test (ES=0.62; 95% CI: 0.14, 1.11). While baseline characteristics of the two groups were similar and intention-to-treat analysis was used, there was no blinding and it is unclear if co-intervention occurred. In a final study, Pollard et al randomized people to six treatments over two weeks of manual therapy consisting of myofascial mobilization and manipulation (n=26) versus sham treatment of palmer contact and placebo interferential current of the same dose (n=26)\(^8\). There was no difference in pain (VAS pain ES=0.58; 95% CI:-0.04, 1.20) although the manual therapy group had significantly improved function (VAS function ES=0.81; 95% CI: 017, 1.43). The methodological quality of this study is questionable as it is unclear if blinding occurred, baseline characteristics were similar, or if there was co-intervention.

In summary, the data from this review indicates that there may be some benefit in terms of pain and function in the short term from manual therapy but the small sample size and methodological quality of the individual studies and heterogeneity limiting meta-analysis approaches, compromise interpretation of the results. There is ongoing requirement for larger, methodologically sound studies of manual therapy with longer follow-up.
Technology: Tele-rehabilitation

Access to rehabilitation professionals is limited for a variety of reasons including too few practicing professionals per population, cost of service and geographic factors where individuals living in rural or remote communities must travel long distances for care\textsuperscript{9,10}. Hence, alternative methods of care delivery using technology are attractive and may have potential to increase and ease access to care. Telemedicine has generally been used to promote access to specialist care and has been shown to be feasible and acceptable to patients\textsuperscript{11-13}. Russell and colleagues extend the use and evaluation of technology in the context of a rehabilitation intervention for people who had total knee arthroplasty\textsuperscript{14}.

This study was a single blinded, randomized controlled non-inferiority trial that sought to demonstrate that the outcomes achieved through rehabilitation delivered via the internet (intervention group) were equivalent to those of the usual standard of care of face-to-face outpatient physical therapy (control group). Participants were recruited in the post-operative period while still inpatients after unicompartmental or unilateral total knee replacement if they were greater than 18 years of age and spoke English. Exclusion criteria included inability to walk with the use of a walking aid, medical comorbidity that would impact rehabilitation and unwillingness to refrain from additional therapy for the study duration. Randomization was conducted in blocks to either the intervention or control group with stratification to one of two intervention physical therapists.

Rehabilitation for both groups included a standardized inpatient rehabilitation programme followed by a six-week programme post discharge, consisting of a single 45 minute treatment session per week that commenced approximately one week after hospital discharge. Treatment focused on development and review of a home-exercise programme that participants were to
complete twice a day at home and was based on a standardized clinical pathway protocol that provided a week-by-week guide on relevant assessment, treatment and goal setting. Content included range of motion, strengthening, mobility, management of oedema, education and home exercises and the therapist chose techniques and exercises most relevant to the patient to address these issues. Rehabilitation for the control group was delivered within the outpatient physiotherapy department. The tele-rehabilitation group received care through real-time interaction with a physical therapist over low bandwidth videoconferencing via dial-up internet connection. For the study, therapists and participants were located in separate remote locations of the hospital with the patients in a setting that resembled a home environment containing typical household items such as chairs, towels, and a tape measure. Under the guidance of the remote physical therapist, patients used self-applied techniques and received an exercise programme and education.

Outcome data were collected prior to and at six weeks following rehabilitation by an individual blinded to treatment allocation. The authors evaluated the equivalency of the treatment arms over the six weeks using the following measures: global WOMAC score (primary outcome), Patient-specific Functional Scale, the Spitzer Quality-of-Life Uniscale, the timed-up-and-go (TUG) test, and pain intensity rated on a visual analogue scale (VAS). Active and passive knee flexion and extension, quadriceps muscle strength, girth at the knee and gait using the Gait Assessment Rating Scale were recorded. Additionally, participants completed a daily exercise log. The intervention group also completed a questionnaire relating to their satisfaction with the experience of and perception of the tele-rehabilitation sessions. Sample size calculations based on non-inferiority with alpha=0.05 and 80% power required 27 participants per group.
Of the 65 participants, 34 were randomized to the control and 31 to the intervention group and there was one drop-out from each group who did not have follow-up data, leaving 33 and 30 analyzable participants respectively. The groups were comparable at baseline with the exception that the intervention group had on average seven degrees less active knee flexion (p=0.04) and they had on average two cm greater limb girth measured at the knee (p=0.02). Overall, both groups demonstrated significant improvements in all outcomes between baseline and six weeks follow-up. Equivalency of the two treatments was demonstrated for the primary outcome, WOMAC global, with the tele-rehabilitation group improving slightly more than the control group. There also were overlapping 95% confidence intervals and non-significant differences for the secondary outcomes with the exception of the Patient-specific Functional Scale and the WOMAC stiffness subscale with the difference in favour of the tele-rehabilitation group. Additionally, there were no significant differences in compliance with the home exercise programme between groups and the tele-rehabilitation group reported high levels of satisfaction.

In summary, this high quality trial demonstrated that, in the face of standardized clinical care pathways, outpatient rehabilitation and internet-based rehabilitation achieved similar good outcomes at six weeks post surgery for people having total knee replacement. The major limitation of this study was that the tele-rehabilitation intervention was administered within a simulated home environment within the hospital setting. Hence, the group did not have the option of turning off the device and the internet connection was easily monitored. This may not represent real-world application for those living in rural and remote communities. However, the study does support the potential for using technology for providing rehabilitation where access is limited. Additional trials are required to support these findings, including longer-term follow-up and cost-effectiveness studies.
Outcome

*Performance measures*

Performance measures are observed, often timed, distance or count-producing tasks performed under standardized conditions. Timed walk tests, stair climb or the timed-up-and-go (TUG) are often used in people with mobility problems. Three studies have been published in the past year that support the use of performance measures in addition to patient-reported outcomes for people with hip and knee OA.

In a study of 93 people with hip OA, Wright et al evaluated the convergent validity of the physical function subscale of the WOMAC (WOMAC-PF) and a battery of five performance measures (TUG, 40 meter self-paced walk test, 30 second chair stand, 20 cm step test and the Sock test). After using confirmatory factor analysis to support the unidimensional nature of the WOMAC-PF, exploratory factor analysis confirmed that the performance measures loaded on first factor which explained 42% of variance, and the WOMAC-PF on the second factor explaining 26% of variance. The Sock test did not load on either factor with factor loadings of 0.19 and 0.17 respectively. The factor loadings for the TUG, 40 meter self-paced walk test, 30 second chair stand and 20 cm step test were 0.94, 0.93, -0.67 and -0.66 respectively and the WOMAC-PF loading was 0.84 (Note: negative signs indicate opposing scale orientation of the measure.) These results support performance measures and self-reported physical function as measured by the WOMAC-PF as two constructs.

Stratford and colleagues conducted a secondary analysis of outcomes of a cohort with primary total hip or knee replacement for OA (n=85, 45 of whom had TKR) to evaluate the systematic magnitude of the differences in patient-reported outcomes, specifically the Lower
Extremity Functional Scale (LEFS) that quantifies perceived difficulty with a various activities and the WOMAC-PF, compared to performance measures, the Six-minute Walk Test and the TUG\textsuperscript{16}. Outcome data were collected prior to surgery and between nine and 13 weeks post-surgery. Using regression analyses with a robust error term for clustered data, the authors tested the following alternative hypotheses: 1) the relationship between the self-report and performance measures would be the same pre and post-surgery; 2) there would be a consistent but different relationship based on time; or, 3) the relationships would be inconsistent. There were statistically significant differences from pre- to post arthroplasty for the LEFS and WOMAC-PF. However, there were no significant differences in the Six-minute Walk Test or the TUG with the 95% confidence of the mean difference including zero for the total group and for the subsets by hip and knee. Regression analyses supported the second hypothesis, that is, that there were significant but consistent differences based on time with the self-report measures overestimating performance, irrespective of the measure. Overestimation was greater in those with hip arthroplasty compared to knee arthroplasty, 13 and 11 points for the LEFS and 19 ad 12 points for WOMAC-PF.

In a third retrospective study of 39 patients with TKR, Stevens-Lapsley et al compared self-report using the Knee injury Osteoarthritis Outcome Score (KOOS) and performance measure (TUG, Six-minute Walk Test and Stair Climb Test) outcome findings, specifically change pre- and post-surgery. Measures were taken within two weeks of surgery and one, three and six months following TKR. By one-month post surgery, the pain, activities of daily living and quality of life subscales of the KOOS improved significantly and there was a trend towards significant improvement in the symptom subscale. By three and six months post surgery, all five subscales (including the sports and recreational subscale) had improved significantly from pre-
surgery values. In contrast, all of the performance measures had statistically significant declines at one-month post surgery with statistically significant, although clinically insignificant, improvement by three and six months post TKR. By six months post surgery, the Six-minute Walk Test improved on average by 43 meters, the TUG by 1.3 seconds and the Stair Climb Test by 3.6 seconds. Additionally, the correlations between the change scores of the KOOS activities of daily living subscale and the 6 minute walk test were not statistically significant at any time intervals.

In summary, the data from these three studies support that performance measures represent different components of ‘function’ for people with hip and knee and that there is a difference in perception of what people perceive they can do and what they actually do. As such, the interpretation of improvement following hip or knee replacement varies by use of self-report measures as compared to performance measures. These results need to be interpreted with the recognition that each of these studies is retrospective and that the data originally were collected in the context of another study question. However, these studies indicate that the use of both self-report and performance measures inform patient outcome.

**Participation**

Participation has been defined by the World Health Organization as involvement in a life situation\(^1\) and includes interactions in leisure, education, employment and other social roles. In the past year, two papers have demonstrated the impact of OA on participation.

In a study by Pollard et al, 413 people on average one month prior to hip or knee replacement completed self-report measures of impairment (symptoms), activity (limitations in mobility and activities of daily living) and participation\(^17\). Using confirmatory factor analysis, a well-fitting three-factor model supporting the constructs of impairment, activity limitation, and
participation restrictions was achieved. The three factors were correlated: impairment and activity and activity and participation each $r=0.76$ and impairment with participation $r=0.58$. Structural equation modeling was then conducted to evaluate the structural relationship of the a priori defined paths among impairment, activity and participation. The pathway standardized coefficients demonstrated significant pathways between impairment and activity and between activity and participation suggesting that the impact of impairment on participation is fully mediated through activity.

In a second study, Ayis and colleagues re-analyzed data from three trials (two knee OA which are described here and one back pain with sciatica which is not described) to determine if outcome measures that assessed activity and participation individually were more sensitive to change than those that combined activity and participation. Based on prior classification work, the WOMAC and Short-form 36 items were reclassified as purely activity, purely participation or a combination of activity and participation and summative scores for each were created.

One study of 150 people with knee OA compared the effect of arthroscopic lavage with intraarticular corticosteroid. The original results demonstrated that both groups had improved WOMAC pain and function at two and four weeks post treatment with no significant difference between the treatment arms. At 12 and 26 weeks, the benefit of lavage was maintained whereas the intraarticular steroid benefit decreased resulting in a statistically significant benefit for the lavage group. In re-analyzing the data, the effect of irrigation was greater for the combined activity/participation items than for the activity only items. The effect sizes at two, four, 12 and 26 weeks were 0.08, 0.16, 0.38, and 0.51 and 0.01, 0.04, 0.32 and 0.38 for the lavage and
intraarticular steroid groups respectively, indicating that irrigation may have had greater impact on the participation component.

The second knee OA trial included 325 people from primary care practices who were randomized to control (telephone advice), physiotherapy or an enhanced pharmacy intervention (review)\textsuperscript{21}. The original study results demonstrated significant improvements in WOMAC pain at three months for the pharmacy and physiotherapy groups with no group differences at six or 12 months. WOMAC-PF was significantly improved in the physiotherapy group at three months with small but non-significant improvement in the pharmacy group. On re-analysis of the data, there was a positive effect for the pharmacy group at three months with a larger effect on activity (ES=0.20) than for the combined activity/participation items (ES=0.16). In contrast, the effect for physiotherapy was larger for the activity/participation items (ES=0.45) than for activity (ES=0.34). The pharmacy effect decreased after three months whereas the physiotherapy effect on activity/participation, although decreased, was maintained at six and 12 months (ES of 0.18 and 0.19 respectively).

In summary, these two papers highlight that participation and activity limitations are distinct constructs that is differentially impacted depending on the treatment in people with knee OA. Use of outcomes that capture participation in further studies will be informative in understanding the impact of OA and treatment interventions.

Summary and Conclusion

Key publications for the past year related to rehabilitation interventions address manual therapy and tele-rehabilitation. There is an ongoing need for large, high quality randomized trials to evaluate the effectiveness of manual therapy for hip and knee OA. The studies to date have
had small sample sizes with limited control for confounding and bias. Additionally, their heterogeneous nature has limited evaluation through meta-analysis.

Inclusion of performance measures and evaluation of participation in conjunction with currently used self-report questionnaires may be informative as researchers and clinicians seek to understand the impact of OA and response to interventions.

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Davis: literature review, interpretation and drafting of manuscript

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References


