Evidence-Based Practice Group Answers to Clinical Questions

"Continuous Passive Motion Devices as Rehabilitation for Spinal Cord Injuries"

A Rapid Systematic Review

By

WorkSafeBC Evidence-Based Practice Group

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Clinical Services – Worker and Employer Services

About this report

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About the Evidence-Based Practice Group

The Evidence-Based Practice Group was established to address the many medical and policy issues that WorkSafeBC officers deal with on a regular basis. Members apply established techniques of critical appraisal and evidence-based review of topics solicited from both WorkSafeBC staff and other interested parties such as surgeons, medical specialists, and rehabilitation providers.

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Background and Objective

Artromot® is a continuous passive motion device (Figure 1 and 2), developed by Ormed GmbH & Co. (www.ormed-djo.de). The device is promoted as a mean to prevent post-surgical joint stiffness, improve healing of joint cartilage, tendons, ligaments and soft tissue, and for reducing oedema and pain as well as reducing length of hospital stay and overall duration of treatment (http://www.ormedortho.com/artromot.htm). At present, there are five different types of Artromot® models available on the market, each addressing a specific anatomical joint: the Artromot® S3 for shoulder joint, the Artromot® K2 and K3/K4 for hip and knee joints, the Artromot® E for elbow and the Artromot® SP2 2M for ankle joint (http://www.ormed.djoglobal.eu/).

Figure 1. Artromot® knee

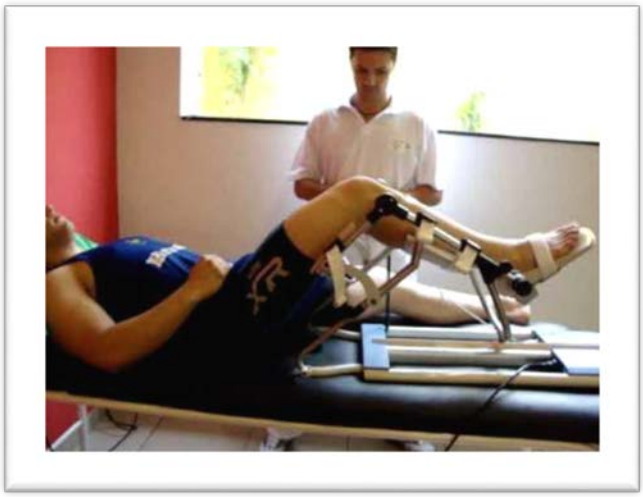

Figure 2. Artromot® knee in action

Passive motion (movements) is widely utilised for the treatment and prevention of contractures in people with a variety of conditions including spinal cord injury, dementia, as well as for those with serious injuries and medical problems associated with unconsciousness[13]. It is often provided on an ongoing daily basis to people with chronic disabilities and it has been part of routine care for people with or at risk of contractures for at least 60 years. In this intervention an individual's joints are cyclically moved through their available range of motion by another person, typically a therapist or a care giver. The primary goal is to maintain or increase joint mobility by influencing the extensibility of soft tissues overlying joints. These movements are also intended to decrease secondary complications associated with cartilage degeneration. Typically, passive motion is administered for a few minutes to the joints of patients who cannot self-mobilize because of paralysis, pain or limited consciousness. To date, there is no consensus regarding the speed at which passive motion should be administered and it is still not clear how this intervention is effective[25].

Continuous passive motion (CPM) as a practice/treatment method was first introduced by Salter et al. in the 1960s as a way of providing regular movement to the knee using an external motorised device that passively moves the joint through a pre-set arc of motion[13]. At present, the indications for CPM include: total joint arthroplasty, articular cartilage defect, ligamentous reconstruction, osteoarthritis, release of contracture, intra-articular fracture and reflex sympathetic dystrophy. Although controversial, CPM has been used by many surgeons as part of the standard post-operative management of patients post-total knee arthroplasty. It is believed that CPM stimulates venous and lymphatic flow and maintains the range of the motion of the joint[15].

In this systematic review, we investigated the efficacy and/or effectiveness of the Artromot® as a rehabilitation tool for spinal cord injury patients. We then expanded this objective by looking into high-level, high-quality evidence on the efficacy and/or effectiveness of continuous passive motion devices in general.

Methods

- A comprehensive, systematic literature search was conducted on February 7, 2019.
- The literature search was done in two stages:
    - The first stage of the literature search was done on commercial medical literature databases, including Cochrane Database of Systematic Reviews® (2005 to February 6, 2019), ACP Journal Club® (1991 to January 2019), UK York University Database of Abstracts of Reviews of Effects® (1st Quarter 2016), Cochrane Clinical Answers® (January 2019), Cochrane Central Register of Controlled Trials® (December 2018), UK NHS Health Technology Assessment® (4th Quarter 2016), UK NHS Economic Evaluation Database® (1st Quarter 2016), BIOSIS Previews® (1969 to 2008), Embase® (1974 to 2019 February 06), Medline Epub Ahead of Print®, Medline In-Process & Other Non-Indexed Citations®, Medline Daily Update® and Medline® (1946 to February 06, 2019), which are available through the Ovid® platform.

    This first stage search was conducted by employing the keyword "artromot".
    - The second stage of the literature search aimed to identify high-level, high-quality studies investigating the efficacy and/or effectiveness of continuous passive motion devices in treating different disease/conditions.

    This second stage search was limited to evidence available in the Cochrane Database of Systematic Reviews® (February 6, 2019) via the Ovid® platform. The search was done by employing combination keywords of (continuous **ADJ** passive **ADJ** motion)
- A search via the Microsoft Bing® search engine was also conducted, prior to the literature search, in order to gain more information on Artromot®. This internet search identified several websites with more information on this product (see Background and Objectives).
- No limitations, such as on the date, language and country of publication, were employed in any of these searches.
- A manual search was also conducted on the articles that were retrieved in full.
- The website of the Spinal Cord Injury Research Evidence (SCIRE) Project (https://scireproject.com/evidence/rehabilitation-evidence/) by the Rick Hansen Institute was also searched for relevant information.

Results

- Six[1-6] published studies were identified through the first stage of the literature search. Upon examination of the titles and abstracts of these six[1-6] studies, one[3] study was thought to be relevant and was retrieved in full for further appraisal.
- Literature search on the Cochrane® database of systematic review identified further twenty studies[7-26]. After examining the titles and abstracts of these 20[7-26] Cochrane reviews, three[13,15,25] systematic reviews were thought to be relevant and were retrieved in full for further appraisal.
- No further study was identified from the manual searches.
- As such, four[3,13,15,25] published studies were retrieved in full for further appraisal in this systematic review.
- Schulz et al.[3] compared the benefit of having controlled active motion vs. continuous passive motion, in addition to standard physiotherapy immediately after total knee arthroplasty, in a small (n=50) randomized controlled trial (RCT) (level of evidence 1. Appendix 1). The Artromot® Active K device was employed in both treatment groups through machine setting adjustments in this study. All patients started post-operative motion programs two days after surgery. The patients were hospitalized for 8-10 days post-surgery and continued their rehabilitation program in outpatient care for an additional 30 days. Numerous outcome measurement tools, including range of motion, pain intensity, and knee associated problems (measured by Knee injury and Osteoarthritis Outcome Score (KOOS)) were employed and measured during pre-surgery, after inpatient care (day 4-5 and 8-9 post-surgery) and after 30 days outpatient care. At 30 days outpatient care, the authors found that there was no statistically significant difference between continuous active motion and continuous passive motion groups with regard to their KOOS symptoms score, KOOS activities score and knee range of motion. Although the authors reported statistically significant differences between the two groups with regards to their KOOS pain score and KOOS quality of life score, it is not clear whether these differences were clinically significant. Further, the authors did not provide a third comparison group (regular post-operative physiotherapy alone) hence there is no data or analysis available for comparing between the effect of continuous passive or active motion, versus regular physiotherapy only. *It should also be noted that the reported outcomes from this small RCT need to be interpreted with caution due to potential selection bias (unclear patient selection, unclear randomization), and an unclear/unstated primary outcome (hence producing an unclear hypothesis). As well, the report did not provide any sample size calculation and there is evidence of*

multiple statistical tests being conducted and reported in this study without adjusting the type 1 error level.

- A high-quality systematic Cochrane review (level of evidence 1. Appendix 1), investigating the efficacy/effectiveness of CPM following total knee arthroplasty in people with arthritis, was reported by Harvey et al.[13] The authors found that:
    - There was moderate-quality evidence showing that CPM did not have clinically important short-term, medium- or long-term effects on active knee flexion
    - There was low-quality evidence showing that CPM did not have clinically important short-term effects on pain
    - There was moderate-quality evidence showing that CPM did not have clinically important medium-term effects on function
    - There was moderate-quality evidence to indicate that CPM did not have clinically important medium-term effects on quality of life
    - There was very low-quality evidence showing that CPM reduced the risk of manipulation under anaesthesia
    - There was low-quality evidence showing that CPM reduced the risk of adverse events, such as delayed healing, haemarthrosis, falls, deep venous thromboses, wound infections, pulmonary emboli, knee haematoma and a patellar rupture
    - There was insufficient evidence to determine the effect of CPM on participants' global assessment of treatment effectiveness

The authors concluded that CPM did not have clinically important effects on active knee flexion ROM, pain, function or quality of life to justify its routine use in rehabilitation of patients post-total knee arthroplasty.

- A high-quality Cochrane review (level of evidence 1. Appendix 1), investigating the effectiveness of CPM in preventing venous thromboembolism (VTE) in patients after total knee arthroplasty, was reported by He et al.[15] The authors found that of the eleven low-quality RCTs included in their systematic review, there was no evidence to support that CPM had any effect in preventing VTE after total knee arthroplasty. The authors also cautioned that sensitive methods such as venography or sonography were not always employed to diagnose deep vein thrombosis and the CPM was applied differently across studies, varying in range of motion, duration of CPM per day and the number of days after the surgery.
- In another high-quality Cochrane review (level of evidence 1. Appendix 1), Prabhu et al.[25] reported the application of passive motion in treating and preventing contracture. The review included two good

quality primary studies totaling 122 patients with neurological conditions, comparing passive motion treatment with no passive motion treatment. Neither of these passive motion modalities clinically or statistically reduced spasticity. The authors concluded that it was not clear whether passive motion was effective in treating and preventing contractures among patients with neurological conditions, including those with spinal cord injuries.

- The SCIRE project develops, maintain as well as regularly updates, high-quality systematic reviews (level of evidence 1. Appendix 1) on topics that are relevant patients with spinal cord injuries (https://scireproject.com/evidence/rehabilitation-evidence/). We screened systematic reviews they have produced and identified seven[27-33] systematic reviews relevant to our topic. None of these provided data on the efficacy and/or effectiveness of the Artromot® or other types of continuous passive motion treatments as a rehabilitation tool for patients with spinal cord injuries.

Summary

- At present, there is a small, low-quality RCT reporting on the benefit of employing controlled active motion vs. continuous passive motion (both using Artromot®), in addition to standard physiotherapy immediately after total knee arthroplasty, with regard to patient-reported KOOS pain scores and KOOS quality of life scores. Although the differences between these two scores (evaluating active motion and passive motion) were statistically significant, it may not be clinically significant.
- At present, there is no study reporting the application of the Artromot® system among patients with spinal cord injuries.
- At present, there is no evidence on the efficacy and/or effectiveness of CPM in rehabilitating patients with spinal cord injuries.

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Appendix 1

WorkSafeBC - Evidence-Based Practice Group Levels of Evidence

(adapted from 1,2,3,4)

1	Evidence from at least 1 properly randomized controlled trial (RCT) or systematic review of RCTs.
2	Evidence from well-designed controlled trials without randomization or systematic reviews of observational studies.
3	Evidence from well-designed cohort or case-control analytic studies, preferably from more than 1 centre or research group.
4	Evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled
5	Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.

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