# Physiotherapy and physical functioning after total knee arthroplasty

Effects of interventions and examination of practice

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**Doctoral Thesis**

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Oslo, June 2014 Vigdis Bruun-Olsen

**To my mother**

# SUMMARY

## Physiotherapy and physical functioning after total knee arthroplasty

### Effects of interventions and examination of practice

**Background:** Physiotherapy is a common practice after total knee arthroplasty (TKA), aimed at optimizing the patients' recovery of physical functioning, both in the short and long term of the recovery process. In spite of extensive physiotherapy, patients with TKA often have reduced physical functioning like limitations in long distance walking and stair climbing long time after the operation. The evidence for the effectiveness of one physiotherapy modality above another and what may have contributed to its effect is uncertain and further research is needed.

**Aim:** The overall aim of this thesis was to examine the significance of physiotherapy on physical functioning for patients who had undergone  total knee arthroplasty (TKA). Specific aims were: 1. To investigate whether continuous passive motion (CPM) given during hospital stay had an effect on physical functioning and pain above active post-operative exercises (paper I). 2. To compare the immediate and long-term effects of a walking skill intervention, starting six weeks after the operation, to usual physiotherapy care, on physical functioning and pain (paper II). 3. To describe how and why the physiotherapists were doing adjustments in the walking skill intervention and thereby how the intervention was tailored to the local context (paper III).

**Materials and methods:** The first two papers comprised two randomized controlled trials (RCTs), examining the effects of two different, physiotherapy interventions. The first intervention was performed during hospital stay (paper I) while the second intervention was performed between six to 12-14 weeks after TKA surgery (paper II ). Paper III comprised descriptions of how the latter intervention was adjusted in various clinical situations.

*Participants:* Patients with osteoarthritis of the knee operated for primary TKA at one (paper I) or two (paper II) local hospitals in Norway were included. Sixty-three patients were randomized to either a continuous passive motion and active exercise group or active exercises alone (paper I), and another 57 patients were randomized to either a walking skill group or usual physiotherapy care (paper II). In paper III, the 29 patients with TKA already included in the walking skill group in paper II and 35 patients with total hip arthroplasty (THA) participated in the training group.

*Interventions:* Paper I: Continuous passive motion (CPM) is a machine where the operated knee is moved passively in flexion and extension several hours each day during hospital stay with the intention to improve range of motion in the knee. The experimental group got CPM in adjunct to active exercises while the control group got active exercises alone. The exercises in both groups consisted of active assisted and active flexion and extension exercises of the hip/knee, active isometric contractions of the quadriceps muscle, walking training using a walker or crutches, and eventually climbing stairs on crutches.

Paper II: The experimental group only trained exercises in transfers and walking in solely weight-bearing positions with the intention to improve walking skills. The control group got

usual physiotherapy care containing exercises mostly in lying, sitting and standing with little walking included. All the patients got 12 training sessions each.

*Outcome measures*: Outcomes of physical functioning and pain were assessed before the operation (paper I and II), at one week and three months (paper I) and at six weeks, immediately after and nine months after the intervention (paper II). Outcomes were assessed by performance based measures (paper I, II), and self-reported measures (paper II). The primary outcome measures in study I were active knee flexion. Passive knee flexion, active and passive knee extension, Timed up and Go (TUG), timed 40 meters walking, stair climbing and pain were assessed as secondary outcomes. In study II, the primary outcome measure was 6 minutes walk test (6MWT). Range of knee motion (ROM), Index of muscle function (IMF), Timed stands (TST), Figure of eight balance test, stair climbing, Knee Osteoarthritis Outcome Score (KOOS) and self efficacy in activity were assessed as secondary outcomes.

*Data analysis*: To examine the effects in study I, independent sample t-tests were applied. To examine the effects in study II, an analysis of covariance was used (ANCOVA), with adjustments for gender and each pre-intervention score. When examining self reported measures, adjustments were made for education as well.

Paper III. Field and reflection notes of our own training sessions were written directly after each training. Data comprised subsequent descriptions of self-observations by two physiotherapists. Concrete actions of training performed by patients and physiotherapists were described in field notes. Reflection notes were written about why these actions were performed.

*Data analysis*: Excerpts of the texts related to adjustments were coded manually. Examples of codes were; adjustments when doing tasks, and adjusting tasks targeting a specific impairment. Then links between codes related to tasks and reasons for doing adjustments from a physiotherapist's point of view were performed. The combination of codes were sorted and grouped into subthemes labelled for example as how various tasks were adjusted to enable the patient to perform, or how the tasks were adjusted to the patients' aspirations for future recovery. Four analytic traces were elicited and followed in the empirical material related to how the physiotherapy evaluation was modified to patient's future aspirations, how the patient's future aspirations were modified by the patient throughout training, how the patient's future aspirations influenced the task to be trained, how normalisations of walking were approached through the doing of the task training itself. From these four analytic traces, two themes emerged.

**Results:** Paper I: No statistically significant differences between the continuous passive motion (CPM) and active exercise group or the active exercise group alone were found in any of the outcome measures of physical functioning neither at discharge from hospital nor three months after surgery (paper I).

Paper II: Statistically significant better six-minutes-walk test (6MWT) score was found in favor of the walking-skill group with mean (95% CI ) of 39 meters (2-76), $p = 0.04$ directly after the intervention. The difference between the groups in 6MWT persisted, with mean 44 meters (8-80), $p = 0.02$, nine months after the intervention. No differences in other outcome measures were found. The patients tolerated weight-bearing as early as six weeks after surgery without adverse effects (paper II).

Paper III: How various adjustments were performed by the physiotherapists were described in two themes: Adjusting task training to the physiotherapy evaluation and the patient's aspirations for future recovery, and normalizing walking through adjustments.

**Conclusion:** In examining the significance of physiotherapy on physical functioning after TKA, this thesis shows: Continuous passive motion had no additional effect on physical functioning and pain above active exercises in the short term recovery period after TKA. From 6-14 weeks after surgery, the walking skill intervention had better effect on walking distance than usual physiotherapy care both immediately and nine months after the intervention. How the physiotherapists adjusted the tasks in various ways to enable the patient to manage the exercises in the walking skill intervention, may have contributed to the reported effects.

# LIST OF PAPERS

I. Bruun-Olsen V, Heiberg KE, Mengshoel AM: Continuous passive motion as an adjunct to active exercises in early rehabilitation following total knee arthroplasty - a randomized controlled trial. Disabil Rehabil 2009;31(4): 277-83.

II. Bruun-Olsen V, Heiberg KE, Wahl AK, Mengshoel AM: The immediate and long term effects of a walking-skill program compared to usual physiotherapy care in patients who have undergone total knee arthroplasty (TKA): A randomized controlled trial. Disabil Rehabil 2013;35(23):2008-2015.

III. Bruun-Olsen V, Wahl AK, Heggen KM, Heiberg KE, Mengshoel AM: On the inside of a walking - skill program for patients who have undergone total hip (THA) or knee arthroplasty (TKA). A qualitative study. Submitted to Disabil Rehabil, May 2014.

**Key words:** Physiotherapy, physical functioning, total knee arthroplasty, walking skills, clinical trials, complex interventions, qualitative research.

# ABBREVIATIONS

| | |
|---|---|
| 6MWT | Six-minute walk test |
| BMI | Body Mass index (kg/m$^2$) |
| CI | Confidence interval |
| Fig. 8 | Figure-of-eight |
| ICF | International Classification of Functioning, Disability and Health |
| IMF | Index of muscle function |
| ITT | Intention to treat |
| LCS | Low contact stress |
| KOOS | Knee injury and osteoarthritis outcome score |
| OA | Osteoarthritis |
| OARSI | Osteoarthritis Research Society International |
| QOL | Quality of life |
| RCT | Randomized controlled trial |
| ROM | Range of motion |
| SD | Standard deviation |
| SPSS | Statistical Package for Social Science |
| THA | Total hip arthroplasty |
| TKA | Total knee arthroplasty |
| TST | Timed-stands- test |
| TSC | Timed- stair -climbing test |
| TUG | Timed -Up and Go test |
| WOMAC | Western Ontario and Mc Master Universities Osteoarthritis Index |

# 1 INTRODUCTION

In my more than 30 years as a physiotherapist, I have always been close to the clinical field. Over time, I have become increasingly curious about and interested in physiotherapy practice, with respect to the benefits of different interventions on physical functioning; how one becomes a skilled practitioner; and how physiotherapy is performed in practice, including the decision-making process. In recent years I have worked in the field of orthopedics, specializing in patients who have had total knee arthroplasty (TKA). Total knee arthroplasty is a common orthopedic procedure and the number of patients undergoing the procedure in the future is expected to continue to rise (1).

Physiotherapy has traditionally been an aspect of the routine aftercare provided to patients following elective knee arthroplasty. Research indicates that even if the patients' physical functioning improves following TKA, patients may still experience considerable limitations compared to their age-matched peers, such as an inability to walk long distances or engage in demanding physical activities for nine months (2) to one year (3) after the operation. Thus questions have to be raised as to whether physiotherapy is taken to its potential after TKA to improve these patients' physical functioning.

Physiotherapy interventions are usually complex with many interrelated elements. Hence in evaluation, to address outcomes as well as to develop insights into how the intervention is tailored to the local context is recommended (4). The overarching aim of this thesis was therefore to examine the significance of physiotherapy on physical functioning after TKA by examining the effects of two physiotherapy interventions, and further to develop insight into how the latter intervention was adjusted in many clinical situations.

## Physiotherapy and physical functioning

Physiotherapists belong to an authorized, professional discipline within the health services. This discipline provides services to individuals and populations to develop, maintain and restore movement and functioning throughout the lifespan (5). The World Confederation of Physical Therapists (WCPT) has proposed the following description of physiotherapy and physiotherapists: Physical therapists can help people at any stage of life, when movement and functioning are threatened by aging, injury, diseases, disorders, conditions or environmental factors. Physical therapists help people maximize their quality of life, looking at physical, psychological, emotional and social wellbeing. They work in the health spheres of promotion, prevention, treatment/intervention, habilitation and rehabilitation (5).

Even though optimization of physical functioning has always been one of the primary tasks in physiotherapy, the prevailing understanding of precisely what physical functioning means – and, consequently the approaches to optimizing it -- have evolved over time (6). The first modern physiotherapist in the Nordic countries was Martin Ling, a Swedish army officer in the early 1900s (7). At that time, general gymnastics was an integral part of military education. Ling was an avid athlete, particularly in fencing. His involvement in gymnastics convinced him that exercise facilitate healing processes within the body and thereby influence overall health. Accordingly, he developed an exercise system designed to promote normal movement. His work is widely considered to be an important precursor of contemporary physiotherapy (7).

Physicians involved in physiotherapy subsequent to Ling introduced a number of significant technical innovations, including thermal treatments, electrotherapies and various types of mechanical apparatus. Each of these modalities was designed to improve physical functioning by ameliorating a specific physiological abnormality, such as idiopathic scoliosis. It could be said that while Ling's focus was on self-healing to promote overall physical functioning and health, physicians who entered the field after him introduced external remedies to target specific abnormalities in the body. Although they are rarely differentiated explicitly, these two approaches continue to be evident in practical physiotherapy, as well as in physiotherapy research. For example, physiotherapists working with patients who have any number of physical diseases now recommend general exercise and physical activity to activate the self-healing process and thus improve physical functioning (8-10). However, physiotherapists may also suggest specific programs – for example, to improve joint flexibility by stretching the joint capsule (11). These programs may involve an electrical apparatus, a training apparatus or hands-on physiotherapy.

Current physiotherapy applies theories and information derived from anatomy, physiology, psychology, sociology and other disciplines concerned with movement, functioning and well-being. For example, to deepen their understanding of how movements are performed in everyday life, physiotherapists may draw on knowledge from biomechanics, as well as neurological research on the control of muscles and joints. They may also use insights and theories developed in psychology and other social disciplines. How people move can reflect behavioral challenges, such as patients' fear of moving and lack of motivation or confidence in their ability to move. Moreover, everyday functioning is also nested in the social context in which people live. How we move is fundamental to our existence; we experience the world through our bodies. How we understand and use our bodies in movement is also shaped by cultural norms and views.

Integrating these ideas into practices that improve human functioning requires a theoretical framework, and it has been claimed that physiotherapy is based on a "bricolage" of theories from several fields to understand the complexity of human functioning (6). Some physiotherapists look at human functioning through a lens of biopsychosocial theory, which posits that how an individual functions is determined by biological and mental factors related to the social environment in which she/he lives (12;13). Another approach is to acknowledge that an individual's way of functioning is determined through interaction with others; it is influenced by them, as well as the context (14).

In this thesis, the concept of physical functioning is understood and investigated from both of these perspectives. In the first two studies, the rationale for the two interventions examined and the outcomes that were measured were derived from a biopsychosocial perspective. The focus of the third study is how physiotherapists work in many clinical situations with patients who had undergone TKA after osteoarthritis to improve their physical functioning. In this case, the perspective is that the patient's functioning is construed, personalized and dependent on the context in which it is performed.

## Osteoarthritis

### Prevalence, pathogenesis, risk factors and diagnosis

All of the patients included in this thesis had a total knee replacement (TKA), inserted in response to severe osteoarthritis of the knee. Osteoarthritis (OA) affects synovial joints, most commonly in the knee, hip and hands (15). It is quite widespread in the Western world (16). The prevalence of all types of OA in the general population is approaching 13 percent; approximately 7 percent of the population suffers from knee OA (17). Among the elderly, OA is a major cause of chronic musculoskeletal pain and impaired physical functioning. By the age of 80 nearly everyone has OA in one or more joints (15).

OA is characterized by inflammatory and degenerative processes within the synovial joints (18). The degenerative processes include progressive cartilage loss, sclerotic changes in subchondral bone tissue and formation of osteocytes (18). In addition, soft tissue structures may be affected by synovial tissue proliferation, thickening of the joint capsule, laxity of ligaments and weakness of muscles around the joint (15;19).

In general, increased age, obesity (20) and being female are the most common risk factors for developing OA (15). Genetic factors, along with joint mal-alignments such as varus or valgus deformities of the knee, have been identified as significant risk factors for OA of the knee (19). Although OA is related to the "wear and tear of life," connected to damage of joint cartilage and surrounding tissues of the joint, it appears that participation in high-impact activities such as sports does not seem to be a risk factor for developing OA (21;22).

A diagnosis of OA may be based on radiographic, pathological or clinical findings (23;24). According to the internationally used clinical criteria published by The American College of Rheumatology (24), which rely on both patient history and a clinical examination, a patient can be classified as having OA of the knee when knee pain is accompanied by at least three of six symptoms: Age over 50, knee stiffness in the morning, crepitus, bony tenderness, bony enlargement and no palpable increase in synovial warmth; combined with radiographic criteria such as osteophytes and/or laboratory criteria like erythrocyte sedimentation rate ( ESR< 40 mm/hr ).

## Clinical symptoms and physical functioning

Pain and stiffness are often the first and predominant symptoms of knee osteoarthritis that lead patients to consult their doctor or a physiotherapist (25). Typically, the patient initially reports that the pain is exacerbated by weight-bearing activities and relieved by rest (26). At an early stage of the disease, the pain gradually increases as the knee is made to bear weight over an extended period of time. When the disease has progressed, pain is usually also present while the patient is taking weight off the knee or the knee is at rest (26).

Chronic knee pain may negatively influence neuromuscular activity, which in turn may inhibit the patient's coordination, balance and muscle strength -- especially in the knee extensors and muscles around the hip (27). This, in turn, may affect the patient's ability to walk. A patient with OA of the knee may also experience problems like morning joint stiffness, joint swelling, and loss of knee range of motion (19). When compounded with pain, impairments in body structure and function -- such as knee flexibility, muscle strength and balance -- increase the patient's risk of becoming dynamically unstable while getting up or walking (27) and may increase the incidence of falls (28;29). All of these challenges may constrain the patient's ability to perform normal activities of daily life (25).

To avoid pain, patients with an OA knee often try to unload the affected knee while walking, which creates a limping effect. Some of them deal with this by using a walking aid, such as a cane. However, even with the use of a walking aid, intermittent unloading of the affected knee may lead to alterations in gait patterns, as well as muscle weakness, further reducing their ability to walk long distances –consequently reducing their aerobic capacity (15;30). Alterations in gait patterns may also change the amount of pressure put on the contralateral hip and knee joint (31), which can lead to problems in other weight-bearing joints and ultimately affect the patient's ability to walk.

Whether individually or cumulatively, all of these different symptoms may limit movement to such a degree that OA has been labelled the most common cause of disability in older people (15). Typical problems that appear in everyday life include difficulties in rising from a chair, climbing stairs, lifting and standing (15), as well as walking long distances or at a normal speed (15;30;32). All of these limitations can make it difficult to engage in many activities of daily life, as well as participate in many leisure and social activities. For a significant number of patients, the challenges become so severe that they are dependent on others and unable to work (19).

### Treatments for OA of the knee

No cure has been found for OA; the existing treatments are designed to reduce pain and mitigate activity limitations (18). Strategies to alleviate knee pain, stiffness and muscle weakness and thus possibly slow progression of the disease include both pharmacological and non-pharmacological treatments. The latter may be educational programs; walking aids; weight-reduction regimens; and/or physiotherapy, in the form of exercises (33;34). Surgical treatments, such as insertion of an artificial knee joint (TKA), are sometimes a final option.

Pharmacological treatments mainly consist of analgesics to relieve pain and stiffness, which may allow a patient to move better (35). Ordinary paracetamols are the most commonly prescribed. If they prove ineffective, medical personnel may prescribe a non-steroidal anti-inflammatory drug (NSAID). Other pain relief options include local injection of a corticosteroid (35,36).

Pharmacological treatment is usually accompanied by educational programs and physiotherapy interventions, in the form of exercises. The educational programs typically focus on pain management, joint protection, weight-reduction and the importance of staying physically active (37). These programs have been found effective in pain reduction and improving participation in daily activities (36;37).

Physiotherapy in the form of exercises is a common treatment strategy to reduce pain and improve physical functioning in patients with OA of the knee (34). Researchers who have conducted systematic reviews and meta-analyses have concluded that among patients with mild to moderate OA of the knee, physiotherapy such as muscle-strengthening and aerobic exercises is effective in reducing pain and improving self-reported physical functioning (38; 39). Aerobic exercises and home-based muscle strengthening were found to be equally beneficial (40). Among the aerobic exercises, walking programs have been shown to be effective in improving gait, reducing pain and increasing aerobic capacity (41); aquatic exercises have reduced pain (42). Although which type of exercise programs  treat OA knee most effectively remains subject to debate, there is substantial evidence that both muscle-strengthening and aerobic exercises have at least short-term beneficial effects on pain, muscle strength and physical functioning in patients with mild to moderate OA of the knee (34). Maximizing adherence to an exercise regimen seems to be a key element in determining the success of this form of therapy (43).

The long-term benefits of exercise are still open to question. Based on an observational study, researchers concluded that the beneficial effects of an exercise regimen designed to strengthen the extensor muscles of the knee lasted between one and three years, and diminished after five years (44). Although exercises do seem to alleviate patient symptoms and improve their physical functioning (43), so far little evidence has been found that exercise can mitigate the disease itself.

Many patients with OA of the knee are eager to maintain a physically active life (45). However even if they initially benefit from treatment, as they grow older their pain and impaired physical functioning may become so severe that ordinary walking and other everyday activities become an ordeal. At that point, surgical treatment, such as insertion of a total knee arthroplasty (TKA), may be the only treatment option. Prior to their TKA insertion, all of the patients studied for this thesis had a long history of pain and impaired physical functioning due to osteoarthritis. An orthopaedic surgeon had recommended the operation based on their medical history, along with an assessment of their perceived degree of pain and the extent to which their physical functioning was impaired. Before making a final decision to operate, the surgeon had obtained the results of a radiological examination verifying osteoarthritic changes in the joint.

## Total knee arthroplasty

The number of total knee arthroplasties performed in response to osteoarthritis each year has been increasing rapidly in both Norway and other parts of the world (46). In 2012, nearly 4000 patients had a TKA for osteoarthritis in Norway (47). The mean age of the patients was 69, which is similar to the ages of the patients in the present thesis.

The objective of TKA surgery is to provide the patient with a pain-free, well-aligned and stable knee joint, approaching a normal knee (48). Though it has been refined over the years, TKA has existed since the 1860s, when Themistocles Gluck, a German surgeon, implanted a primitive ivory hinge joint in a patient’s knee (49;50). In the 1950s, surgeons began implanting cemented hinge joints made from acrylic, and subsequently from cobalt and chrome. Unfortunately, all of these hinge joints failed fairly quickly. Their major defect became apparent in 1971, when researchers discovered that the normal knee joint does not rotate on a single axis like a hinge; the femoral condyles roll and glide on the tibia with multiple instant centers of rotation. Once this was understood, a hinge knee arthroplasty was constructed. It was modified during the 1970s into an artificial joint containing several independent components that allowed more natural movement. These knee replacements, with their dramatically improved kinematics, were the forerunners of the total knee arthroplasties inserted today (49;50) .

Today’s total knee implants are designed to optimize range of motion and pain-free movements, even in high-impact activities. This seems likely to ensure their longevity, even if patients are active (48). Several types of total knee prosthesis are currently implanted in Norway. The Low Contact Stress (LCS ) version is used in approximately 50 percent of the surgeries (Figure 1). Since its introduction in 1977, this implant has been remained largely unchanged (51). The LCS prosthesis is cemented and there are no impact restrictions after surgery. The mobile bearing components within the artificial joint allow decoupling of the rotational forces in the knee when the patient is walking. This probably mitigates any tendency of the implant to loosen (51). Immediately after TKA surgery, apart from pain relief, enhanced range of motion is seen as a key outcome (52). A review comparing the different types of prosthesis found that the degree of flexion obtained with the LCS prosthesis was exceeding 100º which would enable the patients to obtain normal walking and stair climbing after surgery (53). Current implants seek to optimize range of motion and pain-free movements even for more vigorous activities and have therefore been designed to maximize longevity also for active patients (48). Therefore it seems like the implant may endure physical activities approximating a natural knee joint.

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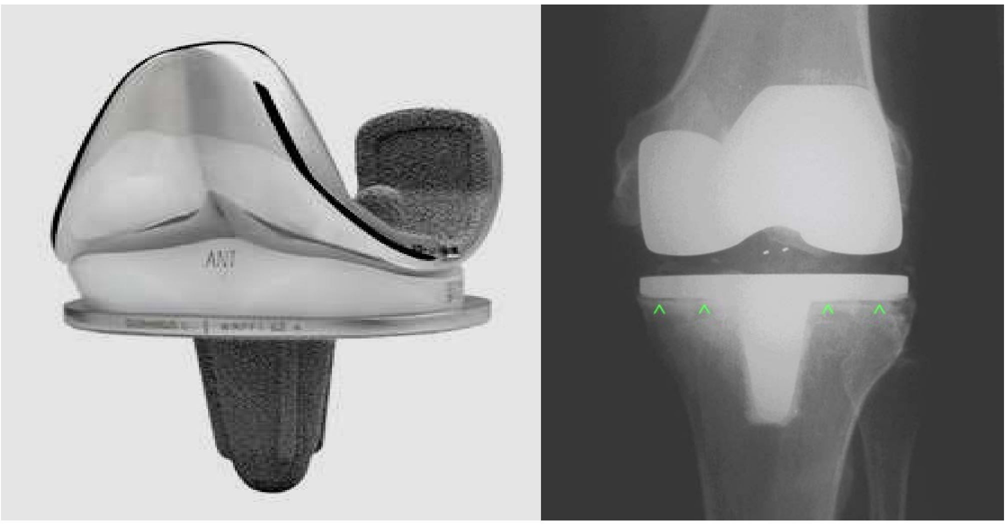

A B

**Figure 1 A, B: Low contact stress prosthesis (LCS) with a rotating platform**

1A: The implant. With permission © from Ortomedic, Norway. 1B: X-ray of an inserted LCS prosthesis. From Sadoghi et al, BMC Musculoskelet Disord . 2011; 12: 142. The publisher permits unrestricted use, distribution and reproduction in any medium, provided the original work is properly cited.

### Clinical symptoms and physical functioning after TKA

Insertion of an artificial knee joint is considered major surgery (49). During the operation, the surgeon has to cut and later reattach several tendons, the joint capsule and ligaments. This leads to post-operative knee pain and swelling, which may restrict knee movement. These problems may persist a long time after the patient is discharged from the hospital (2). Moreover, during the healing process, excessive fibrous tissue may develop in muscles and the fibrous capsule around the joint, leading to contractures. This can greatly restrict the knee's range of motion, even if the joint surfaces initially glide normally. Insertion of an artificial joint can also damage nerve receptors within the knee joint or in the surrounding muscles. This may cause disturbed joint proprioception or delayed muscle activation, which in turn may decrease postural and motor control in activities such as standing up and walking (54). Thus, in spite of the gradual healing of tissue and the use of joint surfaces that approximate normal gliding movements, potential post-surgical dangers include impaired knee flexibility, balance difficulties, and limitations in walking ability.

Even after surgery to replace their painful knee joint with TKA, many patients still experience impairments in body function such as reduced range of motion and muscle weakness, coupled with limitations on their activities that are a legacy of their many years of OA. For example, a compensatory movement pattern to avoid pressure on a painful limb may have become habitual, and even caused OA in the other knee (55). Moreover, researchers who conducted a study of patients who had end-stage knee osteoarthritis prior to surgery reported that when compared to healthy adults without knee pain, they had 36 percent less quadriceps strength, took 60 percent longer to climb stairs and covered 31 percent less distance on the six-minutes-walk-test (6MWT) (56). Rather than disappear following TKA, such limitations are often magnified by the loss in muscular strength that surgery entails (56;57). Therefore, altered weight-bearing, impaired balance (58) and gait problems may still persist after surgery. Thus the surgery itself and limitations transferred from the patients' prior osteoarthritis may have an impact on the patient's physical functioning after TKA.

**Long term outcomes of physical functioning after TKA**

The primary expectations of patients who choose to have total knee arthroplasty are that it will relieve their pain and enable them to resume to an active life (59;60). Typically, their pain diminishes in the months after the operation (2), however their muscular strength, as well as their walking and stair climbing ability remain considerably below that of age-matched peers (56). Moreover, in a previous longitudinal study, we found that, patients who found it hard to climb stairs prior to TKA still found it a challenge nine months after their surgery (2). In a comparison with age-matched peers, 68 percent reported difficulties in ascending several flights of stairs, versus 45 percent of their peers. Sixty-three percent said they found it hard to walk more than two km; 45 percent of their peers did. Eighty-eight percent reported problems with bending and squatting, versus 49 percent of their peers (2). These somewhat disappointing results are consistent with the findings in other studies of long-term outcomes of physical functioning following TKA (3;61;62). Although today's implants have been designed to tolerate more vigorous activities (48), many of the patients continue to experience a lower level of physical functioning than their age-matched peers. Possible explanations include limitations in the prosthesis itself, the recommendations of health professionals regarding physical activity, and the types of physiotherapy provided to patients following TKA. Thus it appears to be a need to investigate what kind of physiotherapy that is given to these patients in their recovery phase after TKA.

## Physiotherapy and physical functioning after TKA

Physiotherapy plays an important role in post-TKA rehabilitation, both during the hospital stay and in the ambulatory phase after discharge from hospital. The application of physiotherapy is based on the assumption that patients do not recover their physical functioning spontaneously after surgery; they have to be trained to regain it (57). The overall aim in physiotherapy is to surpass the patient's natural recovery and further optimize it by minimizing or avoiding persistent impairment in the knee's range of motion, muscle weakness and/or limitations in walking and transfers (e.g. moving from sitting to standing)(63). Traditionally, physiotherapy is applied in the form of exercises.

### Physiotherapy and physical functioning during the hospital stay

In Norway, physiotherapy interventions after TKA start on the first post-operative day and continue daily until patients are discharged from the hospital -- usually after six days. The daily physiotherapy sessions consist of active-assisted or active knee flexibility exercises in bed or on the side of the bed to prevent deep vein thrombosis and joint stiffness, as well as to promote muscle activation and facilitate tissue healing (64). The physiotherapist also assists patients in their attempts to walk with a walking aid, with weight-bearing on the knee (65;66). These interventions are usually complex, combining many interactive elements (4;67).

While the patients are still in the hospital, improvements in knee range of motion have often been considered the most vital outcome in terms of physical functioning (53). The reason for this may be that the patient's range of motion is frequently impaired post-operatively due to pain, swelling and a thickened fibrous capsule, as well as the development of excessive scar tissue, leading to a stiff knee. Range of motion is assumed to be an important precondition for transfers and walking normally. Researchers have demonstrated that flexion of approximately 70º is necessary for the swing phase of a walking gait, 90º for ascending and descending stairs and more than 90º for getting up from a normal chair (53). Therefore the minimum flexion of the knee necessary for normal activities of daily life is considered to be at least 90º. Reaching at least this level of flexion together with optimization of knee extension is the primary focus of physiotherapy during the in-hospital recovery phase (53). The preferred method is to take the knee joint through its full range of motion several times a day. This movement can be initiated by either a physiotherapist or a continuous passive motion (CPM) machine while the patient is in hospital.

Little research has been done on the effects of exercises on range of motion during the post-operative hospital stay (68; 69). In the one study, the researchers examined the effect that increasing the frequency of physiotherapy exercises (to twice daily as opposed to once) had on range of motion. The exercises involved active and passive knee movements, activating the quadriceps muscle and shifting from sitting to standing and then to walking. The researchers found no difference in results between the group that did the exercises once daily and the group that did them twice, leading them to question the use of multiple physiotherapy sessions during the in-hospital recovery phase (66). As this was the only study we found that looked at the effect of active exercises alone on range of motion during the hospital stay, we concluded that the widespread belief in the value of exercises in promoting recovery of range of motion has been based primarily on experience rather than evidence (68).

The focus of studies examining the possible benefits of various physiotherapy interventions during the hospital stay on range of knee motion seems to have been on effects of the Continuous Passive Motion (CPM) apparatus in combination with active exercises (11). The CPM machine passively flexes and extends the knee. It is typically used on patients several hours a day while they are in the hospital (Figure 2). CPM is used in combination with active exercises to reduce swelling and to promote restructuring of the fibrous tissue around the joint, and thereby possibly enable the joint to move better.

**Figure 2. A continuous passive motion machine**

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The authors of a Cochrane review performed prior to the first study concluded that no consensus or guidelines existed for the application of CPM procedures (11). Overall, they found that for several procedures, CPM combined with physiotherapy exercises was slightly more effective than exercise alone in improving active knee flexion and reducing the duration of the hospital stay (11). The authors concluded that CPM in combination with physiotherapy exercises had a beneficial short term effect on knee flexion, but no long term effect. However, they questioned the clinical significance of the short term effect, and noted that none of the studies under review had assessed the effects of CPM and physiotherapy exercises on the ability of patients to perform activities such as transfers, stair climbing and walking.

CPM was a common procedure in the hospital where I worked. Its use was determined by the orthopedic surgeons there. From my perspective as a clinical physiotherapist, the application of CPM was time consuming, and I also had the impression that it sometimes increased patient pain. This motivated me to investigate the effectiveness of the hospital's current practices, as well as to investigate the additional effects of CPM to active exercises on knee ROM, pain and swelling -- both at the time patients were discharged from hospital and three months later, where activities like walking and stair climbing also were assessed.

**Physiotherapy and physical functioning after discharge from the hospital**

In Norway, patients who have received TKA are usually transferred from the hospital to a rehabilitation centre after six days. They then go to an outpatient physiotherapy facility for exercises two to three times a week for several weeks. No evidence-based clinical guidelines have been formulated recommending what kind of physiotherapy exercises patients should receive after they have been discharged from the hospital (70). The physiotherapy typically provided seems to consist of muscle strengthening exercises with light weights, range of motion exercises and walking with the aid of a cane or other device (68). After roughly six weeks—the exact time depends on the individual patient's walking ability, balance and level of pain—patients are encouraged to gradually discontinue using their walking aid. At the end of treatment, health workers usually tell the patient that he/she can resume low-impact activities (68;70;71). However, from the patient's point of view, apart from pain relief, the reason for having TKA surgery seems to be to regain their former ability to participate in activities such golfing, dancing and walking long distances (59). This suggests that there is a significant disparity between health care worker recommendations and patient expectations.

Even though physiotherapy after TKA is a common practice, relatively few studies have examined the effects of physiotherapy exercises on physical functioning after discharge from the hospital. The authors of a systematic review in 2007 initially identified and evaluated 27 studies concerning physiotherapy interventions after discharge (72). Six of these met the inclusion criteria for the systematic review. Trials were included if they compared two different physiotherapy interventions or compared a particular physiotherapy intervention with usual care or no physiotherapy. Usual care was defined as continuation of exercise programs provided during the hospital stay after the patient went home. These consisted primarily of active range of motion exercises, stretching, isometric quadriceps contractions and walking with a walking aid. In the individual studies, the content of the interventions was either not specified (73;74), or included exercises involving range of motion (75); muscle strengthening (76); or sitting and standing, without major emphasis on walking and weight-bearing activities (77;78) – although engaging in the latter two activities may significantly accelerate progress toward a physically active life. The intervention's initiation time was either not specified (74;78), one week after discharge (75), or up to two months after surgery (77). Only three of the studies (75;77;78) actually measured walking ability as an outcome. The authors concluded that overall, the interventions had provided modest to moderate short term benefits for range of motion and self- reported physical functioning but had no long term effect (77;78). With regard to walking ability, the authors of the systematic review concluded that physiotherapy did not affect a patient's walking in tests at three and twelve months. In reporting these findings, they concluded that based on current evidence, physiotherapy appears to have "no long term benefits "(72).

Based on the studies included in the review article, the physiotherapy interventions provided in the first few months after discharge to patients who have had TKA vary considerably, in both time of initiation and content. As experts believe that to be effective exercises must have a certain level of intensity in both impact and duration (10), it could be that the reason no benefit was evident from physiotherapy given in the first months after TKA was that the interventions studied consisted largely of low intensity exercises, with only minor emphasis on training in walking – an essential aspect of most strenuous activities of daily life.

As clinical physiotherapists, we assumed that to resume a physically active life, patients had to be able to walk fairly long distances, walk quickly, step over obstacles without falling and walk on uneven ground. To cite two common situations, walking speed is crucial for crossing a wide street safely, and motor control is essential when walking in the forest. Unfortunately few studies have been done examining the effects of training in transfers and walking after TKA. In the systematic review cited earlier (72), only two of the studies examined (77;78) included walking and weight-bearing endurance exercises. One of these interventions placed a heavy emphasis on walking training; the researchers reported that this intervention provided short term benefits in terms of the distances patients were subsequently able to walk (77). Based on their findings, the authors of this study tentatively recommended that to optimize physical functioning like walking, in the future, physiotherapy after discharge from a hospital should include exercises consisting of tasks performed in everyday life. Based on this conclusion, we developed a walking skill intervention.

Apart from being based on findings and suggestions from previous studies in the field, the walking skill intervention was informed by my prior clinical experience with stroke patients. Researchers have found evidence that physiotherapy may enhance the daily activities and walking outcomes achieved by these patients through exercise programs that include direct, intensive training in functional tasks or activities (79;80). Based on current theories of motor control, they believe that actual training in walking skills is essential to optimizing the walking skills of stroke patients. The core elements in these theories are supervision and training in walking tasks that include balance exercises, along with feed-back (81). Training in a specific walking activity that needs improvement is also consistent with the principle of specificity training applied in sports medicine. Experts in that field have concluded that the closer training resembles the actual task to be improved, the better the outcome (82;83). Moreover researchers have found that task training is more effective than muscle resistance training in improving the ability of older women to perform tasks of everyday life (84). By training in walking activities, muscle strength, balance and range of motion impairments are built in and trained through the walking activity itself. These theoretical assumptions were the foundation on which we developed our walking skill intervention.

**Table 1. A systematic review of the effects of physiotherapy after discharge from a hospital in patients with TKA (72)**

| Citation | Participants | Time of intervention | Comparison of interventions | Content of interventions | Measures | Results |
|---|---|---|---|---|---|---|
| Frost et al. [78]<br>2002 | Unilateral TKA<br>n= 47 | After discharge, time not specified | 1. Functional exercise group<br>2.Traditional exercise group | 1.Warm up in sitting, chair rise, leg lifts, walking for one minute with increased time each day<br>2. Static quadriceps in sitting, knee bending in lying and standing, straight leg raise. | Leg extensor power, walking speed, pain during walking, range of movement (ROM) | No significant differences between groups: trends to favor the functional group |
| Kramer et al.[75]<br>2003 | Unilateral TKA<br>n=160 | Beginning within one week after discharge | 1. Home-based exercises<br>2. Individual clinic-based treatment | 1.Home-based: ice, walking, ROM<br>2.Additional individual modification of exercises in clinic | Knee Society clinical rating scale; WOMAC, SF 36, 6MWT, knee flexion | No significant difference between groups. |
| Rajan et al.[74]<br>2004 | Primary TKA for arthrosis<br>n= 120 | After discharge , time not specified | 1.Outpatient physiotherapy (PT)<br>2. No PT | 1. Outpatient treatment not specified, 4-6 times after discharge | ROM in degrees | No significant differences between groups |

| | | | | | | |
|---|---|---|---|---|---|---|
| Codine et al. [76]<br><br>2004 | Unilateral TKA<br><br>n= 60 | 10-30 days after surgery | 1. Sub-maximal hamstrings training<br><br>2.Usual care | 1.Submaximal training of hamstrings muscle using eccentric force<br><br>2.Usual care | ROM by goniometer.<br><br>Isometric muscle force, Knee Society Clinical Rating sc. | Significant difference in favor of the experimental group, for extension only |
| Moffet et al. [77]<br><br>2004 | Primary unilateral TKA<br><br>n=77 | 2 months after surgery | 1. Functional rehabilitation<br><br>2.Usual care | 1.Warm up in sitting, strength exercises in sitting, functional tasks 15-20 min, walking endurance, cool down<br><br>2. Supervised rehab. visits at home. Content not specified | Functional ability, 6MWT, SF 36, WOMAC | Significant difference in favor of the functional group in 6MWT at 4 and 6 months, not after one year |
| Mockford et al.[73]<br><br>2004 | Unilateral TKA<br><br>n=150 | After discharge | 1. Nine sessions of PT over six weeks within 3 weeks of discharge<br><br>2. No outpatient PT | 1. Content not specified | Range of motion by a goniometer,<br><br>Oxford knee American Knee Society, Bartlett patellar score,<br><br>SF12 | Outpatient PT improved ROM at three months |

## The theoretical framework for papers I and II

The theoretical framework of papers I and II was based on the biopsychosocial understanding of functioning, which incorporates the patient's physical, mental and social dimensions. The latest version of the International Classification of Functioning, Disability and Health (ICF) (85), published in 2001 by the World Health Organization(WHO), is underpinned by the biopsychosocial understanding.

Physiotherapists have increasingly found that the ICF provides a useful and common language for describing the impacts of disease on different dimensions of functioning (86). The ICF consists of two parts, each of which contains several components. Together, they constitute different aspects of functioning. The first part categorizes Functioning and Disability as the two components of Body Functions and Structure, as well as of Activities and Participation. Impairment**s** in Body Functions and Structure include weak muscle strength and impaired range of motion. The limitations in Activity and Participation component refer to the observed or individual perspective on functioning **–** for example, a patient's limitations in walking or climbing steps (87). Participation refers to the patient's ability to take part in everyday activities that form part of a social life. Part two of the ICF covers contextual factors in a person's life and living situation that affect functioning, such as Environmental and Personal Issues (88).

In the ICF, functioning is understood as a complex interaction between the health condition of the individual and contextual and personal factors. This way of regarding functioning treats it as an interactive, dynamic process, rather than linear or static. Approaching physical functioning through an effort to influence one dimension, such as Body Function and Structure, may have an impact on other dimensions, such as Activity and Participation. The interplay between the dimensions is always multi-directional (85). For example, a patient who improves her walking ability is likely to find that her participation in social life also improves, and, ultimately, improvements in her social life are likely to improve her walking ability.

For this thesis, I used the ICF model and its framework, both in planning the effect studies and in choosing the outcome measures. In paper I, the exercise program that was studied consisted predominantly of flexibility exercises performed in bed. Both the passive flexibility exercise intervention (CPM) and the primary outcome fell into the category of Body Function. However, I also assumed that knee flexibility would influence a patient's ability to walk and climb stairs; therefore activity level assessments of walking and stair climbing as secondary outcomes were considered. In contrast, in paper II, I examined the effect on Activity Level of a more multi-factorial exercise program based on walking activities. The program also included training in body functions, which was embedded in the walking activities themselves. The primary outcome which was chosen was on walking. Whether or not the patients reported that limitations on their everyday life activities had diminished and if restrictions on their participation in sports and leisure activities had been reduced were also assessed. As the patients differed with respect to which of their body functions were impaired and to what extent, the exercises chosen had to be appropriate to their abilities and needs. Hence the effect of the program on various impaired body functions – including joint range of motion, muscle strength and balance – were assessed as secondary outcomes. Moreover, as the program was planned to be patient-centered, the activities targeted in the training were chosen based on the ones each patient most wanted to improve in and therefore found most meaningful.

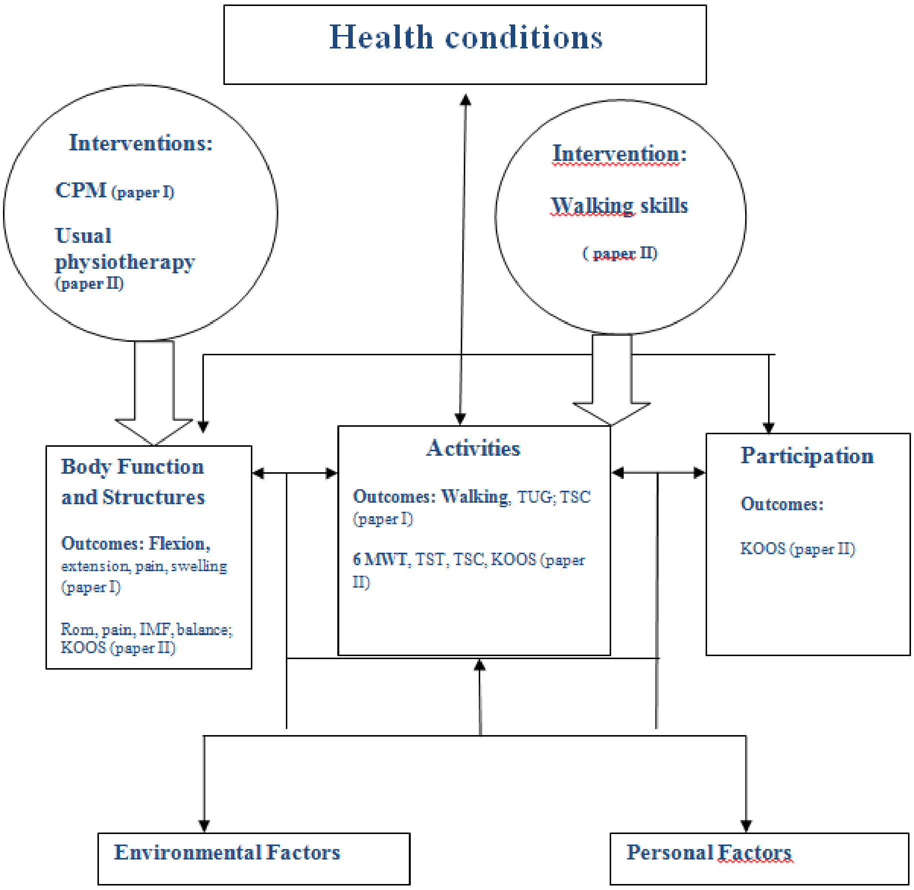


**Figure 3. Interventions and outcomes assessed in studies I and II and their relationships to items in the International Classification of Functioning, Disability and Health (ICF)**

In sum, the interventions we examined and the outcome measures we chose for the first two studies in this thesis come under several components of the ICF model, investigated as normalizations of limitations in two ICF components: Body Function and Structures, and Activities and Participation. Moreover, the primary outcome variables investigated in both studies corresponded to the aims of the exercise program, while the secondary outcomes corresponded to several components within the ICF model. Therefore the aims of the training programs corresponded directly to the outcomes that we measured based on the ICF model.

**Outcomes to assess physical functioning after TKA**

In physiotherapy, the same outcome measures have traditionally been applied to assess the severity of patients' OA and their normalization of limitations (recovery) following TKA. When we planned the present studies there was no real consensus on the best outcome measures to assess physical functioning after TKA (89;90). In planning for studies I and II we decided to capture various aspects of physical functioning outlined in the ICF model by using both performance-based and self-reported measures (91-93).

A broad picture of the patient's physical functioning after TKA is usually obtained through performance-based measures of physical functioning. These tests measure a patient's actual physical performance (91;93). To assess range of motion, physiotherapists typically use a goniometer in both the short and long term phases of the recovery process. In the long term recovery phase after TKA, outcome measures to assess the patient's physical capacities and transfers include the six-minutes-walk-test (6MWT), the timed up-and-go test (TUG); and various stair climbing tests (91). In studies I and II of this thesis, we assessed aspects of physical functioning reflecting various domains of the ICF through a battery of tests: for knee range of motion (studies I and II), 40-meter timed walking (study I) or 6MWT (study II), timed -stair climbing (TSC) (studies I and II), figure-eight balance (study II), Index of Muscle Function(IMF) (study II), timed stands (TST) (study II) and timed up-and-go (TUG) (study I). The Osteoarthritis Research Society International (OARSI) has recently issued a consensus-derived set of performance-based tests to assess physical functioning in patients with OA hip and knee or following joint replacement (94). These include the 40-meter fast-paced walking test, the 6MWT, the TUG and the TSC used presently (94).

Physical functioning after TKA is also frequently assessed through self-reported measures. Their inclusion is believed to give a broader picture of the construct of physical functioning, which is strongly influenced by pain (92;95). Self-reported measures are assumed to address and reflect how the patients actually experience performance of activities, as opposed to their ability to perform them. Self-reported physical functioning after TKA is frequently assessed by the Western Ontario and Mc Master Universities Osteoarthritis Index (WOMAC) (96). In planning the second interventional study, we decided to include the Knee Injury and Osteoarthritis Outcome Score (KOOS), which is an extension of the WOMAC (paper II). The KOOS contains items that measure quality of life, as well as sport and recreation activities related to the knee, thus reflecting a broad understanding of physical functioning (97;98). It includes items related to the different dimensions of the Body Functions and Structure component of the ICF, such as stiffness and pain, as well as components of Activity and Participation, such as getting out of a car, getting dressed and climbing stairs. In addition to using the KOOS, we assessed patients' self-efficacy in performing activities of daily life with a questionnaire based on activities relevant to patients with TKA. It was designed to elicit information such as patients' confidence in their ability to walk long distances or avoid stumbling and falling outdoors.

The thesis applies commonly used performance-based measures (papers I and II) and self-reported measures of physical functioning (paper II). The outcome measures are also widely applied, and were included so that our results can be compared with previous research. In addition to reflecting the aims of the interventions tested, the outcome measures capture the "umbrella" construct of functioning found in the ICF model and embrace its associations between Body Function and Structures, as well as Activities and Participation.

## The rationale and theoretical framework for paper III

As already described, the walking skills program in paper II goes beyond the flexibility and muscle strengthening programs usually evaluated in the field of arthroplasty (72). These programs have typically relied on various forms of technical apparatus (99;100) and focused on Body Functions and Structure normalizations, such as joint flexibility (101) or muscle strength (99;100). In our walking skill intervention, in contrast, we embedded and addressed training in Body Structures and Functions such as balance, muscle strength and joint flexibility in the walking activity itself, rather than relying on a technical apparatus or hands-on techniques. As noted earlier, this approach was inspired by current theories of motor control (81) and specificity training as it is applied in sports medicine (83;102), which aligns the intervention as closely as possible to the task it is designed to improve.

As one the physiotherapists conducting the program, I found that providing a training program for a group of patients while accommodating each patient's abilities and needs required a great deal of individualization. During the walking skill intervention, we both realized that our individualizations efforts included a variety of adjustments to the walking tasks and how they were approached. As these adjustments were discussed only briefly in paper II, we became increasingly interested in what they were meant to accomplish and how they were performed. It became apparent to us that how the adjustments were performed constituted an important and hitherto undescribed part of the program that could have a significant effect on the rate and level of improvement in walking skills. Furthermore, we surmised that these adjustments were an important factor in the patients' progress, which may in turn have intensified their dedication to the recovery process (103). Moreover, as clinical physiotherapy interventions are claimed to be more dynamic and varied than described in RCTs (104), we decided that a more detailed and systematic description of these adjustments would create a more accurate and nuanced account of the walking skill intervention. This could enhance its value for other clinical physiotherapists.

Our walking skill intervention was a complex non-pharmacological approach, with many potential "active ingredients" (4). A complex intervention combines different components to create a whole that is more than the sum of its parts. This complicates the evaluation process (4;105). The New Medical Research Council has developed updated guidelines for the evaluation of complex interventions that recommend integration of outcomes, as well as descriptions that can provide insight into how the intervention works or is tailored to its local context (4). From this perspective, descriptions of how adjustments in our walking skills intervention were performed could also be seen as a way of developing insights into how it was tailored to the context and thus provide an elaboration of the effects reported in paper II.

In physiotherapy, the ways in which interventions are performed have rarely been addressed. One exception is a study in which physiotherapy practice was examined through close observations of the two initial encounters between patients with musculoskeletal disorders and physiotherapists with a background in either manual therapy or psychomotor physiotherapy. The researcher examined how the physiotherapists actually addressed the patients' physical functioning during the process of assessing them and found that their focus in both approach and assessment correlated with the type of physiotherapist they were (106). This suggests that physiotherapy practices and approaches are influenced by the context and culture in which the physiotherapist works. In another recent study, a research physiotherapist examined how children with congenital heart disease who were in a group-based program adapted to their movement limitations through improvisation. The researcher found that the children had developed a far more extensive movement repertoire than she had anticipated

(107). The researchers who conducted both of these studies looked at clinical practice, applying a qualitative inquiry approach and using close observation data collection. However, they participated in somewhat different ways during both the data production process and the analysis. Thornquist (106) closely observed the performance of both the physiotherapists and the patients and wrote her observations down immediately afterward. Bjorbaekmo, on the other hand (107), performed movements together with the children, experiencing for herself how they were created. Accordingly, their degree of closeness to the production of data differed. Thornquist used data derived from the physiotherapists and patients (106); Bjorbaekmo was an active co-producer of the data that she used in her study (107).

In the present thesis, my two quantitative studies were based on biopsychosocial theory, and I was a distant observer. I chose this approach because the objective of effect studies is to examine whether there is a causal relationship between a well-described intervention and the outcomes measured (108). This approach makes it imperative to blind the assessor to the processes of group allocation and prior measures to ensure that she/he will not influence the data. The effects of intervention should be valid in other clinical settings and separable from the person who is delivering it. In papers I and II, I dealt with these issues by blinding the assessor and by allocating patients to groups in a random way. I also made every effort to ensure that the intervention was performed and described in a way that facilitates replication by others.

The research question posed in paper III concerned how our own physiotherapy practice was performed. Accordingly, it was addressed using qualitative inquiry. In this study, in contrast with the quantitative studies presented in papers I and II, we scrutinized data from self-observations. Therefore, we had to consider the relationship of the researcher to the data quite differently. We wrote our field notes as concretely as possible, describing how we and the patients acted, as well as why we, in our role as physiotherapists, acted the way we did. Brinkmann, a psychologist as well as a researcher, has argued that the researcher’s own experiences can provide valuable data for learning about particular life situations (109). This study is based on a similar approach. In our role as researchers, we view our physiotherapy practice as our life situation and ourselves as participants in the context under inspection. We believe that this makes us valuable co-producers of the data we are collecting. Self-observations of our own practice can therefore be a plausible and useful mechanism for exploring our own practice and learning from what we discover. This perspective underpinned the data collection, data analysis and interpretations in the study that is presented in paper III.

Our aim in this study was not to explain associations between variables, but to understand the complexity, latitude and variety of our own practice through qualitative inquiry (109). Our theoretical positioning was inspired by Gannik's concept of situational analysis (14). This positioning rests on an insider perspective, through which peoples' attitudes and actions are understood and closely related to the context in which they are participating and acting. Our intention was to study human actions based on underlying motives and reasons. Consequently, we created and determined our scope of actions based on our relationship with the patients, their expectations and ours prior to and within each clinical situation, our preconceptions as physiotherapists and our judgment in each clinical situation (14). More specifically, the focus of our inquiry was on how we, as the physiotherapists conducting the intervention, adjusted and construed our actions in collaboration with the individual patients so that each of them could most effectively pursue and advance in her/his recovery process. Put simply, this study attempted to understand how this walking skill program works from the inside.

One may question, however, how much self-observation of our own practice can really tell us. In response, we once again refer to Brinkmann. He suggests that in inquiries concerning everyday life, when the researcher explores her own experiences of being a participant, she should write from her own participating stance (109). He goes on to argue that we all continuously engage in self-observations as we go about our daily lives, and yet we also have a capacity to distance ourselves from what we are doing. The challenge is to study our own practice, to describe and analyze it, and at the same time to reconstruct what we discover with conceptual audacity. Our goal should not be to neutrally mirror the world, but to use theory to understand our own practice in new and perhaps surprising ways. If we succeed, our practice can be both recognizable and valuable to others working in similar contexts (109).

The objective of study III was therefore to describe how an intervention was tailored to the local context -- more specifically, how and why we as physiotherapists performed adjustments in particular clinical situations within a walking skill intervention. Study III may be seen as an elaboration of the reported effect from the complex walking skills intervention discussed in paper II. We believe that this will make our walking skill intervention more understandable and transferable within clinical physiotherapy, and deepen our understanding of its efficacy.

# 2 AIMS OF THE THESIS

The overall aim of this thesis was to examine the significance of physiotherapy on physical functioning in patients with osteoarthritis who had undergone total knee arthroplasty (TKA).

**The specific aims were:**

1: To examine whether continuous passive motion (CPM) had an effect on pain, knee ROM and walking ability above the effect of active post-operative exercises in patients with TKA, one week and three months after the operation (Paper I).

2: To compare the immediate and long term effects of a walking skill program in weight-bearing performed from six weeks to 12-14 weeks after total knee arthroplasty (TKA) with usual physiotherapy care, on performed and self-reported physical functioning and pain, with a follow-up nine months after the intervention (Paper II).

3: To describe how and why the physiotherapists were performing adjustments during the walking skill intervention using self-observations, and thereby develop insight into how this intervention was tailored to the local context (Paper III).

# 3 MATERIALS AND METHODS

## Ethics

All three studies were carried out in accordance with the principles outlined in the Helsinki Declaration. The study protocols were approved by the Ethics Committee for Medical Research, Norway and the Norwegian Social Sciences Data Inspectorate.

An important ethical principle followed in this thesis is the principle of voluntariness through informed consent (110). The patients who were scheduled for TKA surgery received both written and oral information on the study, and they were asked to voluntarily participate. In all the studies information about the purpose of the studies, the content of physiotherapy, potential benefits and adverse effects were given. In study I and II the patients were asked again for participation before each new assessment. The patients were also informed that they could withdraw from the studies at any time without any negative consequences for their further treatment. A written informed consent was signed by the patients before inclusion.

A further important ethical principle to consider is the risk of adverse effects (110). The assessments were not considered harmful in neither of the studies. The CPM routine was part of the usual post-operative routine in the hospital involved and consequently not considered harmful (paper I). In paper II, however, prior to the intervention we questioned whether solely weigh-bearing training as early as 6 weeks after TKA could impose adverse effects like more pain. The patients were informed about our uncertainty before the training started and were encouraged to report adverse effects.

The principle of confidentiality was followed in all studies (110). In the data sets, the personal identifications were replaced by a code and kept separated from the data in a locked cabinet. Further it was not possible to identify individual patients in the publications.

## Recruitments of patients

The participants were consecutively recruited from one (paper I) or two (paper II, III) general hospitals in Norway where they were hospitalized for TKA surgery between October 2003 to March 2005 ( paper I) or from October 2008 to June 2010 (paper II, III). The participants were included if they filled the inclusion criteria and agreed to participation.

The inclusion criteria were (paper I, II, III): Primary total knee replacement due to osteoarthritis (24). The OA diagnosis was set by an orthopedic surgeon (24) and based on clinical symptoms as well as X-rays findings. Further, the patients had to be fluent in written and spoken Norwegian language, and have good cognitive function. In paper II and paper III, the participants also had to live in the vicinity of the hospital (approximately 30 km) to be able to attend training.

Exclusion criteria were: Rheumatoid arthritis or prosthesis in the hip on the same side (paper I, II, III). In paper II and III, patients with a heart disease or neurological disease that would influence training were excluded; as well as patients with known drug abuse. Around 70 patients were found eligible for participation in study I, while 101 were found eligible and invited to participate in study II. Twenty-nine patients with TKA already included in the experimental group in paper II and 35 patients with total hip arthroplasty (THA) constituted the walking skill group (paper III).

### Patient characteristics

Personal information was collected and used to describe the material. On the first preoperative assessment, a questionnaire was applied collecting sosio-demographic data (paper I, II, III) such as age, sex, height and weight (paper II, III), educational level, co-morbidities ( paper II) as well as swelling (paper I). Body mass index (BMI) was calculated from self-reported height and weight ($kg/m^2$) in paper II.

## Quantitative studies (paper I and II)

To evaluate the effects of the two different physiotherapy interventions, single blind randomized controlled trial (RCT) design was applied with a control group and an experimental group (paper I, II).

In paper I assessments were performed preoperatively and immediately after the intervention at six days, and at three months. In paper II assessments were performed preoperatively (not reported), at six weeks, between 12 to 14 weeks and nine months after the intervention. Different physiotherapists recruited the participants in paper I, while two physiotherapists recruited the participants in paper II. Two physiotherapists were blinded and performed all the follow-up assessments in paper I and one was blinded and performed all the follow-up assessments in paper II. The patients were randomly allocated to an experimental group or a control group (paper I and II). The randomization procedures were as follows: Seventy, pre-coded opaque and sealed envelopes, 35 for each group, were prepared beforehand containing a note that assigned the patients into an experimental group or a control group. In paper I, the experimental group received continuous passive motion (CPM) and active exercises, while the control group received active exercises alone. In paper II, the experimental group received only training in walking skills with transfers and walking while the control group received usual physiotherapy care.

In paper I, the sample size was estimated to have an adequate statistical power to detect a difference of 15º in active flexion of the knee between the groups which was considered as a clinical relevant difference; with α value set to 5 % and β value set at 0.2. The sample size was then calculated to be 55 participants for two groups (108). In paper II, the sample size was estimated to have an adequate statistical power to detect a difference of 50 meters in walking distance between the groups with a SD of 70 (111), α level set at 5 % and β value set at 0.2. The sample size was then calculated to include 30 persons in each group (108). With a drop out rate of approximately 10 % it was initially decided to include 70 patients in both papers.

**Data collection**

Effects on physical functioning were assessed with performance-based measures (paper I, II) and self -reported measures (paper II)**.** Together, various aspects of physical functioning in the ICF model such as Body functions and Structures ( paper I and II) and Activities and Participation were captured (paper II). An overview of the outcome measures and assessments are presented in table 2.

**Table 2. Overview of data collections and assessments (paper I and II)**

| Sociodemographic variables | Before surgery | 6 days post surgery | 6 weeks post surgery | 3-4 months post surgery | 1 year post surgery |
|---|---|---|---|---|---|
| Age | I, II | | | | |
| Gender | I, II | | | | |
| BMI[1] | II | | | | |
| Education | I, II | | | | |
| Co morbidities | II | | | | |
| Swelling | I | I | | I | |
| **Performance-based measures** | | | | | |
| 6MWT[2] | II | | II | II | II |
| 40 m walk test | I | | | I | |
| Active ROM [3] | I, II | I | II | I, II | II |
| Passive ROM [4] | I | I | | I | |
| TST[5] | II | | II | II | II |
| TUG [6] | I | | | I | |
| IMF [7] | II | | II | II | II |
| Figure eight | II | | II | II | II |
| TSC[8] | I, II | | II | I, II | II |
| **Self reports** | | | | | |
| Pain (VAS) [9] | I | I | | I | |
| Pain (KOOS) [10] | II | | II | II | II |
| Symptoms(KOOS) | II | | II | II | II |
| Function (KOOS) | II | | II | II | II |
| Sport (KOOS) | II | | II | II | II |
| QOL (KOOS) [11] | II | | II | II | II |
| Self efficacy | II | | II | II | II |

[1] Body mass index, [2] Six-Minute walk test, [3] Active knee flexion and extension, [4] Passive knee flexion and extension, [5] Timed stance test, [6] Time- up-and- go,[7] Index of muscle function,[8] Timed stair climbing test ,[9] Visual Analogue scale, [10] Knee injury and Osteoarthritis Outcome Score, [11] Quality of Life

**Performance-based measures of physical functioning**

*Range of motion (paper I and II)*

The test evaluated the total range of motion in the knee. In paper I, active and passive knee flexion and knee extension were measured separately and presented as active and passive flexion and extension. In paper II, active knee extension and knee flexion were measured and summed up as the total amount of active movement (ROM) in the knee joint (paper II).

Active knee flexion was measured with a goniometer with the hip in 90 $^{o}$ flexion and the patient in supine position. The goniometer swivel was placed over the joint space, with one arm aligned with the greater trochanter and the other along the line running from the fibular head to the lateral malleolus of the ankle (112). The knee was moved actively by the patient to maximum flexion and the range measured in degrees. The knee joint was moved further passively through its full range in flexion by the physiotherapists and the degrees were measured. Active knee extension was measured with the patient in a supine position with the ankle resting on a bolster and the goniometer in the same position as for flexion. The knee was actively extended and the range measured in degrees. The knee joint was moved further passively by the physiotherapist. The degrees were measured. Flexion and extension in the knee joint were measured according to the protocol from Norkin and White (112). Inter-tester reliability for measurements of the knee joint by a goniometer is considered to be high (113).

*40 meter walk test (paper I)*

The test evaluated the time spent walking 40 meters. The patients were instructed to walk 40 meters in a corridor at a rapid, but safe speed and to use a walking aid if needed. The time was recorded in seconds. The test is recommended to be included in the recent Osteoarthritis Research Society International (OARSI) recommendation for measurements of physical functioning in patients with hip and knee OA (94).

*The six-minute walk test (6MWT) (paper II)*

The test evaluated the maximal distance walked at a comfortable speed along a 40 meter corridor in six minutes. The distance was measured in meters, and the more meters the better. A walking aid was used if needed. A change of 20 meters was considered a small meaningful change, while a change of 50 meters was considered a substantial meaningful change (111).

The six-minute walk test is considered to be a useful measure of sub-maximal exercise capacity in patients with OA and TKA (114). The test is safe and considered more reflexive of activities of daily living than other walking test (115). Moreover, the test is an indicator of ability to ambulate in the community (116), such as safely crossing a traffic intersection on time. The test has been favored as a performance-measure because of its high responsiveness to change over time (117), and it is found reliable and valid in older adults (116).The test is also found to have a high correlation with other mobility tests in older adults (118). The test is recommended in the recent OARSI recommendations (94).

*Timed up and Go (TUG)(paper I)*

The test evaluated the ability to rise from a chair and walk a short distance. The patients were instructed to rise from a chair (height 44-47cm) with an armrest, walk forward, turn, walk back and sit down in the chair.  The time was recorded in seconds. A time of 11-12 seconds is considered normal (119). The test has been found to have excellent test-retest reliability and discriminate validity for balance in older adults (120). This test is also recommended in the recent OARSI recommendations (94).

*Timed stair climbing test (TSC)(paper I and II)*

The test evaluated the patient's capacity when ascending and descending a given number of stairs. The patients were instructed to walk up and down a flight of stairs consisting of eight steps with a step height of 16 cm and to use alternate legs (paper I and II.)  In paper I the patients were not allowed to hold on to the rail or use a walking aid. In paper II, the patients were instructed to ascend and descend as fast as they could and were allowed to support themselves by a rail. The time was measured in seconds and reduction in time was considered to signify improvement. The two stair climbing tests were instructed differently as in one of them the patients (paper II) were allowed to hold on to a rail. Therefore the stair climbing time is not quite comparable between the groups in the two papers.

*Timed-stands test (TST) (paper II)*

Time-stands test (TST) evaluated the patient’s capacity to transition from a sitting to a standing position. The patients were asked to rise from and sit down on a chair with a height of 45 cm, ten times and as quickly as possible, without using the armrests. The time spent was recorded. The test has shown good test-retest reliability, validity, and responsiveness for patients with chronic diseases (121).

*Figure-of-eight test (paper II)*

The figure-of-eight test evaluated dynamic walking balance. A figure of eight was marked on the floor, with an inner and an outer circle. The outer diameter was 180 cm, while the inner diameter was 150 cm, The distance to walk in between the outer and inner circles was 15 cm. The patient started the test between the two circles and was told to walk twice around the figure of eight at a self-selected speed without stepping on the lines. The number of steps on or outside the marked lines were counted, the more steps, the worse score. The test has been found to be responsive, reliable and valid in older adults (122).

*Index of muscle function (IMF)(paper II)*

The IMF comprises 13 items for evaluating muscle strength, balance and endurance in lying, sitting, and standing positions. The patient’s performance was observed and evaluated on a 3 point scale (range 0-2, where 0= no difficulty, 1 = some difficulty, 2 = severe difficulty) (123; 124). The index produces a sum score with 40 as worst possible score. The test has acceptable validity and reliability when compared to other performance-based tests in patients with OA (124).

*Knee circumference (paper I)*

Knee circumference was measured over the joint space and recorded in centimeters (cm). A change in circumference was used to determine the size of swelling.

**Self-reported measures of physical functioning and pain**

*Knee Injury and Osteoarthritis Outcome Score (KOOS)(paper II).*

The KOOS is a disease specific measure of physical functioning evaluating knee pain and knee problems in patients with knee OA and after TKA (97;125;126). The KOOS is an extension of the Western Ontario and Mc Master Universities Osteoarthritis index (WOMAC) and the most commonly used outcome measure of patient-relevant treatments effects in osteoarthritis (97;98). When compared to the WOMAC, the KOOS also contains items about quality of life and sport and recreation activities related to the knee. The test comprises five subscales: pain, symptoms, functioning in daily living, functioning in sport and recreation, and knee-related quality of life. KOOS is used over both long and short intervals to assess changes in physical functioning (98). A score of 100 indicates “no problems,” while a score of 0 indicates “extreme problems”. A change beyond 10 points is considered a clinically relevant change in any of the sub items of KOOS. The test has been found reliable and valid in patients with knee problems (125).

*Self-efficacy scale (paper II)*

Perceived self-efficacy is concerned with peoples` confidence in their capabilities to produce given attainments (127). Presently, these attainments were related to activities of transfers and walking which the walking skill intervention had the intention to approach. A self-efficacy scale for activity was developed by two of the authors, inspired by the theory of Bandura (128). The scale on self-efficacy in activity contained ten questions asking to which degree the patients felt confident in performing ambulation and transfer activities. Examples of these questions were bending down, squatting, ascending several flights of stairs without using a handrail or crossing an intersection in time (Appendix1). Each question featured a scale from 0 to 10, where 0 is “very uncertain” and 10 is “very certain” in coping with the activity in question. The responses to each question were added up to calculate a sum score (0-100).

*Pain intensity (paper I)*

Present knee pain was reported on a 100 mm visual analogue scale (VAS) where 0 indicated "no pain" and 100 indicated "unbearable pain" (129). Compared to questionnaires, the VAS has been found reliable and valid when it came to each individual‘s perceptions regarding pain (129).

*Exercise log (paper II)*

Information about the contents of the usual physiotherapy care was obtained from exercise logs filled in by the patients according to a structured questionnaire. The questions were related to whether the exercises were performed with or without supervision by a physiotherapist. Further, if they were performed in lying, sitting or standing positions, and performed with or without weights (Appendix 2).

**Physiotherapy during hospital stay**

*Active exercise group (paper I)*

The patients in both the experimental and the control group performed exercises supervised by a physiotherapist. The exercises consisted of active or active assisted flexion and extension movements of the hip/ knee, active isometric contraction of the quadriceps performed in bed, walking with a walker or crutches and eventually climbing stairs. The post-operative training program was conducted according to the same guidelines for all the patients. The exercises were performed daily, starting on day one after surgery, lasting approximately 30 minutes and as long as the patients were in hospital, and the exercises were adjusted to the patient's degree of pain.

*Continuous passive motion and active exercises (paper I)*

The experimental group was given passive motion of the knee in a continuous passive motion (CPM) machine in adjunct to active exercises during hospital stay. The procedure for application of the continuous passive motion was as follows: On the day of the operation the machine was set between 70°-100° for flexion and the newly operated knee was moved continuously in flexion and extension for two hours duration twice that day. The next day the machine was set to maximum of 0-100° flexion and the knee was kept in movement continuously for two hours three times a day. The knee was moved in the CPM machine each day until the patient was discharged from hospital, usually after one week. Between the sessions the knee was placed in the extended position.

**Physiotherapy after discharge from hospital**

*The usual physiotherapy care group (paper II)*

The patients in the control group received usual physiotherapy care participating in 12 individual physiotherapy sessions which took place twice a week from six weeks to 12–14 weeks after the operation, lasting approximately 40 minutes each time. Information about the contents of the usual physiotherapy care was obtained from exercise logs filled in by the patients according to a structured questionnaire. According to the logs, the usual physiotherapy care contained a combination of range of motion and strengthening exercises with weights; mainly performed while sitting or standing. The exercises logs are described in Appendix 2.

*The walking skill group (paper II)*

The patients in the experimental group participated in 12 physiotherapy sessions each twice a week from six weeks to 12-14 weeks after the operation. The training sessions lasted approximately 70 minutes each time and took place in a large gym at a local hospital in Norway. The main focus in the walking skill group was training in different weight bearing positions. The training consisted of transfers in standing, stretching up and bending down, sitting down and rising up from a chair in different ways, lunges in different ways, walking over obstacles resembling walking outdoors, walking in stairs up down and sideways, and walking at different speeds with stops and turns in a long corridor until they became short of breath. Impairments like range of motion hampering the actual walking task was built into each walking activity. The walking tasks were performed in a variety of ways and with several repetitions. Continuous supervision was given by the physiotherapist throughout training to enable the patient to load the knee properly. The targets and content of the walking skill training is described in paper II and Appendix 3. The patients did not participate in any other organized training than the walking skill program during the interventional period.

**Figure 4. Images from the walking skill group.**

With kind permission from the patients involved

**Statistical analysis**

The statistical software program for Windows, version 12.0 ( paper I) or 18.0 ( paper II) were used for the statistical analysis. The level of statistical significance was set at 5%. In both papers, descriptive statistics for continuous data were given as mean values with their standard deviations (SD). For categorical variables, proportions or frequencies were calculated.

The chi-square test was used to analyze differences between the groups before the interventions started with respect to categorical data, while normally distributed continuous data were analyzed using independent sample t-tests ( paper I and II). To examine within group differences between two time points in continuous variables, paired sample t-tests were used (paper I and II). The results are given as mean scores at different time points and their standard deviations (SD).

In paper I, to examine the difference in change scores between groups, independent sample t-test were used. The results are given as mean scores at different time points with their standard deviations (SD). In paper II, differences in change scores between groups were analyzed by an analysis of covariance (ANCOVA). In this analysis the data were adjusted for pre-test scores and gender in the performance-based measures and for educational level as well in the self-reported measures. The results are given as adjusted mean differences in change scores between the groups at different time points and their 95% confidence intervals (CI), and their eta square effect sizes to aid in the interpretation of the data. A partial eta square value between 0.01 and 0.05 is considered a small effect, between 0.06 and 0.13 a moderate effect and between 0.14 and 1 a large effect (130).

Missing data in paper I were excluded (n=4), and data from 63 patients were included in the analysis. Missing data in paper II were treated according to the principle of intention to treat (ITT), by carrying the last observation forward or backwards the efficacy was set to 0. Data from all included patients were therefore also included in the analysis (n= 57).

## Qualitative study (paper III)

To address the research question of how we as physiotherapists adjusted the walking skill intervention to the local context, a qualitative design based on self-observations was applied.

**Data collection**

We as the physiotherapists conducting the intervention were both responsible for the development of the intervention as well as doing the research related to how the intervention was performed in clinical situations. This gave us several roles in the research process. As experienced physiotherapists we benefited from years of practice when designing the program. As clinical physiotherapists we had a strong belief that training in walking skills which reflected the walking demands of everyday life would have positive effects on the patients' recovery in walking (81). As researchers, we also believed we were be able to keep a certain distance (109).

As we started to conduct the intervention, we initially wanted to describe our own training sessions as a sort of assurance of quality. As we continued to conduct the training sessions, we soon discovered that both we and the patients performed various adjustments that were not covered by the standardized descriptions in the previous RCT. We discussed and soon agreed on the need and possible benefits of getting data about how we performed the intervention; especially what sort of adjustments we were doing and why. A helpful tool was self-observations by describing concretely how the patients and physiotherapists acted in various clinical situations, as well as reflective notes on how we as physiotherapists reasoned on the actions in the various clinical situations.

Immediately after each training session in which we had participated, we described what we and the patients had been doing during the prior session as well as describing reflections on our actions. Accordingly, we had a dual aim, both to be actively involved in creating clinical situations as well as to describe and reflect upon our own prior session afterwards (131). In the beginning, the field notes were rather unfocused and described both the patients' expressions related to the group and the training; as well as which tasks that were performed. Examples of the patients' expressions were: " Despite all the training I have done, I have never trained balance like this" or "How on earth do I get sweaty from doing these easy exercises?"  In this way the patients' preconceptions and expectations to physiotherapy became elicited. It seemed like the present physiotherapy approach was experienced differently than physiotherapy in which they had previously taken part. The reflection notes described how each patient performed the tasks, as well as how the physiotherapists reflected on what it was like to conduct the group. Examples were the quotes: "We are having fun" or "Being  a physiotherapist can be exhausting, nearly as a member of a service."

Over time, the field notes became more focused, comprising descriptions of the purpose of the particular training situations and the actions of the patients and the physiotherapists. The reflection notes increasingly included the physiotherapists' views, reflections and evaluations of their own and the patients' actions, of their successes and failures. How the physiotherapists adjusted and construed their actions with the patients in various ways with the underlying motive to enable the patients to move forward and normalize walking was the focus presently. The data material for analysis comprised the field and reflection notes of self-observations from 50 training sessions written up separately by my physiotherapy colleague and myself. Since we were both involved in different situations during a session, our notes included rich descriptions and reflections of a variety of clinical situations.

**Data analysis**

In the beginning the field notes were read separately by two of the authors of paper III (1 and 5), to get an overall view of the data. In later phases, data were read again by two other co-authors (author 2 and 3) who were outsiders to the project. A guiding question was: what do these data tell us about tailoring the intervention to the context? By context we meant different clinical situations, with different patients doing various activities listed in the training program.

We identified excerpts of the texts related to adjustments and coded these parts of the notes manually. Examples of codes were; adjustments when doing tasks, and adjusting tasks targeting a specific impairment. Then links between codes related to training sessions and reasons for doing adjustments from a physiotherapist's point of view were performed. The combination of codes were sorted and grouped into subthemes labelled for example as how various tasks were adjusted to enable the patient to perform, or how the tasks were adjusted to the patients' aspirations for future recovery. Four analytic traces were elicited in the empirical material related to how the physiotherapy evaluation was modified to patient's future aspirations, how the patient's future aspirations were modified by the patient throughout training, how the patient's future aspirations influenced the task to be trained, how adjustments were made in the task training itself through the doing of the task. These various adjustments or modifications were closely interwoven and shed light on the complexity of how the intervention was practiced.

In the beginning several field notes were analysed by one of my co–authors and myself ( author 1 and 5). Initially we discussed our overall understanding and coding of the texts. The further analysis was performed solely by me who was one of the physiotherapists leading the group. To question my own subjectivity, the text and interpretations were critically appraised and continuously discussed with the three co-authors not attending the sessions (author 2, 3 and 5). Persons with different professional backgrounds and methodological competencies were involved in the analytic process, continually raising questions to issues that initially may have been taken for granted, and thereby my own subjectivity was further questioned and addressed.

# 4 THE MAIN RESULTS

## Participants

In paper I, seventy patients were found eligible and asked to participate, while three patients declined. Sixty-seven patients were included and measured before the operation and one week after surgery. Four patients did not attend the follow-up at three months and were not included in the analysis. Thus a total of 63 participants were included in the analysis, 33 in the active exercises group (control group) and 30 in the continuous passive motion and active exercises group (experimental group).

In paper II, one-hundred-and-one patients were found eligible before the operation. Twenty patients declined to participate when invited preoperatively, while 24 patients declined further participation when invited again after six weeks. In total 57 patients were included in the analysis, 28 in the usual physiotherapy care group (control group) and 29 in the walking skill group (experimental group). In paper III, 29 patients in the walking skill group and 35 patients with THA took part in the walking skill intervention. The descriptions of the patients with TKA included in paper I, paper II and paper III are presented in table 3.

**Table 3. Preoperative descriptions of the patient groups (paper I, II, III)**

| | **n= 63** | **n= 57** | **n= 29[1]** |
|---|---|---|---|
| Age (years), mean (SD) | 69 ± 10 | 69 ± 9 | 68 ± 8 |
| Men/ women in % | 30 / 70 | 44 / 56 | 38 / 62 |
| Education > 12 years n (%) | 29 (46) | 34 (60) | 20 (71) |
| Pain, mean (SD) | 49 ±18 | 47 ± 16 | 52 ± 3 |
| Active ROM (º), mean(SD) | 120 ±16 | 117±11 | 116 ± 13 |

[1] The experimental group in paper II

# Results : Paper I-III

## Paper I:

**Continuous passive motion as an adjunct to active exercises in early rehabilitation following total knee arthroplasty – a randomized controlled trial.**

The objective was to investigate whether continuous passive motion (CPM) had an effect on pain, knee ROM and walking ability above the effect of active post-operative exercises in patients with TKA, one week and three months after the operation.

There were no statistical differences between the treatment groups in any outcome from preoperatively to discharge from hospital nor after three months. The patients in both groups deteriorated in their active flexion from preoperative scores to three months after surgery. The CPM group deteriorated from mean (SD) 121º± 14 to 105º ± 18 in active flexion while the control group deteriorated from mean (SD) 127º± 12 to 109º ± 14. For the whole group, a 50 % reduction in pain score was found after three months ($p<0.01$). Compared with the scores before surgery, a statistically significant impaired knee flexion range of motion ($p<0.01$) and a statistically significant decrease in number of patients able to climb stairs were found after three months for the whole group ($p< 0.01$). Accordingly 28 patients were able to climb stairs at three months as opposed to 40 before surgery. Those able to climb stairs at three months had significantly less pain ($p = 0.04$), better active flexion ($p < 0.001$), better TUG score ($p < 0.001$) and were younger than those unable to do so. There was no correlation between range of motion and walking distance after three months.

In conclusion, CPM was not found to have any additional short time effect in any of the outcomes measured compared with active physiotherapy exercises alone. After three months considerable pain relief was obtained for the whole group, the patients preoperative ROM was not restored and the number of patients able to climb stairs had decreased.

## Paper II:

### The immediate and long-term effects of a walking-skill program compared to usual physiotherapy care in patients who have undergone total knee arthroplasty (TKA). A randomized controlled trial

The objective was to examine the immediate and long-term effects of a complex walking-skill program performed from six weeks to 12-14 weeks after surgery in solely weight-bearing transfers and walking, compared with usual physiotherapy care, on performance-based and self-reported physical functioning, pain and perceived self-efficacy, in patients after total knee arthroplasty (TKA).

Both groups improved in most outcome measures from six weeks to 12-14 weeks (T1 to T2). The patients in the walking skill group improved their walking distance from mean (SD) 368 ± 89 meters to 477± 92 meters, directly after the intervention, and further to 492 ± 90 meters nine months after the intervention (T3). The usual physiotherapy care group improved their walking distance from mean (SD), 332±107 to 413± 105 meters directly after the intervention, and further to 425±93 meters, nine months after the intervention (T3). In 6MWT, a statistically significant difference in change scores between the two groups from T1 to T2 was found in favor of the walking skill group with mean (CI ), 39 meters (2-76), p = 0.04 and an effect size of 0.07. The difference between the groups in 6MWT persisted nine months after the intervention (T3) of mean (CI), 44 meters (8-80), p = 0.02, with an effect size of 0.10. In the 6MWT there was no statistically significant difference in the change scores between the two groups from T2 to T3. No statistically significant differences between the groups in any of the secondary performance-based outcome measures were found. Weight-bearing was tolerated without adverse effects.

Immediately after the intervention, in the self-reported KOOS sports and recreation, a statistically significant difference in change scores between the two groups was found in favor of the walking-skill group, p = 0.008, with an effect size of 0.13. Further in the perceived self-efficacy in activity scale, a statistically significant difference in change scores between the two groups was found in favor of the walking skill group, p = 0.03 with an effect size of 0.08.

These statistically significant differences between the groups did not persist nine months after the intervention.

In conclusion, both the patients in the walking skill group and the usual physiotherapy care group improved during the observational period. The group performing the walking skill program from six weeks to 12-14 weeks after TKA, showed a statistically significant improvement in walking distance with clinical relevance compared to usual physiotherapy care both immediately after the interventions and at follow up nine months after the intervention. Training in weight-bearing was tolerated.

## Paper III:

### On the inside of a walking skill program for patients who have undergone total hip or knee arthroplasty

**A qualitative study**

**Purpose:** A complex walking skill intervention was reported effective by two RCTs in improving walking for patients who had undergone total hip (THA) or knee arthroplasty (TKA). When evaluating such interventions, there are recommendations for addressing outcomes as well as develop insights into how the intervention is tailored to the local context.

This paper reports a qualitative study of how we performed the intervention in practice. The questions to be addressed were: How and why were the physiotherapists doing adjustments of the walking skill intervention? How could a deeper and more detailed understanding of how the intervention was practiced add value to the outcomes of the intervention?

**Methods:** Field and reflection notes from two physiotherapists' self-observations of 50 training sessions performed during 6 months were analyzed.

**Findings:** The paper describes how walking skills were improved and normalized through a series of adjustment depending on the mutual understanding that gradually developed between the physiotherapist and the patient. The adjustments were made according to how the patients aspirations differed, what impairments they needed to improve, the severity of their impairments and how these influenced the patients' ability to walk. The physiotherapist's ability to draw on her expertise, including her practical knowledge, proved to be of critical importance in examining each patient's performance and tailoring the exercises to meet each individual needs.

**Conclusion**: The adjustments of the various tasks, may have contributed to the effect documented in the RCTs. This study may therefore be an early attempt to bridge the gap between evidence drawn from two RCTs and expanding evidence elicited by insight into how a complex intervention was tailored to the local context. In seeking to demonstrate clinical efficacy, different sorts of evidence has to be valued.

# 5 DISCUSSION

This thesis examined the significance of physiotherapy on physical functioning in patients with osteoarthritis who had undergone total knee arthroplasty (TKA). In the short term recovery period after TKA, continuous passive motion had no additional effect on range of motion or other aspects of physical functioning above active physiotherapy exercises, neither one week nor three months after surgery (paper I). From 6-14 weeks after surgery, physiotherapy in terms of the walking skill intervention had better effect on walking distance than usual physiotherapy care, both immediately and nine months after the intervention (paper II). Apart from training in weight-bearing described in more standardized terms in the RCTs, the in-depth examination of how and why the physiotherapists were doing various adjustments in specific clinical situations may have contributed to the reported effect (paper III). These findings are discussed in the respective three papers. If one looks across the papers, core issues found relevant for further discussion are related to exercise intensity and specific kind of exercises performed both during hospital stay and after discharge from hospital, and to methodological considerations related to all three studies.

In general, exercises are believed to depend on a certain intensity with respect to for example repetitions and exercise duration time, as well as the specific kind of exercises performed, to exert their effects (10). Thus, the differences in training intensities between the experimental and control groups in both paper I and II may contribute to explain the efficacies. The first issue raised presently is related to the impact of the intensity of the physiotherapy exercises applied during hospital stay (paper I). In the control group, usual physiotherapy care consisted of repetitive assisted and active ROM exercises as well as assisted walking with a walking aid. In adjunct to this, in the experimental group the number of ROM exercises was increased considerably by adding six hours of daily repetitive passive motion exercises with the aid of the CPM machine. Accordingly, in paper I, one may say that we examined the assumption that the more repetitions of ROM exercises, the better the outcome in knee flexibility. However, even with an extensive number of repetitions through a prolonged exercise time, no additional effects on range of motion above usual physiotherapy were found. Therefore, our study in paper I does not support the assumption that the higher intensity of ROM exercises, the better the outcome in ROM. These results are in accordance with two Cochrane reviews investigating the effects of various CPM procedures (11;132) with exercise duration times lasting from five to twenty hours a day (11). Taken together, it is therefore a relatively strong evidence that a considerably increased number of repetitions of ROM exercises is of no importance for improving ROM during hospital stay. However, questions may be raised as to whether CPM alone could replace active exercises in the postoperative phase after TKA, as their efficacy was equivalent. To my knowledge this has not yet been studied. As a clinical physiotherapist, I will argue that there are several important reasons for emphasising active instead of passive exercises during hospital stay, for instance to prevent post-operative circulatory complications and promote muscle activation (9;10). Therefore in my opinion, a possible replacement of active exercises with solely passive exercises for several hours a day during hospital stay seems inappropriate.

The second issue raised presently is related to the effect of the intensity of physiotherapy exercises and the specific kind of exercises applied after discharge from hospital. Before starting the intervention, I had a prior assumption that the closer the training approached the walking activity to be improved, the better the outcome in walking (81;82). Figure 3, page 30 in this thesis illustrates that the specific kind of exercises performed in the experimental and control group in paper II differed. The usual physiotherapy care group contained exercises more on impairment level in both weight-bearing and non-weight-bearing positions. The walking skill group on the other hand contained training in solely weight-bearing on activity level. However, also the difference in exercise duration time between the groups may have been of importance for the efficacy of the walking skill program. The exercise duration time in the walking skill group exceeded that of the usual physiotherapy care group, as the walking skill group trained for approximately 70 minutes versus 40 minutes in the usual physiotherapy care group. Therefore, both exercise duration time as well as the specific kind of exercises performed differed between the groups. Therefore I cannot say whether the efficacy of the walking skill intervention was a result of the specific kind of walking exercises performed, their intensity or both. Consequently it would have been preferable that both the experimental group and the control group had trained in the same exercise duration time, to examine the significance of the specific kind of exercises. Nine months after the intervention, 83% of the patients in the walking skill group had changed their walking distance more than 50 meters as opposed to 71% in the usual physiotherapy care group. Even if the effects on walking were rather small, and we do not really know whether it was the intensity or specific kind of exercises that exerted the effects, one may still consider the results from study II as promising. An important reason for this is the prior assumption that training in weight-bearing positions should be minimised in the first months after TKA; as they are largely believed to be influenced by pain (133). However, the patients in the walking skill group tolerated training in fully weight-bearing positions for as long as 70 minutes twice a week, as early as six weeks after surgery without increased pain, compared to the control group. Another study has supported our results on the tolerance of weight-bearing training after TKA (133). Based on these findings we therefore suggest that weight-bearing task training may be a new and promising way to approach these patients' physical functioning after TKA. However, to establish its efficacy more studies should be performed. As walking activities are complex to address and the patients' capabilities in walking vary, new studies should be performed according to the New Medical Research Council Guidelines for developing and evaluating complex interventions (4).

As the patients tolerated training in weigh-bearing, one may consider other important clinical implications from the walking skill program than assessed presently. Firstly, in other musculoskeletal pain disorders there is evidence for that fear of pain from doing activities reduces the patients' level of physical activity (134). Patients often have a lot of pain after their TKA operation which in turn may make them scared to put pressure on and load the knee and thereby reduce their activity level (135). Therefore one may argue, that by making the patients confident in walking activities of daily life may have facilitated and motivated the patients to continue to walk outside training. Thus, a weight-bearing training program may support them in returning to an active life. Thereby the patients may continue to stay physically active with all the health benefits this may add (136). As a physiotherapist I would argue that to practice walking tasks may be easier to perform as an integrated part of daily life than doing impairment training in non-weight-bearing often used in physiotherapy.

Table I in paper II show that the patients included in the walking skill group initially had different perquisites both with respect to their pain level; as well as to their physical capacity. Therefore the physiotherapists had to modify and adjust the walking tasks in various ways; to take these different perquisites into considerations to enable the patients to succeed and progress with their exercises. Thus, for the physiotherapist to conduct the intervention was experienced rather challenging. One may therefore argue that for the physiotherapist, this training required a lot of creativity, stamina, effort and practical knowledge to enable the patients to succeed in spite of pain. The adjustments performed by the physiotherapist may therefore have been an important premise for enabling the patients to perform the tasks in the program and thereby keep up the intensity in training. Moreover, physiotherapy interventions usually are described in terms of exercise duration times or number of repetitions (137). From a physiotherapy point of view I therefore think paper III thematizes how complex a physiotherapy practice can be and what it requires to perform it. In retrospect, we therefore consider that in the development and evaluation of the walking skill intervention we should have been in line with the new Medical Research Council Guidance and performed an early phase piloting (4). This would possibly have enabled us to have captured the complexity of the walking skill intervention to a greater extent

## Some methodological considerations

Presently, I will consider some methodological strengths and weaknesses across the studies in this thesis. The studies presented in paper I and II are both examining the effects of interventions applying an RCT design which is considered to be the most appropriate design for examining a relationship between cause (intervention) and effectiveness (108;138). With respect to fulfilling the quality of an RCT according to the evaluation published in the database for physiotherapy research PEDRO, paper I fulfilled 7 out of 10 criteria whereas paper II fulfilled 8 out of 10 (139). Thus, the methodological quality of both studies was found to be good.

Two of the missing scores in both studies were on lack of blinding of the patient and the therapist. Blinding is difficult to achieve when effects of exercise programs are examined, as those receiving and delivering interventions know what they are taking part in (140). Moreover, the researchers are obliged to inform the patients about what the researchers want to examine. Presently, in paper I, the physiotherapists in both groups were delivering usual care physiotherapy for the patients in the ward. It is therefore probable that the physiotherapists involved did not take any special interest in the study. In paper II, on the other hand, the walking skill intervention was delivered by a research colleague and myself. Therefore in study II, I had double roles, being the physiotherapist conducting the intervention as well as the primary researcher. This might have biased the results as I had a special interest and was involved in the walking skill program. The other physiotherapists treating the patients in the control group on the other hand, had little knowledge about the study (141). When I conducted the intervention, however, I rather became involved in the process of delivering and adjusting the exercises in order to enable each patient to manage, instead of being focused on the study. So to say, during the training sessions I became fully engaged in fulfilling my role as a physiotherapist more than having the role as a researcher. Thus, I would argue that the problem of not blinding the physiotherapists was more or less equivalent in the two studies.

Our intention when we planned to examine the effects of the walking skill intervention was to evaluate it in a strict RCT design. When a colleague and I started to practice the intervention, we first wanted to describe what we were doing as a sort of assurance of quality. Based on my own experiences of how challenging it was to conduct the walking skill program, I became increasingly eager to learn about what these experiences would imply for those who potentially would like to replicate the program, and to understand more about what the intervention actually comprised. During this practice we discovered that we had to adjust the tasks to enable the patients to perform the exercises. Gradually, I realized that this had to be described to meet the critics often raised on the scarce descriptions of the interventions examined for their effectiveness in RCTs (104). Therefore through the descriptions in paper III, the internal validity of the effect study in paper II was strengthened. In that respect we have in some ways met the recommendations of nesting the programme to the context as forwarded by the Consort (142) and the Medical Research Council Guidance (4).

On the other hand, one may still question the trustworthiness of our self-observations. Here it is essential to consider closeness and distance in the phases of creating data, e.g. data collection and analysis. In collecting the data I had a closeness to the practice I studied; as I was experiencing the walking skill intervention through conducting it. Through the lenses of a clinical physiotherapist, I therefore wrote down what we found challenging during this practice and why. These descriptions therefore elicited an insider perspective of how we ourselves construed the physiotherapy practice. We believed that through self-observations, inspired by Brinkmann (109), we had an unique possibility to describe the challenges experienced by conducting the walking skill program from a physiotherapist's perspective. An enhanced critical distance may possibly have been better accomplished by an outsider taking video recordings of us conducting the walking skill program. In videos, a more fully reconstruction of the program would have been obtained. However how and why each clinical situation was experienced as being a challenge would then have been missed out. Thus we think that our self-observations are valid data for the present purpose. In the systematic analysis of data, we kept a critical distance to the data material by involving several researchers with different backgrounds, not familiar to the training program, to scrutinize the analyses. Thereby my preconceptions were under constant questioning and the trustworthiness improved.

Another issue to be discussed is how the results both in paper I and II are interpreted. The interpretations may be dependent on issues including the success of the randomization, the statistical analysis applied and the outcome measures chosen. In paper I, the randomization was rather successful, and all the patients that were initially included also completed the intervention in the group to which they were allocated. However, four patients dropped out for various reasons during the follow-up time. An intention to treat analysis (ITT) could have been applied at this time point and thereby we would have gained one point more in the Pedro evaluation. We have reanalyzed the data and the use of an ITT did not change the results. Moreover the patients' compliance to treatment was good. Therefore my overall interpretation is that we can rely on the results from study I.

In paper II, in spite of concealed allocation, the randomization of patients into entirely comparable groups was not altogether successful. Therefore the differences between the groups were adjusted for in the statistical analysis according to recommendations (143) to make the groups as comparable as possible before the intervention started. As data were missing on two patients in the walking skill group, an intention to treat (ITT) analysis was applied. Even if an ITT analysis is preferred by many researchers (144), and also given points according to Pedro (139), one may question the way we used ITT presently. Natural recovery occurred in both patient groups. Therefore imputing a score of zero change in the patient's outcomes after the interventional period is rather conservative and may have underestimated the treatment effect (145). However, as the number of missing was small this did not impact the results.

One further relevant issue to discuss is whether the assessment methods chosen to assess the primary outcome of the walking skill program reflected the purpose and content of the program. The walking skill training program was aimed to mirror the demands of outdoor activities and included training that challenged ambulatory balance, muscular strength, flexibility and endurance (paper II). The ability to walk outdoors is likely to be more challenging than the ability to brisk walking on flat floors assessed by the 6MWT. Despite the findings of an improved 6MWT, it would have been preferable to assess walking in a broader sense. For example, as we in paper III elicited that an essential aspect of the adjustments of tasks in the walking skill program also implied normalizing the patient's gait pattern, this could have been addressed more directly by examining walking patterns by the application of an electronic walkway. This measure to detect deviations from normal gait has recently been applied in patients with total hip arthroplasty (146) and could be applied in future research. Thus, we think that we were not able to completely capture the purpose and content of the walking skill program by our primary outcome measure.

A sample representing the population is a key factor for controlling threats to external validity in a RCT. The external validity may become particularly influenced by a strong selection of patients. In such cases the results can only be extrapolated to a sample of patients similar to the study group (108). The patients in the present studies were recruited from two local hospitals in Norway. However, the recruitment of patients was slightly different in the two papers. The patients in paper I were recruited consecutively from hospitalized patients from the entire country, and only few patients declined participation in the study. In paper II however, a larger number of patients refused to participate. Importantly there were no differences in any preoperative measures between those who were willing and those who refused further participation in the six weeks before the intervention started. Moreover, an inclusion criterion in paper II was that the patients had to live in the vicinity of the hospital to be able to attend to training. However, in spite of different recruitment procedures, the groups in the two papers were similar in age and pain intensity and comparable to the age of a general Norwegian population with TKA (1). Taken together, the results in paper I may therefore be extrapolated to a population of patients who are to be operated for TKA in Norway. With respect to paper II, in spite that they also were comparable with respect to age and pain, the patients who are willing to take part in exercise groups are probably more motivated for exercise than those not willing. Therefore the results from paper II can be extrapolated to patients with TKA willing to take part in active exercises.

# 6 CONCLUSION

This thesis has addressed the significance of physiotherapy on physical functioning after TKA; by examining the effects of two physiotherapy interventions on physical functioning, one during hospital stay and the other after discharge from hospital. Moreover, this thesis has described how the latter intervention was tailored to the local context, to elaborate on its reported effects.

This thesis shows that a high intensity passive motion intervention by a CPM procedure given during hospital stay, aiming at regaining range of motion has no additional effect on range of motion above active physiotherapy exercises neither after one week nor after three months. The effects of a higher intensity walking skill intervention on walking distance suggest that it is feasible and effective to train in weight-bearing to improve walking after TKA, as early as six weeks after surgery. The patients tolerated the training without any increase in pain. However, several adjustments of the exercises had to be performed to enable each patient to perform the training. The adjustments tailored to each individual's aspiration for improvement and different prerequisites may have contributed to the effects.

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# ERRATA:

In paper I, table 1. At baseline, the scores in the 40 m walking test is corrected: CPM group 44 ±39, control group 41±16.