

How a dual-action cycle ergometer with variable-length pedal cranks can replace a CPM machine for acute post-knee surgery rehabilitation, and do much more.

An extended white paper and technical review

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Executive Summary

Background—CPM machine

Early repetitive movement of an operated joint promotes wound healing, assists in removing fluids from the periarticular tissues, and diminishes the risk of arthrofibrosis. For these reasons, surgeons have prescribed the continuous passive motion (CPM) machine to knee reconstruction and replacement patients for acute-stage therapy for almost 40 years. It is the only available repetitive mechanical technology that can be used independently by patients at home.

Repetitive movement of an operated joint, CPM sole mechanical device, but value questioned

Recent studies, however, demonstrated that the CPM machine does not significantly improve range of motion (ROM) six weeks post-surgery in comparison with control groups. The studies have led medical practitioners to question its value. Further, physicians now prescribe more aggressive mobility therapy in the acute stage to prepare patients for earlier discharge. Consequently, fewer patients are given access to this device.

Gap in continuum of care

This trend creates a gap in the continuum of care. Nevertheless, patients' physiological and psychological needs clearly persist for such treatment in the acute stage of rehabilitation. Early repetitive movement of an operated joint likely continues to be important to wound healing and controlling collagen deposition and alignment. Patients who are prone to excess scar tissue formation may be particularly at risk without a repetitive mechanical means of exercising the joint early to prevent disordered collagen deposition and transformation leading to arthrofibrosis. And patients need to see their knee move in reproducible patterns that gradually increase their ROM, at home, under their control, to confirm their hope in recovering their lost mobility.

Disappearance of CPM therapy in the acute stage of rehabilitation creates a **gap** in the continuum of care.

Not substituting a more effective replacement for the CPM machine could lead to increased incidence of arthrofibrotic knees, patient dissatisfaction,

and greater downstream costs following knee surgery. These consequences directly oppose the objectives of healthcare reform of making improved patient care more broadly accessible, improving patient experience, and reducing post-surgery costs.

Hospitals and CJR lump-sum payment model

Further, participating hospitals must control their costs under the recently mandated Comprehensive Care for Joint Replacement (CJR) bundled payment model rules or face penalties. Immediate discharge to home after TKA is seen as the lowest cost option for post-operative rehabilitation. However, it is difficult to monitor patient compliance with home exercise programs. A mechanical treatment device that can be used at home, with compliance monitoring, may be useful in guaranteeing consistent outcomes within the allotted time and reducing risk and healthcare costs.

Substitute for CPM machine

A suitable substitute would have to meet and substantially exceed the capabilities and impact of the CPM machine. At a minimum, it would have to be accessible to the patient within 24-48 hours of surgery and be portable and simple for home use. Additionally, it should be useful over the entire course of

rehabilitation, including “prehab.” Outcomes must carry over to the rest of the patient’s life, with demonstrable short- and long-term functional benefits such as recovery of age-normal muscle function and functional mobility including sit-to-stand strength, normal gait, gait speed and consequent confidence. It would be helpful if it were also more broadly applicable than lower extremity rehabilitation and benefitted other patient and user groups.

Suitable substitute for CPM meets and exceeds capabilities, produces long-term functional benefits.

Cycle ergometer

In this extended white paper we show that a cycle ergometer is a useful platform for designing a mechanical device that could fit the complex space of modern knee rehabilitation more completely than the CPM machine. At a high level, the design requirements include

Cycle ergometer is a useful design platform for CPM substitute

- (1) easy-to-adjust, built-in variable-length pedal cranks,
- (2) variable pedal crank length from a minimum of about 2” to at least 6”,
- (3) a safely mountable and adjustable recumbent seat,
- (4) ample and adjustable step-through space,
- (5) modular components for portability, and
- (6) a secondary mechanism that gives patients sufficient leverage to rotate the pedals with their hands (i.e., dual-action) for passive movement in the acute -early stages.

Science: Stationary exercise bike with short pedal cranks

A stationary exercise bike equipped with a set of short pedal cranks that allows cycling exercise earlier in rehabilitation is not a new idea. It was first reported in 1988, appears as an intervention in modern orthopedic therapy handbooks, and is in limited use today. A variable-length pedal crank arm which is easily adjusted by a therapist or patient extends the concept of the short-crank cycle ergometer and collapses multiple stationary exercise bikes with differing fixed pedal crank lengths into a single frame.

“Short-crank ergometer”
listed as early intervention:

Hospital for Special
Surgery. “Handbook of
Postsurgical Rehabilitation
Guidelines for the
Orthopedic Clinician.”
Elsevier Health Sciences.
2008.

Equivalency of short-crank cycling to therapeutic effects of CPM

The alternating flexion and extension of the operated knee while completing pedal rotations likely accomplishes the same fluid-pumping effects attributed to the CPM machine, with the same benefits of long-term joint mobility. The key words are “completing pedal rotations,” which acute-stage post-operative TKA and knee reconstruction patients cannot do unless the bike’s pedal crank is very short, no longer than about 2 inches long (about 60° maximum flexion).

Passive to Active-assisted to Active to Resisted

Pedaling a dual-action bike with short cranks will expedite transition from the passive movement stage into active-assisted as the knee extensors begin to fire and participate in the powered stroke of the pedal rotation.

Active-assisted movement continues until the operated leg can fully drive the pedal through its power stroke at a given pedal crank arm length and tension setting. The cycle ergometer naturally progresses the knee to active and resisted movement at normal speed.

In the first two weeks after surgery

Many revolutions at the low range of motion offered by short pedal cranks can be accomplished in the critical first two weeks post-surgery, under the patients' control, without tipping the wound back into inflammatory process. *Flexion* can be incrementally increased by methodically adjusting the pedal crank length and seat position. Pedaling in reverse with a short crank at higher



tension can *enhance recruitment and activation of the quadriceps muscles as well as reduce extension lag* through mechanically-driven short arc quad sets. These are the essential elements of higher intensity exercise implemented earlier and at lower ROM which suggest *long-term benefits of quadriceps strength and functional motion*.

Psychological impact

Such a device that can be implemented in rehabilitation immediately post-surgery also may exert a positive psychological effect on knee reconstruction and replacement patients. The positive feedback from completing pedal rotations at this early stage—*in their comfort zone, without pain*—builds their confidence. It will help dissipate fear, diminish guarding of the lower

extremities, expedite healing, and make them believers. They will likely improve their exercise self-efficacy as they see even incremental progress through the clear and systematic milestones provided by the progressing settings of seat and pedal positions and tension, and speed and duration of exercise.

Positive feedback from pain-free early pedaling builds confidence, diminishes muscle guarding, enhances recovery.

Anybody with limited ROM can benefit

Many patient groups presenting limited ROM can benefit from its use. Seniors can be strengthened and their gait speed increased to protect them from falling via non-weight bearing exercise. People can prepare the muscles and other soft tissue around their knees for surgery or perhaps strengthen and stretch them sufficiently to avoid or postpone surgery and eliminate pain. Arthritis patients can exercise pain-free within their acceptable range of motion and perhaps even progress ROM, strength and gait speed where previously it was impossible to exercise. Athletes can keep the upper body moving to maintain physical and psychological conditioning while they recover from lower limb injuries. Post-rehab patients with arthrofibrotic knees may avoid manipulation under anesthesia and additional procedures with the attendant pain, accumulated risks, and long-term cost to the individual, hospital, and society. A variable-length pedal crank cycle ergometer with integrated adjustable seat may be the best mechanical exercise modality to provide the *incremental, systematic, and progressive exercise required to remodel these contracted soft tissues over time.*

Seniors, pre-op and arthritic patients, athletes.

Patients with **arthrofibrotic knees** might avoid manipulation under anesthesia and additional procedures.

Summary

The specially designed exercise bike is a single, simple mechanical device but it has the potential of bridging the patient's therapy across the continuum of care from pre-operative preparation to acute post-operative therapy, to home and outpatient rehabilitation, and finally to a traditional stationary exercise bike or road bike after discharge. It is a natural and patient-managed means of optimizing medical resources and patient engagement, especially in the home.

In this extended white paper we contrast and compare two fitness bikes and one rehabilitation cycle ergometer with variable-length pedal cranks, the SciFit Pro2®, ROM3® Rehab System, and OrthoBike™ OB1, according to the features that must be present to justify a suitable CPM substitute.

Review two fitness bikes and one rehab bike against requirements for CPM substitute.

Of the three, only the OrthoBike OB1 can replace the CPM machine for acute-stage rehabilitation and home-use. The Pro2 is a standard in the outpatient clinic for advanced rehabilitation that does not require an adjustable pedal crank. The ROM3 adjustable pedal system, although manifoldly complicated, may provide specific benefits to more advanced patients in the outpatient clinic who can mount and pedal a single-action fitness bike.

