Is there an Alternative to Immediate Home Physical Therapy Following Total Knee Arthroplasty?

A randomized controlled trial comparing home physical therapy, telemedicine-guided exercises, and an e-stim garment

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I. BACKGROUND AND SIGNIFICANCE

In July 2016, a meta-analysis was published that compared the effectiveness of home-based exercises with individualized outpatient physical therapy programs. Though the 11 studies examined were high in statistical heterogeneity, with moderate quality and small sample sizes, the analysis found no clear difference between home-based exercises and standard PT programs after total knee replacement. Outcome measures included knee range of motion (ROM) and various functional measures at 3, 6, and 12 months [1].

Other studies have confirmed these findings. In 2009 Coppola and Collins conducted a similar review of randomized controlled trials to compare PT with home exercise. Though the trials were generally not applicable to an older population with frequent comorbidities, the review also found no clear difference between the modes of therapy [2]. Artz et al. demonstrated improved physical function in patients receiving PT exercises compared to any other physical therapy technique, though in his study there were patients who had supervised PT exercises at their homes [3].

Other studies have examined outcomes such as knee ROM and questionnaire-based measures such as WOMAC, KSS and OKS, and have found a correlation between positive outcomes on both scores [4]. These various patient-reported measures were found to be no different between PT patients and alternative-method patients in two studies by Kramer et al. [5] and Ko et al. [6]. Even hospital readmission rates (within 6 weeks of surgery) were comparable between methods [7].

With the recent rise in the use of telemedicine for diagnosis and treatment, telemedical approaches to physical therapy, such as home-based exercise programs, have grown in popularity. Rather than sending patients home with a simple sheet of instructions, online rehab programs allow for regular updates to exercise programs as well as mechanisms for patients to provide real-time feedback on their progress. Given the comparability of home-based exercise to traditional PT, telemedical approaches may be worth considering in the future. For patients using an online program, the concomitant lowering of cost would certainly increase the overall value of this mode of treatment.

A second alternative to traditional physical therapy is known as neuromuscular electrical stimulation (NMES). This technique, colloquially called “e-stim,” is used to engage the quadriceps muscle, which undergoes a dramatic weakening, up to a 60% loss of strength, following total knee arthroplasty [13]. In e-stim, electrodes are thus positioned around the thigh; many NMES technologies integrate these electrodes into a brace that the patient wears. The

electrodes then conduct electrical signals to the muscle, mimicking the nervous system's own action potentials and causing the muscle cells to contract. The level of stimulation increases with the intensity of the current, which can be controlled by the patient in today's NMES devices.

For patients who receive total knee replacements, combining e-stim therapy with physical therapy in the preoperative and early postoperative stages has been shown to reduce knee extensor lag, decrease length of stay, and improve short-term walking speed up to one year after surgery. One study found that electrical stimulation improved the American Knee Score and the Oxford Knee Score for patients six weeks out of surgery. Statistically significant changes in walking speed and functional recovery were both noted [14].

As mentioned above, we also know that one month after TKA, quadriceps muscle strength has typically dropped by about 50–60% of its preoperative levels [15]. This weakness tends to persist in the years following surgery, often causing loss of balance, falls, and greater difficulty with standing up or climbing stairs. Literature on the topic suggests that NMES may effectively (though not perfectly) attenuate the loss of quad strength and improve functional performance following total knee replacement [16–19]. Although the learning curve has required supplementary education at times, such devices are less expensive than physical therapy and would thus be a welcome alternative to PT if its effects are indeed comparable.

Overall, we propose a non-superiority treatment study that will compare our traditional standard of care (home visiting physical therapists) with telemedical home-based therapy and with e-stim technology.

II. SPECIFIC AIMS

The purpose of this study is to investigate the superiority of telemedicine-guided physical therapy and e-stim devices in the first three weeks after a total knee replacement, compared with the current standard of care of home physical therapy. We propose equal outcome measures such as quadriceps strength, rage of motion, proprioception, functional tests, and general outcome measures at 2–3 months following total knee replacement.

We propose that a decrease of cost for outpatient physical therapy by 50% without decreasing outcome by more than 10% would create value, but that any decrease in cost must not result in a decrease in outcomes.

III. SUBJECT ENROLLMENT

Subjects for this study include all patients who are aged 18 or older and electing to undergo unilateral total knee replacement (TKR) with Dr. Wolfgang Fitz at Brigham and Women's Faulkner Hospital (BWFH) regardless of sex or other status.

Inclusion criteria:

- Age 18 or older
- Owns a device with internet connection

- Can download the E-vive application for the contractile garment (has sufficiently up-to-date phone or tablet, or has family member with such a device).
- Has a rudimentary understanding of Internet technology, especially e-mail
- Has a flexion of 90 º and flexion contracture of 5 º at the point of discharge
- Approved by a physical therapist to participate safely in the study at the time of discharge

Exclusion Criteria:
- Rheumatoid arthritis
- History of epilepsy
- Implanted and body-worn electronic medical device, including cardiac pacemakers, neural stimulators, insulin pumps, etc.
- Poor understanding of the use of the brace/electrical stimulation
- Lesions on the skin over the thigh
- Uncontrolled diabetes
- Uncontrolled hypertension
- Bilateral TKA or UKA planned
- If female, pregnant
- Cannot use non-operated leg postoperatively to propel active motion splint, caused by neurological or muscular diseases such as complete or incomplete paralysis or other causes of weakness with an inability to bend or extend knee
- Loss of sensation in operated or non-operated leg
- Has below- or above-knee amputations of non-operative leg
- Below- knee amputation of operated side
- Chronic pain syndrome with inability to walk
- Taking chronic narcotics and/or is taking more than 10mg codeine per day, or any Hydrocodone, or more than 200 mg of tramadol, or any other narcotics prescribed for moderate to severe pain
- Involved in pain clinics for chronic pain, or pain that is not related to the knee
- Has been diagnosed with knee disorder other than osteoarthritis, post-traumatic osteoarthritis, gout, pseudo gout, or any inability to walk due to disorders unrelated to the knee (e.g., hip disorders, spinal stenosis, paralysis, hemi-paralysis)

V. STUDY PRODECURES

Patients who are undergoing total knee replacement (TKR) with Dr. Wolfgang Fitz at Brigham and Women's Faulkner Hospital and meet all eligibility criteria will be informed about the study and asked if they would like to participate. The research assistant (RA) will screen upcoming surgeries and mail a letter describing the study to all qualifying patients to inform them of the study. If the patient has not contacted the study team within one week after this letter is mailed, the RA will call the patient by phone and ask whether the patient agrees to participate. Those who show interest will be offered the opportunity to discuss with both the RA and Principal Investigator (PI). Upon agreement, the patient's consent will be obtained and they will be randomly assigned to a treatment group using a computer-generated randomization.

A standardized mean difference of 0.90 has been reported in the previous published studies for quadriceps muscle strength between control and NMES intervention groups. This study will require 26 patients per group using this standardized mean difference, along with 80% power and the level of significance (p-value) set to 0.05. Adding in a 10% expected dropout rate, planned enrollment will be 29 patients per group for a total enrollment of 87 patients.

Approximately 2-3 months before surgery, patients will sign informed consent and will be randomly assigned to one of 3 treatment groups, to be described in detail below. Patients in all groups will receive a standardized telemedical "Pre-Hab" program (iGetBetter, Southborough, MA) to be followed in anticipation of surgery. This program includes both strengthening exercises and proprioception exercises. Prior to enrolling in the Pre-Hab program, all patients will undergo our standardized functional testing, including proprioceptive evaluation. The RA will also give each patient a live tutorial on how to use iGetBetter.

During their preoperative appointments, all patients will undergo preoperative testing to assess joint function and leg strength. Tests will measure sit-to-stand capabilities, quadriceps strength, distance walked in 2 minutes, walking speed, proprioception (balance), and range of motion.

Before surgery, Patients in Group 1 (the first treatment group) will receive no treatment except for iGetBetter; this is the current preoperative standard of care. After surgery, Group 1 patients will be given a Post-Op program from iGetBetter to use for 2–3 months. For the first 3 weeks, patients will only use iGetBetter. After those 3 weeks have elapsed, the patient will receive outpatient physical therapy in addition to iGetBetter, approximately twice per week for the next 6–8 weeks as all other groups.

Before surgery, Patients in Group 2 (the second treatment group) will receive iGetBetter like the other groups. They will also receive CyMedica's "E-vive" conductive garment and asked to download the corresponding smartphone application. They will be instructed to wear the e-stim garment two times each day, for 20 minute intervals each, for the 3 weeks immediately before surgery, and to change the electrodes weekly.

Stimulation from the garment will have the following parameters: frequency of 50 Hz; pulse duration of 5 ms; time on: 12.8 seconds; and time off: 10 seconds. The total contraction time in a 20-minute treatment will be 11 minutes. The waveform will be pulsed and asymmetrical.

Patients will be instructed on the proper use of the brace, including not to apply the two therapies consecutively to provide sufficient recovery time between sessions (recommended therapy is one session in the morning and one session in the afternoon/evening), and not to engage the NMES beyond what he or she can tolerate.

After surgery, Group 2 patients will immediately continue using the E-vive e-stim device, starting on the DOS. They will be taught how to use the device safely over their surgically repaired leg. For the first 3 weeks, they will only use the E-vive device, 2 times per day. After those 3 weeks have elapsed, the patient will receive outpatient physical therapy in addition to the E-vive home-based e-stim therapy, approximately twice per week for the next 6–8 weeks.

Before surgery, Patients in Group 3 (the control group) will receive no treatment except for iGetBetter; this is the preoperative standard of care. After surgery, Group 3 patients will receive the postoperative standard of care for total knee replacements at BWH. For the first 3 weeks, patients will receive home physical therapy. After those 3 weeks have elapsed, the patient will receive outpatient physical therapy approximately twice per week for the next 6–8 weeks.

Patients in all groups will attend two routine follow-up visits. The first will occur one week after surgery; there patients will have their dressing changed and receive narcotic prescriptions. At the second follow-up, which will occur 2–3 months after surgery, patients will receive the functional testing described above. We will also calculate total cost of the three different treatment modalities.

Additional routine data — including postoperative complications for infection, readmission rates, and routinely collected functional outcome measures — will be recorded at this 2- to 3-month visit. For all groups, the standard of care is to administer an opioid consumption diary in which patients submit VAS scores for pain, nausea, and satisfaction. The PI will review this diary with the patient during the first postoperative visit, and then again at the second. We will measure patients' pain, both in terms of VAS scores and in terms of total pain medications consumed. Each of these measures will be used for analysis at the completion of the study.

VI. BIOSTATISTICAL ANALYSIS

We will be comparing the three separate groups in the trial to see whether there exists a statistically significant difference between them. Variables in which we are interested are all detailed in the previous section. When comparing the three branches, all analyses will be run at a type I error rate of 5%.

VII. RISKS AND DISCOMFORTS

It is possible that the iGetBetter group could have worse outcomes than the other two groups if a patient does not log into the program, or does too many (or too few) of the exercises prescribed. However, our current experience is a high compliance rate with iGetBetter exercises and good hip and knee strength and standing balance 2 months after total knee replacement. Risks associated with a web-based rehabilitation program will be minimized by closely monitoring all information recorded by the patient. If patients are recording high pain scores or not recording exercises, the PI will be notified and the RA will contact those patients.

It is also possible that the E-vive group could have worse outcomes than the other two groups if the patients use the device too little or too much, or if they do not supplement the stimulation of the quad with stretches from outpatient physical therapy designed to improve range of motion. The device is linked through a smartphone to monitor compliance and range of motion. On rare occasions, E-vive therapy can result in skin reactions such as rash, inflammation, irritation, or electrode burns.

It is possible that the three groups may demonstrate different levels of postoperative outcomes and patient satisfaction — though we do not have a clear hypothesis as to which groups will yield the highest and lowest scores.

All risks and strategies for mitigation will be clearly explained during the consent process.

VIII. POTENTIAL BENEFITS

While no benefit to participation is ensured, it is possible that the patients in Group 1 may benefit from improvement of hip and knee strength and improved standing balance, and our preliminary unpublished results prove this. Patients are also tethered to Dr. Fitz through their pain, satisfaction, and sleep reports. Patients in Group 2 might demonstrate similar increased muscle strength and similar range of motion compared to the other groups. Due to the established nature of PT, our current standard of care (Group 3) will show similar or better outcomes compared to Group 1 and Group 2 measured by our outcomes variables.

Results of this study may also help to improve treatment options for patients recovering from TKRs.

IX. MONITORING AND QUALITY ASSURANCE

Data which could indicate a potential complication, whether related to the study or not — such as heightened risk of adverse outcomes, insufficient range of motion on the operated joint, or inability to use the web-based program — will be addressed by the PI immediately and reported in accordance with PHRC guidelines. The PI will determine if the study should be altered in any way or stopped for safety reasons.

Reasons for stoppage include a rate of adverse events greater than 10% in either group. These checks will help to ensure validity and patient safety. Unanticipated problems and adverse events will be reported to the PHRC in accordance with PHRC guidelines.

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