

EARLY SUPERVISED CLINICAL EXERCISE FOLLOWING TOTAL KNEE ARTHROPLASTY IMPROVES OUTCOMES

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ABSTRACT:

- **Study Design:** Cohort study with an age and sex-matched control group.
- **objectives:** To assess the clinical outcomes of a Supervised Clinical Exercise (SCE) compared to those of a group of age-matched and sex-matched controls who underwent a home based exercise program.
- **Background:** Total knee arthroplasty (TKA) successfully alleviates pain from knee osteoarthritis but deficits in function can persist long term. Despite these well-known deficits, there is little evidence supporting the use of rehabilitation interventions following TKA.
- **Methods:** Eight patients, who participated in the SCE program, were compared to 8 age and sex-matched patients who participated in a Home Based Exercise program (control group). Patients were assessed preoperatively, and at 3.5, 6.5, 12, 26, and 52 weeks postoperatively. Assessment of patients included measures of pain, range of motion (ROM), functional performance, and quadriceps strength.
- **Results:** There were no differences in knee ROM and pain between the SCE and control groups at any postoperative time point. At the 3.5-week and 12-week (end of rehabilitation) time points, the SCE group had better functional performance and quadriceps strength compared to the control group ($P < .05$). At the 52-week time point, the SCE group continued to demonstrate better functional performance compared to the control group ($P < .05$), along with greater quadriceps strength ($P = .08$).
- **Conclusion:** A SCE program leads to better short and long-term strength and functional performance outcomes compared to a home based exercise program. The SCE program did not impair knee ROM and did not result in any musculoskeletal injuries in SCEs small group of patients.

Key Words: joint replacement, older adults, osteoarthritis, rehabilitation

INTRODUCTION

A number of total knee arthroplasties (TKAs) are performed each year in India, secondary to the pain and physical limitations caused by knee osteoarthritis (OA). Over the next 2 decades, the number of TKAs performed yearly is expected to grow dramatically. Although TKA reliably reduces pain and improves self-reported function in patients with end-stage OA, the recovery of strength and function to normal levels is rare, which predisposes patients to future disability. One month after TKA, quadriceps strength drops to 60% of preoperative levels, even when traditional postoperative rehabilitation is initiated within 48 hours after surgery.

The quadriceps weakness persists years after surgery, based on comparisons with age-matched controls.

Similarly, functional performance declines precipitously by up to 88% in the first month after TKA and reduced function persists, with reports of 18% slower walking speed and 51% slower stair-climbing speed compared to age-matched controls at 12 months after TKA. Secondary to these strength and functional deficits, 75% of patients report difficulty negotiating stairs years after their TKA. Moreover, 52% of patients after TKA report some limitation in performing functional activities, compared to only 22% of age-matched individuals without knee disorders.

Despite these known impairments and activity limitations, there is little evidence to help guide rehabilitation of this population. In 2003, the National Institutes of Health concluded that “the use

of rehabilitation services is one of the most under studied aspects of the preoperative management of patients following total knee replacement.” In 2007, the most recent meta-analysis on the effectiveness of physical therapy following TKA concluded that physical therapy has no long-term benefits. However, these conclusions were based on only 5 studies that met the inclusion criteria for the Meta analysis. One potential reason for the lack of demonstrated efficacy of these trials is that none of the included trials examined the use of a high-intensity, long-duration rehabilitation program initiated immediately after discharge from the hospital. There is preliminary evidence that a progressive high-intensity rehabilitation program can lead to improved outcomes in this population, though this program was initiated 1 month after surgery, when strength and functional deficits were already profound. However, there are concerns in the orthopedic community that a higher intensity intervention initiated immediately following hospital discharge could lead to increased pain and swelling and ultimately to poorer range of motion (ROM) and functional outcomes.

The purpose of this study was to assess the clinical outcomes of a SCE group, long duration rehabilitation program after TKA, initiated after discharge from the hospital, compared to those of a Home based exercise program.

METHODS

Study Design

This was a prospective, cohort study of patients who completed a Supervised Clinical Exercise (SCE) after TKA, with comparison to an age and sex-matched cohort of patients who completed a Home based exercise program (control group). Patients were assessed 1 to 2 weeks preoperatively, and 3.5, 6.5, 12, 26, and 52 weeks postoperatively. The 52-week assessment time was chosen for long-term follow-up, as patients recovering from TKA typically plateau in strength and functional gains by this time. The study was approved by Singhanian University Review Board. Informed consent was obtained from all participants, and the rights of participants were protected.

Participants

Eight patients (mean SD age, 65.3, 5 females, 3 males) who underwent a primary unilateral TKA

and completed SCE were compared to an age-matched (5 years) and sex-matched control group of patients who completed a Home based exercise intervention (mean SD age, 65.1, 11.5 years; 5 females, 3 males) as part of an ongoing clinical trial. Patients participating in SCE intervention were consecutively recruited from the community from February 2011 to December 2011. Patients who completed the home based exercise intervention were control subjects in an ongoing clinical trial and recruited from the community. The patients in both groups were included if they were between the ages of 50 and 85 years and were under-going a primary unilateral TKA for end stage knee OA. Patients in both groups were excluded if they had uncontrolled hypertension, uncontrolled diabetes, body mass index greater than 35 kg/ m², significant neurologic impairments, significant contra lateral knee OA (as defined by a verbal numerical pain rating of greater than 4/10 with walking or climbing stairs), or other unstable, lower extremity orthopedic conditions.

Interventions

Average length of stay in the hospital for both groups was 3 days, and patients were treated twice daily by staff physiotherapists at their respective hospitals. Both groups began their assigned interventions upon discharge from the hospital. Both intervention groups had the following common elements in their rehabilitation programs: passive knee ROM exercises; patella-femoral joint mobilization (as needed); incision mobility; cycling for range of motion; lower extremity flexibility exercises for the quadriceps, calf and hamstring, Modalities (ice or heat as needed); gait training; and functional training for transfers and stair climbing. All patients were given a home exercise program (HEP) to be performed twice daily during the acute phase of recovery (first 30 days) and then daily until discharge from therapy. For both intervention groups, the HEP included ROM exercises, and weight-bearing and non-weight-bearing strengthening exercises for the quadriceps, hamstrings, hip abductors, hip extensors, and plantar flexors. The intensity and types of exercises performed for the HEP were similar to those performed during the supervised home and outpatient physical therapy sessions. However, patients in the SCE group did not perform machine-based resistive strengthening as a part of their HEP.

Control Intervention

Following discharge from the hospital, patients were treated in the home setting for 6 visits over 2 weeks, after which they were treated in outpatient physical therapy for an average of 10 visits over 6 weeks. Therefore, the total number of physical therapy sessions (home and outpatient) for this group after discharge was 16 visits over 8 weeks. All home health and outpatient physical therapists followed a standardized rehabilitation protocol, as previously described. Both weight-bearing and non weight bearing exercises were initiated with 2 sets of 10 repetitions, and then progressed to 3 sets of 10 repetitions. For strengthening exercises, weights were increased to maintain a 10 repetition maximum targeted intensity level; however, the maximum weight utilized for any strengthening exercise was a 4.5 kg (10 lb) ankle weight. Resistive exercises consisted of quadriceps setting, seated knee extensions, straight leg raises, side lying hip abduction, and standing hamstring curls. Body weight exercises consisted of step-ups, side step-ups, step-downs (5- to 15-cm step), terminal knee extensions, single limb stance, and wall slides.

CSE Intervention

Following discharge from the hospital, patients were treated in the home setting for 3 visits in the first week, after which patients were treated in outpatient physical therapy for 2 or 3 times per week until the completion of postoperative week 12, for a total of 25 visits. Both weight bearing and non- weight-bearing exercises were initiated with 2 sets of 8 to 10 repetitions, then progressed by increasing the resistance or difficulty of the task. Exercises were progressed, based on achieve

Table: Postoperative Outcome Measures by Group

Time/Variable	SCE Group	Control Group
3.5 weak postoperative		
• Stair Climbing test	23.6+-5.8	39.6 +-
• Time up & go test	8.9+-2.0	18.5 +-
• Six minute walk test	381.0+-	13.6 +-
• Knee flexion	73.0	4.4
• Knee extension	96.0+-9.0	302.0+-
• NPRS Resting	2.8+-7.1	88.0
• NPRS quadriceps strength	1.1+-2.1	91.0+-
• NPRS stair climbing test	1.4+-2.2	14.0
	1.1+-2.0	8.8+-6.5
		2.3+-1.4
		2.0+-1.9

climbing test		1.3+-1.2
6.5 weak postoperative		
• Stair Climbing test	15.0+-4.4	22.9+-
• Time up & go test	8.0+-1.8	10.4
• Six minute walk test	439.0+-	10.9+-3.9
• Knee flexion	73.0	374.0+-
• Knee extension	105.0+-	97.0
• NPRS Resting	12.0	103.0+-
• NPRS quadriceps strength	1.4+-6.0	16.0
• NPRS stair climbing test	1.1+-1.4	4.9+-4.4
	0.3+-0.8	1.0+-.8
	1.0+-1.4	0.8+-0.9
		1.9+-1.8
12 weak postoperative		
• Stair Climbing test	12.2+-3.1	17.7+-9.2
• Time up & go test	7.1+-1.4	9.1+-2.5
• Six minute walk test	439.0+-	447.0+-
• Knee flexion	93.0	98.0
• Knee extension	115.0+-	112.0+-
• NPRS Resting	12.0	11.0
• NPRS quadriceps strength	0.1+-5.1	1.6+-2.4
• NPRS stair climbing test	0.4+-0.7	0.1+-0.4
	0.4+-0.8	0.3+-0.8
	0.8+-1.2	0.5+-1.1
26 weak postoperative		
• Stair Climbing test	11.1+-2.9	15.1+-8.1
• Time up & go test	6.6+-1.1	9.1+-2.4
• Six minute walk test	532.0+-	457.0+-
• Knee flexion	73.0	82.0
• Knee extension	120.0+-	114.0+-
• NPRS Resting	12.0	8.0
• NPRS quadriceps strength	1.9+-4.6	1.4+-3.0
• NPRS stair climbing test	0.4+-1.1	0.3+-0.7
	0.4+-1.1	0.0+-0.0
	1.3+-1.9	0.4+-1.1
52 weak postoperative		
• Stair Climbing test	10.4+-2.8	17.3+-
• Time up & go test	6.5+-1.3	14.2
• Six minute walk test	552.0+-	8.8+-4.0
• Knee flexion	69.0	470.0+-
• Knee extension	122.0+-	117.0+-
• NPRS Resting	12.0	6.0
• NPRS quadriceps strength	-3.3+-4.4	-1.0+-5.2
• NPRS stair climbing test	0.0+-0.0	0.3+-0.8
	0.0+-0.0	0.3+-0.7
	0.4+-1.1	0.9+-2.1

-ment of predetermined milestones in addition to patient tolerance of the treatment. The Appendix provides a description of exercises and criteria utilized for this group. All exercises were progressed as tolerated, except when the following occurred: subjective complaints of decreased walking endurance, soreness for 2 hours or greater following the previous session, a decrease in knee ROM by 5° or more, an increase in knee joint swelling of 2 cm or more, or an increase in resting verbal numeric pain rating of 2 points or more. If the patient had 2 or more of the above findings, treatment for the subsequent session was adjusted to decrease intensity level to allow for recovery. If the only finding was soreness lasting 2 to 24 hours, then treatment was held at a similar intensity for that treatment session but only for exercises targeting the sore muscle group(s).

Resistive training was initiated with an adjustable ankle weight but progressed to machine-based strengthening once a patient was not achieving fatigue with the ankle weight. Eccentric resistive strengthening was initiated when the patient met criteria for progression from phase. Eccentric strengthening was performed utilizing a weight machine, with both lower extremities used for the concentric phase of the exercise and the surgical lower extremity alone for the eccentric phase.

OUTCOMES

Pain

Pain was measured utilizing a 11-point verbal numeric pain rating scale (NPRS), with 0 representing no pain and 10 represented the worst pain imaginable. Patients were asked for their NPRS prior to testing, during the stair climbing test (SCT) and muscle power. These tasks were chosen because they are demanding tasks during which patients frequently report knee pain.

Range of Motion

Active knee ROM was measured in the supine position using a long-arm goniometer. For active knee extension, the heel was placed on a 10-cm block and the participant was instructed to actively extend the knee. For active knee flexion, the participant was instructed to actively flex the knee as far as possible, keeping the heel on the supporting surface. Throughout this manuscript,

negative values of extension represent hyperextension.

Functional Performance

Measures of functional performance included the stair climbing test (SCT), timed up-and-go test (TUG), and 6-minute walk test (6MW). The SCT measures the total time to ascend, turn around, and then descend a flight of stairs. Patients were tested on 1 of 2 staircases during the study due to a change in facilities. One patient from the control group was tested on a 10-step stair case with a 17.1 cm step height. The remainder of patients from both groups was tested on a 12-step stair case with a 17.1 cm step height. The absolute times of the control patients with 10 step data were adjusted by a factor of 1.2 to allow for comparison between groups. The minimally detectable change associated with the 90% confidence interval for this measure has been estimated to be between 2.6 and 5.5 seconds in patients recovering from TKA, depending on the time point assessed. The TUG measures the time to rise from an arm chair, walk 3 m, turn around, and return to sitting in the same chair without physical assistance. The MDC for the TUG in patients the first 1.5 months after TKA is 2.49 seconds. The 6 MW measures the total distance walked by an individual over 6 minutes. The MDC 90 for the 6MW test is 61.34 m in patients the first 1.5 months after TKA.

STATISTICAL METHODS

Primary Outcome and Endpoint The difference in SCT time between groups at 12 weeks (end of intervention) was chosen as the primary outcome, because stair climbing is a demanding task that poses difficulty for more than 75% of patients after TKA. Secondary outcomes were pain, knee ROM, quadriceps strength, 6 MW distance, and TUG time. Secondary time points of interest were 3.5 and 52 weeks after TKA.

Sample Size Estimate Sample size estimates were performed using SAS Version and data from a cohort comparison study comparing community-based rehabilitation to a higher intensity patient 1 year after TKA. We expected at least similar magnitude of effect on the SCT 12 weeks after TKA for this study (mean SD, 2.62±1.90 seconds). We estimated that a sample size of 8 patients per group would provide 80% power to detect a difference of 2.62 seconds

between groups on the SCT, using a 2-tailed independent samples t test level of .05.

Data Analysis

SAS Version 9.2 was used for all statistical analyses. The alpha level was set to .05 for all statistical comparisons. The data for all patients on all outcomes at all time points, except for 2 patients in the CSE group who were missing quadriceps activation data at the 6.5-week (n = 1), 26-week (n = 2), and 52-week (n = 2) time points, were complete. Missing data for the 2 CSE group patients were due to the patients declining this test secondary to discomfort. Statistical analysis of baseline differences between groups was carried out using an independent-samples unequal variance t test.

Differences between groups in the primary outcome and all secondary outcomes at 3.5, 6.5, 12, 26, and 52 weeks after TKA were analyzed using restricted maximum likelihood estimation of a multivariate repeated-measures mixed-effects model using all available data. All models were conditioned on the outcome at baseline to account for any baseline differences and to increase statistical precision. All models contained fixed effects for group, time, and a group-by-time interaction, as well as a random effect for paired subjects between groups. Post hoc testing was performed using linear contrasts of pair wise comparisons between groups if a significant group-by-time interaction was found or if a significant group main effect was found in the absence of an interaction. All values are reported as mean, SD, unless otherwise stated.

RESULTS

Preoperatively, participants in both groups were similar on all variables except for active knee flexion. The CSE group having 11° greater knee flexion (P = .02; 95% CI: 1.9, 20.1). All patients in the CSE group were able to progress to phase 4 of the program, except for 1 patient, who only progressed to phase 3 secondary to continued challenges with this phase and increased knee pain with attempts to advance beyond this phase. During rehabilitation of the CSE group, no patient necessitated decreasing treatment intensity based on the criteria established for progression. No individual in either group experienced a musculoskeletal injury during rehabilitation. Postoperatively, no group differences were found between groups for active knee

flexion (P = .76; 95% CI: -12, 9.0) or extension (P = .24; 95% CI: -5, 1) ROM. Active knee flexion for the CSE group was 122°±12° compared to 117°±6° for the control group at 52 weeks. Active knee extension for the CSE group was -3°±4° compared to -1°±5° for the control group at 52 weeks (negative values represent hyperextension). Similarly, no group differences were found between groups for resting pain (P = .51; 95% CI: -0.7, 0.4), pain during the SCT test (P = .96; 95% CI: -1.0, 0.9), or pain during quadriceps power testing (P = .74; 95% CI: -0.8, 0.6).

Postoperatively, a significant group by time interaction was found for TUG (P = .02) and quadriceps strength (P = .02). No significant interactions were found for SCT (P = .22), 6MW (P = .71), or quadriceps activation (P = .43). A significant group main effect was found for SCT (P < .005; 95% CI: -14.2, -2.7) and 6 MW (P < .001; 95% CI: 42, 146). There was no significant group main effect for quadriceps (P = .06; 95% CI: -0.3, 15.9). Post hoc testing was performed on quadriceps strength, TUG, SCT, and the 6 MW tests. Values reported for the 3.5-, 12-, and 52-week time points below are adjusted for baseline performance and include a random effect for pair. At 3.5 weeks after TKA, the CSE group performed 16.4 seconds faster on the SCT (P = .006; 95% CI: 1.5, 7.1) (FIGURE 2), walked 104 m farther on the 6MW (P = .001; 95% CI: 44, 164) (FIGURE 3), and had 0.3 Nm/kg greater quadriceps strength (P = .01; 95% CI: 0.1, 0.6) compared to the control group.

At 12 weeks after TKA, the CSE group performed 5.8 seconds faster on the SCT (P = .01; 95% CI: 1.3, 10.4), 1.9 seconds faster on the TUG (P = .04; 95% CI: 0.1, 3.8), and had 0.4 Nm/kg greater quadriceps strength (P = .01; 95% CI: 0.1, 0.8) compared to the control group. The CSE group also walked further on the 6MW test (P = .06; 95% CI: -4, 146), although this difference did not quite reach statistical significance.

At 52 weeks after TKA, the CSE group performed 7.3 seconds faster on the SCT (P = .04; 95% CI: 0.5, 14.1) and walked 107 m farther on the 6MW (P < .001; 95% CI: 55, 158) than controls. The CSE group also had greater quadriceps strength (P = .08; 95% CI: 0.0, 0.6) compared to the control group, although this difference did not quite reach statistical significance. Differences between the 2 groups on the TUG were no longer significant (P = .12; 95% CI: -0.6, 5.1).

DISCUSSION

The purpose of this study was to assess the clinical outcomes of a SCE compared to a HBE program. Results indicate that utilization of a CSE program initiated early in the course of recovery after TKA led to superior strength and functional outcomes, without leading to increased pain or decreased knee ROM outcomes, in this small group of patients.

There were 2 key differences between the rehabilitation programs utilized for this study. Patients in the CSE group had 25 visits over 12 weeks, whereas patients in the control group had 16 visits over 8 weeks. Thus, the 2 groups had similar treatment frequency in the first 2 months, but the CSE group was treated for an additional month. The second primary difference between the 2 programs was the level of intensity chosen for resistive strength training and the difficulty of the functional exercises utilized. Patients in the CSE group performed machine-based resistive strengthening of all major lower extremity muscle groups, whereas patients in the control group did not utilize resistive training beyond levels accomplished by the use of ankle weights or resistive bands.

The CSE group also performed more complex functional exercises, such as balance reaching, multidirectional lunging, and agility exercises, once more basic functional exercises were mastered. Individuals with end-stage knee OA have quadriceps weakness prior to TKA. Following surgery, quadriceps weakness becomes more profound and does not recover to the level of healthy adults. Quadriceps weakness has potential to impact function greatly, as quadriceps strength is related to stair-climbing ability, gait speed, chair rise ability, and risk for falling. One month after TKA, quadriceps strength decreases by as much as 60%. The mechanism for this Profound, acute decrease is primarily explained by deficits in quadriceps voluntary activation rather than atrophy. However, more than a year after

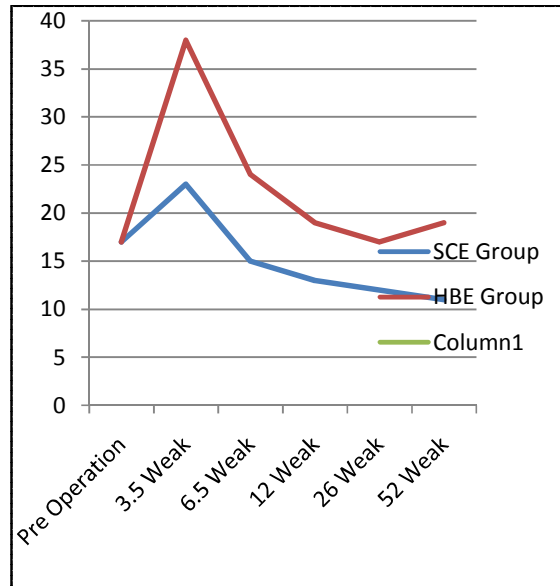


Figure 1. Comparison of stair-climbing test time by group over time. Lower times indicate better performance. Error bars are standard error of the mean. *Difference between groups ($P < .05$). Abbreviation: SCE, Supervised Clinical Exercise group.

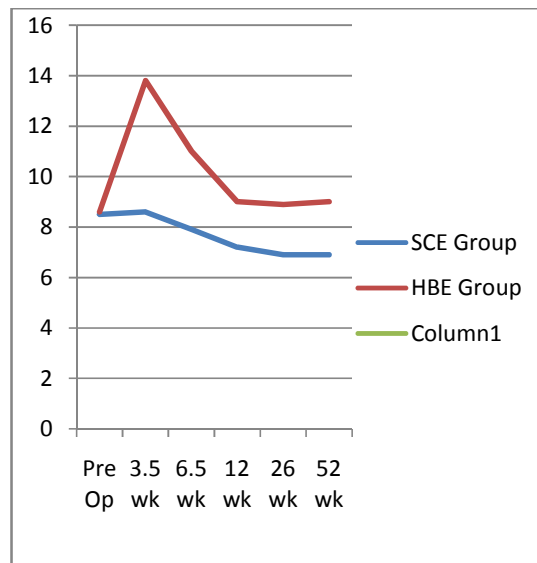


Figure 2. Comparison of timed up-and-go test times by group over time. Lower times indicate better performance. Error bars are standard error of the mean. *Difference between groups ($P < .05$).

TKA, quadriceps atrophy plays a more dominant role in the persistent strength losses observed. Preliminary evidence suggests that progressive resistive exercise is capable of reversing activation deficits. However, no investigation to date has examined the ability of resistive exercise training to decrease activation deficits in the first month following TKA, when it is most profound. In this study, quadriceps Strength was greater in the CSE group compared to the control group at the 3.5- and 12-week time points. However, while quadriceps activation tended to be greater in the CSE group compared to the control group ($P = .06$; 95% CI: $-0.3, 15.9$), the difference in quadriceps activation between groups was not statistically significant. Due to the small sample size of this study, clinically important differences in quadriceps activation could not be ruled out. A larger trial is needed to determine a more precise effect of the CSE intervention on quadriceps activation.

Functional performance on the SCT, TUG, and 6 MW are decreased prior to TKA in patients with end-stage knee OA compared to healthy adults. Following recovery from TKA utilizing traditional rehabilitation techniques, patients have 105% longer SCT times, 63% longer TUG times, and 28% shorter 6MW distances compared to healthy adults of similar age. In this study, functional performance on the SCT and TUG was superior in the CSE group compared to the control group at 3.5 and 12 weeks after TKA.

Overall, the CSE group had significantly better 6MW distances compared to the control group, with the exception of the 12-week time point, at which the difference was 71 m ($P = .06$; 95% CI: $-4, 146$). At 52 weeks after TKA, the CSE group continued to demonstrate clinically superior outcomes on the SCT and 6 MW tests. However, at 52 weeks, differences on the TUG were no longer statistically different. This is most likely due to a ceiling effect with the TUG, as mean performance of the CSE group on this measure was 6.5 seconds at 52 weeks. Mean performance for the Tug in this age group has been reported to be between 5.6 and 8.0 seconds, which indicates that the CSE group had recovered to normative levels on this measure at 52 weeks. Mean performance on the SCT at 52 weeks for the CSE group was 10.4 seconds. Average performance by healthy adults on the SCT is 8.9 ± 1.7 seconds, which indicates that the CSE group recovered to within 1 standard deviation of normative performance by 52 weeks. Mean

performance on the 6 MW test for the CSE group was 552 m at 52 weeks.

Key differences between the CSE program detailed in this cohort study and the articles examined in the meta-analysis are (1) the total number of physiotherapy sessions (2) intensity of treatment. In the meta-analysis, the total number of physical therapy treatments ranged from none (home exercise program only) to, which is substantially lower than the 25 visits provided to the CSE group. The intensity of exercise programs described was also far lower than that utilized for the CSE intervention. None of the exercise programs in the meta-analysis utilized resistance beyond ankle weight

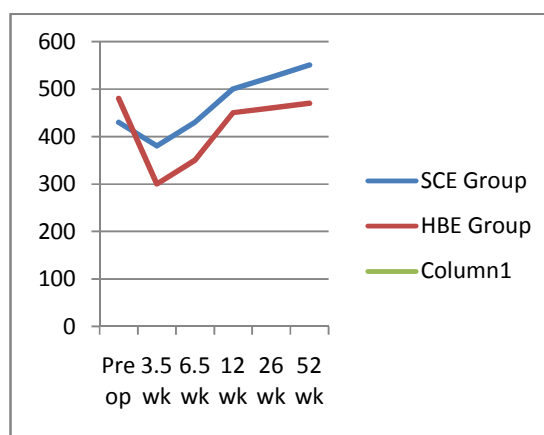


Figure 3. Comparison of 6-minute walk distances by group over time. Longer distances indicate better performance. Error bars are standard error of the mean. *Difference between groups ($P < .05$). †Difference between groups ($P = .06$).

or resistive bands. Additionally, none of the exercise programs in the meta-analysis utilized higher level functional exercises such as lunges. Based upon personal communication with therapists and orthopaedists, the reason for this focus on lower resistance, less intense programs is the belief or assumption that a more aggressive program will lead to increased pain and decreased ROM. However, these detrimental effects were not observed in the patients included in the CSE group compared to the control group. Because individuals following TKA need to recover not only from the surgery itself but also from functional deficits present prior to surgery, it may be unrealistic to expect them to overcome these deficits with a brief and low-intensity intervention.

The primary limitations of this study are a lack of randomization, lack of blinding, and small sample size. A larger blinded, randomized controlled trial is needed to reduce potential bias and determine if the results observed in this cohort study are consistent in a larger population of patients. Additionally, patient compliance and activity levels were not tracked in this investigation. Differences in activity level, as well as patient compliance, might have affected the observed differences between groups.

CONCLUSION

The CSE program described in this cohort study demonstrated significantly greater short-term and long-term strength and functional performance increases compared to a HBE program. The CSE program was initiated immediately following hospital discharge and did not compromise knee ROM outcomes, cause musculoskeletal injury, or increase pain in this small group of patients. Key differences between the 2 programs were a greater number of treatment sessions over a longer period and the use of machine-based resistive strengthening and higher level functional exercises.

KEY POINTS

Implication: The implementation of supervised clinical exercise interventions after TKA should be considered, as the results of this study suggest the potential for better functional short and long term outcomes.

Caution: A small sample size and lack of randomization and blinding may limit the strength of conclusions from this study.

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