Effectiveness of structured exercise program on the functional outcomes in total knee replacement

P. Antony Leo Aseer¹*, G. Arun Maiya², M. Mohan Kumar³, P.V. Vijayaraghavan⁴

¹Professor, Faculty of Physiotherapy, Sri Ramachandra University, Chennai ²Professor, Dept. of Physiotherapy, School of Allied Health Sciences, Manipal University, Manipal ³Professor, Dept. of Orthopedics, Sri Ramachandra University, Chennai

*Corresponding Author:
Email: antonyleo@yahoo.com

Abstract
Background: Total knee replacement (TKR) surgery has become the most successful surgery for patients with severe debilitating arthritis. Numerous factors influence the outcomes in TKR Post-operative physiotherapy and rehabilitation greatly influences the outcome of TKR. Despite the high incidence of TKR in recent years there is no post-operative rehabilitation approach being incorporated effectively to address the muscular and functional deficits following surgery.

Objective: The main objective of the study is to analyze the effectiveness of structured rehabilitation program on the functional outcome of patients following total knee replacement.

Materials & Methods: All patients who were planned to undergo elective primary TKR were recruited. Subjects posted for revision TKR, rheumatoid arthritis posted for TKR, immediate post-operative complications like deep vein thrombosis, signs of infection, TKR for Post-fracture cases were excluded. Eighty subjects enrolled for the study were randomly allocated to control and experimental group using simple random sampling. The control group receives standard care and experimental group receive structured exercise program comprising range of motion, staged training of quadriceps, vastus medialis strengthening exercises, early balance training and functional retraining. Outcomes including pain severity, knee joint mobility, isometric muscle strength, six minute walk test and functional outcome using KOOS scale were measured post-surgery and after 3 months follow up.

Results: In experimental group, follow up measures of pain severity (p<.0001), knee joint extension range (p<.0016), isometric strength of hamstrings (p<0.0008) shows statistically significant results than control group. Whereas, in experimental group, follow up measures of knee flexion range (p<.0001), isometric strength of quadriceps (p<.0001), six minute walk test (p<.0001), functional outcome subscale of KOOS-signs and quality of life (<.0001) shows statistical highly significant results than control group.

Conclusion: The structured exercise program was effective in improving the primary and secondary outcomes following primary total knee replacement.

Keywords: Total knee replacement, Structured exercise program & KOOS

Introduction
Total knee replacement (TKR) is the commonest surgical intervention following end stage osteoarthritis. The major indicators include severe tibiofemoral and patellofemoral joint pain, loss of knee joint mobility, functions and severe deformity. During the past 5 years, the number of TKR performed in India has increased an average of 30% each year and the same growth rate is expected to continue in the forthcoming decade. In India a total of 45,000 TKR were performed in 2010 and this may translate into more than 350,000 TKR per year by the end of the decade(1).

Over the past four decades, joint replacement surgery has become the most successful surgery for patients with severe debilitating arthritis. Patients who undergo TKR show marked improvements in function and reduction in pain compared with their pre-operative condition(2,3). However recovery of functional ability is a variable and not all patient experience significant improvements in pain and function(4,5).

Recent studies(6-8) have suggested that the mid-vastus and sub-vastus approaches have some advantages with regard to functional recovery of muscle strength and post-operative pain. Out of the five approaches, medial Para-patellar and mid-vastus are the commonest approaches practiced among orthopedic surgeons. Immediate post-operative rehabilitation is shaped by variety of factors including type of prosthesis, surgical techniques and approaches. Post-operative physiotherapy and rehabilitation greatly influences the outcome of TKR.

Therefore rehabilitative efforts should focus on activities that help patients to improve performance of activities of daily living. The basic drawback in post-operative rehabilitation is adhering to a protocol or a “cookbook approach”. The muscle impairments following TKR varies with different surgical approaches, but till date exercises are not designed according to the post-operative needs. The guidelines for rehabilitation progression should be tailored to the individual patient, respecting the tissue healing
parameters. It is believed that certain factors would best predict long-term outcomes. Identification of these factors will aid in the creation of targeted therapeutic interventions to maximize postoperative functional ability\(^9\).

Despite the high incidence of TKR in recent years there is no post-operative rehabilitation approach being incorporated correctly to address the muscular and functional deficits following surgery\(^{10}\) and no studies have focused on evaluating the effects of tailored rehabilitation protocols\(^9\) and yet not analyzed in Indian population too. Muscle impairments are not well defined and understudied aspect of post-operative management of TKR\(^{11}\). Mostly rehabilitation programs are designed on increasing range of motion and strengthening muscles but measures to improve balance is neglected\(^{12}\).

Hence, the present study intends to analyze the effectiveness of structured rehabilitation program on the functional outcome of patients following total knee replacement.

**Materials and Methods**
The study was a single blinded, randomized controlled trial

**Study Setting and Participants:** All patients who were planned to undergo elective primary TKR are recruited in the study. The study participants included with diagnosis of degenerative joint disease of knee joint for TKR and of both genders were included. Subjects posted for revision TKR, rheumatoid arthritis posted for TKR; immediate post-operative complications like deep vein thrombosis, signs of infection, TKR for Post-fracture cases were excluded. The study proposal was approved by the Institutional Ethical Committee.

**Randomization and Interventions:** A total of 85 subjects were assessed of which 80 subjects enrolled for the study and was randomly allocated to control and experimental group using simple random sampling. The experimental group received structured exercise program, and the control group received the standard care. After screening process, a verbal explanation of the study protocol is made. An informed consent is obtained for authorizing their participation in the study.

All participants are educated about the importance of exercises, ambulation after knee joint surgery. Simple educational tips regarding use of knee immobilizer, ways to use walker, knee positioning and scar mobilization were educated. The exercise protocols are from immediate post-operative day one till discharge and at home care.

**Standard care:** The standard care includes bed mobility exercises, range of motion exercises, strengthening exercises for quadriceps muscle, and full weight bearing standing and walking using walker support. The exercise training period is for 2 weeks and information related to duration, intensity and frequency of exercises were given.

**Structured Protocol:** The structured rehabilitation protocol was developed and based on principles of TKR rehabilitation, a modified aggressive strengthening protocol formulated by Joseph A. Zeni in 2010. Based on principles, the protocol deals with the early measures after unilateral Total knee replacement comprising range of motion, staged training of quadriceps, vastus medialis strengthening exercises, early balance training, closed chain exercises and functional retraining. The staging of quadriceps training starts from activation of muscles during inhibited state, encouraging terminal knee extension and early recruitment of vastus medialis obliques(VMO). Later it is progressed to strengthening exercises followed by VMO activation in standing and incorporating closed chain exercises. Balance training includes symmetrical weight shift training within parallel bars, single arm raise as like forward reach, diagonal pattern of movement and standing in foam pad. As early balance training is initiated, proper care and education are imparted to reduce fear and prevent fall.

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**Fig. 1a:** Symmetrical weight bearing training in parallel bars, **1b:** Early balance training-forward arm reach
The structured exercise program is designed in four stages. Stage one comprises of education of the overall program, importance to joint positioning, use of walker, bed mobility exercises, use of continuous passive motion and initiation of full weight bearing standing and walking. Greater emphasis is given for symmetrical loading of limbs and supported standing against wall. Stage two has progression of exercises including isometric training of knee musculature, active assisted knee mobility exercises, and early initiation of balance training within parallel bars with arm and without arm support. The strengthening of quadriceps and Hamstring muscle were started in stage three. Greater emphasis was given to quadriceps in terminal knee extension and recruiting vastus medialis obliques in high sitting position. Balance training is progressed to unstable surface standing on foam pad, tilt board and reaching arm forward and diagonal direction and greater reinforcement given towards effective weight bearing of operated side. Closed chain exercises, the most functional type of exercises following TKR are incorporated in stage four. It included wall slides, mini squats, forward and lateral step ups. VMO activation exercises are further performed in standing. Care is given for effective unsupported ambulation and supported stair ascent and decent training. Overall the structured program caters all needs of replaced knee joint, building confidence for early return of activity and reaching community at the earliest.

Both control and experimental group are educated about adherence of exercises at home care set up. An exercise adherence format has been given at time of discharge, which reminds them to follow exercise as educated. Further all subjects are provided with an educational booklet on TKR rehabilitation with pictorial representation of key exercises and tips for early recovery.

**Outcomes and follow up:** Subjects demographic details and clinical details are obtained at baseline. The details include age, gender, occupation, sidedness, clinical details including medical diagnosis, presence of deformity and body mass index(BMI). Knee joint specific evaluation includes severity of pain using visual analog scale, Knee joint mobility of flexion and extension range of motion using goniometer, Isometric strength testing of Quadriceps and Hamstring muscle measurement using hand-held dynamometer, Six minute walk test(6MWT) and functional outcome using KOOS scale.

**Isometric strength testing of Knee musculature:** The quadriceps muscle is tested in subject positioned in high sitting with knee joint flexed in 70 degrees with the dynamometer probe placed over the lower end of shin. Subjects are instructed to push the dynamometer in attempting to knee extension. Therapist is positioned in front of subject with firm holding of dynamometer in place. Further subjects are reinforced to kick as firm as possible. Each contraction of knee extension is held for five seconds and three trials measured with thirty seconds rest interval between measures. The same procedure is followed for measuring isometric strength testing of Hamstring muscle except the subjects are positioned in prone lying with available knee flexion.

**Six minute walk test:** The 6-minute walk test is a functional ability test measures the distance covered by subject in six minutes. The Walking surface area is free of obstacles and two cones are placed at two extremes. Subjects are instructed to discontinue walking if any discomfort felt and use of walking aid was optional.
They were motivated to walk back and forth the distance with normal speed and distance covered in six minutes was measured.

Results

Overall 85 subjects were assessed for eligibility, 80 subjects who met the criteria underwent baseline testing and randomization of samples done. From the 40 subjects were assigned to the control group and the 40 subjects assigned to the experimental group, 32 and 30 participants, completed the study respectively and were included for analysis.

Baseline measurements analysis

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Control</th>
<th>Experimental</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>59.53±3.32</td>
<td>61.77±3.41</td>
</tr>
<tr>
<td>Gender-Female</td>
<td>23</td>
<td>17</td>
</tr>
<tr>
<td>Gender-Male</td>
<td>09</td>
<td>13</td>
</tr>
<tr>
<td>BMI-Pre surgery</td>
<td>28.16±2.74</td>
<td>27.29±1.80</td>
</tr>
<tr>
<td>BMI-Post surgery</td>
<td>27.15±2.47</td>
<td>26.07±1.51</td>
</tr>
<tr>
<td>Sidedness-Right</td>
<td>16</td>
<td>20</td>
</tr>
<tr>
<td>Sidedness-Right</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Total</td>
<td>(n=32)</td>
<td>(n=30)</td>
</tr>
</tbody>
</table>

Table 1 presents the mean age in control and experimental group is 59.53±3.32 & 61.77±3.41 respectively. Twenty three females & 9 males participated in control and 17 females and 13 males in experimental group. In both groups, right sided TKR (n=36) numbered more then left sided (n=26). Body mass index (BMI) was calculated preoperatively for all samples (and for a sample of 32 post BMI values were analyzed, which reveals minimal reduction of BMI following TKR(control pre-BMI- 28.16±2.74, post-BMI-27.15±2.47, in experimental group pre-BMI-27.29±1.80, post BMI-26.07±1.51). Out of 62 samples, 41 underwent median para-patellar approach, 30 midvastus &1 subvastus approach. The pre-operative quadriceps angle is 19.87±1.63 and post-operative the mean angle is 13.73±1.27 shows reduction of quadriceps angle following surgery.

Knee Osteoarthritis Outcome Score (KOOS): It is a 42 item, patient administered, validated questionnaire with five subscales including pain, symptoms, activities of daily living, sports and recreation and quality of life. All 42 items are equally weighted from 0 to 4. Each subscale are calculated and transformed into 0 to 100. In the present study, as sports and recreation subscale were not applicable to acute TKR subjects. Hence the subscale was not considered for evaluation.

All the outcomes are measured at the time of discharge (2 weeks following surgery) and after three months of follow up.

Data analysis: The data were analyzed using SPSS software using t-tests. For both groups descriptive statistics were calculated.
Primary and secondary outcomes

Table 2: Primary & secondary outcomes of control & Experimental group after post-surgery

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Control</th>
<th>Experimental</th>
<th>t-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain severity</td>
<td>4.53±0.49</td>
<td>3.37±0.78</td>
<td>-2.61</td>
<td>.006</td>
</tr>
<tr>
<td>Flexion ROM</td>
<td>67.19±4.53</td>
<td>71.5±5.52</td>
<td>-1.24</td>
<td>0.109</td>
</tr>
<tr>
<td>Extension ROM</td>
<td>6.58±1.87</td>
<td>4.83±1.91</td>
<td>+1.34</td>
<td>0.0927</td>
</tr>
<tr>
<td>Extensor isometric strength</td>
<td>4.37±0.5212</td>
<td>4.94±0.74</td>
<td>-1.29</td>
<td>0.1010</td>
</tr>
<tr>
<td>Flexor isometric strength</td>
<td>3.46±0.51</td>
<td>3.65±0.53</td>
<td>-0.55</td>
<td>0.2921</td>
</tr>
<tr>
<td>6MWT</td>
<td>108.79±30.27</td>
<td>180.89±37.69</td>
<td>-3.04</td>
<td>.0017</td>
</tr>
<tr>
<td>KOOS-PAIN</td>
<td>29.31±5.64</td>
<td>27.13±6.23</td>
<td>+0.53</td>
<td>0.2990</td>
</tr>
<tr>
<td>KOOS-SYMPTOMS</td>
<td>44.94±5.47</td>
<td>33.83±3.53</td>
<td>+2.03</td>
<td>0.0234</td>
</tr>
<tr>
<td>KOOS-ADL</td>
<td>35.27±3.60</td>
<td>6.9±6.0</td>
<td>-1.41</td>
<td>0.0802</td>
</tr>
<tr>
<td>KOOS-QOL</td>
<td>22.94±8.29</td>
<td>31.17±4.96</td>
<td>-1.71</td>
<td>0.0462</td>
</tr>
</tbody>
</table>

Table 2 shows all the parameters showed good mean differences in experimental group than control group. Comparing with the initial measurement, follow up measures revealed good improvement in all parameters of experimental group. In experimental group, follow up measures of pain severity (p<.001), knee joint extension range (p<.0016), isometric strength of hamstrings (p<.0008) shows statistically significant results than control group.

Table 3: Primary & secondary outcomes of control & Experimental group in follow up

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Control</th>
<th>Experimental</th>
<th>t-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain severity</td>
<td>1.63±0.57</td>
<td>0.56±0.32</td>
<td>+3.24</td>
<td>.0001</td>
</tr>
<tr>
<td>Flexion ROM</td>
<td>86.37±2.15</td>
<td>96.93±4.20</td>
<td>-4.67</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Extension ROM</td>
<td>1.47±0.82</td>
<td>0.13±0.27</td>
<td>+3.07</td>
<td>0.0016</td>
</tr>
<tr>
<td>Extensor isometric strength</td>
<td>5.14±0.66</td>
<td>7.64±0.73</td>
<td>-5.18</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Flexor isometric strength</td>
<td>3.97±0.47</td>
<td>5.06±0.48</td>
<td>-3.31</td>
<td>.0008</td>
</tr>
<tr>
<td>6MWT</td>
<td>186.14±34.24</td>
<td>370.98±28.77</td>
<td>-8.47</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>KOOS-PAIN</td>
<td>47.68±7.10</td>
<td>64±3.48</td>
<td>-4.32</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>KOOS-SYMPTOMS</td>
<td>58.41±4.153</td>
<td>69.07±2.76</td>
<td>-4.31</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>KOOS-ADL</td>
<td>43.22±3.80</td>
<td>68.14±1.12</td>
<td>-12.65</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>KOOS-QOL</td>
<td>35.94±6.94</td>
<td>60.2±4.64</td>
<td>-5.86</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>

(ROM-Range of Motion, 6MWT-six minute walk test, KOOS-Knee Osteoarthritis Outcome survey)

Whereas, in experimental group, follow up measures of knee flexion range (p< .0001), isometric strength of quadriceps (p<.0001), six minute walk test (p< .0001), functional outcome subscale of KOOS-symptoms, ADL and quality of life (< .0001) shows statistical highly significant results than control group.

Discussion

This randomized controlled trial highlights the importance of structured exercise program on the functional outcome following primary total knee replacement. The exercise program is designed to promote early mobility, training quadriceps in staged manner, aggressive strengthening of knee musculature, functional training and early balance training. The findings of the study showed better improvement in experimental group of all primary and secondary outcomes on initial evaluation (i.e.) post-surgery. On Follow up, the experimental group showed statistically significant improvements in pain severity (p<.0001),
knee joint extension range (p<.0016), and isometric strength of hamstrings (p=0.008). Furthermore, knee flexion range (p<.0001), isometric strength of quadriceps (p<.0001), six minute walk test (p<.0001), functional outcome subscale of KOOS-symptoms, ADL and quality of life (p<.0001) shows statistically highly significant results than control group. The Subjects in structured exercise group with balance training exhibited early recovery, walked independently with longer distances. On initial measures the differences in 6MWT between groups is 72m, whereas the distance increased to 184m on follow up in experimental group. Hence the structured exercise program comprising all essential components in acute TKR rehabilitation was found to be effective. Ultimately the most anticipated outcomes in TKR rehabilitation as like knee flexion range(mobility), isometric strength of Quadriceps (strength), Six minute walk test(functional activity) and KOOS subscales(Functional outcome) were noted to show significant improvements in experimental group.

The key important anatomical structure for complex weight bearing activities is Quadriceps muscle. The staged training of quadriceps from acute stages of TKR is well represented in results. This significant increase in isometric strength testing of Quadriceps muscle has reported in a study described the time course of recovery of impairments and function after TKR, as well as to provide direction for rehabilitation efforts[13]. The high correlation between quadriceps strength and functional performance suggests that improved postoperative quadriceps strengthening is important. Further in 2008 it is also revealed that postoperative rehabilitation addressing quadriceps strength should take over these impairments and ultimately result in improved functional outcomes[10].

Six minute walk test is the most simple but reliable test in measuring the functional performance in TKR. The intra-tester reliability is noted to be higher among TKR patients[14]. In experimental group on follow up visit, there was a marked difference in mean of 6MWT (370.98±28.77) and was highly significant. This result is in accordance to a study by Robin[15] in 2011 on the effectiveness of an eccentric strengthening rehabilitation program in TKR showed improvements in the primary physical function testing of SF-36 and 6MWT. A recent meta-analysis in 2015 revealed that most studies on rehabilitation of TKR have employed 6MW at as tool to measure the walking performance[16].

The one among the commonly used joint specific outcome measure following TKR is Knee Osteoarthritis Outcome Score (KOOS) and has been validated tool in measuring outcomes in TKR. The study results exhibits high significance namely symptoms and quality of life subscales (<.0001).This study result represents greater improvements in symptoms, early recovery and enhanced quality of life. In 2013, it has been reported that KOOS is an attractive measure for surgical and conservative treatment comparisons[17].

On analyzing the overall primary and secondary outcomes, the structured exercise program showed better to good recovery in terms of specific joint functions, ability to perform activities of daily living and enhanced quality of life.

The structured program catering the various needs of replaced knee was validated by experts practicing musculoskeletal Physiotherapy and proved to possess good content validity. The program did not produce any adverse effects; subjects were able to accommodate early balance training in a safe manner. Although post discharge, subjects were monitored directly through house visits and telephonic means. An exercise adherence chart has been provided to remind them of continuing exercises at home setup and many failed to produce the chart during follow up. Inspite all subjects are provided with a booklet on TKR rehabilitation, some subjects reported less adherence towards exercises. The other limitations noted lack of effective supervision in home setups, less guidance to properly perform exercises and varied dosage of exercises.

In future, staged balance training in TKR will be considered. These results are applicable to those who underwent Unilateral TKR for degenerative joint disease of Knee joint complex.

Conclusion
The structured exercise program was effective in improving the primary and secondary outcomes following primary total knee replacement. Early implementation of balance training has favored the early return of functional activities as like walking and stair climbing.

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Conflicts of interest
None identified/declared.

References
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