

We understand the importance of thoroughly researching the latest tools before implementing them at your hospital. We are committed to complete openness in our evidence-based solutions. In the three reports below is a summary of our detailed research and results that led many hospitals to implement the RIET protocol using the LRU Pillow for knee surgery post-operative care. Make data-driven decisions when it comes to providing the best knee care for your patients.

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## REPORT 1

### **Total Knee Arthroplasty**

#### **Why are early post-operative knee flexion and extension range of motion important?**

Studies have shown that the current measures of success following a total knee replacement (pain and ROM) may not be enough to ensure a positive experience and a return to safe functional levels (ref.3).

- 24% fall within the first year ( 4).
- Total knee replacement patients walk 18% slower (2,3).
- Total knee replacement patient climb steps 51% slower (2,3).
- Total knee patients typically have a 20-25% quadriceps strength deficit prior to surgery, 4 months post-op they have a 40% deficit, and one year later they return to a 20 – 25% deficit (2,3,5).

\*Investigators have linked the decline in walking speed and stair climbing to persistent quad deficit (3).

While it might be true that long term ROM outcomes are similar while using various early treatment interventions, the statistics above show that other outcome measures are being left unaddressed. We must not only measure pain and ROM in these patients, instead we also must focus on the functional outcome.

Early ROM is that achieved in the first two weeks after surgery. The goal of this accelerated program is to have 0-120 degrees of motion early. If we can achieve this early ROM by the time the patients are finished with their home health visits, then outpatient therapy can focus on strength, proprioception, neuromuscular re-education, balance, and gait quality.

ROM is, of course, an extremely important outcome, and we cannot achieve ROM without adequate pain control. Below are the knee flexion requirements for various tasks to be performed properly.

- Climb Stairs                    83 degrees
- Descending Stairs        100 degrees
- Sitting Down                    93 degrees
- Tying shoes                    106 degrees
- Lifting Grandchild        117 degrees
- Gardening                    125 degrees

*(Taken from Are You Boomer Ready: Total Joint Rehabilitation a CEU Course by John O'Halloran)*

Achieving this ROM is just the tip of the iceberg in TKA rehabilitation. If we do not achieve ROM that allows function, therapy cannot and should not move further with higher level rehabilitation.

### **Outpatient Therapy**

To work on ROM: patients are brought in 2-3 times a week. They have more problems pushing themselves to achieve full ROM due to pain or a simple inability to produce the needed mechanical advantage to move the knee. Therefore, skilled intervention is needed to achieve ROM that will allow a return to normal tasks.

To work on Strength, Balance, Neuromuscular re-education, and Proprioception: patients can be seen 1 time per week or even every other week with a bigger focus on a home program and progressions. These exercises are more easily performed in the home setting.

Outpatient therapy copays are getting higher with \$25 - \$75 becoming normal. Even 20% copays are not unusual anymore. This is cost-prohibitive for some of the population.

Outpatient therapy goals will define the final outcome for the total knee population. If patients begin their OP therapy visits with the ROM goal met, functional outcomes can then be the focus of the precious few visits that insurance companies are allowing.

### **TKA Rehabilitation Protocol**

Based on this information, early intervention should focus on promoting ROM. As mentioned above, managing pain will certainly impact how aggressively the patient is able to work on the knee ROM. Another important component that will affect joint ROM is the edema that is present. Edema can have detrimental effects on knee ROM, especially flexion. Further, once swelling begins in a lower extremity, it is challenging to reverse and can linger for months jeopardizing outcomes.

### **Effects of Swelling in TKA**

- Decreases muscular contraction in the muscles surrounding the joint. (Protective Shut Down)
- Stiffness
- Pain
- Poor Proprioception



Edema control can give patients an advantage and a head start with rehabilitation. Edema control has been used for decades utilizing Rest, Ice, Compression, and Elevation (R.I.C. E.). Therefore, the best TKA protocol follows these principles:

1. Rest: “limited activity” Instead of being up in a chair and walking constantly, patients are up only for therapy sessions, bathroom breaks, and when doing exercises.
2. Ice: in our setting this is achieved with an Ice Man ice machine
3. Compression: There is actually a small compression component when wrapping the ice pad around the knee
4. Elevation: LRU pillow

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## REPORT 2

### **The Effects of the LRU Pillow versus the CPM Machine on Active Assistive Knee Range of Motion at Hospital Discharge. A Retrospective Summary**

**Investigators: Scott Johnson, PT , Jennifer Delcamp, MD, and Matthew Lawless, MD**

#### **Background**

Pain relief and return of function are the main goals following total knee arthroplasty. One measure of return of function in the acute phase has been range of motion. A continuous passive motion (CPM) machine is a standard postoperative treatment used to regain range of motion following total knee replacement surgery. The efficacy of this piece of equipment has not been supported consistently in the research (1-10). The CPM machine is heavy and cumbersome and requires assistance for proper use. The risk of injury to caregivers exists due to the CPM's size and weight. Positioning can be difficult, especially in



obese and short patients, and if inadequate can cause additional stress to the knee. Extension can be difficult to achieve and the CPM must be used in a bed due to its size. A more portable option may produce better compliance, edema control, and ultimately achieve desired range of motion following a total knee replacement.

### **Hypothesis**

Edema control is one of the keys to success in regaining range of motion following a total knee replacement. Coupling edema control, through appropriate positioning and elevation, with a standard exercise protocol will yield optimal ROM outcomes. Achieving and maintaining full extension with positioning in the acute postoperative phase will lead to better outcomes for extension. Focusing on elevation will control edema, which will lead to good outcomes for flexion. A specially designed dense foam pillow (LRU 2031) which maintains the knee in an extended position while elevating the lower extremity, will achieve the same results in active assistive ROM as the CPM machine.

### **Specific Objective**

Determine the efficacy of using the LRU pillow following a total knee replacement compared to a CPM machine. Will the use of the LRU pillow, along with a standard exercise protocol, yield better active assistive knee range of motion at hospital discharge compared to the use of a CPM machine with the same standard exercise protocol?

### **Significance**

The outcomes may reveal a better alternative to the CPM machine following total knee replacements and other knee surgeries. The risk of injury to caregivers may be reduced due to the size and weight of the machine. Alternatives to the CPM machine may reduce healthcare costs to medical providers, patients, and/or insurance companies.

### **Methods**

This was a retrospective chart review of knee AAROM for patients receiving total knee arthroplasties. All data was obtained from charts of one hospital from January 2011 to October of 2011. The AAROM numbers were obtained from the last acute care physical therapy notes. 111 patients received a CPM machine during their hospital stay while 131 patients received the LRU Pillow. The average length of stay was 3.0 and the average number of physical therapy sessions during the acute hospital stay was 3. Active assistive range of motion of the surgical knee was measured with the use of a long arm goniometer, aligned against anatomical landmarks, by a physical therapist or physical therapist assistant. Active assistive range of motion was defined as an exercise in which an external force assists specific muscles and the knee joint to move through the available excursion. Measurements were taken with patient lying supine. Each patient received the same exercise regime during their acute hospital stay.

### **Results**

The results are listed in Table 1. The percentage of patients achieving full extension (defined as 0-5 degrees) in the CPM group was 87% (97/111) and in the LRU group was 95% (124/131). The percentage of patients achieving at least 85 degrees of flexion was 67% (74/111) in the CPM and 85% (111/131) in the LRU groups, while the percentage of patients



achieving at least 90 degrees of flexion was 60% (67/111) and 82% (107/131) for CPM and LRU groups respectively.

## LRU VS. CPM

### *Range of Motion Outcomes*

	0-5 Degrees	≥ 85 degrees	≥ 90 degrees
CPM (n=111)	87% (97/111)	67% (74/111)	60% (67/111)
LRU (n=131)	95% (124/131)	85% (111/131)	82% (107/131)

### **Discussion**

The CPM has been used to help regain motion following TKA for many years. The CPM however has several downsides. The size and weight makes care of the extremity cumbersome and sometimes dangerous. The machine has moving parts that may malfunction and also requires an electrical outlet with a cord and potential fall risk. The design of the CPM precludes use in anything but a large firm surface (such as a bed). Positioning of the machine can be difficult and may hold the knee in a flexed position, making achieving full extension difficult. The CPM is an expensive piece of equipment that is only used as a rental for only a small percentage acute post operative period. It was our hypothesis that if we could use a pillow to hold the knee in extension and provide elevation that the motion following total knee arthroplasty would remain the same, without exposure potential downsides to the CPM. Our results (as originally reported in a prospective study) have shown that the use of the LRU provides at least as good postoperative motion, without many of the downsides associated with CPM use.

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## REPORT 3

### **Effects of the LRU pillow on Active Assistive Knee Range of Motion and Pain Scores Following Total Knee Replacement Surgery**

A main goal following Total Knee Arthroplasty (TKA) is, in addition to pain relief, restoration of function. A continuous passive motion (CPM) machine is frequently used to help achieve this goal. However, the efficacy of the CPM machine has not been consistently supported in the research. Brousseau et al in a meta-analysis of the efficacy of passive motion following TKA showed that CPM combined with physical therapy may offer beneficial results for patients but these benefits must be weighed against the inconvenience and expense of the CPM.<sup>2</sup>



The CPM machine is heavy and cumbersome. It requires assistance from caregivers for proper use and positioning in the machine and is a risk to caregivers given the size and weight of the machine. CPM machines are also a challenge to patients who are short or obese as the machines are not custom fit to the patient and only come in standard sizes. Improper positioning can cause stress to the knee and cause the patient to be uncomfortable during use. It also must be used mainly in bed secondary to the size of the machine and use in a chair or couch could be unsafe.

A more portable alternative to the CPM machine may produce better compliance, and edema control and achieve the desired post-operative range of motion seen with the CPM. It is thought that edema control is one of the keys to successfully regaining knee function following TKA. Our hypothesis is that coupling edema control, through appropriate positioning and elevation, will a standard exercise protocol with yield desirable ROM that is equal to the results seen with CPM coupled with a standard exercise protocol. One hypothesis is achieving and maintaining full extension with positioning in the acute postoperative phase will lead to better outcomes for post operative extension. Focusing on edema control will lead to optimal outcomes for post-operative flexion and leg control. A dense foam pillow (LRU 2031) (Fig. 2) was specially designed to achieve these goals. It maintains the knee in an extended position while elevating the lower extremities to help with edema control. We believe that patients will achieve at least the same results of active assistive ROM and visual analog pain scores using the LRU pillow with a standard physical therapy protocol in a more cost-effective way than those using the CPM with a standard physical therapy protocol.

### **Materials and Methods**

This prospective randomized control trial was approved by the institutional review board at our hospital. Patients receiving total knee arthroplasties from the senior investigator's office were randomized (by SPSS 11.0 (SPSS Inc., Chicago, IL)) to either receive a CPM machine post-operatively or an LRU pillow. Twenty patients were enrolled, ten in each group. The CPM machine and LRU pillow were used for 2 hours on and 2 hours off from 8 am to 10 pm. It was then used continually from 10 pm to 8 am.

Five days prior to surgery baseline pain scores, using the analog pain score, and active assistive ROM of the operative knee were obtained. All patients then underwent TKA performed by the senior investigator. Patients then were randomized and received either a CPM machine or LRU pillow in the PACU following surgery. The end of the hospital stay was defined as the completion of physical therapy on post-operative day 2. At this point post post-operative active assistive knee range of motion and pain scores were recorded. After discharge the patient was instructed to continue using either CPM or LRU for 18 hours a day until their follow-up visit on post-operative day 16. At this point all patients were instructed to not use their CPM/LRU from this point on. Final active assistive knee ROM and pain scores were collected 2 months postoperatively.

The active assistive range of motion of the surgical knee was measured with the use of a long arm goniometer, aligned against anatomical landmarks, by a physical therapist or physical therapist assistant. Active assistive ROM was defined as an exercise in which an

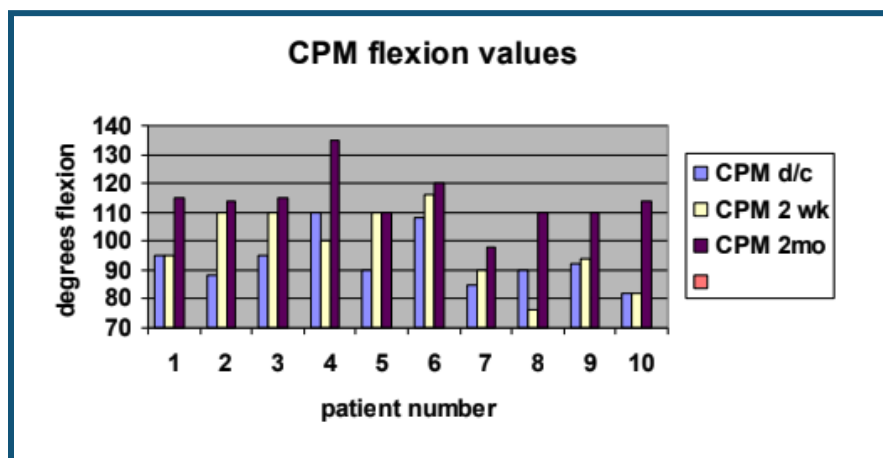


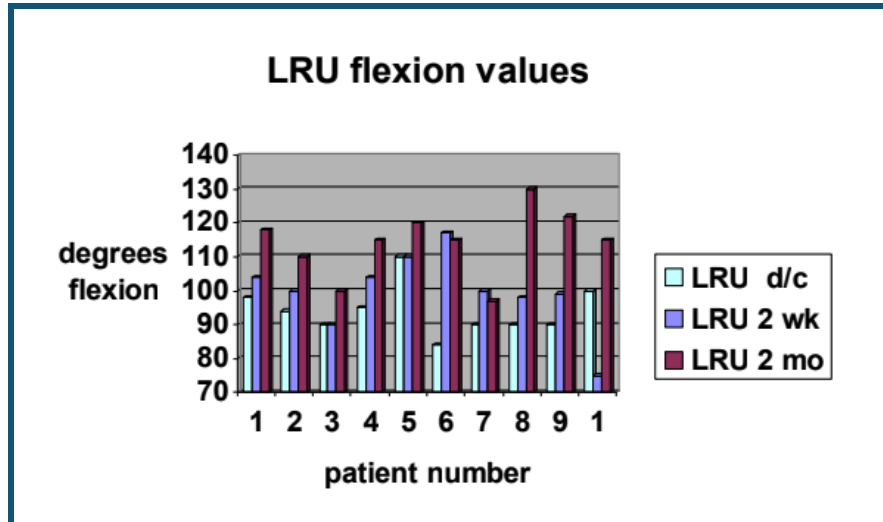
external force assists specific muscles and the knee joint to move through the available excursion. Measurements were taken with the patient lying supine. Active assistive ROM was recorded 5 days preoperatively, 2 days postoperatively, 16 days postoperatively, and 2 months postoperatively.

Each patient was treated with the same peri-operative pain regimen. This consisted of 15mg Toradol IV pre-operatively and every 6 hours post-operatively during their hospitalization. 150mg of Lyrica PO was given pre-operatively and 75mg BID was given post-operatively during their hospitalization. Post-operatively each patient also received scheduled 1000mg of Tylenol every 6 hours and 5-10mg of Oxycodone every 4 hours. At discharge, every patient was given Tylenol 100mg every 6 hours, Celebrex 200mg BID, Oxycodone 5-10mg every 4 hours PRN, and Lyrica 75mg BID. This regimen was continued until post-operative day 16 at which time patients were instructed to use these pain medications as needed.

Differences between the study groups with respect to age were analyzed using the T-test and the Mann-Whitney Test. Differences with respect to sex were analyzed using Fisher's Exact Test. The differences between pain scores and active assistive ROM at 5 days pre-operatively, 2 days post-operatively, 16 days post-operatively and 2 months post-operatively were also compared between our two groups and analyzed using the T-Test and the Mann-Whitney Test. A p-value of < 0.05 was considered significant. Results:

Ten patients were randomized to receive the CPM machine post-operatively and ten patients were randomized to receive the LRU pillow post-operatively. The groups were analyzed with regard to age and sex. There were 3 males and 7 females in each group. The average age was not statistically significant ( $p= 0.239, 0.686$ ) and for the CPM group was 66 (+/- 9) and for the LRU group was 62.8 (+/-7). Tables 1 and 2 summarize the flexion numbers for CPM and LRU groups, respectively. There was no difference in the ROM in extension or flexion at any time point. The average flexion at discharge was 93 and 94, at 2 weeks was 98 and 100, and at 2 months was 114 and 114 degrees respectively between the CPM and LRU groups. There was no difference in the pain scale numbers at any point between groups.





### Discussion

The use of a CPM machine post-operatively in patients who have undergone TKA is a standard practice along with a physical therapy program. Our study hypothesized that the benefits seen with a CPM machine can be achieved with a lower cost and a more convenient LRU pillow. We believe that the pillow contributes to similar post-operative ROM and pain due to the positioning of the leg in extension and elevation. The LRU pillow is also cost-effective when compared with the CPM machine. (See attachment). At our institution, the cost of the LRU pillow is \$80.00 while the cost of the CPM is \$90 - \$240 (\$30-60/day for 2 to 3-day hospital stay). Extended usage to 2 weeks would increase the range to \$450-900. The patient then has no access beyond 2 weeks.

Numerous studies have shown mixed results with regard to post-operative ROM, pain control and length of hospital stay with the use of a CPM machine. Brousseau et al showed that the CPM machine was beneficial but must be weighed against the inconvenience and cost associated with the CPM. The LRU pillow shows equivalent results to the CPM without the inconvenience or cost.

Our study has shown that patients who used the LRU pillow had as good of results as those using the CPM machine post operatively. There were several limitations to this study. Firstly, our sample size was small. Secondly, although all patients stated compliance with the study protocol we had no way to ensure this.

With regards to each group, they did not differ significantly when comparing age and sex but we did not analyze to see if they differed in weight, height, BMI, or co-morbidities. Each of these factors could have contributed to the post-operative outcome. When evaluating each patient pre and post-operatively several physical therapists were involved in each patient's care. This could lead to variable active assistive ROM measurements at each follow-up.

In conclusion, our study was able to show a cost-effective and convenient alternative to the CPM machine that achieves equivalent results when paired with a standard physical therapy





program and pain regimen. Further studies will need to be conducted with larger patient samples to validate this study but it does show a promising alternative to the CPM machine that can contribute to decreased hospital costs and improved patient safety.

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