Results and Analysis of Pilot Studies

conducted on the ROM3® Rehab System

About the ROM3 Rehab System

It has been observed that after a knee trauma, including injury or surgery, patients who undergo earlier movement, more movement, and more active movement of the joint tend to enjoy greater range of motion and better overall outcome than patients who perform less movement, delayed movement, or only passive movement of the joint.

The ROM3 Rehab System is an application of the above datum. A patented technology, it was designed to facilitate earlier movement and active movement of the affected joint, as well as more comfortable movement, consequently allowing and inviting more motion.

More information about the ROM3 technology, shown here, can be found at www.ROM3rehab.com.

Purpose of the Pilot Studies

Pilot studies are generally performed to assess the effectiveness of the materials, apparatus and procedures that will be used in larger-scale studies. The results gained from pilot studies help researchers determine the feasibility of engaging in additional work in the area and also helps researchers determine the most appropriate strategies to assess the data.

The information gained from pilot studies can also help to determine the value of continuing to explore the effectiveness of an invention, which is one of the primary purposes of the two pilot studies described below.

The two pilot results presented in this document concern the results from inpatient and outpatient rehabilitation protocols. Combined, the results strongly indicate that the ROM3 is usable immediately after surgery and is highly effective in assisting recovery after knee surgery by achieving more rapid Range of Motion.

The pilot studies were also useful in that the data collection protocols suggested that the instrument should be modified and streamlined so that the physical therapists will all be using the same metric and will not find the instrument to be cumbersome or burdensome. The results of the pilot studies have provided useful data and areas for modification so that imminent large-scale studies will yield the most informative data.

Inpatient Rehabilitation Pilot Study

Goals of the Study

The three main goals of the study were:

1. To explore the usability and safety of use of the ROM3 Rehab System immediately after TKA.
2. To determine if use of the ROM3 Rehab System immediately after TKA has a significant effect on patients' range of motion and speed of recovery.
3. To determine if use of the ROM3 Rehab System immediately after TKA has a significant effect on lengths of stay and cost.

Description of Sample

The inpatient rehabilitation pilot study was conducted at Labette County Medical Center in Parsons, Kansas. The study consisted of 107 cases—13 cases in the ROM3 group (five male, eight female) and 94 in the comparison group.

Patients of both the ROM3 group and the comparison group were representative of all three surgeons at Labette County Medical Center. Twelve of the patients in the ROM3 group had a single total knee arthroplasty (TKA, i.e., total knee replacement) while one patient had TKA in both knees. Therefore, the total data set included 14 TKAs.

After surgery, each patient received standardized therapy per current rehabilitation protocols at Labette County Medical Center, where the data was collected.

Patients in the ROM3 group used the ROM3 Cycle in addition to the usual therapy protocol for a period of 7-15 minutes per day on each of post-op days #1-#4. All other therapy was kept the same for both groups.

Results & Analysis, Inpatient Rehabilitation Study

1. **Ability to safely use the ROM3 Cycle**. ***The most important datum from the pilot study is that patients were able to safely use the ROM3 Cycle one day after surgery (1 day post-op).***

   In actual fact, *all* of the cases in the ROM3 group were able to use the ROM3 Cycle for at least 8 minutes on each of the 4 days of the study.

   Twelve of the 13 cases in the ROM3 group were able to use the ROM3 Cycle immediately. One patient did not initially use it due to being admitted into the Intensive Care Unit (ICU) following surgery, and instead used the device later.

   Therefore, for those patients who were medically stable, 100% were able to use the device. There were no complications, worsened conditions, or cases in which a patient was medically stable but couldn't use the ROM3 Cycle because its use extended beyond the patient's ability—even post-op day #1.

This is, itself, a very important finding since usability and safety by all patients is vital. It is commonly observed that a substantial percentage of TKA patients have severely limited range of motion after surgery. A device for the purpose of helping patients who have limited range of motion to recovery more quickly would be of little value if their limited range of motion prevented them from using it, or if its use worsened their condition.

The findings indicate that the ROM3 Cycle may be used in the fashion that was intended, that is, immediately following surgery.

2. **Effect of the ROM3 Rehab System on range of motion and speed of recovery**.

It has been observed that 90° range of motion is an important milestone in recovery, since below 90° ROM, patients tend to struggle and experience discomfort and lack of functional mobility; above 90° ROM, patients demonstrate a greater level of functional independence and can better assume their own burden of care—a major goal of post-op therapy. Therefore 90° ROM was chosen as a key benchmark for this inpatient pilot study.

All cases in the ROM3 group reached 90° range of motion in 4 days or less, except one patient (a patient with bilateral TKAs who reached 90º in only one knee within 4 days).

There were three patients in the ROM3 group who reached 90° ROM on the first day after surgery. Each of these individuals continued to improve, and each reached an additional 4° - 5° or more using the ROM3 Cycle.

Of the 94 patients in the comparison group, only 40.5% reached the critical 90° ROM benchmark within 4 days. Of the other 59.5%, most achieved 90° ROM in 5 to 10 days; and several with very stiff knees took longer than 10 days.

Thus 100% of the ROM3 group reached the important milestone of 90° ROM between 1 and 6 days faster than the majority (59.5%) of the comparison group.

3. Effect of the ROM3 Rehab System on length of stay and cost.

Within the comparison group, the 40.5% that reached 90° ROM by post-op day #4 were discharged from the hospital in similar timeframes as the ROM3 group.

For the 59.5% of the comparison group that took longer than 4 days to reach 90° ROM, hospital stays averaged 1.6 days longer than the ROM3 group.

These additional 1.6 days of care, though relatively small, were quite expensive for the hospital, costing an average of $3,252.08 more per patient than the average cost per patient in the ROM3 group.

Additionally, the maximum total cost for a longer stay patient in the comparison group was $10,211.19 more than the average cost per patient in the ROM3 group.

Since hospitals receive flat rate reimbursements based on the diagnosis, regardless of the actual length of stay, the additional days of care are at the hospital's expense—hospitals are not typically reimbursed for additional days of care. Thus hospitals have direct economic benefit from discharging patients as quickly as possible.

Had the ROM3 technology and resultant savings been applied to the entire comparison group (assuming the results from the pilot study hold true across a larger scale), the savings would have been even more substantial:

94 patients x 59.5% = 56 patients (whose hospital stay and cost could have been reduced)

56 patients x $3,252.08 average extra cost = $182,116.48 (potential savings on 94 patients)

From this projection, it can be extrapolated that use of the ROM3 Rehab System with TKA patients for just 4 days immediately after surgery would generate an average cost savings of $1,907.41 per patient due to earlier discharge.

It is noted that a large and growing number of joint replacement surgeries today are performed on an outpatient basis in surgery centers. These outpatient centers typically discharge patients the same day; therapy still generally begins on day #0 or day #1 post-op but at home or in another venue.

The location and setting of the patient and therapy equipment is not considered the key element of this inpatient pilot study. Rather, the key element was the timing of the delivery of the ROM3 therapy—i.e. in the days immediately following TKA.

With this in view, it is expected that the savings generated by use of the ROM3 Rehab System immediately post-TKA will naturally accrue to whatever entity is responsible for the cost of therapy within the respective healthcare model, regardless of the location or setting. Under a fee-per-service model, payors may reap the benefit in the form of a reduced reimbursement. In a bundled payment model, the organization responsible for reducing the number of therapy sessions will be rewarded. Cash patients will pocket the savings themselves.

Outpatient Rehabilitation Pilot Study

Goals of the Study

The three main goals of the study were:

1. To determine if the ROM3 Rehab System is usable by TKA patients with joint pain and limited range of motion in outpatient therapy.
2. To determine if use of the ROM3 Rehab System in outpatient therapy beginning 3-5 weeks after TKA has a significant effect on patients' range of motion.
3. To determine if use of the ROM3 Rehab System in outpatient therapy affects speed of recovery and/or number of therapy visits needed to reach full recovery.

Description of Sample

The pilot study consisted of 29 outpatient therapy cases—15 in the ROM3 group (eight male, seven female) and 14 in the comparison group (four males and ten females). All of the patients had single TKAs performed at Kansas City Orthopaedic Institute, a leading orthopaedic hospital.

After surgery and prior to the pilot data collection, each patient in both groups had received therapy during their inpatient stay in the hospital, followed by 2-4 weeks of in-home therapy.

Next, beginning 3-5 weeks after surgery, each patient received outpatient physical therapy per current rehabilitation protocols at Kansas City Orthopaedic Institute, when the pilot data was collected. For patients in the ROM3 group, use of the ROM3 Cycle for a period of 8-15 minutes was substituted for the usual therapy protocol. All other procedures were kept the same for both groups.

All patients in both groups received therapy from the same therapist only, and all outcome measurements for both groups were conducted by a single therapist, minimizing variables and ensuring uniformity of measurement technique.

Results & Analysis, Outpatient Rehabilitation Study

1. **Ability to use the ROM3 Cycle**. 100% of the patients in the ROM3 group were able to use the ROM3 during their initial visit and in all subsequent visits.

   All patients from both groups had continuing joint pain and indicated that excessive flexion or extension of the affected joint increased pain exponentially. Nevertheless, patients from the ROM3 group indicated they could comfortably use the ROM3 Cycle without prohibitive pain.

   Several from the ROM3 group had very limited range of motion at the beginning of therapy—too limited to perform a single revolution on a stationary bike—but were still able to use the ROM3 Cycle. One patient had severely limited range of motion, with only 47° of knee flexion at initial visit. This patient was likewise able to pedal the ROM3 Cycle on the first visit and on all subsequent visits, and showed significant improvement in range of motion.

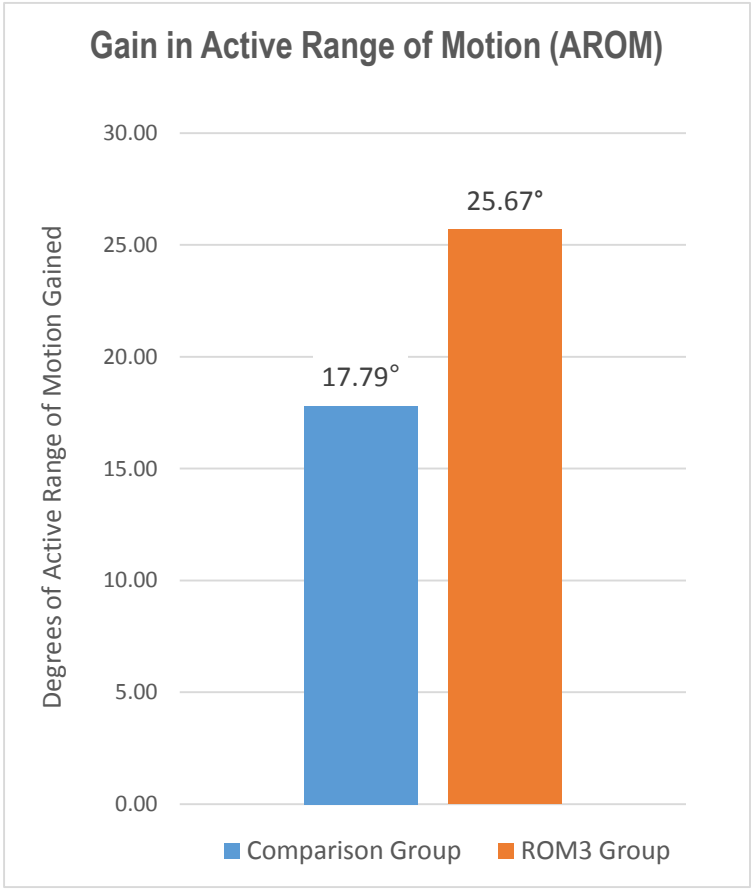
Once again, this is a very important finding since usability by all patients is vital. It is commonly observed that a substantial percentage of TKA patients continue to have limited range of motion for weeks post-op—including some at 4-6 weeks post-op. A device for the purpose of assisting patients with limited range of motion would be of little value if their limited range of motion prevented them from using it.

These results indicate that the ROM3 Rehab System is usable in one of its primary intended uses—enabling therapeutic, productive motion for virtually any medically stable TKA patient at several weeks post-op.

2. **Effect on Range of Motion**. The data from the two groups were compared examining the active range of motion (AROM) from initial exam to discharge. The two groups were compared on the gain in AROM.

   The mean AROM gain for the ROM3 group was 25.67° versus 17.79° for the comparison group. (See Figure 1.)

Figure 1. Gain in Active Range of Motion (AROM)

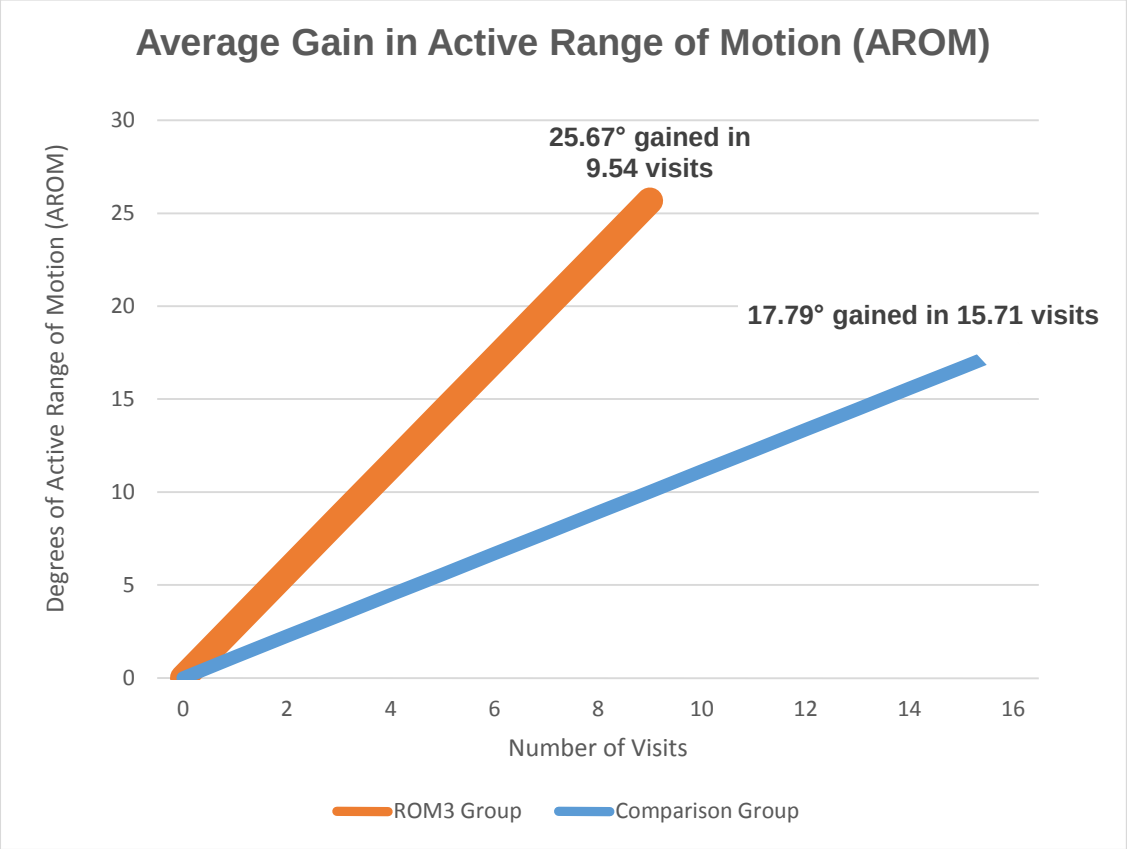


The ROM3 group's results included superior gains in both knee flexion and extension. All but two ROM3 group patients reached 0° extension, while in the comparison group, 9 out of 14 did not achieve 0° by discharge.

3. **Speed of Recovery, Number of Visits.** The ROM3 group had significantly fewer visits until discharge compared to the comparison group, $t(27) = 2.16$, $p < .039$. The ROM3 group required an average of 9.54 visits until discharge, while the comparison group required an average of 15.71 visits.

   This is impressive by itself as the ROM3 patients not only achieved a greater average range of motion, but did so in 40% fewer visits. (See Figure 2.)

Figure 2. Average gain in active range of motion (AROM) over number of visits



Due to faster recoveries, patients in the ROM3 group saw a reduction in necessary therapy visits by an average of 6.17 fewer visits per patient. Assuming an average charge of $100 per visit, this implies a $617 average savings per patient, and with better outcomes.

Conclusions

The results of the pilot studies provide preliminary indications that the ROM3 is an effective apparatus for use with patients who completed TKAs. In summary, the major results of the pilot study indicate that:

1. Patients, including those with joint pain and severely limited range of motion, are able to comfortably and safely use the ROM3 after TKA surgery, including as early as the day of surgery and the day after surgery.
2. TKA patients who use the ROM3 Rehab System, whether immediately after surgery or several weeks later, either inpatient or outpatient, reach greater levels of range of motion faster and recover earlier.
3. TKA patients who use the ROM3 Rehab System immediately after surgery have shorter hospital stays (or fewer therapy sessions, depending on healthcare model). This alone can save an average of more than $1,900 per patient in cost of care.
4. Patients who use the ROM3 Rehab System during outpatient physical therapy required an average of 6.17 fewer visits than those in the comparison group, a 40% reduction in therapy visits, and an additional cost savings of $617 per patient.
5. The tremendous gains seen in the pilot work indicate considerable improvement over the current state-of-the-art TKA rehabilitation treatment.

The results of the two pilot studies provide a very useful examination of the potential of using the ROM3 for TKA rehabilitation. Patients find the device usable immediately after surgery, their progress is more rapid, and their lengths of stay and/or number of visits for rehabilitation are significantly fewer.

Large-scale data with more evaluation points are expected to provide even stronger and clearer results. Pilot data, being smaller in size, generally provide encouraging, but statistically insignificant results[1].

The results from both the Inpatient and Outpatient Pilot Studies indicate that the ROM3 is not only an effective device in the rehabilitation of total knee replacement, but is also quite useful in reducing the cost of such rehabilitation.

When one factors in these results with the fact that more than one million patients undergo TKAs annually[2], the difference in savings by using the ROM3 Rehab System both immediately after surgery and later in outpatient therapy could be in excess of $2.5 billion dollars per year.

The volume of TKAs is forecasted to reach 3.5 million per year within 14 years[3], suggesting this savings could reach more than $8.8 billion dollars annually.

Pressure to reduce healthcare costs is extremely high and rising. It is safe to assume that both providers and payors will be interested in such a savings.

Increased Use

As stated, these studies examined data from patients who each had less than a dozen uses of the ROM3 Cycle, either for just 4 days immediately after surgery, or not beginning until 3-5 weeks post-op. The question arises as to whether an increased use of the ROM3 Cycle, such as on a daily basis throughout the recovery process, might produce even faster recoveries, better outcomes, and greater cost savings.

Certain healthcare providers have begun combining both inpatient and outpatient use of the ROM3 Rehab System, and added home use of the ROM3 Cycle between discharge and outpatient therapy. Under this structure, patients use the ROM3 Rehab System regularly from date of surgery through 5-10 weeks after—some 35-75+ uses. Tracking and analysis of outcome data from this thorough rehabilitation protocol is imminent; it appears to offer even quicker recoveries, fewer visits required, and greater cost savings.

It will require randomized controlled trial studies with larger sample sizes before the ROM3 will be argued to be the next generation of accepted protocol for total knee replacement rehabilitation. However, the pilot data and results presented in this paper provide a glimpse of the power of the results that the ROM3 Rehab System produces.

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[1] *A Note on Small Sample Sizes and Statistical Significance*:

Statistical significance when examining two or more groups involves an estimate of variability due to between group differences and an estimate of variability due to within group differences. Between group differences occur as a function of differences between groups. The ROM3 Rehab System produces significantly shorter time in rehabilitation, for example. The means for the ROM3 are smaller in terms of the number of rehab visits or length of stay in an inpatient unit. However, there are going to be individual differences within each group. Some people are going to respond to rehab faster than others. This is why it is important to randomly assign individuals to groups as the researcher will not know these individual characteristics of patients prior to treatment. To generate significant results, the ratio of between-groups and within-groups variability is determined. If the differences between groups, between-group variability, is larger than the variability between patients, within-group variability, the result will be statistically significant.

The between-group variability between the treatment and comparison groups must be much larger than the variability that naturally exists between individuals within a group. When this occurs, the ratio of between-group versus within-group variability becomes larger, suggesting that there are real and important differences between the groups.

The larger the sample size the greater the probability that significant results will occur when there are real differences. Conversely, the smaller the sample size the less probable that significant results will occur, due to the lack of power to find real differences, even if they exist.

The fact that the differences between the ROM3 and comparison groups were so robust that significant results were found in the pilot studies suggests two things: 1. that using the ROM3 Rehab System produces clinically significant results that can be seen even in small samples, and 2. that it is more probable that those differences are real differences. As a result, it is expected that the results from large-sample-size studies will be even more convincing.

Larger sample sizes generally produce less within group variability as the samples become better estimates of the populations they are representing. Thus the ratio becomes increasingly larger. It is anticipated that the results from further research with larger sample sizes will produce more impressive results. Such studies are now commencing.

[2] Gittins M(1), Doucette D. Total joint arthroplasty: tips for improving efficiency. Am J Orthop (Belle Mead NJ). 2014 Mar;43(3 Suppl):S1-4. PubMed PMID: 24911640.

[3] Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am. 2007 Apr;89(4):780-5. PubMed PMID: 17403800.