

## Summary of Outpatient Pilot Study of the ROM3® Rehab System

An independent pilot study of the ROM3 Rehab System was conducted to determine:

- a. if the ROM3 Rehab System can be used in outpatient therapy by TKA patients with joint pain and limited range of motion;
- b. if the ROM3 Rehab System has a significant effect on range of motion; and
- c. if the ROM3 Rehab System affects speed of recovery and/or number of therapy visits needed to reach full recovery.

The results strongly indicate that the ROM3 is highly effective in assisting recovery after knee surgery by achieving more rapid Range of Motion. The study also provided useful data on procedures and areas for modification in preparation for imminent large-scale studies.

### Description of Sample

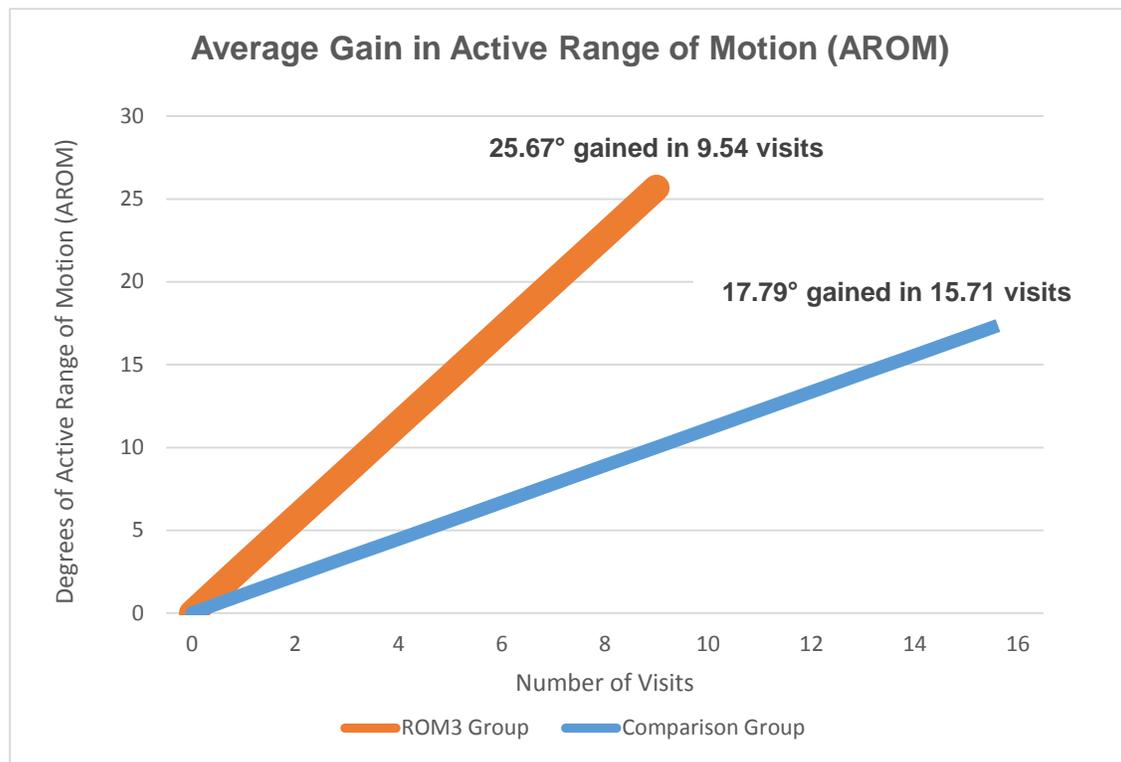
The pilot study consisted of 29 outpatient therapy cases—15 in the ROM3 group (eight male, seven female) and 14 in the comparison group (four males and ten females). All of the patients had single TKAs performed at Kansas City Orthopaedic Institute.

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, followed by outpatient physical therapy at Kansas City Orthopaedic Institute where 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.

### Key Findings

- 100% of the patients in the ROM3 group were able to use the ROM3 Cycle in all visits.
- All ROM3 group patients could comfortably use the ROM3 Cycle without prohibitive pain. This included a patient with severely limited range of motion—only 47° of knee flexion at initial visit—who would have been otherwise unable to pedal a stationary bike.
- The mean active range of motion (AROM) gain for the ROM3 group was 25.67°, versus 17.79° for the comparison group. Thus the ROM3 Rehab System appears to yield a significant improvement in patients' range of motion.
- The ROM3 group's results included superior gains in both knee flexion and extension. All but two ROM3 group patients reached 0° extension; in the comparison group, 9 out of 14 did not achieve 0° by discharge.
- The ROM3 group reached those gains in an average of 9.54 visits until discharge, while the comparison group required an average of 15.71 visits—a reduction of 6.17 visits per patient. Thus the ROM3 patients not only achieved a greater average range of motion, but did so in 40% fewer visits. (See Figure 2.)
- Assuming an average charge of \$100 per visit, this implies a potential average savings \$617 per patient, and with better outcomes.

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



## Conclusions

The study provided preliminary indications that the ROM3 is an effective apparatus for use with TKA patients in outpatient therapy, even several weeks after surgery. Patients find the device usable, their progress is more rapid, and their number of visits for rehabilitation is significantly fewer. The tremendous gains seen in the pilot work indicate considerable improvement over the current state-of-the-art for TKA rehabilitation treatment.

The results from the study also indicate that the ROM3 is quite useful in reducing the cost of such rehabilitation. This is considered to be a significant factor, since, under the new bundled payments model, providers that can demonstrate faster recoveries and a meaningful savings in patient visits are likely to attract a growing share of patient referrals.

Pilot data, being smaller in size, generally provide statistically insignificant results<sup>1</sup>.

Large-scale data from randomized controlled trial studies with more evaluation points are expected to provide even stronger and clearer results. Such studies will be needed before the ROM3 can 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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<sup>1</sup> 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.