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# A Home-Based, Remote-Clinician-Controlled, Physical Therapy Device Leads to Superior Outcomes When Compared to Standard Physical Therapy for Rehabilitation After Total Knee Arthroplasty

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## ABSTRACT

**Background:** The optimal postoperative rehabilitation regimen following total knee arthroplasty (TKA) is not clearly defined. The advent of telerehabilitation offers potential for increased patient convenience and decreased cost, while maintaining similar outcomes to traditional physical therapy (PT). Therefore, we evaluated a novel, home-based, clinician-controlled, multi-modal evaluation and therapy device with telerehabilitation functionality for TKA.

**Methods:** A total of 135 consecutive TKA patients receiving standard therapy protocol (STP) were compared to 135 consecutive patients receiving a home-based clinician-controlled therapy system (HCTS). Outcomes were assessed at 2, 6, and 12 weeks, including visual analog scale (VAS) for pain, knee injury and osteoarthritis outcome score JR (KOOS JR), and knee range of motion (ROM) measured by the same certified physical therapists.

**Results:** Postoperative knee ROM was greater in the HCTS group at all time points throughout the study period ( $P < .001$  at 2, 6, and 12 weeks). VAS and the KOOS JR functional scores were statistically better ( $P < .001$ ) in the HCTS group at all time points and exceeded the threshold for minimal clinically important difference (MCID) for both VAS and KOOS JR. There were significantly fewer cases of arthrofibrosis requiring manipulation under anesthesia (MUA) in the HCTS group (1.48 versus 4.44%).

**Conclusion:** Following TKA, a novel, home-based, clinician-controlled, multi-modal therapy device was superior to standard PT during the first 12 weeks postoperatively for ROM, KOOS JR, and VAS (with all scores exceeding the MCID) and had substantially fewer manipulations for arthrofibrosis.

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There is agreement that physical therapy (PT) is beneficial postoperatively following total knee arthroplasty (TKA), however, the type, duration, location and supervision of therapy continues to be debated [1,2]. Variation in PT protocols and modalities can result in suboptimal outcomes at greater costs to patients and insurers [3]. Optimum solutions incorporate therapeutic motion, which is

recommended by over 96% of American Association of Hip and Knee Surgeons to strengthen the quadriceps muscle and to improve knee range of motion (ROM) [4,5].

The various available PT solutions can be categorized as follows: (1) outpatient PT; (2) at-home supervised or unsupervised PT; and (3) at-home PT with remote supervision (telerehabilitation). This study compared outpatient PT alone with telerehabilitation alone using a specialized, novel device for remote rehabilitation. The home-based, clinician-controlled therapy system (HCTS), multi-modal evaluation and physical therapy system (ROMTech, Brookfield, Connecticut) used in this study utilizes adaptive technology which capitalizes on the functional benefits of traditional, center-based therapy, while also providing the convenience of a supervised telerehabilitation program at home. The system includes a

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portable device which is delivered to the patient's house and utilizes patient and physician-specific adaptive technology to assess ROM and quadriceps muscle recovery. It adapts and advances the delivery of therapeutic motion to optimize the postoperative rehabilitation.

This study evaluated a consecutive cohort of TKA patients from a single surgeon's practice before and after the implementation of this HCTS into the postoperative protocol. The purpose of this study was to compare functional outcomes (visual analogue scale [VAS] pain, ROM measured by the same certified physical therapist, and KOOS JR) following TKA with either standard outpatient PT and those treated with a novel HCTS (telerehabilitation) protocol.

## Materials and Methods

### Study Participants

After approval from a local institutional review board, a retrospective review was performed on a consecutive series of patients who underwent TKA by a single, high-volume, fellowship-trained arthroplasty surgeon (Eric Slotkin) between February 01, 2021, and February 01, 2022 ( $n = 317$  total TKAs). This consecutive cohort of patients included the 6 months before and 6 months after the transition of the new HCTS postoperative protocol, which occurred in August of 2021. The inclusion criteria were any patient undergoing a primary TKA for primary or secondary osteoarthritis. The only patients excluded from the study included: (1) bilateral TKAs at the same setting; (2) previous surgery on the ipsilateral knee; or (3) deformity requiring higher level of implant constraint. This resulted in a review of 270 consecutive TKA patients, including 135 TKA patients in the standard therapy protocol (STP) and 135 TKA patients in the HCTS groups and an exclusion rate of 15%. Demographic data collection included age, sex, and body mass index. Preoperative baseline KOOS JR scores and knee ROMs were also documented. No funding was received for this study.

### Surgical Procedure

All surgeries were performed with the use of a tourniquet through a subvastus approach utilizing a cemented, fixed-bearing, cruciate-retaining unity (Corin, Cirencester, United Kingdom) TKA implant with a congruent liner. All surgeries were performed with the same standardized surgical protocols. Manual Instrumentation was used to place the implants and patellar resurfacing was performed for all patients. All patients in both cohorts were managed utilizing the same intraoperative and postoperative pain protocols, venous thromboembolism protocol, and wound closure with subcuticular sutures and a water-resistant dressing.

### Physical Therapy Interventions

Preoperatively, all patients were provided with the same informational brochure with the following prerehabilitation exercises to be performed at home (unsupervised): quadricep and hamstring muscle sets, ankle pumps, and straight leg raises as recommended by the American Academy of Orthopaedic Surgeons (AAOS) [6]. The postoperative in-hospital therapy protocols were the same for both groups: early mobilization on the day of surgery and 30 minutes of structured PT twice daily until discharge.

In the STP group, all received a minimum of 4 weeks of in-person, outpatient therapy sessions 2-3 times per week. All outpatient therapy sessions took place within the surgeon's own therapy center adjacent to his clinic and staffed by 3 certified physical therapists as well as 4 therapy assistants, all employed by the surgeon. The same multi-faceted structured therapy program

was utilized for all STP patients. The program included active, active-assisted, and passive ROM stretching; core, quad, and hamstring strengthening and conditioning; gait and ambulation training; and the use of therapeutic equipment which included recumbent and upright bicycle, treadmill, and Biodex (Biodex, Hirshey, New York).

For the HCTS group, the in-home, electro-mechanical therapy device was delivered directly to the patients' house and utilized as an interactive touchscreen which prompted each patient to participate in multiple therapy sessions per day. This novel therapy device incorporates a number of rehabilitation features including low-impact, therapeutic motion of the affected limb within controlled, customizable protocols, and a variable pedal radius that adjusts to the patient's ROM recovery. Sessions proceed through multiple motion modalities including passive, active-assisted, active, and resistive motions. In passive mode, the device actuates the patient's leg through a comfortable arc and ROM with no assistance from the patient. In active-assisted mode, the patient actuates the device, with powered assistance from the device as needed. In active mode, the patient actuates the device with no assistance. In resistive mode, the patient actuates the device against resistive force applied by the device. The device automatically adapts to each patient's individual knee ROM with an electronically variable and gradually expanding arc of motion. This accommodates the very limited ROM most patients have in the operative knee during the first few weeks of recovery, while allowing adaptive and progressive increases in the knee ROM throughout the course of the recovery.

Other components of the device include sensor technology and instrumentation which measures and records patient activity and biometric data; a streaming data service, which transmits the recorded data to a connected clinical team for evaluation; a communication platform connecting the clinical team with the patient remotely; and a clinician-side web-based dashboard allowing the clinical team to remotely alter the in-home device functions, track patient progress, and intervene as needed to optimize compliance and outcomes.

Treatment durations ranged from 3 to 6 weeks depending on a number of factors including clinician protocols, patient speed of recovery, and patient financial considerations. No formal additional PT was prescribed for the HCTS group. The progress of HCTS group patients was automatically recorded in each session and available for real-time monitoring on a secure and Health Insurance Portability and Accountability Act-compliant internet dashboard. For this study, the dashboard was monitored by a physical therapist employed by the surgeon. HCTS patients were contacted as needed at the discretion of the surgeon and/or therapist. Patients were automatically contacted by the surgical team if they reported two consecutive sessions of a VAS pain score  $>8$  or other indicators that were outside the expected parameters. HCTS patients also had an abbreviated evaluation by the physical therapist during their routine 2-, 6-, and 12-week postoperative visits with the surgeon at which time knee ROM measurements were obtained using a goniometer by the same therapists and any therapy-related questions answered.

### Outcome Measures

All patients returned for in-person visits at 2-, 6-, and 12-weeks postoperatively. The primary outcome measure of interest was active knee ROM as measured by a certified physical therapist. Secondary outcome measures included a VAS for pain and the KOOS JR score. Further perioperative outcomes observed included need for manipulation under anesthesia (MUA), infection requiring

surgical intervention, and deep venous thrombosis, within the 90-day postoperative period.

MCID of the VAS pain score was set at 1.5 as per prior studies [7]. MCID for the KOOS JR score was determined via the distribution method by taking one-half of the SD of the preoperative KOOS JR scores of the total sample [8]. Using this methodology, the MCID for the KOOS JR score for this study was 5.9 points. Postoperative scores that increase equal to or greater to the calculation were considered to achieve MCID [9].

### Data Analyses

Data were analyzed using Excel (version 16.55, Microsoft, Redmond, Washington). Descriptive statistics for continuous data are expressed as means and SDs, and *P* values of <.05 were considered significant. Continuous data were analyzed using independent sample *t*-tests. Categorical data were evaluated with *chi*-square tests to assess for differences between groups and Fisher's exact tests when expected counts were less than 5.

### Results

There were no statistical differences in baseline characteristics between the STP and HCTS groups, respectively: mean age (70 versus 68, *P* = .154), body mass index (32.6 versus 32.7, *P* = .96), preoperative knee extension (3 versus 2, *P* = .07), mean preoperative knee flexion (119 versus 119, *P* = .81), and baseline preoperative KOOS JR score (21.0 versus 18.9, *P* = .119) (See Table 1).

Because HCTS patients averaged 2.9 sessions per day compared to STP patients who received therapy sessions 2–3 times per week, the HCTS patients accumulated more therapeutic sessions faster than the STP patients. HCTS patients with Medicare insurance received the device for 21 days, whereas, HCTS patients who had commercial insurance used the device for an average of 31 days. On average, HCTS patients received 84 total monitored therapy sessions with the in-home system compared to 19 total outpatient therapy sessions per STP patient, which equates to 65 more monitored therapeutic sessions per patient on average.

Statistically significant differences were found at all time points for all outcome measures in favor of the HCTS group (See Table 2). The HCTS group had substantially less pain, satisfying the MCID of 1.5 at all time intervals: 2 weeks (6.2 versus 7.7), 6 weeks (3.6 versus 5.2), and 12 weeks (1.4 versus 2.9) compared to the STP group (all with *P* < .0001).

Total knee ROM (flexion and extension) was greater in the HCTS group compared to the STP group at all study time points (See Figure 1). At 2 weeks, total knee ROM was 97 (range 69–122) in the HCTS group compared to 83 (range 45–102) in the STP group (*P* <

.0001). At 6 weeks, the total knee ROM was 114.9 (range 88–131) in the HCTS group compared to 98.1 (range 73–124) in the STP group (*P* < .0001). At 12 weeks, total knee ROM was 125.2 (range 103–135) in the HCTS group compared to 117.6 (range 102–132) in the STP group (*P* < .0001). This is in the setting of similar preoperative total knee ROM between the HCTS and STP groups (116 versus 116, *P* = .33). The HCTS group had significantly higher KOOS JR scores at both time intervals: 6 weeks (61 versus 47) and 12 weeks (84 versus 74) compared to the STP group (both *P* < .0001) (See Table 2).

Adverse events and need for MUA were recorded within the 12-week postoperative period. The HCTS group had lower incidence of MUA (1.5 versus 4.4%) and infection (0 versus 1.3%) and higher incidence of deep venous thrombosis (1.5 versus 0.7%) (See Table 3).

### Discussion

In this review, an in-home rehabilitative protocol utilizing the novel HCTS outperformed a standard outpatient STP following TKA. The HCTS patients had substantially less pain, higher total knee ROM, and improved patient reported outcome measures at the 2-, 6-, and 12-week postoperative time intervals.

Regarding pain, the HCTS group not only had statistically less pain, but clinically less pain (below the MCID of less than or equal to 1.5), at all time periods during the 12-week recovery.

The KOOS JR is a validated, outcome-measuring tool designed to assess the most relevant issues in patients who have end-stage knee osteoarthritis undergoing TKA—patient-reported joint pain, stiffness, and function in daily living. The patients in the HCTS group had substantially improved KOOS JR scores when compared to the STP control group at all postoperative time points. This is in spite of the HCTS group having a statistically lower KOOS JR score preoperatively, which suggests that the relative improvement in the HCTS protocol was even better than what this study detected. The difference in the KOOS JR scores also satisfied the pre-determined MCID of 5.13 at all postoperative evaluations. This shows that the function improvements in the HCTS group are both statistically significant and clinically relevant with the validated KOOS JR scoring instrument. It is noted that these outcomes occurred with no further therapies being prescribed in the HCTS group other than the therapeutic modalities on the HCTS device alone at home.

As stated, HCTS patients, with access to the therapy device in their homes, received 2–5 monitored therapy sessions per day, an average of 84 sessions per patient, which was 65 more therapy sessions per patient on average than the STP group during the same time period. This greater frequency and quantity of sessions is believed to be one of the major causes of improved results from the HCTS protocol. Also, within each therapy session, the HCTS

**Table 1**  
Patient Demographics and Baseline Function With Bivariate Analysis Comparing Standard Therapy Protocol (STP) to Home-Based Clinician-Controlled Therapy System (HCTS) Groups.

Baseline Demographic/Function	STP (N = 135)	HCTS (N = 135)	<i>P</i> -value
Age (mean, [SD, min-max])	69.8 (8.6, 44 to 90)	68.1 (10.8, 37 to 90)	.154
BMI (mean, [SD, min-max])	32.6 (6.5, 19 to 49)	32.7 (6.6, 17 to 54)	.96
Insurance Status			.194
Private	39/135, 29%	49/135, 36%	
Medicare	96/135, 71%	86/135, 64%	
Preop Knee ROM			
Extension (mean, [SD, min-max])	3 (2.9, -3 to 10)	2 (2.7, -2 to 10)	.07
Flexion (mean, [SD, min-max])	119 (7.7, 95 to 135)	119 (4.5, 95 to 130)	.81
Pre-operative KOOS JR Mean (SD, min-max)	21 (9.9, 8.3 to 53)	19 (10.6, 8.3 to 50)	.119

SD, standard deviation; BMI, body mass index; ROM, range of motion; KOOS, Knee injury and Osteoarthritis Outcome Score.

**Table 2**  
Post-operative Outcomes With Bivariate Analysis Between Standard Therapy Protocol (STP) and Home-Based Clinician-Controlled Therapy System (HCTS) Groups.<sup>a</sup>

Outcome	STP (N = 135)	HCTS (N = 135)	P-value
Pain (mean, [SD, min-max])			
2 wk	7.7 (1.4, 4 to 10)	6.2 (1.7, 2 to 10)	<b>&lt;.0001</b>
6 wk	5.2 (1.2, 2 to 8)	3.6 (1.5, 0 to 8)	<b>&lt;.0001</b>
12 wk	2.9 (1.2, 1 to 7)	1.4 (1, 0 to 4)	<b>&lt;.0001</b>
Knee Extension			
2 wk	8 (2.6, 2 to 15)	5 (2.8, 0 to 13)	<b>&lt;.0001</b>
6 wk	4 (1.9, 0 to 10)	2 (1.6, 0 to 6)	<b>&lt;.0001</b>
12 wk	2 (1.6, -3 to 5)	0 (1.1, -2 to 4)	<b>&lt;.0001</b>
Knee Flexion			
2 wk	91 (8.1, 52 to 105)	102 (8.3, 78 to 126)	<b>&lt;.0001</b>
6 wk	102 (7.3, 78 to 124)	117 (6.9, 93 to 131)	<b>&lt;.0001</b>
12 wk	119 (5.4, 102 to 132)	125 (4.6, 107 to 135)	<b>&lt;.0001</b>
KOOS JR Mean (SD, min-max)			
6 wk	47 (11.1, 21 to 73)	61 (12.4, 16 to 85)	<b>&lt;.0001</b>
12 wk	74 (7.6, 59 to 92)	84 (8.9, 63 to 100)	<b>&lt;.0001</b>

SD, standard deviation; KOOS, Knee injury and Osteoarthritis Outcome Score.

<sup>a</sup> Boldface indicates statistical significance.

protocols utilized smooth-glide, low-impact, nonweight-bearing, therapeutic motion with multiple modalities (including passive/device-actuated motion and device-assisted motion) within a gradually expanding arc of motion which is thought to more comfortably increase ROM compared with the STP protocol. It is thought that patients participating in multiple sessions per day helps accelerate quadriceps muscle strength and reduce joint swelling and stiffness. Reduced lower extremity edema causes a positive cascade of secondary improvements including less pain, greater joint ROM, which increases overall patient mobility.

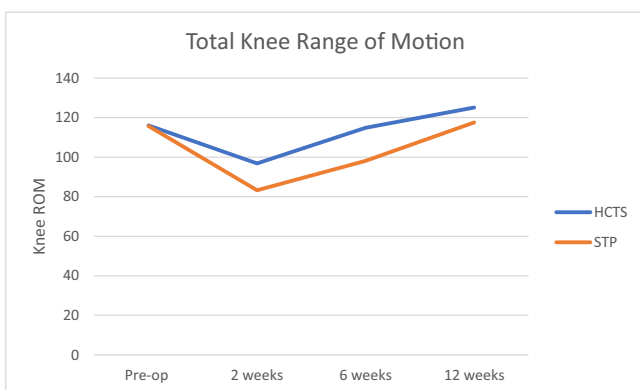
The advantage of outpatient PT compared to unsupervised home-based PT programs has been called into question by a 2013 systematic review [10] and eight subsequent randomized controlled trials (RCTs) that demonstrated no difference in outcomes between the two modalities [11–18]. Notably, some did allow or encourage crossover of participants into the outpatient PT arm which would suggest that some patients may benefit from outpatient PT.

Remote clinician supervision and control have been shown to be responsible for improved outcomes as they allow rapid identification of non-compliance, inadequate or excessive therapy, non-optimized treatment protocol, or non-optimum progress, which allows for earlier intervention; which has been reported to be associated with improved patient engagement and

satisfaction when compared to standard unsupervised regimens [19,20].

Telerehabilitation is a newer option that could potentially provide the benefits of outpatient PT with the convenience and cost-effectiveness of home-based programs. Three recent randomized controlled trials compared virtual telerehabilitation to outpatient PT [21–23]. While no significant difference in outcomes was seen between the groups, the telerehabilitation protocol substantially lowered the 3-month health care costs [23]. The rise of telerehabilitation offers opportunities to bridge the gap between patients who prefer greater supervision while minimizing issues of access and reducing overall cost [24].

One limitation of this study is the generalizability of our results to other institutions. The primary surgeon employs his own physical therapists within his office who did briefly meet with the HCTS group patients during the 2-, 6-, and 12-week visits in order to measure their knee ROM with a goniometer (no hands-on treatments were provided). This was done to have consistency in the ROM measurements between the HCTS and STP groups, but also introduced an opportunity for the therapists to answer any therapy related questions to the HCTS group. Therefore, the HCTS group treatment was not strictly telerehabilitation and this model may not be available in all settings. Furthermore, this is a retrospective study which by nature introduces possible biases. We attempted to minimize sampling bias by including a consecutive series of patients without any other procedural differences between the treated groups by a single surgeon. We attempted to reduce measurement bias in two ways. The VAS and KOOS JR scores were administered to all patients as self-reported surveys without any clinician oversight. Also, the same physical therapists measured the knee ROM on all patients. Nevertheless, the therapists were not blinded to the rehabilitation protocols. Also, preoperative knee



**Fig. 1.** Total Knee Range of Motion (ROM) Compared Between Telerehabilitation Protocol (Home-Based Clinician-Controlled Therapy System [HCTS]) and Standard Therapy Protocol (STP) at Pre-op, 2, 6, and 12 wk postoperatively.

**Table 3**  
Adverse Events With Bivariate Analysis Between Standard Therapy Protocol (STP) and Home-Based Clinician-Controlled Therapy System (HCTS) Groups.

Adverse Event	STP (N = 135)	HCTS (N = 135)	P-value
MUA	6/135, 4.4%	2/135, 1.5%	.28
Infection	1/135, 0.7%	0/135, 0%	1
DVT	1/135, 0.7%	2/135, 1.5%	1

MUA, manipulation under anesthesia; DVT, deep venous thrombosis.

ROM was only estimated visually by the surgeon during the pre-operative visit and, therefore, is not an accurate comparison with the postoperative measurement methodology.

## Conclusion

In conclusion, a supervised (clinician-controlled), in-home rehabilitation protocol using a novel, multi-modal, evaluation and physical therapy device with variable arc adjustment and remote intervention capability was superior to a standard physical therapy protocol at the 2-, 6-, and 12-week periods following TKA. Clinically relevant improvements above the MCID in pain and patient-reported functional scores were seen at all time points. There were also substantially fewer manipulations for arthrofibrosis. While further studies are necessary to verify these conclusions and ensure their generalizability, the results presented here justify continued use and interest in this innovative new rehabilitative technology.

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