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Full Length Article

Is clinically measured knee range of motion after total knee arthroplasty ‘good enough?’: A feasibility study using wearable inertial measurement units to compare knee range of motion captured during physical therapy versus at home

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ABSTRACT

Total knee arthroplasty is highly successful, in part due to range of motion (RoM) recovery. This is typically estimated goniometrically/visually by physical therapists (PTs) in the clinic, which is imprecise. Accordingly, a validated inertial measurement unit (IMU) method for capturing knee RoM was deployed assessing postoperative RoM both in and outside of the clinical setting. The study's objectives were to evaluate the feasibility of continuously capturing knee RoM pre-/post-op via IMUs, dividing data into PT/non-PT portions of each day, and comparing PT/non-PT metrics. We hypothesized IMU-based clinical knee RoM would differ from IMU-based knee RoM captured outside clinical settings. 10 patients (3 M, 69 ± 13 years) completed informed consent documents following ethics board approval. A validated IMU method captured long duration (8–12 h/day, ~50 days) knee RoM pre-/post-op. Post-op metrics were subdivided (PT versus non-PT). Clinical RoM and patient reported outcome measures were also captured. Compliance and clinical disruption were evaluated. ANOVA compared post-op PT and non-PT means and change scores. Maximum flexion during PT was less than outside PT. PT stance/swing RoM and activity level were greater than outside PT. No temporal variable differences were found PT versus non-PT. IMU RoM measurements capture richer information than clinical measures. Maximum PT flexion was likely less than non-PT due to the exercises completed (i.e. high passive RoM vs. low RoM gait). PT gait flexion likely exceed non-PT because of ‘white coat effects’ wherein patients are closely monitored clinically. This implies data captured clinically represents optimum performance whereas data captured non-clinically represents realistic performance.

1. Introduction

Total knee arthroplasty (TKA) successfully treats end stage knee osteoarthritis (OA) [1–3], improving pain, quality of life, and clinic and/or laboratory measured range of motion (RoM) [4–7]. To achieve improvements post-TKA, care often involves homogenous, broad-based physical therapy (PT) [8–12]. Clinical flow at our institution attempts ensuring recovery (Fig. 1A) via homogenous inpatient PT, at-home or outpatient rehabilitation, and longer-term follow-ups. This homogeneity likely facilitates wound healing, pain reduction, and recovering RoM necessary for activities of daily living (ADL; e.g. stair ascent) [1,9,11, 13–15]. Accordingly, establishing RoM recovery is critical for evaluating healing and TKA/PT efficacy.

Currently, clinicians rely upon static goniometric or visual knee RoM measures to evaluate recovery [16–18]. Unfortunately, these knee RoM measurements are limited because they 1) are discrete (singular

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Abbreviations: RoM, Range of motion; PT, Physical therapy; PTs, Physical therapists; IMU, Inertial measurement unit; ANOVA, Analysis of variance; TKA, Total knee arthroplasty; OA, Osteoarthritis; ADL, Activities of daily living; MOCAP, Motion capture; 3D, Three dimension; LPF, Low-pass filter; FFT, Fast Fourier transform; EMR, Electronic medical record.

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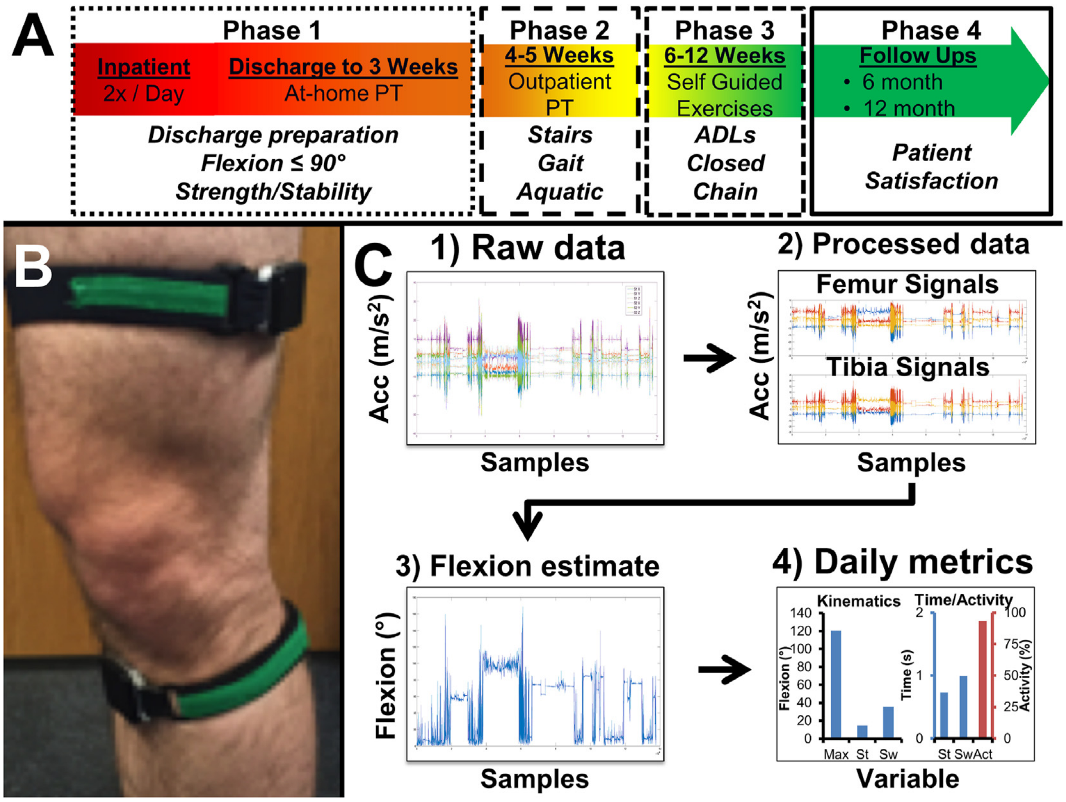

Fig. 1. (A) Postoperative total knee arthroplasty (TKA) physical therapy (PT) clinical flow, (B) Inertial measurement unit (IMU) sensor donning locations, and (C) Data process flow from 1) raw data input to 2) processed data including low pass filtration, bony segment differentiation, and sensor/anatomy misalignment removal to 3) daily continuous knee flexion estimate to 4) daily outcome metrics.

time-points), 2) are conducted in idealized capture locations (routine PT exams in laboratory/clinic settings), 3) fail to measure motion capabilities through entire dynamic RoM (i.e. only maximum RoM), and 4) are low-resolution [19–21]. While goniometric/visual maximum knee RoM are low-cost, quick, and simple, they likely fail to fully encapsulate patient function. Previous studies highlight these limitations including poor accuracy/precision [22,23] and maximum knee RoM failing to improve post-TKA (i.e. cannot evaluate recovery if equal to pre-TKA values) [24]. Additional studies show little connection between goniometric knee RoM and well-established post-TKA measures of function (e.g. pain, quality of life) further limiting this measure's value establishing recovery [25,26].

Optical motion capture (MOCAP) and fluoroscopy are additional knee RoM measurement methods with improved precision/accuracy that capture more dynamic RoM information [27–30]. However, like goniometry, both are restricted to well-controlled laboratory/clinical settings. Moreover, these methods are costly (>$10 k and >$200 k, respectively) and require significant technical training to operate/interpret. As such, improved post-TKA RoM recovery measurement techniques are necessary. Because clinicians rely on RoM measures collected during routine PT/clinical exams, it is vital to evaluate RoM measurement methods deployable both in well-controlled clinical/laboratory settings (i.e. where RoM is evaluated) ***and*** in realistic environments where patient function may differ (e.g. at home).

Inertial measurement units (IMUs) are novel wearable technology allowing portable knee RoM capture [31–34]. IMUs collect linear acceleration, angular velocity, and magnetic field strength which are leveraged to quantify the object's orientation to which IMUs are affixed (e.g. femur, tibia). This has been utilized evaluating outcomes spanning gross (e.g. activity classification) [35–37] to fine precision (e.g. RoM) [31,32,38,39]. Accordingly, knee RoM is quantifiable via IMUs in both clinical settings ***and*** more realistic scenarios (e.g. at the patient's home). However, studies typically only evaluate knee RoM ***either*** in well-controlled laboratory/clinic settings [31,33] ***or*** in patients' self-selected environments [32]. And despite reliance on knee RoM captured clinically during routine PT visits to establish recovery, no studies exist demonstrating if clinical RoM is equivalent to knee RoM outside of well-controlled environments (e.g. patient selected environments).

Accordingly, objectives of this initial pilot study were utilizing a previously validated IMU-based knee RoM measurement method to evaluate feasibility of 1) continuously capturing knee RoM pre-/post-TKA via IMUs ***both*** during ('PT') ***and*** outside of PT ('non-PT'), 2) dividing data into PT and non-PT segments, and 3) comparing PT and non-PT IMU-based metrics in a typical consecutive caseload of one orthopaedic surgeon. Because patients are encouraged during PT (verbally, physically, etc.), we hypothesized all IMU-based metrics will be significantly different PT versus non-PT. Specifically, we hypothesized IMU 1) kinematic measures (i.e. maximum, stance phase, swing phase RoM) are greater during PT, 2) temporal measures (i.e. stride, stance, swing time) are less during PT, and 3) activity level is greater during PT. Failing to reject these hypotheses, this would imply reliance on clinically captured RoM to establish recovery may be misguided.

2. Materials and methods

2.1. Overview

This study was reviewed/approved by our institution's ethics review board (The Committee for Protection of Human Subjects, Dartmouth College). Following ethics board approval, we utilized a previously validated IMU-based method for capturing continuous, long-duration knee RoM from patients pre-/post-TKA [32]. This method was validated across walking speeds/RoMs with error analyses showing agreement with gold-standard MOCAP at midstance, toe-off, and midswing but slight heel-strike bias (~5°). Accordingly, we avoided heel-strike RoM measures, and focused instead on midstance/midswing as well as unbiased temporal and activity level information.

At the highest level, subjects donned temporally synchronized IMUs ($f_s = 128$ Hz, range: ±6 g; Emerald, APDM Inc., Portland, OR, USA) each day. IMUs were rigidly attached above/below the knee (Fig. 1B; Superior to lateral femoral epicondyle & Inferomedial to tibial tuberosity) via silicone-backed elastic straps leveraging 3D acceleration to quantify relative sagittal segment orientation (i.e. knee flexion). Following receipt of informed consent, patients were instructed on appropriate sensor use (i.e. sensor placement, charging, etc.) and given visual/text-based guides including the same information. Further demonstrations were provided if questions arose during deployment. 3D acceleration then continuously recorded to microSD cards 8–12 h/day. At daily terminus, IMUs were doffed/recharged. This process was repeated daily for the study duration. Sensors were then returned for analyses.

2.2. Data processing

Knee flexion was continuously calculated each day via relative IMU motion (Fig. 1C): 1) Raw accelerometer input, 2) Pre-processing: LPF (5th order Butterworth, $f_{cutoff} = 5$ Hz), assessing to what segment each IMU was attached, removing sensor/anatomy misalignment (described in detail below), 3) Calculate continuous knee flexion, and 4) Output daily kinematic (maximum, stance/swing phase RoM), temporal (stride, stance, swing time), and activity level metrics [32,40].

For each day's data, sensor orientation was noted during initial donning via accelerometer values from known positions (i.e. a_{actual}). If accelerations indicated inappropriate sensor positioning (i.e. $a_{actual} \neq a_{correct}$), actual data were rotated to 'correct sensor position' data using 3D rotation matrices in MATLAB (***vrrotvec*** and ***vrrotvec2mat***). A similar process was employed throughout sensor use to evaluate sensor position changes during use (e.g. sensors jostled). Unusable data (e.g. sensors slipped down leg) were removed accordingly. Once sensors were replaced to correct positions, sensor position was re-evaluated and rotated similarly using ***vrrotvec*** and ***vrrotvec2mat***.

Following, data pre-processing, continuous knee RoM was computed each day. Kinematic outcome variables were then quantified from daily continuous knee RoM. Maximum RoM was the greatest knee RoM achieved daily. Gait was located via fast Fourier transform (FFT) frequency analysis [41,42] defined as the 1-min epoch with greatest 0.75–2.25 Hz content magnitude. Within that epoch, individual strides were identified by locating repeated, characteristic, bimodal knee flexion curves indicative of over-ground ambulation (Fig. 2B). Heel-strike occurred at the local knee flexion minima before the lesser local knee flexion maxima (HS, dotted line). Toe-off occurred at the local knee flexion minima following the lesser local knee flexion maxima and immediately before the absolute knee flexion maxima of that stride (TO, dot-dash line). Stance/swing phases were from initial heel-strike to toe-off and from toe-off to subsequent heel-strike, respectively. Accordingly, stance/swing time were the duration of stance/swing phases, respectively. Stride time was the sum of stance and swing times. Similarly, stance/swing RoM were peak RoM achieved during stance/swing phases, respectively. Finally, thigh acceleration was broken into 1-min epochs for activity level computation. Within each epoch, activity was computed as shown in Equation (1). Any epoch with A greater than 110 m/s^2/min were 'active' whereas epochs less than this value were 'inactive' [40,43,44]. Final activity level was quantified as the percent of daily 'active' epochs.

$$A = \sum_{i=1}^{n} \sqrt{a_{x_i}^2 + a_{y_i}^2 + a_{z_i}^2} \tag{1}$$

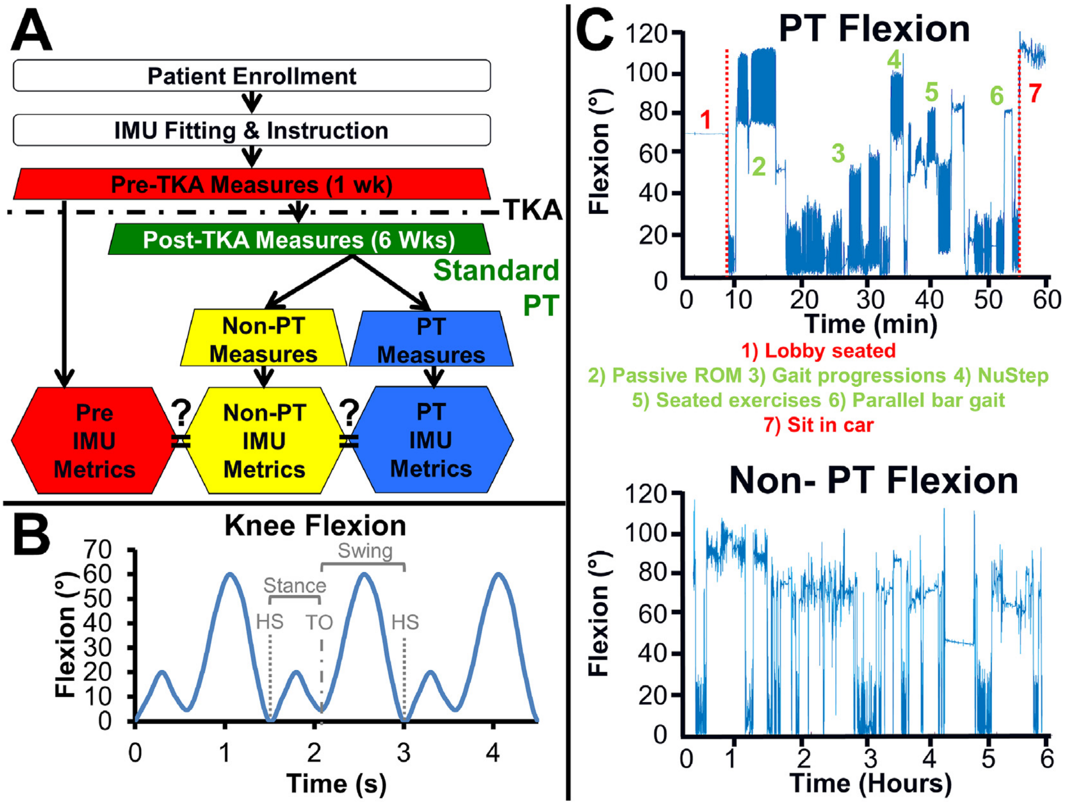

Fig. 2. (A) Study design flow block diagram including patient enrollment, inertial measurement unit (IMU) fitting and instruction, pre-total knee arthroplasty (TKA) measures lasting 1-week, TKA surgical event, post-TKA measures lasting 6-weeks, and subsequent data bifurcation into data captured during physical therapy (PT) and non-PT data; (B) Definitions of how gait cycles were defined including heel strike (HS) and toe-off (TO) quantifying stance phase and to subsequent HS defining swing phase; and (C) An exemplary subject's knee flexion during physical therapy (PT) and outside PT.

2.3. Study flow (Fig. 2A)

Following obtaining informed consent from each subject, patients from one surgeon's consecutive caseload were fitted with IMUs and instructed on use. Inclusion criteria included no contralateral pathology, no other lower extremity musculoskeletal/neuromuscular pathology, no terminal illness expected to result in death within one year, and whole study participation. To minimize clinical disruption and unnecessary trips to our institution, enrollment occurred at already scheduled routine one-week pre-TKA clinical appointments. Patients then continuously wore IMUs during waking hours for one-week pre-TKA on their impacted leg without clinical interventions (e.g. injections).

All TKAs were performed via the medial parapatellar approach (implant types in *Results*). Postop day one, IMUs were replaced on patients. Again, to minimize clinical disruptions, reduce unnecessary returns to our institution, and align with previously scheduled post-operative appointments at six-weeks post-TKA, subjects wore IMUs six consecutive weeks after surgery. During this period, our institution's standard, broad-based PT was prescribed (detailed PT in *Methods 2.4*). Sensors were then returned to researchers during each patient's post-TKA follow-up appointment at six-weeks post-op. Daily postoperative time was bifurcated into PT/non-PT portions by comparing electronic medical record (EMR) appointment dates/times with IMU sensor timestamps. Finally, measures calculated during PT portions of the day were compared to the same measures calculated during non-PT portions of the day.

2.4. Postoperative rehabilitation

Post-TKA, homogenous rehabilitation was prescribed per our institution's clinical guidelines [45]. Generically, four phases exist (Fig. 1A): 1) Acute inpatient to week three, 2) Weeks four-five, 3) Weeks six-twelve, and 4) Follow-ups. Goals of each phase (Fig. 1A, italicized) demand specific exercises including passive/active RoM, static stretches, and non-gait activities (e.g. straight leg raises) during ‘Phase 1’; stairs, gait progressions (e.g. single limb stance), and aquatic therapy during ‘Phase 2’; and at-home exercises including ADLs, ambulation, stairs, and closed chain movements (e.g. step-ups) in ‘Phase 3’. ‘Phase 4’ involves repeated clinic visits to ensure no gross issues (e.g. infection, fracture, etc.) and satisfaction. Within these goals, PT sessions might have exercise variability, however the broader rehabilitation approach and exercise categories were homogenous across subjects.

2.5. Prospective study

Data from a previous study utilizing this method, comparing ‘good’ and ‘poor’ post-TKA RoM were used to estimate subject quantity for the present investigation [32]. G*Power 3.1.9.4 computed predicted sample sizes ($p < 0.05$, power>0.80) using means and standard deviations from that investigation, assuming 15% loss to follow-up. Sample size was 12 with anticipated final enrollment of 10.

Accordingly, 10 TKA patients (three male, 69 ± 13 years) in one surgeon's consecutive TKA caseload were enrolled. Daily data were processed as described above and in detail elsewhere [32]. Sagittal knee RoM was quantified continuously for one-week pre-TKA and six-weeks post-TKA. Sensor-use compliance was evaluated weekly with individuals wearing IMUs < six days removed from that week. Daily pre-TKA IMU knee RoM quantified kinematic (maximum/stance/swing RoM), temporal (stride/stance/swing time), and activity-level metrics. Pre-TKA metrics were averaged for each subject across the days within each week.

Daily post-TKA IMU-based knee RoM was divided into PT (‘PT’) and all other (‘non-PT’) time as described previously. The same metrics as before were quantified daily for both PT/non-PT periods. Each subject's post-TKA PT and non-PT metrics were separately averaged each week. Although other outcome measure frequencies are possible (e.g. hourly, daily, etc.), weekly averages were selected for several reasons. Notably, PT sessions occur once/twice weekly. Thus, measurement frequency less than weekly is inappropriate for comparing PT to non-PT measures (i.e. many days do not have PT to compare PT vs. non-PT measures). Additionally, work from our lab highlighted significant daily variability within a week, indicating making clinical decisions via daily measures is likely too frequent. Finally, weekly measures are currently how many PTs evaluate patient performance. Accordingly, weekly comparisons are a convenient and clinically relevant frequency for evaluating these measures.

Weekly post-TKA average PT and non-PT metrics for each subject were then directly compared to one another and to pre-TKA values via change-score analyses, accounting for some intersubject variability caused by the small sample size. Specifically, pre-TKA average metrics were subtracted from the same subject's weekly average post-TKA PT metrics (PT change score) and separately, weekly average post-TKA non-PT metrics (non-PT change score). Finally, PT and non-PT change scores were averaged across subjects weekly.

Clinical RoM (goniometric maximum) and patient reported outcome measures (PROMs) were also captured per standard clinical practice at clinical appointments one-week pre- and six-week post-TKA. PROMs included PROM Information System (PROMIS) mental/physical component scores (MCS, PCS) [46], Knee injury and Osteoarthritis Outcome Score (KOOS) [47], and pain. Change scores were also computed by subtracting subject's pre-TKA values from their post-TKA values, then averaged across subjects.

Due to the preliminary and small sample size of this investigation, emphases were placed on evaluating sensor use compliance and clinical flow disruption. For completeness however, one-way repeated-measures ANOVA (Minitab 19.2020.1, Minitab, LLC) was completed on IMU measures using capture location (i.e. PT vs. non-PT), time (i.e. week), and interaction (i.e. PT/non-PT by week) factors with alpha (α) set to 0.05. However, small sample size warrants care (as in the discussion) extrapolating statistical results to broader TKA populations.

3. Results

3.1. Patients, TKA device selection, & sensor compliance

Two patients ($n = 2$, two female) underwent revision TKA. The remainder ($n = 8$, five female) underwent primary TKA. All subjects received implants appropriate for their clinical presentation ($n = 2$ P·F·C.® Sigma® TC3 Revision Knee System with Mobile Bearing Tray, $n = 6$ Attune® Knee System, $n = 1$ Attune® Revision Knee System, $n = 1$ Sigma® Uncemented Total Knee System; DePuy Synthes, Warsaw, IN). Subjects were well-healed through post-TKA follow-up. Patients were 69 ± 13 years with fewer right knees replaced (four right) (Table 1).

Compliance evaluated via IMU timestamps showed high compliance pre- (9.7 ± 1.8 h/day, 6 ± 1 days) and post-TKA (8.5 ± 2.3 h/day, 37 ± 4 days). All patients were compliant for weekly averaging. Patients received 1.5 ± 0.5 P T sessions (median ± median absolute deviation [MAD]) per postoperative week lasting 1.1 ± 0.2 h/session.

Fig. 2C shows an example patient's single day knee flexion during PT and non-PT highlighting qualitative differences. PT knee flexion was well-ordered and more ‘active’ indicated by increased motion density. Contrastingly, non-PT flexion showed long duration seated, sedentary behavior (i.e. flexion≈90–100°) separated by short activity bouts.

3.2. Clinical disruption

Sensors deployed herein were unobtrusive (3.65cmx3.61 cm, <50 g) and worn beneath garments. Therapists were blinded from patient participation excluding self-disclosure. For unblinded therapists, none expressed IMU-induced function hindrance during rehabilitation. Therapists remaining blinded expressed no restriction beyond normal post-TKA expectations. Therapist interaction with IMUs was limited to

Table 1

Patient demographics (age, sex, surgical/sensor side, pre-TKA days/hours, total post-TKA days/hours, and post-TKA non-PT/PT hours) as well as clinical maximum goniometric RoM, and PROMs (PROMIS PCS, PROMIS MCS, KOOS, and pain) captured at pre-TKA and 6-weeks post-TKA. Also displayed are change score comparing each subject's post-TKA to pre-TKA values.

Age (years)	69 ± 13
Sex	3 M, 7 F
Surgical/Sensor Side	4 R, 6 L
Pre Days	6 ± 1
Pre Hours per Day	9.7 ± 1.8
Post Days	37 ± 4
Post Hours per Day	8.5 ± 2.2
Post Non-PT Hours	8.0 ± 2.4
Post PT Hours	1.1 ± 0.2

	RoM (°)	PCS	MCS	KOOS	Pain
Pre-TKA	114 ± 12	39.4 ± 5.8	51.3 ± 7.0	47.6 ± 9.9	7 ± 1
Post-TKA	109 ± 14	43.5 ± 3.8	54.6 ± 5.8	61.5 ± 6.6	4.5 ± 1.5
Change Score	−4±7	4.1 ± 5.2	3.2 ± 4.7	13.9 ± 6.7	−3±1

TKA: Total knee arthroplasty; M: Male; F: Female; R: Right; L: Left; RoM: Range of motion; PROM: Patient reported outcome measures; PROMIS: Patient reported outcomes measurement information system; PCS: Physical component score, MCS: Mental component score, KOOS: Knee injury and osteoarthritis score, TKA: Total knee arthroplasty.

* Significant difference.

wound-site checks if worn near the incision. No skin disruptions or wound healing issues were noted.

3.3. IMU-based metrics, evaluation of means, ANOVA

IMU metrics are shown as pre-TKA (dashed line), post-TKA non-PT (solid bars), and post-TKA PT (striped bars). Pre-TKA maximum flexion and non-PT maximum flexion means (Fig. 3A) and change scores (Fig. 3B) always exceeded PT means and change scores. Data capture location (i.e. non-PT vs. PT) was significant for both means (*; non-PT > PT; $F = 9.77$, $p = 0.003$) and change scores (*; non-PT > PT; $F = 10.62$, $p = 0.002$). On average neither improved beyond pre-TKA levels. Time and interaction were not significant for means ($F_{time} = 1.73$, $p_{time} = 0.14$; $F_{interaction} = 0.48$, $p_{interaction} = 0.79$) or change scores ($F_{time} = 0.95$, $p_{time} = 0.45$; $F_{interaction} = 0.42$, $p_{interaction} = 0.83$).

Stance (Fig. 4A) and swing (Fig. 4C) flexion means were greater during PT than non-PT (*; $F_{stance} = 22.62$, $p_{stance} < 0.0001$; $F_{swing} = 52.80$, $p_{swing} = < 0.0001$). Time was a significant factor for stance and swing ROM (‡; $F_{stance} = 3.85$, $p_{stance} = 0.003$; $F_{swing} = 3.79$, $p_{swing} = 0.004$) but interaction was not ($F_{stance} = 1.34$, $p_{stance} = 0.25$; $F_{swing} = 0.30$, $p_{swing} = 0.91$). PT stance change scores (Fig. 4B) were always positive. Non-PT stance change scores were only positive post-TKA weeks four through six. Data capture location was significant for change scores (*; PT > Non-PT; $F_{stance} = 15.13$, $p_{stance} < 0.0001$) as was time (‡; $F_{stance} = 2.90$, $p_{stance} = 0.02$). However, interaction was not significant ($F_{stance} = 0.39$, $p_{stance} = 0.86$). Non-PT swing flexion change scores (Fig. 4D) remained negative, however exceeded zero for PT during post-TKA weeks three through six. Data capture location was significant (*; PT > Non-PT; $F_{swing} = 28.84$, $p_{swing} < 0.0001$). Time ($F_{swing} = 1.69$, $p_{swing} = 0.15$) and interaction ($F_{swing} = 0.16$, $p_{swing} = 0.98$) factors were not significant.

Stride time means (Fig. 5A) always exceeded pre-TKA values during

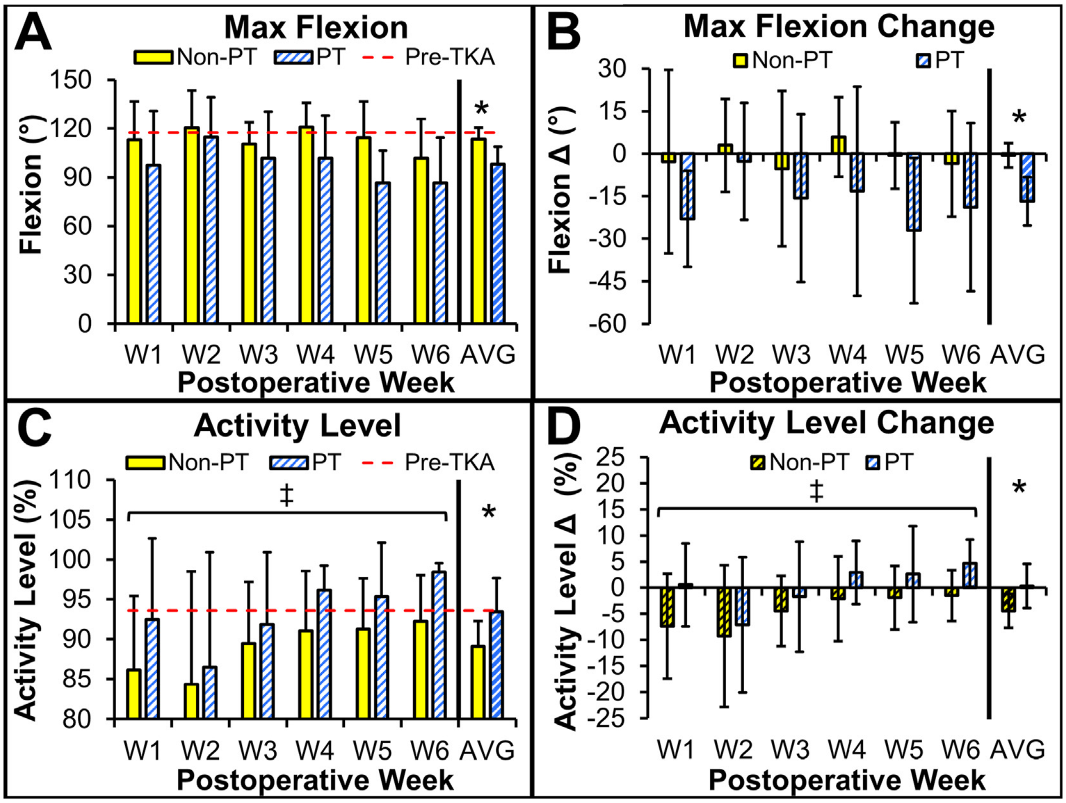

Fig. 3. Maximum flexion (A) means measured before surgery (dashed line), after surgery outside of physical therapy (solid bars), and after surgery during PT (striped bars). Maximum flexion (B) change scores are displayed similarly. Activity level (C) means measured before surgery (dashed line), after surgery outside of physical therapy (solid bars), and after surgery during PT (striped bars). Activity level (D) change scores are displayed similarly. Asterisks (*) denote significant differences between postoperative PT and non-PT values. Double bars (‡) denote significant differences with respect to time.

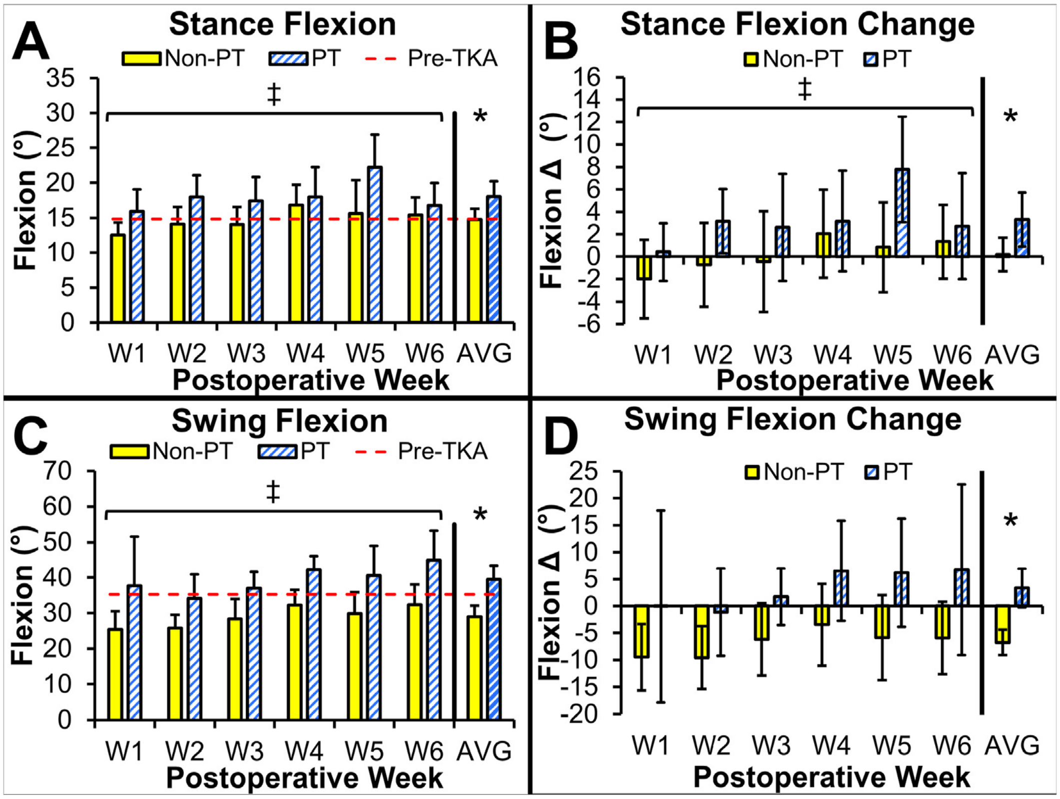

Fig. 4. Stance phase knee flexion (A) means measured before surgery (dashed line), after surgery outside of physical therapy (solid bars), and after surgery during PT (striped bars). Stance phase knee flexion (B) change scores are displayed similarly. Swing phase knee flexion (C) means and (D) change scores are displayed in a similar fashion. Asterisks (*) denote significant differences between postoperative PT and non-PT measures. Double bars (‡) denote significant differences with respect to time.

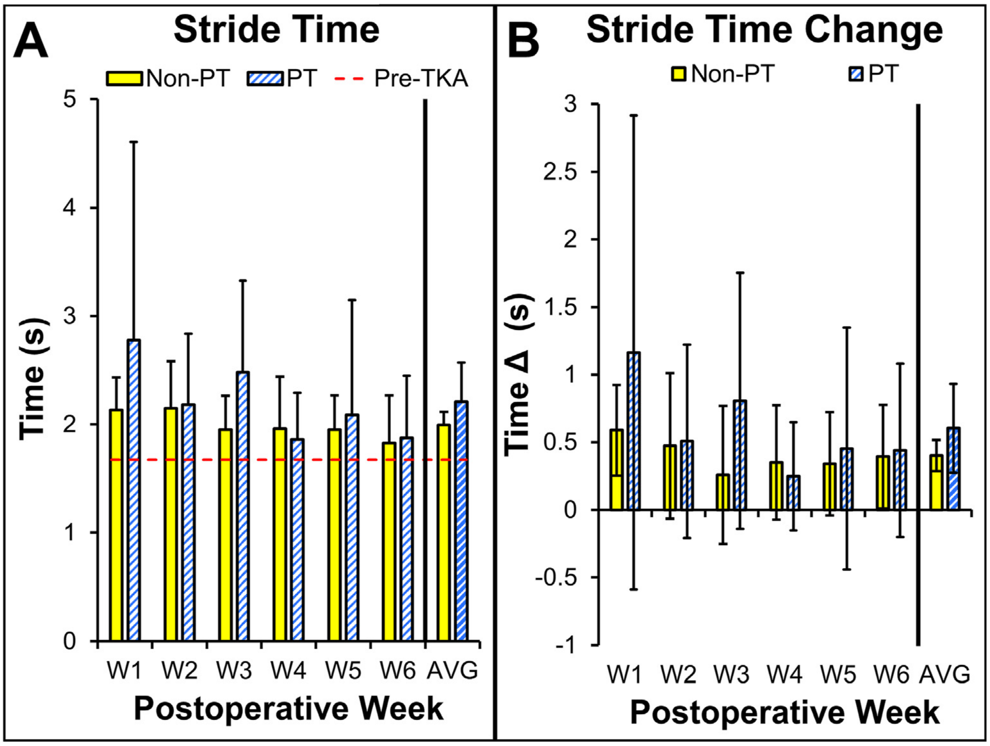

Fig. 5. Stride time (A) means measured before surgery (dashed line), after surgery outside of physical therapy (solid bars), and after surgery during PT (striped bars). Stride time (B) change scores are displayed similarly.

PT/non-PT. Despite data capture location being significant for kinematics, it was not for stride times ($F = 1.46$, $p = 0.23$) or change scores (Fig. 5B; $F = 1.69$, $p = 0.20$) indicating non-PT/PT stride times were equivalent. Further, time and interaction factors were not significant for means ($F_{time} = 0.72$, $p_{time} = 0.61$; $F_{interaction} = 0.16$, $p_{interaction} = 0.98$) or change scores means ($F_{time} = 1.17$, $p_{time} = 0.33$; $F_{interaction} = 0.62$, $p_{interaction} = 0.68$).

Stance (Fig. 6A) and swing time (Fig. 6C) means were predominantly greater than pre-TKA levels during PT and non-PT periods (exception: W6 stance time means). However, neither showed significant differences between PT and non-PT measures ($F_{stance\text{-}time} = 0.22$, $p_{stance\text{-}time} = 0.64$; $F_{swing\text{-}time} = 2.03$, $p_{swing\text{-}time} = 0.16$). Time ($F_{stance\text{-}time} = 0.56$, $p_{stance\text{-}time} = 0.73$; $F_{swing\text{-}time} = 1.11$, $p_{swing\text{-}time} = 0.36$) and interaction factor ($F_{stance\text{-}time} = 0.31$, $p_{stance\text{-}time} = 0.90$; $F_{swing\text{-}time} = 0.33$, $p_{swing\text{-}time} = 0.89$) were not significant for either measure. Stance time (Fig. 6B) and swing time (Fig. 6D) change scores were always positive, and like means, neither were significantly different PT vs. non-PT ($F_{stance\text{-}change} = 0.01$, $p_{stance\text{-}change} = 0.91$; $F_{swing\text{-}change} = 2.62$, $p_{swing\text{-}change} = 0.11$). Time ($F_{stance\text{-}change} = 0.11$, $p_{stance\text{-}change} = 0.99$; $F_{swing\text{-}change} = 2.31$, $p_{swing\text{-}change} = 0.06$) and interaction factors ($F_{stance\text{-}change} = 0.47$, $p_{stance\text{-}change} = 0.80$; $F_{swing\text{-}change} = 0.77$, $p_{swing\text{-}change} = 0.57$) were also not significant.

Patient PT activity level means (Fig. 3C) and change scores (Fig. 3D) were always greater than non-PT. Like kinematics, data capture location was significant (*; PT > non-PT: $F_{means} = 5.62$, $p_{means} = 0.02$; $F_{change} = 6.33$, $p_{change} = 0.01$). Similarly, time was a significant factor for both activity means and change scores (‡; $F_{means} = 3.15$, $p_{means} = 0.01$; $F_{change} = 2.60$, $p_{change} = 0.03$). However, interaction factor was not significant for activity means and change scores ($F_{means} = 0.33$, $p_{means} = 0.89$; $F_{change} = 0.23$, $p_{change} = 0.95$).

3.4. *Clinical RoM & PROMs*

Clinical RoM/PROMs (Table 1) showed clinical RoM degraded post-TKA, however variability exceeded average change ($\sigma = 7^\circ$ vs. $\mu = -4^\circ$). In contrast, PROMIS PCS/MCS scores improved. Yet, like clinical RoM change, variability exceeded average change (PCS: $\sigma = 5.2$ vs. $\mu = 4.1$, MCS: $\sigma = 4.7$ vs. $\mu = 3.2$). KOOS and pain scores both improved, but unlike other PROMs, average change exceeded change variability (KOOS: $\sigma = 6.7$ vs. $\mu = 13.9$, Pain: $\sigma = 1$ vs. $\mu = -3$).

4. Discussion

4.1. *Overview*

This preliminary study showed measuring knee RoM in/out of PT is feasible with high sensor compliance and minimal clinical disruption. Moreover, the results provide further evidence that IMUs offer richer information than clinical goniometric RoM. We found IMUs accurately assess RoM recovery in ***and*** out of clinical settings, providing holistic recovery information. Interestingly, PT metrics differed from outside PT indicating clinical data likely ***does not represent*** how patients perform on their own. Specifically, significant kinematic/activity level differences were discovered between the two settings. We believe this is the first study quantitatively showing RoM measures captured during rehabilitation ***are not*** equivalent to those outside the clinic. As a result, reliance on clinically captured RoM to establish recovery is likely misguided. Instead, we should encourage utilizing novel methods for capturing RoM outside clinical settings.

4.2. *Feasibility: patient compliance*

Patient compliance with new wearable technology is a significant concern [48,49]. As novelty fades, so does compliance. Fortunately, our subjects were highly compliant. However, we urge caution extrapolating to broader TKA populations or other pathologies as our cohort may be anomalous. Notably, study subjects reside in a geography (upper New

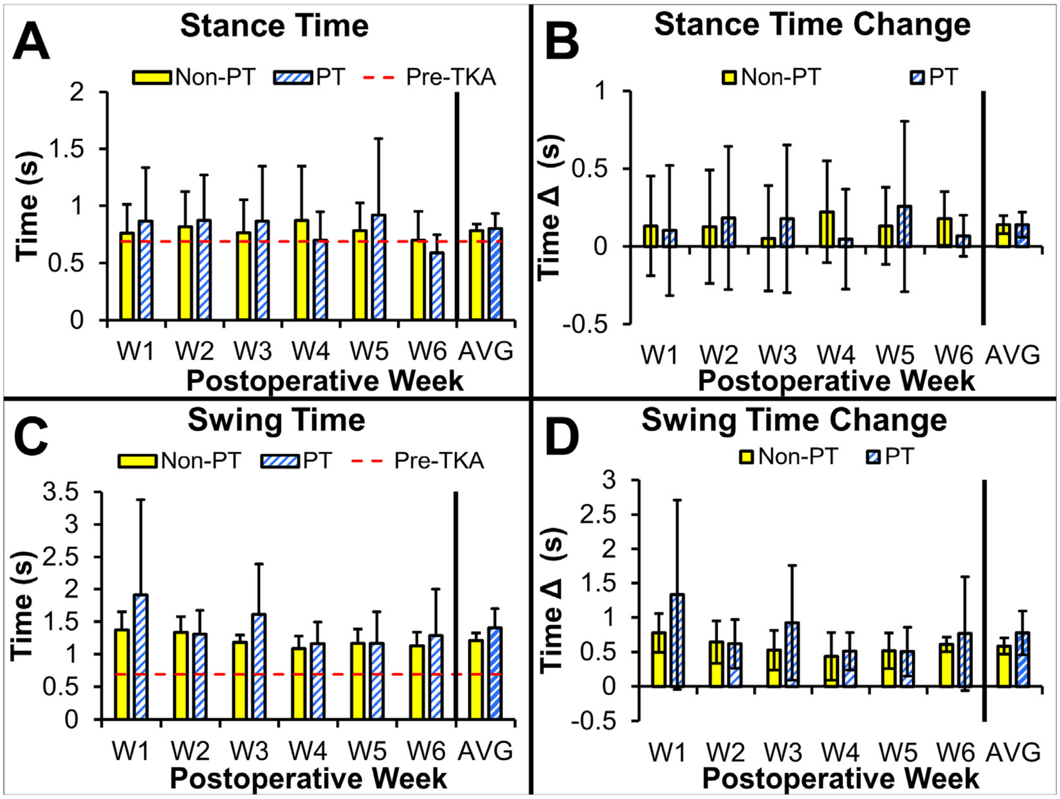

Fig. 6. Stance time (A) means measured before surgery (dashed line), after surgery outside of physical therapy (solid bars), and after surgery during PT (striped bars). Stance time (B) change scores are displayed similarly. Swing time (C) means and (D) change scores are displayed in a similar fashion.

England) known for increased physical activity and socioeconomic status [50,51]. Both factors are linked with increased wearable technology use/compliance [52]. We also believe our deployment approach (i.e. reduced complexity/patient burden) was critical for compliance. Complex prevention/treatment plans typically increase non-compliance [53]. Thus, a simplified protocol was developed wherein patients only had three tasks: 1) Remove sensors from charging docks in the morning, 2) Immediately place one sensor on the proximal-medial shin and one sensor on the distal-lateral thigh (described in lay language), and 3) Recharge sensors at night. The remainder of data collection/analysis was embedded within IMUs (e.g. data storage) or handled computationally by researchers. Thus, patients did not have complex calibrations, sensor buttons/interfaces, or routines. Our ‘set it and forget it’ deployment likely improved compliance.

Despite high compliance as established by duration of weekly sensor-use, many compliance variables remain uninvestigated. Notably, we did not evaluate the potential for ‘gamification’ of rehabilitation using wearables. ‘Gamification’ has been shown to influence compliance [39,54,55]. It is unknown, however, if that would persist herein. Future studies should investigate gamification increasing compliance in patients following TKA (e.g. home rehabilitation compliance, increased daily activity level, etc.).

Finally, present efforts were retrospective in nature (i.e. analyses ***after*** six-weeks post-TKA). Thus, no feedback was provided to clinicians or patients. Similar to gamification, providing feedback to clinicians/patients could potentially influence compliance. We believe patients who think their clinicians receive postoperative performance information via wearables (whether feedback is provided or not) will better comply. However, this remains unknown and should be investigated.

4.3. Feasibility: clinical disruption

At a minimum, wearables should allow therapists to continue seamlessly providing high-value PT. Herein, we achieved these aims. Clinicians were either unaware of sensor use or indicated no rehabilitation interruption. More critically, using sensors did not delay healing, restrict motion, or disrupt the wound. However, this evidence is anecdotal warranting more thorough analyses of clinical flow disruption.

4.4. IMU kinematics metrics

Non-PT maximum RoM means/change scores were significantly greater than PT (reject null hypothesis #1, $H_{0\text{-}1\text{-Max}}$: PT maximum = non-PT maximum). Interestingly, non-PT maximum flexion was similar to established healthy controls (Chapman et al.: 128 ± 12°; Soucie et al.: 133–138°; Roach et al.: 131 ± 11°), indicating non-PT maximum may better represent global maximum flexion capabilities [32,56,57]. We believe PT maximum RoM was predominantly controlled by clinician dictated activities. Thus, if rehabilitation did not require true maximum RoM, true maximum RoM was never achieved. Contrastingly, patients naturally completed true maximum RoM outside PT at least once daily as required by ADLs. Thus, PT maximum RoM was significantly less than non-PT.

Previous work from our lab suggests stance/swing flexion are better metrics establishing recovery [32] with both equaling/exceeding preoperative levels by post-TKA week three. Results herein agree, however ***only during PT***. This supports accepting alternative hypothesis #1 ($H_{A\text{-}1\text{-Stance/Swing}}$: PT stance/swing > Non-PT stance/swing RoM). We also noted time was a significant factor for both stance/swing RoM implying performance proves throughout recovery regardless of measurement location. Interestingly though, despite similar recovery rates for PT/non-PT (stance: 0.6°, swing: 1.7° improvement per week), starting postoperative ROMs differed (PT vs Non-PT stance: 15.6° vs. 11.7°; PT vs. Non-PT swing: 29.4° vs. 22.8°). We attribute this offset to ‘white coat effects.’ In PT, patients are instructed/closely monitored forcing optimum performance. Outside PT, they freely perform gait as desired (i.e. more realistic). This reiterates clinically captured RoM may not faithfully represent true patient function.

4.5. IMU temporal metrics

Despite kinematic differences, no temporal differences were noted failing to reject null hypothesis two (H_{02}: PT stride/stance/swing time = Non-PT stride/stance/swing time). This implies temporal and kinematic gait features may be disconnected. Historically however, temporal variability and fall risk are linked [58–60], with stride time variability >0.1s in “fallers” [58]. Herein, stride time variability always exceeded this threshold, indicating these subjects might have been at increased fall risk. Thus, clinicians should implement fall prevention measures as needed in both locations. Additionally, Brach et al. propose “meaningful change estimates” of gait occurring >0.01s stance/swing time variability [61]. PT/non-PT stance/swing time variability differences always exceeded 0.01s implying PT/non-PT gait were “meaningfully different” though not statistically so. At first, increased PT gait variability was unexpected. However, during PT patients are relearning optimal gait. At home, they revert to well-established gait patterns. Future studies should investigate this “meaningful difference.”

4.6. IMU activity level

Significant activity level differences existed between locations suggesting PT activity is greater/more intense, supporting accepting alternative hypothesis three (H_{A3}: PT activity > Non-PT activity). This was not surprising given clinicians dictate PT activities with little. In contrast, maintaining high activity levels at home appears less likely and may even be discouraged (e.g. “Don't overdo it”). Several investigations corroborate this finding [62,63]. Like stance/swing RoM, time was a significant factor for activity level indicating activity level increased throughout recovery regardless of location. While this is a positive finding clinically (i.e. patients are more active after surgery), the difference between measurement locations indicates capturing data in both settings is vital for establishing the entire patient recovery picture.

4.7. Clinical metrics

Similar to previous studies, maximum clinical RoM and PROMIS PCS/MCS did not improve markedly post-TKA [32,64–68], whereas KOOS and pain scores did [69–71]. Given this matches previous efforts, conclusions herein potentially extend to broader TKA populations.

4.8. Limitations

A significant limitation of feasibility/pilot studies is small sample size (n = 10, herein). Ten patients likely do not represent all individuals undergoing TKA, though this cohort clinically matched previous studies [32,64–71]. This suggests our results ***may*** apply broadly, however future work should include more subjects. Interestingly, despite the small sample size, statistically significant kinematic/activity differences highlight disparity comparing PT versus non-PT, likely resulting from reducing variability by assessing within subjects (e.g. patient #1 PT vs. patient #1 non-PT). Accordingly, sample size impacted our final results less than anticipated, though we caution readers to treat this as a pilot study.

Another limitation herein is TKA variability (e.g. primary versus revision) and device type (e.g. make, model) despite known kinematic differences [72,73]. We attempted reducing surgical variability (i.e. using one surgeon) and subject variability (i.e. comparing each subject's PT ***to their own*** non-PT). However, caution is urged utilizing the results to represent broader TKA populations. We believe enough variability exists between patients to necessitate comparing each patient's performance in one setting to their own performance in another, not necessarily between subjects without normalization (e.g. change scores).

We also did not perfectly control PT variability. Some patients experienced longer inpatient stays (more inpatient PT). Others chose more at-home PT. Moreover, no single therapist was preferred. While this might have influenced our results, they represent clinical care realities. Future efforts should establish differences between specific rehabilitation approaches/providers.

A final limitation are the specific measurements captured and timing thereof. While metrics captured are critical to monitor post-TKA, others likely describe recovery (e.g. strength). Additionally, we captured specific time points. Prior work from our lab highlights post-TKA recovery continuing at least one-year [32]. Future efforts should include longer follow-ups (e.g. six months, one/two years post-TKA).

5. Conclusions

Although post-TKA clinical RoM is convenient, low cost, and simple, IMUs provide more nuanced data. Clinical RoM offers discrete snapshots, whereas IMUs allow continuous assessment throughout recovery both in/out of clinic. Further, IMUs illuminate measures captured clinically are heavily influenced by clinician presence/instruction. Thus, PT measures likely represent optimal performance whereas non-PT measures represent more realistic function. Future studies can further define how specific rehabilitation modalities impact post-TKA performance in/out of the clinic. We conclude that IMU data can directly impact healthcare value by more completely illuminating patient performance.

Author contributions

Ryan Chapman: Conceptualization, Methodology, Data Analysis, Writing, Editing. Wayne Moschetti: Conceptualization, Subject preparation, Reviewing and Editing. Doug Van Citters: Conceptualization, Methodology, Data Analysis, Reviewing and Editing, Supervision.

Declaration of competing interest

Dr. Ryan Chapman has no financial relationships to disclose. Dr. Wayne Moschetti is a consultant, paid speaker, and receives research support from DePuy. He also receives other research support from Medacta/Omni Life Sciences and is a board member for the New England Orthopaedic Society. Dr. Van Citters receives research support as a PI from DePuy, ConforMIS, Launchpad Medical, and TJO.

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