Journal of Biomechanics 84 (2019) 129–137

Contents lists available at ScienceDirect

Journal of Biomechanics

journal homepage: www.elsevier.com/locate/jbiomech
www.JBiomech.com

Stance and swing phase knee flexion recover at different rates following total knee arthroplasty: An inertial measurement unit study

Ryan M. Chapman Ph.D. [a,*], Wayne E. Moschetti M.D., M.S. [b,c], Douglas W. Van Citters Ph.D. [a]

[a] Dartmouth College, Thayer School of Engineering, 14 Engineering Drive, Hanover, NH 03755, United States
[b] Dartmouth Hitchcock Medical Center, Department of Orthopaedics, 1 Medical Center Drive, Lebanon, NH 03766, United States
[c] Dartmouth College, Geisel School of Medicine, 1 Rope Ferry Road, Hanover, NH 03755, United States

ARTICLE INFO

Article history:
Accepted 15 December 2018

Keywords:
Arthroplasty
Knee
Inertial measurement unit
Rehabilitation
Range of motion

ABSTRACT

Total knee arthroplasty (TKA) is the most common joint replacement in the United States. Range of motion (ROM) monitoring includes idealized clinic measures (e.g. goniometry during passive ROM) that may not accurately represent knee function. Accordingly, a novel, portable, inertial measurement unit (IMU) based ROM measurement method was developed, validated, and implemented. Knee flexion was computed via relative motion between two IMUs and validated via optical motion capture ($p > 0.05$). Prospective analyses of 10 healthy individuals (5M, 50 ± 19 years) and 20 patients undergoing TKA (3 lost to follow up, 10M, 65 ± 6 years) were completed. Controls wore IMUs for 1-week. Patients wore IMUs for 1-week pre-TKA, 6-weeks immediately post-TKA, and 1-week at 1-year post-TKA. Flexion was computed continuously each day (8–12 h). Metrics included daily maximum flexion and flexion during stance/swing phases of gait. Maximum flexion was equal between cohorts at all time points. Contrastingly, patient stance and swing flexion were reduced pre-TKA, yet improved post-TKA. Specifically, patient stance and swing flexion were reduced below control/pre-TKA values during post-TKA week 1. Stance flexion exceeded pre-TKA and equaled control levels after week 2. However, swing flexion only exceeded pre-TKA and equaled control levels at 1-year post-TKA. This novel method improves upon the accuracy/portability of current methods (e.g. goniometry). Interestingly, surgery did not impact maximum ROM, yet improved the ability to flex during gait allowing more efficient and safe ambulation. This is the first study continuously monitoring long-term flexion before/after TKA. The results offer richer information than clinical measures about expected TKA rehabilitation.

1. Introduction

Total knee arthroplasty (TKA) reduces pain and improves function/quality of life for knee osteoarthritis (OA) sufferers (Burns et al., 2006). Approximately 4.85M Americans are living with knee replacements ($151B aggregate healthcare costs) (Kurtz et al., 2007; Lavernia et al., 2006; Maradit Kremers et al., 2015). Despite high costs, TKA is highly successful measured by quality adjusted life years driven by satisfaction, pain reduction, and improved range of motion (ROM) (Bourne et al., 2010; Dolan et al., 2004; Losina et al., 2009; Neumann et al., 2014; Noble et al., 2006; Robertsson et al., 2000). Clinicians monitor these metrics before/after surgery, however only ROM is readily captured **and** objective. Moreover, post-TKA physical therapy (PT) goals include increasing ROM (Ghazinouri et al., 2007; Van Citters et al., 2014). Unfortunately, the most commonly captured ROM is maximum knee flexion assessed via idealized repeated measures (e.g. optical motion capture (MOCAP), goniometry, radiography), which are costly and lack scalability. More critically, these measures may not accurately represent knee function during activities of daily living (ADL). As such, improved knee ROM measurement techniques are needed.

One method for capturing 'real-world' knee ROM is inertial measurement units (IMUs). IMUs are miniaturized, electromechanical devices that capture acceleration, angular velocity, and magnetic field strength. Angles are quantifiable using relative motion between IMUs. And, IMUs attached to opposing joint sides allow computing joint angles (e.g. knee flexion). Prior work focuses on improving IMU measurement precision in controlled settings (Bó et al., 2011; Brennan et al., 2011; Cooper et al., 2009; Favre et al., 2009; Seel et al., 2014). Though precision has improved, these methods are computationally demanding with limited expandability. Beyond improving precision, several groups have assessed step count and activity recognition (e.g. walking) (Foster et al., 2005;

* Corresponding author.
E-mail address: rmchapman.th@dartmouth.edu (R.M. Chapman).

https://doi.org/10.1016/j.jbiomech.2018.12.027
0021-9290/

Lugade et al., 2014) while others have captured prescribed activity accelerations and monitored for falls from elderly subjects for three months (Mathie et al., 2004). These studies proved data management/long-term sensor-use feasible, however joint ROMs remain unknown. To our knowledge, few studies have captured continuous, long-duration IMU-based joint ROM especially after TKA.

The aim herein was utilizing a newly developed method for continuously monitoring long-term knee ROM outside clinic environments via IMUs to capture real-world knee ROM from healthy individuals/TKA patients. We have the opportunity to assess two hypotheses. First, because one major predictor of post-TKA maximal ROM is pre-TKA maximal ROM (Callaghan et al., 2000; Ranawat and Boachie-Adjei, 1988; Ryu et al., 1993), we hypothesized our method would show patients exhibiting equivalent pre-/post-TKA maximum flexion outside the clinic. Additionally, reduced pre-/post-TKA gait knee flexion compared to controls is well known (Andriacchi et al., 1982; Astephen et al., 2008; Childs et al., 2004; Dorr et al., 1988; Jevsevar et al., 1993; McClelland et al., 2007; Messier et al., 1992). Thus, we also hypothesized our method would show patients exhibiting reduced gait knee flexion compared to controls outside the clinic.

2. Methods

Four phases were completed developing an IMU-based tool for capturing long-duration knee flexion outside controlled environments. First, theoretical IMU performance on the knee was assessed. Next, the proposed tool was compared to optical MOCAP. Third, daily workflow was developed. Finally, following protocol approval by institutional review board (IRB), we prospectively captured continuous (8–12 h/day, up to 42 days) knee ROM in two cohorts: 1) Healthy, 2) TKA (pre-/post-op).

2.1. Methods: Theoretical Analyses

Triaxial IMUs precisely capture three-dimensional (3D) linear acceleration. Specifically, accelerometers collect static acceleration from their major frame of reference (FOR, gravity) and dynamic acceleration in 3D. Statically they measure 1g on gravitationally aligned axes and 0g on axes orthogonal to gravity (Fig. 1A). Dynamically, they measure 1g on gravitationally aligned axes **plus** dynamic acceleration (Fig. 1B). Thus, accelerometers capture local inertial FOR accelerations.

Simplifying computations, accelerations were converted to 3D vectors (i.e. $\bar{A}_1 = [X_1\ Y_1\ Z_1]$, $\bar{A}_2 = [X_2\ Y_2\ Z_2]$). An angle was computed between each vector and gravity (Fig. 1C). This extrapolated to multiple accelerometers. Using equal gravitational reference, comparing two accelerometers yielded a single angle. Then, distinct accelerometers rigidly affixed to distinct bony segments (Fig. 2A; femur: superolateral to femoral epicondyle, tibia: inferomedial to tibial tuberosity), quantified a single knee joint angle.

Arranged accordingly, purely sagittal knee motion computes angles (θ_{IMU}) equaling true flexion (θ_{REAL}) (Fig. 2B). However, knees have three rotational degrees of freedom (DOF), including frontal/transverse planes (Fig. 2C) (Defrate et al., 2006; Grood and Suntay, 1983). Moreover, dynamic accelerations exist that remain unaccounted without additional inputs (e.g. gyroscope). Thus, IMU angle was true flexion plus error sources ($\theta_{IMU} = \theta_{REAL} + \theta_{Error\_Kinematics} + \theta_{Error\_Dynamics}$).

For this work, these errors are acknowledged but calculated low relative to sagittal ROM investigated. Specifically, frontal-plane error is naturally small due to small amplitude relative to sagittal motion (frontal <5° vs. sagittal >120°) (Kadaba et al., 1990; Kumar et al., 2013; van der Esch et al., 2008). Additionally, transverse kinematics has limited impact on sagittal angle because different transverse position inertial data are equivalent (i.e. $\bar{A}_1 = \bar{A}_1 + \theta_{Trans} = \bar{A}_2$). Moreover, final algorithm coordinate-system alignment (see Methods: Validation) ensured θ_{REAL} was the primary θ_{IMU} source. Dynamic error ($\theta_{Error\_Dynamics}$) was also low due to low accelerations achieved during ADL (Dejnabadi et al., 2006; Kepple et al., 1997; Takeda et al., 2009). For example, combining typical walking angular velocities/femur lengths ($\omega = 1.3$ rad/sec, $r = 0.40$ m, $|a| = r\omega^2$) gives accelerations of 0.68 m/s^2 (0.069 g) resulting in 6.9% error (Tong and Grant, 1999). Furthermore, digital filtration ensured unrealistically high accelerations were removed.

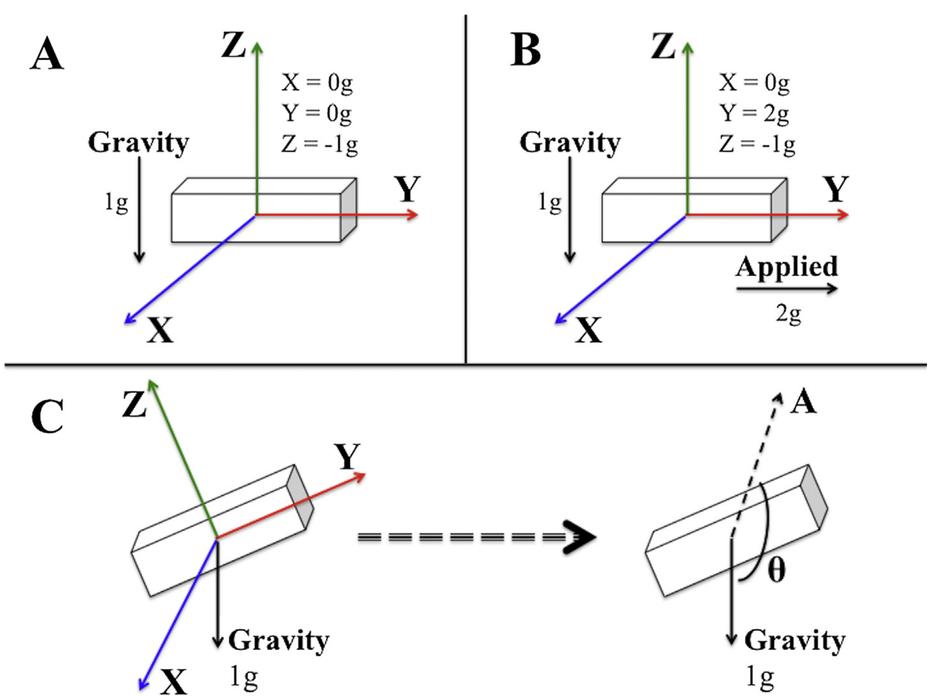

Fig. 1. Basic function of inertial measurement units (IMUs) including (A) static measuring only gravity, (B) dynamic measuring gravity and applied accelerations, and (C) conversion of triaxial IMU data to a single vector and calculation of an angle between acceleration vector and gravity.

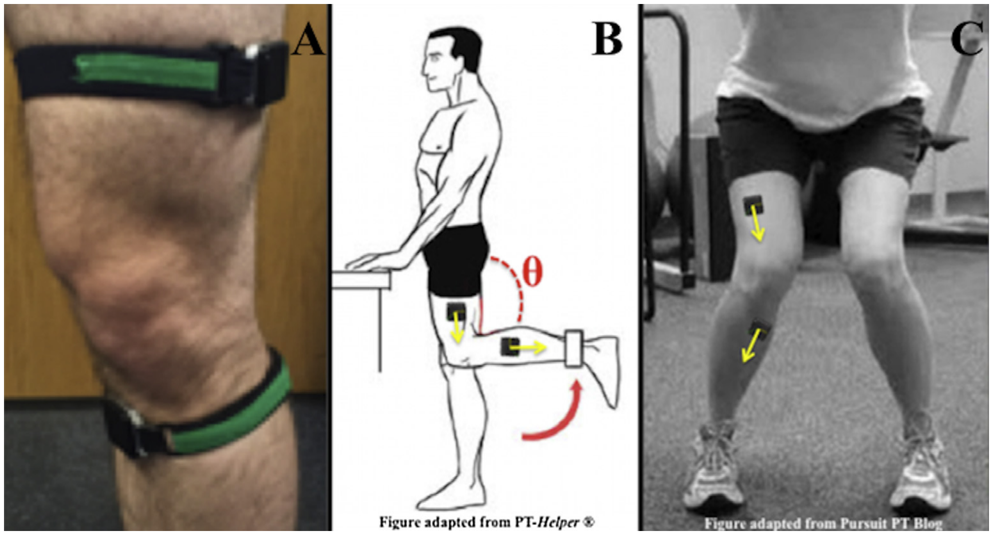

Fig. 2. Lower extremity (A) sensor donning locations, (B) pure sagittal plane knee motion, and (C) frontal plane knee angle adding error to knee flexion estimate.

2.2. Methods: Validation

To quantify our method's accuracy, validation via validated optical MOCAP system was completed (OptiTrack Motive Body 1.10, NaturalPoint, Inc., Corvallis, OR) (Carse et al., 2013; Thewlis et al., 2013). Six S250e cameras were temporally synced/calibrated via manufacturer's recommendations (95% residual error = 0.678 ± 0.159 mm). Validated retroreflective marker-set was placed on lower-body landmarks (Fig. 3A) (Collins et al., 2009; Kadaba et al., 1990). Simultaneously, subjects donned IMUs (APDM, Inc., Portland, OR) as noted previously (Fig. 2A). Both IMU/MOCAP data were captured (f_s = 128 Hz) and knee flexion computed during treadmill walking (1.0MPH, 1.5MPH, 2.0MPH) (Andriacchi et al., 1977; Himann et al., 1988). Two healthy participants (1M, 1F) performed three repetitions each speed (30 s, ~20 strides). Each speed's best repetition (least marker loss) was used for final analyses.

MOCAP flexion (θ_{MOCAP}) was quantified each trial via relative joint angle quaternion sagittal angle conversion (Grood and Suntay, 1983). IMU flexion (θ_{IMU}) was computed as follows (MATLAB R2016a, Mathworks, Natick, MA). Data collection began following undocking and continued after doffing. Thus, unusable data existed before donning **and** after doffing. These periods were removed automatically by locating correctly placed IMUs (i.e. gravitationally aligned, subject stationary).

IMU datasets were filtered forward/backward (fifth-order low-pass Butterworth filter, f_{cutoff} = 5 Hz). Each set was converted to independent vectors ($\bar{A}_{Femur}$, $\bar{A}_{Tibia}$). A rotation matrix ($R_{Initial}$) was computed between $\bar{A}_{Femur}/\bar{A}_{Tibia}$ prior to subject movement accounting for sensor/tibiofemoral misalignment ($R_{Initial}$ rotated $\bar{A}_{Tibia}$ to femoral coordinates: $\bar{A}_{Tibia\_in\_Femur}$). $\bar{A}_{Tibia\_in\_Femur}$ and $\bar{A}_{Femur}$ were compared calculating knee flexion each trial (θ_{IMU}). Repeated strides were averaged for both methods. Error between

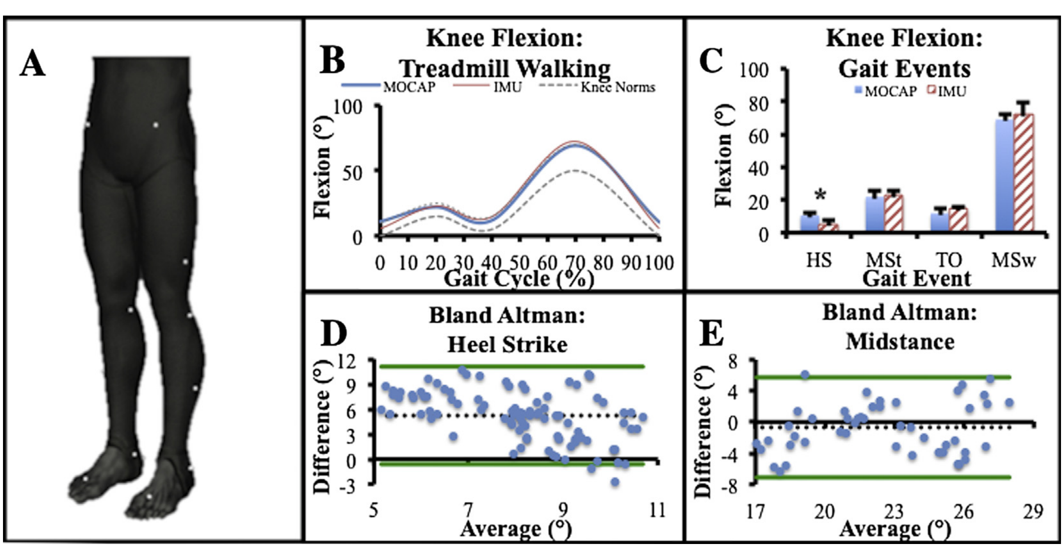

Fig. 3. Validation experiment methods and results including (A) optical MOCAP marker set, (B) average knee flexion curves for two subjects and three speeds during treadmill walking as calculated via optical MOCAP flexion (thick), IMU-based flexion (thin), and normative curves (dashed), (C) average knee flexion at specific gait events (heel-strike, midstance, toe-off, and midswing) for optical MOCAP (solid) and IMU-based (striped) methods, respectively and Bland Altman plots with individual values (dots), average difference (dashed line), and 95% confidence interval (solid lines) for (D) heel strike and (E) midstance.

methods was calculated (θ_{Error}). Error distribution was further analyzed through Bland-Altman plots.

2.3. Methods: Daily Workflow Development

Post-validation, prospective data capture workflow was developed (Fig. 4). Subjects awoke, undocked and donned IMUs as described previously. Sensors temporally synced automatically via manufacturer implemented wireless local area network (LAN). After synchronization, data were captured/stored locally (16 GB MicroSD, up to 18 h/day, 60 days). Additional time periods were automatically noted and removed via variance analysis (variability < 0.5 g) when subjects removed IMUs mid data collection (i.e. bathing). At daily terminus, IMUs were doffed/re-docked terminating capture and recharging IMUs. At study terminus, IMUs were returned and data downloaded/processed offline.

2.4. Methods: Prospective Study

IRB approval was obtained and prospective analyses completed on ten healthy subjects (5M, 50 ± 19 years) and twenty TKA patients (3 lost to follow-up, 10M, 65 ± 6 years). Control subjects were recruited from local universities via email advertisement (inclusion: age>21, no musculoskeletal/neuromuscular impairments impacting lower extremity, no terminal illness resulting in death within one year, clinical full knee extension (<5°) and flexion (≥120°) (Roach and Miles, 1991; Watkins et al., 1991), whole study participation). Arthroplasty patients were selected from a single surgeon's consecutive caseload (inclusion: age>21, single design primary TKA, no contralateral pathology, no other neuromuscular/musculoskeletal impairments impacting lower extremity, no terminal illness resulting in death within one year, whole study participation). Footedness was then assessed for all participants (Waterloo Footedness Questionnaire) (Elias et al., 1998) to determine on what leg IMUs were donned (controls) and for correlations (patients). Subjects participated in tutorials lasting ∼30 min (charging IMUs, IMU donning protocol). Subjects asked questions throughout and were given instructions/contact information for post-tutorial questions.

Controls wore IMUs on their dominant leg (Elias et al., 1998) for one week without interventions (e.g. injection, PT). Patients wore sensors on their affected leg for one-week pre-TKA without interventions (e.g. injections or 'prehab' PT). Patients underwent TKA by the same surgeon via medial parapatellar approach and received single design implant (Attune® Knee System, DePuy Synthes, Warsaw, IN). IMUs were replaced on patients in the recovery room postoperatively and worn daily for six weeks immediately post-TKA. An additional one-week period was captured 1-year post-TKA. Subjects donned/doffed IMUs as instructed upon waking/prior to sleeping daily, respectively. IMUs captured 3DOF acceleration data (f_s = 20 Hz, range: ±6 g) continuously (8–12 h/day) daily.

Daily data were processed as previously described. Knee flexion was computed continuously daily. From daily flexion, outcome metrics included maximum and gait flexion. Gait was located by frequency analysis during one-minute intervals (i.e. 0–1 min, 1–2 min, etc.) and fast Fourier transforms (FFT) each interval. The interval with largest 0.75–2.25 Hz content magnitude (overground gait) (Bertram and Ruina, 2001; Huang et al., 2010) was selected as gait period. Gait period was analyzed for repeated

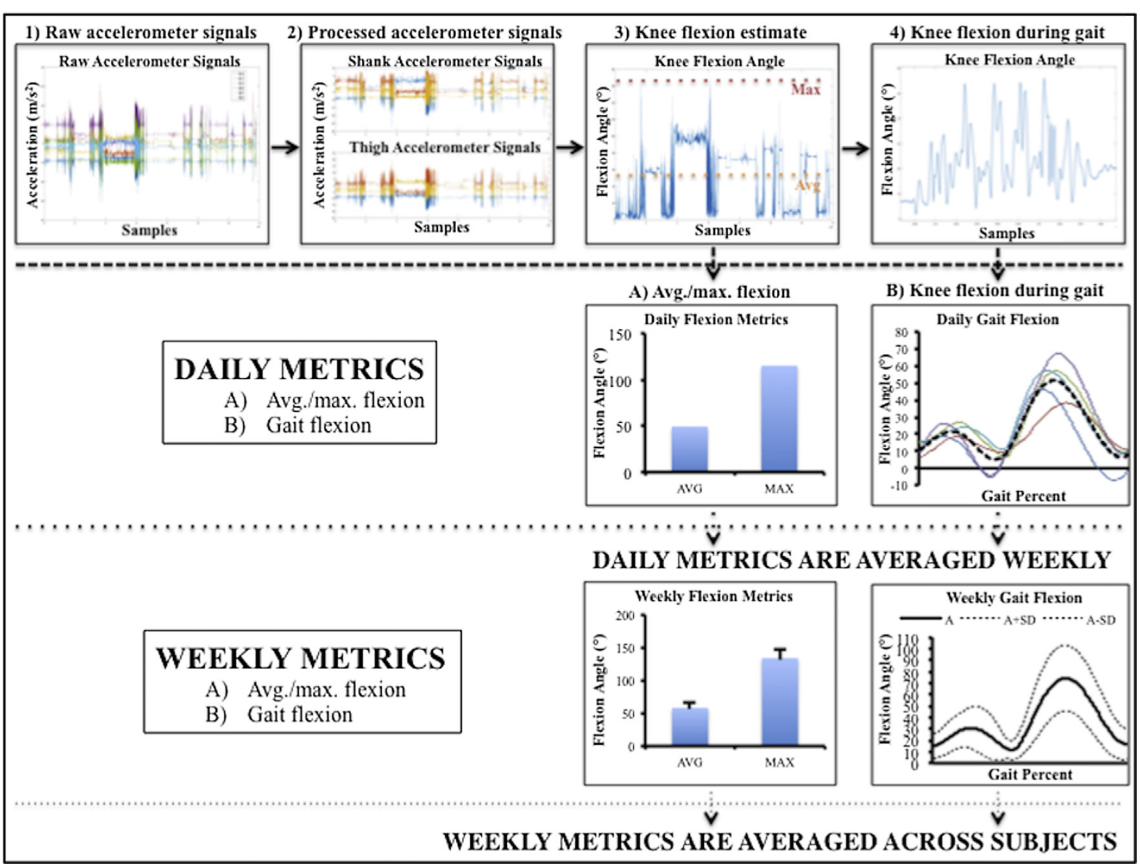

Fig. 4. Data process flow from (1) daily raw accelerometer signals, to (2) daily processed accelerometer signals, to (3) daily knee flexion estimate. Additional computation of (4) flexion during gait and daily metrics including (A) maximum knee flexion and (B) knee flexion during gait. Daily metrics are averaged weekly and weekly metrics are averaged across subjects.

strides by automatically locating heel-strike, midstance, toe-off, midswing, and subsequent heel-strike each stride. Each stride was normalized to gait percent and all strides averaged. Peak stance/swing flexion were then calculated. Data were timestamp analyzed. Any patient non-compliant more than 1-day weekly was eliminated from that week. Daily metrics (maximum, peak stance/swing flexion) were averaged weekly. Weekly averages were averaged across subjects. See Fig. 4 for data flow from input to weekly metrics.

Patient reported outcome measures (PROMs)/goniometric ROM were also captured. Control subject PROMs/clinical ROM were captured at study termination. Patient PROMs/clinical ROM were collected at 1-week preoperative, 6-week postoperative, and 1-year postoperative appointments. PROMs collected were pain, Patient-Reported Outcomes Measurement Information System (PROMIS) physical/mental scores, and Knee Injury Osteoarthritis Outcome Score (KOOS) physical scores (Brander et al., 2003; Fries et al., 2014; Roos and Toksvig-Larsen, 2003).

Appropriate statistics were completed comparing cohort demographics and PROMs (two-tailed t-tests: continuous variables; two-tailed proportions t-tests: non-numeric categorical variables; two-tailed Mann-Whitney-*U* test: numeric categorical variables). Two-tailed t-tests were completed comparing IMU-based metrics between cohorts weekly (pre-, immediate post-, 1-year post-TKA) and between pre-/post-TKA performance each week. Correlations were computed between demographics, PROMs, clinical ROM, and IMU metrics. Alpha-level (α) for t-tests was set to 0.05. Following Bonferroni correction, correlation α was set to 0.0026 (α/n = 0.05/19 = 0.0026).

3. Results

3.1. Results: Validation

Validation results (Fig. 3) demonstrate concordance between IMUs and MOCAP. Flexion between validation subjects was indistinguishable ($p > 0.05$) and averaged accordingly. Flexion between speeds was not different ($p > 0.05$, i.e. 1.5MPH = 2.0MPH = 2.5MPH) and averaged accordingly. Average MOCAP/IMU flexion curves (Fig. 3B: thick/thin lines, respectively) overlay dashed normative flexion curves (Duffell et al., 2014; Ferrari et al., 2008; Rowe et al., 2000). Flexion was not different throughout gait between methods ($p = 0.70$). MOCAP/IMU average flexion at gait events (Fig. 3C: solid/stripes, respectively) showed significant differences at heel-strike (5.4° ± 2.3° vs. 10.7° ± 1.4°, $p < 0.0001$), but were indistinguishable at midstance (22.7° ± 3.2° vs. 21.9° ± 4.0°, $p = 0.54$), toe-off (14.7° ± 1.5° vs. 11.9° ± 3.3, $p = 0.06$), and midswing (72.4° ± 6.8° vs. 69.2° ± 2.8°, $p = 0.20$). Although all gait events showed randomly distributed bounded error about the average difference between methods, Bland-Altman indicated significant bias at heel-strike (Fig. 3D: 5.2°, 95% CI: −0.7°-11.1°). Midstance (Fig. 3E), toe-off, and midswing showed approximately 0° bias.

3.2. Results: Prospective Study

Subject demographics (Table 1) show controls (50 ± 19 years) were younger than patients (65 ± 6 years) ($p = 0.03$). Controls were highly compliant (12.0 ± 4.7 h/day, 7 ± 0 days). Timestamp analyses showed all patients were compliant weekly (>6 days/week) pre-TKA (11.2 ± 3.2 h/day, 6 ± 1 days), immediately post-TKA (11.0 ± 0.8 h/day, 36 ± 4 days), and at 1-year post-TKA (12.8 ± 3.4 h/day, 6 ± 1 days). No other demographic differences were noted ($p > 0.05$).

Control maximum flexion (Fig. 5: 128° ± 12°, solid) was not different from patient pre-TKA (stripes) or patient post-TKA (dotted) maximum knee flexion ($p > 0.05$). Additionally, patient maximum flexion pre-TKA was not different from patient post-TKA ($p > 0.05$).

Maximum stance flexion (Fig. 6) for controls and patients pre-/post-TKA are displayed as mean ± standard deviation (solid, striped, and dotted, respectively). Patient peak stance flexion

Table 1
Subject demographics including μ ± standard deviation for age, footedness, and how long the sensors were worn each day. Also displayed are gender, sensors donned side, and median ± median absolute deviation for number of days sensors were worn.

	Control	Patient	P Value
Age	49.7 ± 18.5	64.9 ± 6.4	***0.03***
Gender	5M, 5F	10M, 7F	0.66
Footedness	0.7 ± 0.5	0.7 ± 0.5	0.96
Sensor Side	8R, 2L	9R, 8L	0.16
# Days Pre-	7 ± 0	6 ± 1	0.28
Hours/Day Pre-	12.0 ± 4.7	11.2 ± 3.2	0.57
# Days Immediate Post-		36 ± 4	
Hours/Day Immediate Post-		11.0 ± 0.8	
# Days 1-year Post-		6 ± 1	
Hours/Day 1-year Post-		12.8 ± 3.4	

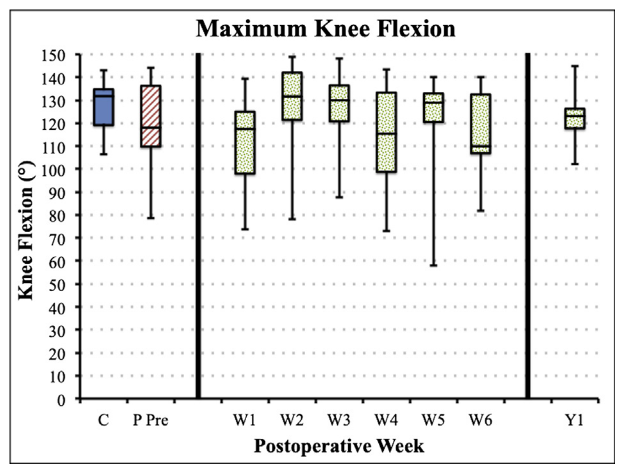

Fig. 5. Maximum knee flexion shown as box and whisker plots for control subjects (solid), patients preoperatively (striped), and patients postoperatively (dotted) shown for preop, 6-week immediate postop, and 1-year postop time points.

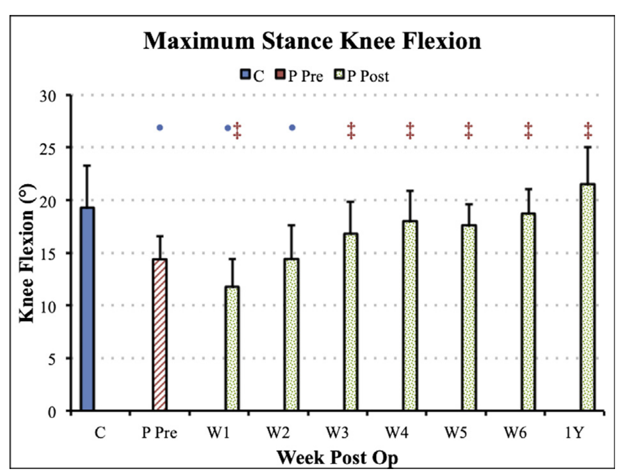

Fig. 6. Maximum knee flexion during stance phase of gait for control subjects (solid), patients preoperatively (striped), and patients postoperatively (dotted) shown for preop, 6-week immediate postop, and 1-year postop displayed as mean ± standard deviation. A dot denotes significant differences ($p < 0.05$) between controls and patients. A double cross denotes significant differences ($p < 0.05$) between patients pre-TKA and patients post-TKA.

pre-TKA/post-TKA weeks 1/2 were less than controls ($p < 0.05$). Post-TKA stance flexion was also reduced below pre-TKA levels during post-TKA week 1 ($p = 0.001$). Conversely, patient peak stance flexion was not different from control levels ($p > 0.09$) and exceeded pre-TKA levels ($p < 0.04$) after post-TKA week 2.

Maximum swing flexion is displayed similarly (Fig. 7). Patients pre-TKA/post-TKA weeks 1–6 were below controls ($p < 0.0009$). Additionally, post-TKA swing flexion was below pre-TKA levels during post-TKA weeks 1/2 ($p < 0.0004$). However, patient peak swing flexion was not different from pre-TKA levels post-TKA weeks 3–6 ($p > 0.07$). Additionally, patient peak swing flexion was indistinguishable from controls ($p = 0.73$) and exceeded pre-TKA levels ($p << 0.001$) 1-year post-TKA.

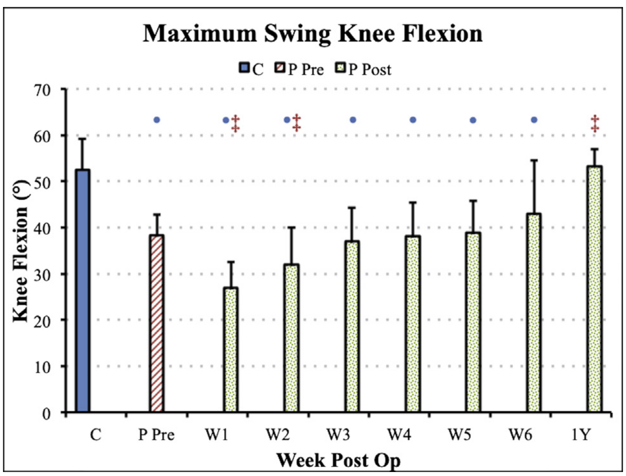

Fig. 7. Maximum knee flexion during swing phase of gait for control subjects (solid), patients preoperatively (striped), and patients postoperatively (dotted) shown for preop, 6-week immediate postop, and 1-year postop displayed as mean ± standard deviation. A dot denotes significant differences ($p < 0.05$) between controls and patients. A double cross denotes significant differences ($p < 0.05$) between patients pre-TKA and patients post-TKA.

Table 2
Patient reported outcome metrics (PROMs) for control, patient preoperative, and patient postoperative appointments. P-values listed are results of student's two-tailed t-tests and Mann-Whitney-U tests as appropriate comparing control, patient pre-TKA, and patient post-TKA. Scores in bold/italicized text denote statistical significance ($p < 0.05$).

	Pain	PROMIS P	PROMIS M	KOOS
Control	1.5 ± 1.5	53.7 ± 8.1	52.4 ± 8.2	93.1 ± 11.4
Pre-	5 ± 2	42.9 ± 5.5	52.4 ± 8.1	58.3 ± 9.2
Post-	3 ± 0	44.5 ± 5.0	50.0 ± 9.0	59.9 ± 10.4
1-Year Post-	0 ± 0	49.9 ± 8.6	49.4 ± 8.9	75.0 ± 15.4
C vs. Pre-	***0.001***	***0.0009***	0.99	***<0.0001***
C vs. Post-	***0.01***	***0.002***	0.53	***<0.0001***
C vs. 1-Year	0.68	0.32	0.45	***0.01***
Pre- vs. Post-	***0.02***	0.38	0.40	0.66
Pre- vs. 1-Year	***<0.0001***	***0.01***	0.33	***0.002***
Post- vs. 1-Year	***0.002***	***0.04***	0.85	***0.005***

All PROMs are in Table 2 (discrete: median ± median absolute deviation; continuous: mean ± standard deviation). Control pain was significantly lower than patient pre-TKA ($p = 0.001$) and immediate post-TKA ($p = 0.01$) values but indistinguishable from patient 1-year post-TKA values ($p = 0.68$). Patient pain improved immediately following TKA ($p = 0.02$) and 1-year post-TKA ($p = 0.002$). Similarly, control PROMIS physical score was greater than pre-TKA ($p = 0.0009$) and immediate post-TKA ($p = 0.002$) scores, yet indistinguishable from 1-year post-TKA scores ($p = 0.32$). Additionally, 1-year post-TKA patient PROMIS physical score was greater than both pre-TKA ($p = 0.01$) and immediate post-TKA values ($p = 0.04$). Control subject KOOS score was greater than patients at all time points ($p < 0.01$). Also, 1-year post-TKA KOOS scores were greater than both pre-TKA ($p = 0.002$) and immediate post-TKA KOOS scores ($p = 0.005$). Goniometric ROM was never different ($p > 0.05$).

Correlation analyses (Table 3) found two significant inverse correlations including pain/maximum stance flexion ($\rho = -0.72$, $p < 0.0001$) and pain/maximum swing flexion ($\rho = -0.56$, $p < 0.0001$). No other significant correlations were noted.

4. Discussion

TKA is one of the most successful elective surgeries. ROM is often measured postoperatively, yet previous work focuses on idealized measures/settings (e.g. laboratory MOCAP). These methods likely undervalue ADL knee function, are costly, require technical training, and thus are inaccessible to clinicians. In contrast, IMUs are deployable at home without technical training, lower cost ($100 vs. $100,000), and thus more clinically accessible than other methods. As such, a continuous IMU-based method was developed, validated, and deployed assessing knee ROM at home.

The method used relative motion between IMUs continuously calculating knee flexion which is critical for ADLs (Rowe et al., 2000), and thus was the focus herein. Validation via MOCAP showed low error throughout treadmill gait and little error at midstance, toe-off, and midswing. Interestingly, our results were higher than a previous fluoroscopy study capturing gait knee flexion (Kozanek et al., 2009), but was equivalent to the results of other studies using a variety of methods (Andriacchi et al., 1982; Baliunas et al., 2002; Lafortune et al., 1992; Piazza and Delp, 1996). Although there is no way to directly compare our result with these studies, it indicates some instances wherein the proposed IMU-based method may overestimate gait knee flexion. We also found error was significant at heel-strike likely from high accelerations created by soft tissue noise ('ringing') secondary to ground contact (Cappozzo et al., 1996; Peters et al., 2010). We have limited this via filtration, however prospective results focused on midstance/midswing. Accordingly, the proposed method has acceptable accuracy at specific gait events compared with current ROM methods with the advantage of portability (Lavernia et al., 2008; Watkins et al., 1991).

Table 3
Spearman (pain) and Pearson (PROMIS physical, PROMIS mental, KOOS) correlation results between TKA patient PROMs and clinical goniometric ROM measures (°). Pearson correlation coefficients between clinical goniometric ROM measures (°) and IMU measures (°) are also displayed. Data are displayed as correlation coefficient and p-values. Significant correlations are bold, italicized text.

	Goniometric ROM	Maximum	Stance	Swing
GoniometricROM		−0.07, 0.68	0.21, 0.17	0.30, 0.05
Pain	−0.42, 0.003	−0.09, 0.60	***−0.72, <0.0001***	***−0.56, <0.0001***
PROMIS P	0.06, 0.69	−0.29, 0.08	0.30, 0.05	0.26, 0.09
PROMIS M	−0.11, 0.46	−0.28, 0.09	−0.16, 0.30	−0.24, 0.12
KOOS	0.05, 0.74	0.08, 0.09	0.05, 0.75	0.15, 0.33

4.1. Discussion: Prospective Study

Beyond validation, data collection usability represents a unique IMU application. Specifically, we explored our first hypothesis: patients would have similar maximum flexion before/after TKA (Callaghan et al., 2000; Ranawat and Boachie-Adjei, 1988; Ryu et al., 1993). This was true using both goniometry and IMUs. Moreover, we found no differences between cohorts for IMU maximum flexion and no correlations between IMU maximum flexion/PROMs. These results strongly support our first hypothesis and confirm previous work establishing pre-TKA flexion as a strong predictor of post-TKA flexion (Callaghan et al., 2000; Ranawat and Boachie-Adjei, 1988; Ritter et al., 2003; Ryu et al., 1993). Perhaps most clinically important, this indicates maximum flexion is likely less useful assessing knee function than previously thought. Interestingly, maximum flexion was exceedingly variable for both cohorts ($\sigma > 12°$ weekly) largely driven by one low maximum flexion individual each week (not always the same person). Capturing this with the validated method suggests the method is sensitive capturing wide knee flexion ranges and is valuable in future diagnostic applications.

Our second hypothesis was patients would exhibit reduced gait knee flexion compared to controls (Andriacchi et al., 1982; Astephen et al., 2008; Childs et al., 2004; Dorr et al., 1988; McClelland et al., 2007; Messier et al., 1992). Preoperatively, corresponding to reduced function, patients exhibited reduced stance flexion compared to controls partially confirming our second hypothesis. Because stance is weight bearing, this is likely painful pre-TKA. Post-TKA, patients improved stance flexion each week and contradicting our hypothesis was indistinguishable from controls after post-TKA week two. This was likely from removal of painful bone-on-bone contact. In support, is the significant negative correlation between pain/stance flexion. As such, this result may have important implications on gait quality including improved impact absorption, stability, and energy efficiency via proper Achilles tendon loading (Endo and Herr, 2014; Kang and Dingwell, 2008; Mann and Hagy, 1980).

Similar to stance and supporting our second hypothesis, patients exhibited reduced swing flexion pre-TKA compared to controls. This was probably caused by antalgic gait, shorter strides, and gait features acquired during stance (Kirtley et al., 1985; Piazza and Delp, 1996; Stauffer et al., 1977). In support of our second hypothesis, post-TKA swing flexion increased each postoperative week, however did not reach control levels until 1-year post-TKA. Interestingly, patients achieving control swing flexion at this time opposes our second hypothesis. This was potentially caused by several factors including muscle contraction weakness post-TKA and gait habits formed pre-TKA (reduced swing flexion). Thus, despite the ability to utilize greater flexion, it remained habitually reduced until 1-year post-TKA. This is aligned with previous studies on patients post-TKA (Bade et al., 2010; Bolanos et al., 1998; Chen et al., 1991; Fuchs et al., 2002; Wilson et al., 1996). Although we did not regulate post-TKA PT, a second factor influencing reduced swing flexion postoperatively is gait training received. Many post-TKA gait-training techniques involve tests focus on time/distance (e.g. TUG test). Generally, no gait quality guidance is provided (i.e. increased swing flexion). As such, patients likely walked however they chose (i.e. decreased swing flexion) despite inefficiencies including increased trip/fall risk from lower foot clearance and decreased energy conservation (Kerrigan et al., 1995; Waters and Mulroy, 1999).

4.2. Discussion: Limitations

This body of work has limitations including with validation. Notably, we only validated via treadmill walking despite patients performing many activities beyond walking. Additionally, validation indicates the proposed method is accurate during midstance, toe off, and midswing however is less accurate during heel-strike likely resultant from ground-contact soft-tissue noise (‘ringing’). Thus, prospective results are viewed within these limitations. Future use of this technique must address heel-strike inaccuracies to facilitate studies regarding heel-strike knee flexion.

A prospective study limitation includes the relatively small sample size (n = 10 controls, n = 17 patients) and singular TKA device make/model. As such, generalizing our outcomes across multiple populations and individuals receiving different TKA devices may not be possible. However, we believe the methods to be translatable to other patient populations or device designs. A second limitation is the prospective cohort’s age difference. One might argue differences were age-related. However, this runs counter to work establishing age-based knee flexion differences begin in subjects older than 75 (Roach and Miles, 1991). As such, the age difference was likely not impactful on final outcomes. TKA patients were also internal controls (i.e. same patients in pre-TKA, post-TKA captures), which strengthens our findings.

Another limitation is potential error sources including IMU misalignment. Although patients were instructed on donning, given instructions, and asked questions, inappropriate IMU donning was possible. Despite not establishing whether patients donned sensors perfectly daily, our algorithm accounted for potential misalignment. And as noted previously, transverse plane sensor alignment has limited impact on final results (i.e. $\bar{A}_1 = \bar{A}_1 + \theta_{Trans} = \bar{A}_2$). Finally, because sensors are attached to straps that encircle each segment, frontal/sagittal plane misalignment is unlikely. Thus, daily donning compliance has limited impact on final results. An additional potential error source was dynamic accelerations unaccounted for by only using accelerometers. However, accelerations achieved were low and likely had limited impact. Moreover, the method filtered erroneously high accelerations and was validated via ‘gold-standard’ optical MOCAP. Thus, dynamics error likely impacted final results little.

Additionally, we only captured data at specific times. Therefore, another limitation is the narrow time windows assessed. Previous work is conflicted on critical improvement times post-TKA and it is possible we missed critical periods. However, many studies indicate the first six weeks and 1-year post-TKA are critical for capturing this (Kennedy et al., 2005). It is possible in these studies, however, that data captures were completed at time points associated with convenient clinical follow-up appointments rather than for physiological reasons. Similarly in our study, 6-weeks and 1-year post-TKA coincided with follow-up appointments at the participating clinical institution.

Finally, biomechanical limitations exist. Sensors were placed unilaterally. However, patients can have altered gait pre-/post-TKA with resultant 40% likelihood of contralateral TKA within 10 years (McClelland et al., 2007; McMahon and Block, 2003; Milner, 2009; Smith et al., 2004). Critically, one patient underwent contralateral TKA just after 1-year following initial TKA. One supposition for this risk is altered contralateral leg biomechanics. Unfortunately, limited sensor quantity prevented monitoring contralateral limbs. Therefore, such definitive conclusions were impossible. Additionally, monitoring other segments (e.g. torso) was not completed. Patients likely completed important tasks (e.g. sit-to-stand) altering other segment biomechanics (e.g. increased trunk flexion) (Li et al., 2013). However, these conclusions are impossible.

Despite significant findings (i.e. stance/swing knee flexion improvement post-TKA), there are inherent limitations focusing narrowly on these variables. For example, activity level is often cited for establishing health status (Services, 2018). However, previous work assessing post-TKA activity via IMUs is conflicted indicating this metric maybe patient specific (Brandes et al., 2011; Harding et al., 2014). Unfortunately, because activity level was not measured herein, no conclusions can be made as such. In future studies, activity level and other metrics including temporal variables and strength/stability will be considered. Critically, although initial assessment of this system was on sagittal knee motion, it is adaptable to other planes (frontal/transverse) and other joint arthroplasty procedures. Furthermore, this system is not limited to total joint replacements. It could be used for other pathologies involving human movement as well as general patient well being (activity level, step count, etc.).

5. Conclusions

Our method represents large forward progress in TKA patient monitoring. Rather than discrete, idealized clinic data, the proposed method examined knee ROM continuously via relative IMU motion rigidly affixed to the leg. Contrary to previous work focusing on maximum flexion following TKA, we discovered gait flexion was more indicative of postop function. Interestingly, stance/swing phase performance recovered at different rates post-TKA with patient stance flexion indistinguishable from controls after post-TKA week 2 but patient swing flexion statistically lower than controls until 1-year post-TKA. As such, we believe stance flexion should be utilized to assess acute knee function recovery and swing flexion should be used to assess longer-term knee function quality post-TKA. Moreover, this study provides clinicians a significant reference for typical recovery following TKA.

Acknowledgements

The authors would like to acknowledge the efforts of Dan Ressler and Lisa Davis at the Clinical Research Unit at Dartmouth Hitchcock Medical Center. Research reported in this publication was supported by the National Center For Advancing Translational Sciences of the National Institutes of Health under Award Number UL1TR001086. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Conflicts of interest

Dr. Ryan Chapman has no financial affiliations to disclose. Dr. Wayne Moschetti received an honorarium from Omni Life Science and Depuy as well as investigator support from Depuy. Dr. Douglas Van Citters received principle investigator support from DePuy Synthes, OrthoSensor, and Launchpad Medical. He also received other financial or material support from ConforMIS and TJO.

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