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Preoperative quadriceps weakness preferentially predicts postoperative aberrant movement patterns during high-demand mobility following total knee arthroplasty☆,☆☆

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ABSTRACT

Background: Nearly all patients with total knee arthroplasty show aberrant movement patterns during tasks requiring greater joint demand compared to matched peers. Greater movement compensation leads to increased loading onto other joints, decreased functional capacity and limited reserve for independence later in life. Understanding how preoperative predictors contribute to postoperative aberrant movement patterns is needed to make better decisions for patients considering total knee arthroplasty.

Methods: Forty-seven patients were tested preoperatively and six months following primary total knee arthroplasty. Demographic (age, sex, body mass), self-reported (knee pain, perception of physical performance, physical activity level), physical performance (quadriceps strength, lower limb power and timed stair climbing) and surgical metrics were collected as predictor variables. Three-dimensional models based on joint mechanic asymmetry during a decline walking task were collected at six months postoperatively. Decline walking is a preferred means to assess the surgical knee's contribution to limb performance during high-demand tasks. Bootstrap inclusion fraction was employed to compare the stability of each predictor variable prior to the final regression model.

Results: Preoperative quadriceps strength ($\beta = 0.33$; $p = 0.04$) showed a significant relationship with knee extensor angular impulse during loading phase. No other predictor variable had any meaningful relationship with aberrant movement patterns ($p > 0.05$).

Conclusion: Our findings highlight patients' preoperative quadriceps strength as a meaningful predictor of postoperative performance. Preoperative quadriceps strength should be addressed when considering the knee's ability to contribute to higher demanding mobility tasks following surgery.

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1. Introduction

Nearly all patients with total knee arthroplasty (TKA) demonstrate aberrant movement patterns following surgery compared to healthy-matched peers [1]. These aberrant movement patterns can be defined as inter-limb asymmetry [2], as patients demonstrate decreased loading and knee flexion motion on the surgical limb compared to the non-surgical knee [3]. Aberrant movement patterns have also been related to poorer physical performance, indicated by slower walking speeds, chair rising and stair climbing ability [1,4–6].

Understanding how preoperative predictors contribute to postoperative physical performance is needed to improve surgical decision making, setting patient expectations and structuring postoperative rehabilitation. Timing and indications for TKA surgery are largely driven by severity of reported knee pain and joint space narrowing based on radiography [7]. However, mounting evidence is indicating that preoperative demographic, self-reported and physical performance metrics are predictive of poorer physical performance following surgery. Older age [8], higher body mass [8], lower limb weakness [2,6], knee pain [9], lower self-perceived function [10] and poorer physical activity level [11] preoperatively have all shown to be indicative of poorer postoperative physical performance. The implant design has also shown to effect postoperative clinical outcomes post-TKA [12]. Although these predictors have shown to be influential on postoperative physical performance, most studies utilize self-reported outcomes as the primary measure to a successful recovery. Self-reported outcomes have shown only modest correlation to actual measured physical performance [13]. These findings indicate physical recovery to preoperative levels requires more time [14], as compared to survey scores, and functional recovery of patients with TKA rarely reaches levels of healthy-matched peers [15].

Higher demanding tasks (i.e. squatting, stair climbing and heavy domestic duties) are generally related to greater functional impairment after surgery as they require more physical capacity and muscular contribution to accomplish [2,10,16]. Studying more physically demanding tasks is important as detecting aberrant movement patterns during simple mobility tasks (i.e. over-ground walking) show low sensitivity to detect functional deficits [17]. A higher demand mobility task, such as decline walking, requires approximately two times greater peak moment demand on the knee extensor muscles during the initial loading phase of gait relative to over-ground walking [18,19].

By identifying preoperative predictors of functional improvement following TKA, clinicians can provide necessary education and develop targeted interventions. These interventions should address normalizing aberrant movement patterns, associated with functional limitations and assist in guiding postoperative prognosis [20]. The purpose of this study was to identify clinical predictors and their influence on aberrant movement patterns during a high-demand decline walking task at six months following TKA. Preoperative predictors were selected a priori based on demographic, self-reported, physical performance and surgical metrics that have shown to influence postoperative recovery. We hypothesized that demographic, self-reported, physical performance and surgical metrics would be predictive of aberrant movement patterns at six months following TKA.

2. Methods

2.1. Participants

An Institutional Review Board (IRB) approved prospective cohort study was conducted identifying patients who underwent a primary unilateral TKA surgery between January 2015 and May 2016. Preoperative predictors were obtained at baseline less than a month [mean 0.7 (standard deviation (SD) 0.3)] prior to surgery and postoperative motion analysis outcomes were collected at six months [mean 6.2 (SD 0.3)] following surgery. Patients with TKA have shown to generally plateau in recovery by six months [21] and this point in recovery is predictive of both low and high functioning tasks 24 months postoperatively [22]. All participants met the following inclusion criteria: between 45 and 75 years of age; non-surgical knee pain less than or equal to 4 out of 10 on a visual analog scale; no comorbidities that would have influenced the balance or walking ability; no current diagnosis or treatment for neurological conditions; no prior knee joint replacement procedure to either limb, no plans of undergoing a TKA on the contralateral limb within 12 months after the initial procedure, ≥110° of maximum arc of knee mobility (expressed by full passive knee flexion and extension motion), no report of knee instability with daily activities and confirmed anteroposterior/mediolateral knee stability (1–2+) based upon clinical examination. All surgical procedures were performed by one of three orthopedic surgeons and all participants were recruited from a single academic medical center (Salt Lake City, UT, USA). Patients were treated in outpatient physical therapy consisting of range of motion, pain/swelling management, gait training, lower limb strengthening/activation and functional retraining. The study was approved by the University of Utah Institutional Review Board and all participants consented to participation prior to enrollment. An a priori sample size calculation was conducted with an expected medium to large sized effect and a two-sided alpha level of $p \leq 0.05$, approximately $n = 55$ patients (effect size = 0.15, medium effect) to $n = 29$ patients (effect size = 0.30, large effect) were needed to achieve 80% statistical power (G*Power) [23]. These findings indicated the available dataset was appropriate for this analysis.

2.2. Procedures

Predictors were based on specific demographic, self-reported, physical performance and surgical metrics and their influence, if any, on postoperative aberrant movement patterns.

2.2.1. Demographic

Participants' age (years) and sex were obtained from the electronic medical record prior to undergoing surgery. Body mass index was calculated based on weight (kg) and height (m) metrics obtained at baseline.

2.2.2. Self-reported

The Patient Reported Outcomes Measurement Information System (PROMIS®) Computerized Adaptive Testing (CAT) was utilized as a proxy for perception of physical function and validated in various orthopedic populations [24,25]. The PROMIS® physical function (PF-CAT) v1.2 item bank, containing 121 items, was developed from 1865 physical-function related items that were identified from prior validated self-reported instruments [26]. Preoperative knee pain was measured using an 11-point numeric pain rating scale (NPRS) as a proxy for pain intensity (0 = no pain and 10 = worst possible pain imaginable) [27]. The NPRS has shown high test–retest reliability in patients with arthritis (r = 0.96) [27]. The 11-point numeric University of California at Los Angeles (UCLA) activity rating scale was collected as a proxy for physical activity level. The UCLA activity rating scale is a valid metric and commonly used in the TKA population [28].

2.2.3. Physical performance

Isometric knee extensor strength was collected on an electromechanical dynamometer (Humac NORM, CSMi, Stoughton, MA, USA) as a measure of quadriceps strength. Participants were positioned in a seated position with the knee flexed to a 60-degree angle. Two submaximal (50% and 75%) and one maximal (100%) contractions were performed, prior to collecting three maximal isometric contractions for analysis. The three maximal trials were averaged and computed as maximal torque output (Nm) for each limb. A quadriceps strength index was computed by dividing the maximal torque output of the surgical knee by that of the non-surgical knee. A percentage of complete symmetry (100%) was represented, with values less than 100% indicating weakness of the surgical limb compared to the non-surgical limb. Maximum isometric strength testing has shown good to excellent reliability (r = 0.81–0.98) [29,30]. Lower limb power testing of the limb extensors was performed using the Leg Extension Power Rig (Medical Engineering Unit, Nottingham, UK) as a measure of lower limb power output. Participants were positioned in a seated position with the knee flexed to 90° in the start position and 10° short of full knee extension in the final position. Two submaximal (50% and 75%) and one maximal (100%) trials were performed, prior to collection of five maximal effort trials. The top three scores were averaged for a single composite score of maximal power output (W) for each limb. A lower limb extensor power index was computed by dividing the maximal power output of the surgical limb by that of the non-surgical limb. Lower limb power testing has shown to be a valid and reliable instrument [31,32]. The timed stair climbing test measures the time it takes to ascend and descend a flight of 12 steps, at the fastest rate at which is safe and comfortable [33]. The timed stair climbing test demonstrates good responsiveness to detecting initial deterioration (Effect Size (ES) = −0.71) with subsequent improvement (ES = 0.84) and is a good proxy of physical performance following TKA [33].

2.2.4. Surgical

Implant design was obtained by querying the enterprises data warehouse following surgery. The indications for type of implant design were left to the discretion of the treating surgeon and based on the integrity of the cruciate ligaments, deformity and/or ligamentous deficiencies. The type of implants evaluated were the posterior cruciate-retaining (CR, reference), anterior-stabilized (AS), posterior-cruciate substituting (PS) and bicruciate-retaining (BCR) designs.

2.3. Motion analysis

Kinematic and kinetic data was collected while each participant walked on a 10 degree decline slope. The kinematic data was collected using the trajectories of 50 retro-reflective markers (14 mm diameter) based on a modified Plug-In-Gait marker set (Vicon, Oxford Metrics Ltd., Oxford, UK) using a 10-camera motion analysis system (Vicon, Oxford Metrics Ltd., London, UK) at a sampling rate of 200 Hz. The kinetic data was collected using a dual-belt fully instrumented treadmill (Bertec Corp; Columbus, OH, USA) at a sampling rate of 1000 Hz.

Decline walking was defined as a high-demand mobility task as it requires two times greater knee internal extensor moment demand during the initial loading phase compared to over-ground walking [16,18]. Decline walking has shown to be a preferred means to assess the TKA surgical knee's contribution to limb performance during high-demand tasks [16]. An acclimation period of three to five minutes was conducted to allow the participants to become accustomed to walking on the sloped treadmill. Following the acclimation trial, a five to 10 minute rest period was provided prior to the official testing session. Participants were instructed to “walk as normally as possible as if walking downhill” at a constrained velocity of 0.8 m/s.

2.4. Data processing

Kinematic and kinetic data were recorded and synchronized using Nexus 2.1.1 software (Vicon, Oxford Metrics Ltd., Oxford, UK). Inverse dynamic computation and extraction of knee extensor angular impulse (ΔL_K) variable were conducted using Visual3D (C-motion, Inc., Germantown, MD, USA). Trajectory and analog data were low-pass filtered at six hertz and 25 Hz respectively using a fourth-order Butterworth digital filter based on residual analysis [34] and visual inspection. Outcome of interest was the absolute summation of the sagittal-plane (x-axis) ΔL_K (area under the knee moment–time curve) of the limb during the loading phase (heel strike to midstance) of the gait cycle. The ΔL_K data was computed during the loading phase to specifically

evaluate the response to the kinetic demand at the knee joint level and normalized to body mass (kg). Angular impulse has shown to be a more comprehensive assessment of joint moments toward producing movement compared to peak moment values [35]. Aberrant movement patterns were defined as an inter-limb asymmetry ΔL_K index score between the surgical and non-surgical limbs. The ΔL_K index score was computed by dividing the extensor angular impulse output of the surgical knee by that of the non-surgical knee. An index of complete symmetry (1.0) was represented, with values less than 1.0 indicating greater asymmetry of the surgical limb compared to the non-surgical limb. Ten successful steps were averaged for analysis. A successful step was defined in which all markers were visible, and the participant could successfully complete a gait cycle without crossing over onto the adjacent force platform.

2.5. Data analysis

To assess the stability of the statistical model, the bootstrap inclusion fraction (BIF) was computed for each predictor variable, which is the percentage of times the variable remains in the final model in a large number of bootstrap resamples in which the variable selection is repeated [36]. The BIF method was utilized knowing multiple predictor variables in a multivariable model are known to increase the likelihood of finding false positive predictors [37]. We obtained 1000 models using 1000 random bootstrap samples with replacement from the original dataset. The initial BIF analysis included the following variables: demographic (age, sex and body mass), self-reported [physical activity level (UCLA), physical function (PF-CAT), residual knee pain (NPRS)], physical performance (quadriceps strength index, lower limb extensor power index, timed stair climbing test) and implant design (CR, AS, PS and BCR). A variable that did not remain significant in the multivariable model in less than 50% of the resamples was defined as unreliable, meaning it would likely not be a significant predictor in future patient samples. As such, predictors with BIFs <50% were thus dropped from the final model. The final BIF analysis included only the variables from the initial analysis that were stable (BIFs ≥50%). In an effort to avoid risk of statistical overfitting, all variables that were borderline stable in the initial BIF analysis were included into a second BIF analysis. The final BIF analysis was conducted to more accurately determine the most stable predictors to incorporate into the linear regression model.

A linear regression model was employed to investigate relationships between the stable predictors (≥50% BIF) and postoperative aberrant movement patterns (ΔL_K asymmetry). Knee extensor angular impulse index scores were computed as the value on the surgical limb divided by the scores on the non-surgical limb. A score equal to 1.0 indicated perfect symmetry, values greater than 1.0 indicated greater scores on the surgical limb, and scores less than 1.0 signified lower scores on the non-surgical limb. T-tests were used to determine inter-limb (surgical vs. non-surgical) aberrant movement pattern differences between limbs. Statistical significance level was set at $p < 0.05$. Effect sizes were calculated based on Pearson correlations (r). Pearson correlations equal to or greater than 0.10 present a small effect, equal to or greater than 0.30 present a medium effect and equal to or greater than 0.50 present a large effect [38]. Data were analyzed using commercially available statistical software (Stata v14.1; StataCorp, LP, College Station, TX, USA).

Table 1
Predictor variables.

Variable	TKA cohort (n = 47)
Age, years	62.7 (7.9)
Sex, male (%)	24 (51.1)
Weight, kg	84.6 (16.0)
Height, m	1.73 (0.1)
BMI, kg/m^2	28.3 (4.3)
UCLA activity scale, no	5.9 (3–9)
PF-CAT T-score, no	39.9 (4.4)
NPRS, no	6.7 (1.8)
UCLA, no	5.9 (3–9)
Quadriceps index, %	69.3 (14.9)
Power index, %	73.2 (16.7)
SCT, s	47.6 (7.2)
CR, no (%)	16.0 (34)
AS, no (%)	15.0 (32)
PS, no (%)	12.0 (25)
BCR, no (%)	4.0 (9)

Note: Values represented as mean (SD), unless otherwise stated. Values for UCLA activity scale represented as mean (range). TKA, total knee arthroplasty; BMI, body mass index; UCLA, University of California Los Angeles; PF-CAT, physical function computerized adaptive testing; NPRS, numeric pain rating scale; SCT, timed stair climbing test; CR, posterior cruciate-retaining implant; AS, anterior-stabilized implant; PS, posterior-cruciate substituting implant; BCR, bicruciate-retaining implant.

Table 2
Bootstrap inclusion fraction (BIF) results for each preoperative predictor prior to data analysis.

Variable	Predictors	M	SD	BIF %
ΔL_K, Nms/kg	Quad index	0.571	0.495	57[a]
	PF-CAT	0.316	0.465	32
	UCLA	0.326	0.469	33
	BCR[b]	0.178	0.383	18
	AS[b]	0.186	0.389	19
	PS[b]	0.184	0.352	18

Abbreviations: ΔL_K, knee extensor angular impulse; Quad, quadriceps; PF-CAT, physical function computerized adaptive testing; UCLA, University of California Los Angeles activity scale; BCR, bicruciate-retaining implant; AS, anterior-stabilized implant; PS, posterior-cruciate substituting implant. Values are expressed as means (M) and standard deviation (SD).

[a] BIF > 50%, indicating the predictor was stable enough to be incorporated into the linear regression model.

[b] Reference was the posterior cruciate-retaining implant design.

3. Results

Initial eligibility screening of 86 participants was conducted prior to surgery. Thirty-seven patients did not meet the eligibility criteria. Twelve patients planned on undergoing a contralateral TKA less than 12 months after their primary TKA due to knee pain, 10 had undergone a TKA on the contralateral knee, seven reported secondary comorbidities that influenced their mobility, five where not interested in participation due to time constraints and three had a body mass index greater than 40 kg/m^2. After surgery, two patients were excluded from the study due to postoperative range of motion complications (arthrofibrosis) requiring a secondary procedure, leaving 47 patients with TKA that completed data collection (Table 1). Implant designs included 16 (34%) with a CR design (Vanguard, Zimmer Biomet, Warsaw, IN, USA), 15 (32%) with an AS implant (Vanguard, Zimmer Biomet, Warsaw, IN, USA), 12 (25%) with a PS implant (Triathalon PS, Stryker, Kalamazoo, MI, USA) and four (nine percent) with a BCR implant (Vanguard XP, Zimmer Biomet, Warsaw, IN, USA).

The initial BIF analysis revealed quadriceps strength index (BIF = 50%), PF-CAT (BIF = 50%), UCLA activity rating scale (BIF = 49%) and implant design (BIF = 50%) predictors were stable enough to incorporate into the final BIF analysis. The final BIF analysis revealed the preoperative quadriceps strength index (BIF = 57%) predictor as the only stable measure influencing postoperative ΔL_K. All other preoperative predictors shown had BIFs <50%, indicating unreliable variables and were not included in the linear regression model (Table 2). The preoperative quadriceps strength index showed a significant positive relationship with the postoperative ΔL_K asymmetry ($\beta = 0.33$; $p = 0.04$; Figure 1; Table 3). The preoperative quadriceps strength index as an individual predictor had a medium effect of explaining postoperative ΔL_K asymmetry ($r = 0.33$, Table 3). No other preoperative predictors had any significant influence on ΔL_K asymmetry at six months postoperatively. Significant ΔL_K asymmetry was observed between the surgical and non-surgical limbs at six months ($p = 0.04$; Figure 2).

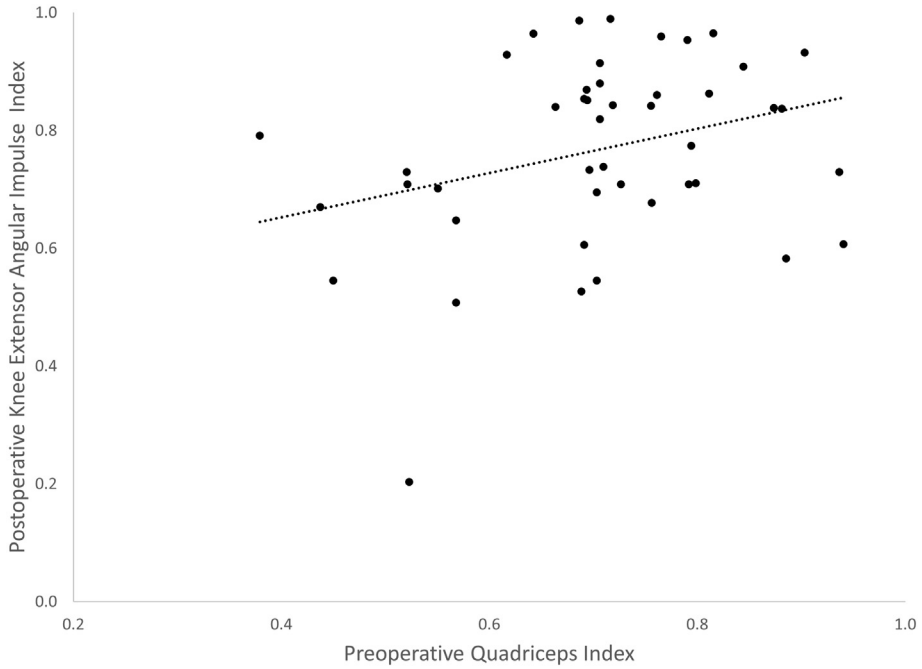

Figure 1. Relationship between preoperative quadriceps index and postoperative knee extensor angular impulse index following total knee arthroplasty.

Table 3
Linear regression model of stable preoperative predictor variable on aberrant movement pattern at six months postoperatively.

Variable	Predictor	B[a]	SE	β[b]	Effect size, r[c]	p-Value	95% C.I.
ΔL_K, Nms/kg	Quad index	0.004	0.002	0.334	0.33	0.04*	0.001, 0.007

Abbreviations: ΔL_K, knee extensor angular impulse during the loading phase; Quad, quadriceps.
[a] Unstandardized regression coefficient.
[b] Standardized regression coefficient.
[c] Effect size categories (0.10 small, 0.30 medium, 0.50 large).
* $p \leq 0.05$.

4. Discussion

The purpose of this study was to identify clinical predictors and their influence on aberrant movement patterns during a high-demand decline walking task at six months following TKA. The primary finding of this investigation was greater preoperative quadriceps strength asymmetry was predictive of greater postoperative aberrant movement patterns, defined as ΔL_K asymmetry, during decline walking at six months following TKA. No other predictor had any significant influence on postoperative aberrant movement patterns. Our findings highlight the importance of addressing preoperative quadriceps strength as it is moderately predictive of postoperative aberrant movement patterns during a mobility task that requires greater mechanical knee demand.

A prior investigation on aberrant movement patterns following primary TKA compared similar preoperative predictor relationships with general weight-bearing asymmetry during a sit-to-stand transfer task and concluded that preoperative quadriceps weakness was the only significant predictor influencing movement compensation [20]. Our data is consistent with these findings, while exploring more specific knee joint kinetics during a later time-point postoperatively. While preoperative muscle weakness has also shown to be related to poorer postoperative time-based physical performance measures [5] and patient satisfaction scores [39], our data is the first to show greater quadriceps deficits contributing to underutilization of the surgical knee during a task requiring greater extensor muscle demand. Aberrant movement patterns reinforce an avoidance of regular quadriceps use and contribute to lack of restoration of physical performance [40]. These findings are important as aberrant movement patterns observed early after surgery are predictive of similar joint mechanics seen 12 months postoperatively [41].

Recent findings show that the longer the patients wait to undergo TKA surgery, the poorer the postoperative physical performance outcomes are [42]. Chronic compensatory strategies and physical inactivity, as a resultant of persistent knee pain, contribute to large deficiencies in quadriceps strength prior to surgery [1,40]. As a result, patients continually show marked quadriceps weakness years following surgery and rarely reach levels similar to healthy-matched peers [40]. Determining the optimal timing for recommending TKA is challenging, however evaluating quadriceps strength might provide valuable information in considering

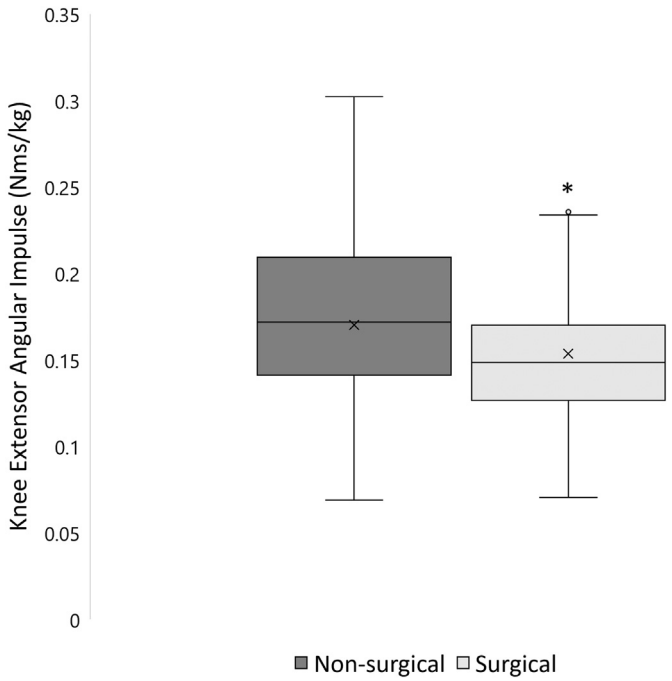

Figure 2. Postoperative knee extensor angular impulse during loading response of decline walking at six months following total knee arthroplasty *$p \leq 0.05$.

the influence it has on joint function following surgery. Preoperative strength training has shown marginal improvements in postoperative clinical outcomes [43]. However, targeted interventions addressing aberrant movement patterns have not been fully explored, which is an important component in restoring optimal physical performance. As the number of surgical interventions continues to rise in managing chronic end-stage arthritis, it is important to educate patients on the impact quadriceps weakness has on postoperative outcomes.

Strength training, particularly quadriceps conditioning, is commonly incorporated into postoperative rehabilitation to restore optimal muscle function. Despite therapeutic efforts to improve quadriceps strength postoperatively, patients continue to present with marked weakness following surgery [40]. Potential explanations for these consistent findings are insufficient therapeutic dosing of strength training and/or suboptimal patient compliance in postoperative rehabilitation. Lower limb power was also studied as a surrogate measure of leg extensor muscle performance. Our findings did not find relationships between preoperative power output and postoperative aberrant movement patterns. This could be explained by the large amount of hip extensor muscle demand required during power testing, while most knee joint kinetic demand during the loading phase of decline walking is made up of eccentric quadriceps and calf muscle contributions [4]. Alternatively, movement symmetry retraining is rarely prescribed in standard rehabilitation practice and may provide an alternative intervention to incorporate pre- and post-TKA to maximize lower limb function, particularly in restoring quadriceps strength. Studies are showing promising evidence that movement symmetry retraining is beneficial in improving aberrant movement patterns following TKA [44–46]. However, further prospective longitudinal designs are needed to determine long-term retention of improved movement quality and how motor retraining influences muscle function.

Our study did not find any predictive influence of preoperative age, sex, body mass, surgical knee pain, perception of physical performance, physical activity level, lower limb power output, stair climbing ability or implant design on postoperative aberrant movement patterns following TKA during decline walking. This was not consistent with our original hypothesis as these alternative predictors, previously found to influence self-reported and time-based physical performance measures, were not related to aberrant movement patterns during a novel high-demand mobility task. Although advanced statistical methods were employed to determine the stability of each predictor, our sample size was only powered to detect medium to large effects. A larger sample size would likely be needed to detect smaller effects, if present, between predictors on aberrant movement patterns. Continual aberrant movement patterns of the surgical limb during higher demanding tasks could be preventing necessary muscular stimuli that is needed to normalize strength deficits and improve physical performance postoperatively. Importance needs to be placed on evaluating more physically demanding tasks as a growing number of patients with TKA are expecting to return to more physically demanding daily life, work and leisure activities [47]. These expectations are increasing as advancements in surgical technology evolve [48] and younger more active individuals are undergoing surgery at higher rates than ever before [49]. Restoring optimal joint mechanics postoperatively, might begin by evaluating patients' quadriceps strength prior to surgery. Providing emphasis on preoperative quadriceps strengthening strategies, including biofeedback and/or movement symmetry retraining for aberrant movement patterns, prior to surgery may be important determinants in restoring normal joint function and improving clinical outcomes.

5. Limitations

This study has limitations that need to be considered when interpreting the data. First, data was obtained on an instrumented treadmill, which may not be the same as an over-ground sloped environment. Second, our sample size was based on detecting medium to large effects, so a larger sample size with alternative predictors is needed to detect smaller effects if present. Third, our findings were representative of a relatively healthy and active cohort, which may have biased the results toward this more homogeneous patient population. Fourth, we did not track duration, type or quality of physical therapy services provided, which could have influenced the results. While these limitations potentially limited our internal validity, we felt our pragmatic study design allowed us to evaluate the average patients' postoperative movement quality and how these predictors influenced gait during a higher demanding task.

6. Conclusion

Preoperative quadriceps strength asymmetry was moderately predictive of aberrant movement patterns at the knee joint during a high-demand decline walking task at six months following TKA. None of the other preoperative predictors had a direct relationship with postoperative aberrant movement patterns. Our findings highlight the importance of addressing quadriceps strength prior to surgery as this predictor directly influences normalizing postoperative aberrant movement patterns during a task that requires greater knee extensor demand.

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Conflict of interest statement

One of the authors certifies that he (CLP), or a member of his immediate family, has or may have received payments or benefits unrelated to this work, during the study period, an amount of USD 100,001 to USD 1,000,000 from Biomet, Inc. (Warsaw, IN, USA).

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