GAIT SYMMETRY IN INDIVIDUALS WITH KNEE OSTEOARTHRITIS

SPATIOTEMPORAL GAIT SYMMETRY IN INDIVIDUALS WITH CLINICAL UNILATERAL KNEE OSTEOARTHRITIS COMPARED TO HEALTHY CONTROLS: A PILOT STUDY

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Title: Spatiotemporal Gait Symmetry in Individuals with Clinical Unilateral Knee Osteoarthritis Compared to Healthy Controls: A Pilot Study

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Abstract

Purpose: This study describes gait characteristics and evaluates whether step length, step time and stance time symmetry index (SI) ratio (differences between limbs divided by the bilateral average) and variables of each limb (limb-specific) can be reliably measured in a sample of unilateral knee osteoarthritis (KOA) and healthy participants. A secondary objective estimates between- and within-group differences and correlations between SIs and limb-specific variables with measures of pain, perceived exertion and physical function over an experimental walking intervention.

Design: Observational cohort. SI and limb-specific variables test-retest reliability and differences in KOA and healthy individuals before and after the walk intervention were estimated.

Methods: Eight subjects were in each of the KOA and healthy groups. The GAITRite® captured step length, step time and stance time on three test occasions. Test-retest reliability was measured over two administrations. Pain (Numeric Pain Rating Scale) and perceived exertion (Borg Rating of Perceived Exertion) were collected before and after each test. The six-minute and treadmill walk tests comprised the experimental walking intervention. Point and interval estimates of SIs and limb-specific variables before and after the walk intervention for test-retest reliability, between- and within-group differences as well as Pearson correlations were obtained.

Results: Limb-specific variables showed better test-retest reliability (ICC 0.94 to 0.97) than SIs (ICC 0.77 to 0.87). Differences were observed in both groups' perceived exertion rating (KOA -7.4 (-8.5 to -6.4); Healthy -6.7 (-8.0 to -5.5)) over the experimental walking

intervention. In the KOA group, high correlations (r = 0.75 to 0.93) were observed between pain and both step and stance times as well as physical function and step length, varying in magnitude and direction depending on which limb was supporting.

Conclusion: The findings suggest that limb-specific measures are reliable and useful as biomechanical indices of compensatory KOA gait, correlating with pain and physical function.

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List of Abbreviations

A	-	Affected limb
ADL	-	Activity of daily living
ANOVA	-	Analysis of variance
BMI	-	Body mass index
CMCC	-	Canadian Memorial Chiropractic College
CI	-	Confidence interval
cm	-	Centimetre(s)
D	-	Dominant limb
HSS	-	Hospital for Special Surgery
Hz	-	Hertz
ICC	-	Intraclass correlation coefficient
KOA	-	Knee osteoarthritis
KOOS	-	Knee Osteoarthritis Outcome Score
m	-	Metre(s)
mm	-	Millimetre(s)
ms	-	Millisecond(s)
m/s	-	Metre(s)/second
MSK	-	Musculoskeletal
ND	-	Non-dominant limb
NPRS	-	Numeric Pain Rating Scale
OA	-	Osteoarthritis
ROM	-	Range of motion

RPE	-	Rating of Perceived Exertion
s	-	Second(s)
SEM	-	Standard error of measurement
SF-36	-	Short Form-36
SI	-	Symmetry index
SIs	-	Symmetry indices
SMWT	-	Six-Minute Walk Test
SPSS	-	Statistical Package for the Social Sciences
SPWT	-	Self-Paced Walk Test
TKA	-	Total knee arthroplasty
QoL	-	Quality of life
UN	-	Unaffected limb
VAS	-	Visual Analog Scale
WOMAC	-	Western Ontario McMaster Universities

Declaration of Academic Achievement

I, Keshena Malik, wrote this manuscript and had editing input from Joy MacDermid, Monica Maly, Michael Pierrynowki, Paul Stratford and John Triano. The scholarly work from other people is properly referenced (with permission under license, where applicable) within the text.

Introduction and Literature Synthesis

The Burden of Illness in Individuals with Knee Osteoarthritis (KOA)

Osteoarthritis (OA) is considered the most common musculoskeletal (MSK) condition affecting individuals of all ages and its prevalence increases with age (Andriacchi et al., 2004; Foroughi, Smith & Vanwanseele, 2009). OA affects 3,000,000 (1 in 10) Canadians (Arthritis Society, 2008), produces significant morbidity, disability, reduced quality of life (QoL) (Felson, 1988; Mündermann, Dyrby & Andriacchi, 2008), and has a profound societal and economic burden on the health care system (Gupta, Hawker, Laporte, Croxford & Coyte et al., 2005).

The most frequent joint affected by OA is the knee (Mündermann et al., 2008; Oliveria, Felson, Reed, Cirillo & Walker, 1995). Knee osteoarthritis (KOA) affects 20 to 40% of individuals over the age of 65 years in North America (Felson, 2004). Research indicates KOA has greater social cost and more associated disability than OA of other joints (Bergstrom et al., 1985).

Walking is a common functional activity of daily living (ADL). Individuals with KOA experience pain, stiffness and decreased range of motion (ROM) of the joint (Heiden, Lloyd & Ackland, 2009; Kaufman, Hughes, Morrey, Morrey & An, 2001). These symptoms significantly limit their ability to walk, contributing to pain and loss of functional independence (Kaufman et al., 2001; McNeil & Binette, 2001; Mündermann et al., 2008). As a consequence, individuals with KOA reportedly adopt altered gait patterns to compensate for these functional limitations (Al-Zahrani & Bakheit, 2002; Kaufman et al., 2001; McGibbon & Krebs, 2002).

Gait Analysis

Gait analysis has allowed researchers and clinicians to better understand biomechanical factors of gait in healthy participants and those with lower limb pathology (Zeni & Higginson, 2009). The mechanics of walking on a level surface are well characterized (Kaufman et al., 2001; Gilbert, Maxwell, McElhaney & Clippinger, 1984; Patterson et al., 2008). Gait analysis quantifies gait variables and provides a useful measure in differentiating individuals with and without KOA (Astephen, Deluzio, Caldwell, Dunbar & Hubley-Kozey, 2008; Lynn, Reid & Costigan, 2007). The presence of KOA affects a multitude of spatial (distance) and temporal (time) gait variables (Al-Zahrani & Bakheit, 2002; Childs, Sparto, Fitzgerald, Bizzini & Irrgang, 2004; Zeni & Higginson, 2009). Such spatiotemporal gait variables include step length, stride length, step time, stance time, single- and double-support time and gait speed which have been evaluated in healthy (Allard, Prince & LaBelle, 2000; Gundersen et al., 1989; Hesse et al., 1997) and diseased populations, such as stroke survivors (Kim & Eng, 2003; Patterson Patterson et al., 2008), lower limb amputees (Mizuno, Aoyama, Nakajima, Kasahara & Takami, 1992; Skinner & Effeney, 1985) and individuals with KOA (Al-Zahrani & Bakheit, 2002; Gok, Ergin & Yavuzer 2002; Stauffer, Chao & Györy, 1977).

It has been suggested in the literature that certain anthropometric, demographic and participant characteristics, such as age, gender and disease severity, potentially influence spatiotemporal variables of an individual's gait. Several studies revealed significant changes in gait patterns associated with advancing age. The most consistent finding of these studies is that older people walk more slowly than younger people, which

has been suggested to be a function of shorter step length and increased time spent in double-limb support (Chui & Lusardi, 2010; Menz, Lord & Fitzpatrick, 2003; Oberg, Karsznia & Oberg, 1993). For example, the study by Menz et al. (2003) investigated 30 healthy young (22 to 39 years of age) and 30 older (75 to 85 years) participants and reported older adults compared to young adults exhibited significantly slower gait speed (older 1.17 metres per second (m/s) (0.19) versus younger 1.33 m/s (0.16), $p < 0.01$), shorter step length (older 0.65 m (0.1) versus younger 0.73 m (0.1), $p < 0.01$) and greater step timing variability ratio (older 0.05 (0.02) versus younger 0.03 (0.02), $p < 0.01$). In another study, Chui & Lusardi (2010) investigated both age and gender effects on spatiotemporal gait variables in a sample of healthy elderly participants (72 to 98 years of age). These authors found significant age effects in spatiotemporal gait variables, with increasing age decreased step length (0.69 metres (m) ± 0.1 ages 70 to 79 versus 0.60 m ± 0.1 ages 80 to 89 versus 0.49 m ± 0.1 ages 90 to 99, $p < 0.001$) and percentage of gait cycle spent in stance (62.9% ± 1.2 ages 70 to 79 versus 63.7% ± 0.8 ages 80 to 89 versus 65.3 ± 1.9 ages 90 to 99, $p < 0.003$) during self-paced walking speed was reported; whereas gender effects were only found for step length (i.e., longer step length found in men (0.69 m ± 0.1) compared to women (0.56 m ± 0.1), $p < 0.001$). In KOA samples, a study by Debi et al. (2009) reported mean step length normalized to leg length to be similar in men and women (0.06 m/leg length ± 0.01 for each group, respectively). McKean et al. (2007) found significant gender differences in stance time in individuals with KOA with men having significantly longer stance time than women (men 0.70 seconds (s) (0.1) versus women 0.60 (0.1), $p < 0.01$). Furthermore, the study by Kiss

(2011) evaluated the effects of both gender and disease severity on the variability of spatiotemporal variables (i.e., cadence, step length, and double-support phase duration) in healthy controls and individuals with unilateral KOA with moderate or severe disease. The study reported that both gender and disease severity in the KOA group had statistically significant gender (the variability of cadence, step length and double-support duration was smaller in men compared to women, $p \leq 0.03$) and disease severity (i.e., increased variability of cadence, step length and double-support phase duration with increased KOA severity, $p \leq 0.03$) effects (Kiss, 2011). The findings regarding gender effects in healthy and KOA samples appear equivocal, however, the findings related to age and disease severity appear consistent in the literature (Imms & Edholm, 1981; Kang & Dingwell, 2008; Messier, 1994; Oberg et al., 1993).

Another prevalent concept in the literature is symmetry of the lower limbs during gait, which has been suggested to predict differences between limbs in some spatiotemporal characteristics (Patterson et al., 2008; Sadeghi, Allard et al., 2000; Stanic, Bajd, Valencia, Kljajie & Acimovic, 1977).

Measures of Gait Symmetry

The operational definition of gait symmetry has been debated in the literature. Some authors have defined symmetry as perfect agreement between the lower limbs (Sadeghi et al., 2000); while others suggest using the term “gait symmetry” when no statistical differences are noted in variables measured bilaterally (Griffin, Olney & McBride, 1995; Gundersen et al., 1989; Hesse et al., 1997). While there is debate regarding the operational definition of gait symmetry, according to Sadeghi et al. (2000),

it is commonly accepted that the term "gait symmetry" is applicable when both limbs behave identically.

Robinson, Herzog and Nigg (1987) were the first to quantify gait symmetry between left and right limbs using a symmetry index (SI). The SI has since been used in the literature to reflect both unilateral limb pathology and limb dominance in diseased and healthy samples, respectively (Kim & Eng, 2003; Roerdink & Beek, 2011; Shorter, Polk, Rosengren & Hsiao-Wecksler, 2008; Teichtahl, Wluka, Morris, Davis & Cicuttini, 2009). The SI is calculated as the difference values between limb variables (i.e., affected and unaffected limbs for individuals with unilateral pathology; dominant and non-dominant limbs for healthy individuals) divided by the bilateral average value (Shorter et al., 2008):

$$SI\ (\%) = [(V_{A\ or\ ND} - V_{UN\ or\ D})/(0.5\ (V_{A\ or\ ND} + V_{UN\ or\ D}))]\ x\ 100$$

Where $V_{A\ or\ ND}$ is the gait variable recorded for the affected or non-dominant limb and $V_{UN\ or\ D}$ is the gait variable recorded for the unaffected or dominant limb.

The limb presenting with signs or symptoms of KOA, based on clinical and/or radiographic criteria developed by the American College of Rheumatology (Altman et al., 1986), is designated the *affected limb* while the *unaffected limb* refers to the healthy knee. The *dominant limb* is designated the preferred limb indicated by the individual, while the *non-dominant limb* refers to the limb providing postural and stabilizing support during activities, such as kicking (Sadeghi et al., 2000).

An SI value of zero represents perfectly symmetrical gait (Kim & Eng, 2003; Robinson et al., 1987; Shorter et al., 2008; Teichtahl et al., 2009). The non-zero *magnitude* of the SI measures the severity of asymmetry and the *sign* (positive or

negative) specifies its direction (Kim & Eng, 2003; Roerdink & Beek, 2011; Teichtahl et al., 2009). A positive shift of the SI indicates that the gait variable was asymmetric with a larger magnitude on the affected or non-dominant limb, while a negative shift denotes a larger magnitude on the unaffected or dominant limb (Herzog et al., 1989; Patterson et al., 2008; Shorter et al., 2008; Robinson et al., 1987).

The relatively symmetrical or asymmetrical spatiotemporal limb behaviour of able-bodied human gait has been evaluated in the literature (Herzog, Nigg, Read & Olsson, 1989; Sadeghi et al., 2000). Some authors reported evidence of symmetry in able-bodied gait. For example, Hesse et al. (1997) reported no significant differences between left and right (limb-specific) differences ($p \geq 0.007$) for stance and swing event time and step length parameters. These authors found no difference in able-bodied participants when initiating gait with either the left or right leg, consequently the data from all 100 trials were pooled for this group (i.e., step length 0.66 m ± 0.19; duration of stance time 38.2% ± 15.7; duration of swing time 42.7% ± 15.2) (Hesse et al., 1997). In another study, Gundersen et al. (1989) reported no within-subject limb-specific (between the dominant and non-dominant limbs) differences for step time (0.54 s equal bilaterally), stance time (0.70 s equal bilaterally) and step length (0.69 m equal bilaterally) in able-bodied gait. Likewise, Allard et al. (1996) reported left and right limb step length (left limb 0.71 m ± 0.1 and right limb 0.73 m ± 0.1) and stance phase duration (61% ± 1.5 and 60% ± 1.7, respectively) in able-bodied gait, revealing slight differences in mean values between the limbs, however, the differences were non-significant ($p > 0.05$). Herzog et al. (1989) reported that none of the able-bodied subjects sampled in their study demonstrated

perfectly symmetrical gait. The authors calculated an upper limit of the symmetry index value (i.e., the difference between left and right limbs divided by the bilateral average) for stance time associated with able-bodied gait and found that the mean stance time symmetry deviated ± 4% from zero. Herzog et al. (1989) reported that neither limb was used preferably in their sample and that the threshold of ± 4% from zero reasonably suggests relative symmetry for stance time. Some authors suggest that able-bodied gait may be naturally asymmetrical due to the different contributions of the lower limbs in propulsion or limb dominance during functional tasks such as walking (Sadeghi et al., 2000; Singh, 1970).

Changes in spatiotemporal variables that occur in conditions involving pathological gait may result in gait asymmetry (Herzog et al., 1989). Gait asymmetry is well studied in stroke suvivors and unilateral lower limb amputee literature (Griffin et al., 1995; Hesse et al., 1997; Isakov, Burger, Krajnik, Gregoric & Marincek, 1997; Kim & Eng, 2003; Marinakis, 2004; Patterson et al., 2008; Prosser, Lauer, VanSant, Barbe & Lee, 2010). The limb-specific (affected or unaffected limb) differences reported include gait speed, step length, stance and swing times between limbs (Griffin et al., 1995; Hesse et al., 1997; Kim & Eng 2003; Patterson et al., 2008). For example, both stroke survivors and lower limb amputees take longer steps with the affected limb compared to the unaffected limb (Mizuno et al., 1992; Skinner & Effeney, 1985). Mizuno et al. (1992) compared 10 right below-knee amputees to five healthy controls and found significant differences ($p < 0.01$) in the step length ratio (i.e., sound or left limb to the prosthetic or right limb) between the amputee group (85% ± 6.3) and healthy controls (96% ± 1.4).

These authors also found that step length was significantly ($p < 0.01$) longer for the affected limb than the unaffected limb (mean difference of 0.05 m) (Mizuno et al., 1992). Likewise, Hsu Tang & Jan (2003) compared step length in 26 hemiparetic subjects and found a significantly ($p < 0.05$) greater step length of the affected limb (0.45 m ± 0.10) compared to the unaffected limb (0.41 m ± 0.12). Stance time in stroke survivors has been reported to be less on their affected limb compared to the unaffected limb (Kim & Eng, 2003; Patterson, Gage, Brooks, Black & McIlroy, 2010). For example, Kim & Eng (2003) reported that stance time of the paretic limb was relatively shorter than the non-paretic limb (paretic 0.79 s ± 0.20 and non-paretic 0.89 s ± 0.20). In addition, mean stance phase duration in unilateral lower limb amputees was shorter (57% of the gait cycle) on the affected limb and longer (63% of the gait cycle) on the unaffected limb (Breakey, 1976). Similar findings regarding the diferences between limb-specific asymmetry and spatiotemporal gait variables may exist in individuals with unilateral KOA.

Relation between Gait Asymmetry of Spatiotemporal Variables in KOA Samples

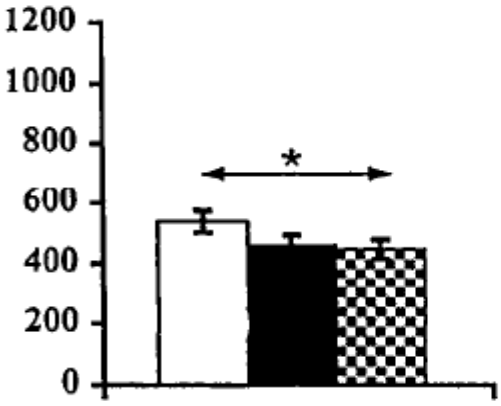
A total of five studies were found in the literature investigating spatiotemporal gait symmetry in samples of individuals with OA (see Appendix A for search strategy). One study assessed gait symmetry in 144 OA subjects with unilateral and bilateral multiple lower limb (hip, knee or ankle) joint involvement compared to age-matched (18 to 70 years) healthy controls (Lafuente et al., 2000). In this study, symmetry was specified as the relative difference in stance time between both limbs, measured using a DINASCAN® walkway system (Lafuente et al., 2000). The participants were evaluated during self-paced and fast-paced level ground walking. It was found that, during self-

paced walking, individuals with KOA tended to spend more time per gait cycle in stance phase (i.e., 5% greater, $p < 0.05$) than healthy controls (Lafuente et al., 2000). These authors also reported that stance time gait asymmetry appeared to become more pronounced (i.e., 10% greater, $p < 0.001$) during fast-paced walking in individuals with OA (Lafuente et al., 2000).

In another study, Bejek et al. (2006) evaluated cadence, step length, swing time, and double-support phase duration as well as the inter-limb asymmetry values (i.e., the difference value for the affected or non-dominant limb and unaffected or dominant limb) of step length and swing time. The data was captured using an ultrasound-based Zebris® CMS-HS three-dimensional motion analysis system at variable level-ground walking speeds (slow, self-paced and fast) (Bejek, Parcózai, Illyés & Kiss 2006). The study sample consisted of 20 subjects with unilateral KOA (45 to 93 years of age), 20 subjects with unilateral hip OA (60 to 82 years of age) and 20 healthy controls (52 to 84 years of age). These authors reported that comparisons of the OA groups to healthy controls at the same gait speed showed significantly ($p < 0.05$) increased cadence (KOA 79.9 steps per minute ± 14.4 versus hip OA 81.5 steps per minute ± 17.5 versus controls 66.9 steps per minute ± 15.8) as well as decreased step length (KOA 0.55 m ± 0.1 versus hip OA 0.54 m ± 0.1 versus controls 0.63 m ± 0.1) and double-support phase duration (KOA 23.1% ± 1.6 versus hip OA 20.5% ± 8 versus controls 22.7% ± 2.1). The step length and swing phase duration asymmetry values, at the same gait speed, in individuals with OA significantly ($p < 0.05$) increased (step length asymmetry value for KOA -38.1 ± 2.8 versus hip OA -39.5 ± 14.4 versus controls -2.5 ± 1.4, $p < 0.05$; swing phase asymmetry value for KOA

-2.3 ± 1.1 versus hip OA -1.1 ± 0.8 versus controls -0.9 ± 0.3) compared to those in the healthy group (Bejek et al., 2006). Also, increasing gait speed influenced cadence and step length in all three groups, however, inter-limb asymmetry values for step length and swing phase duration in all three groups were not influenced by gait speed (Bejek et al., 2006). Swing and double-support phase duration, however, were influenced by gait speed only in the OA groups.

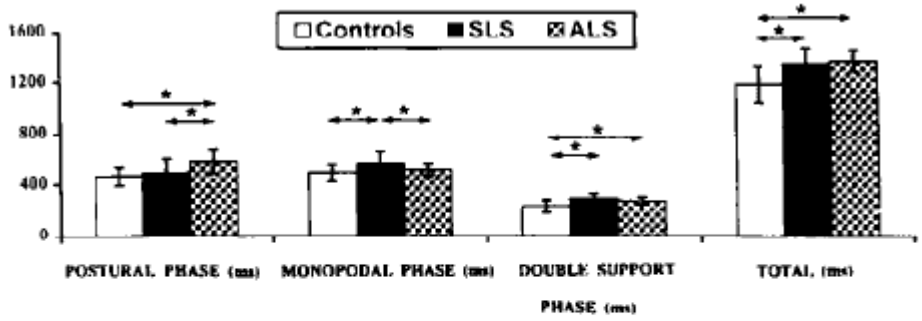
In another study, asymmetries during different phases of gait where examined in a KOA sample. The study by Viton et al. (2000) assessed symmetry of the affected and unaffected limbs during the initiation phase of gait in 12 subjects with unilateral KOA awaiting total knee arthroplasty (TKA) surgery (46 to 83 years of age) compared to 12 healthy controls (66 to 78 years of age). Step length (measured in millimetres (mm)), postural, monopodal, double-support and total phase durations (measured in milliseconds (ms)) were evaluated during level ground gait initiation, using the ELITE® optoelectronic system (Viton et al., 2000). These authors provided graphical comparisons of means and standard deviations (see Figure 1(a) and (b)), actual values were not reported in the article.



STEP LENGTH (mm)

Comparison of the step lengths in patients when the affected limb is supporting (ALS, ⊠), in patients when the sound limb is supporting (SLS, ■), and in control subjects (□). *$p < .05$; **$p < .01$; ***$p < .001$.

(a)



Comparison of the durations of the postural, monopodal, and double-support phases, and of the total movement duration in patients when the affected limb is supporting (ALS), in patients when the sound limb is supporting (SLS), and in control subjects. *$p < .05$.

(b)

Figure 1: Results from Viton et al. (2000) including comparisons of: (a) step length and (b) support duration phases. From "Asymmetry of gait initiation in patients with unilateral knee arthritis," by J.M. Viton et al., 2000, Archives of Physical Medicine and Rehabilitation, 81(2), p. 197. Copyright 2013 by Elsevier. Reprinted with permission.

The study by Viton et al (2000) reported asymmetry in individuals with unilateral KOA compared to healthy controls. For example, the length of the first step was significantly shorter ($p < 0.02$) in individuals with KOA than controls when the affected limb was supporting, however, no significant difference was found when the unaffected limb was supporting (see Figure 1). These authors also found that the total duration of the step initiation phase in the KOA group was increased when both the affected limb was supporting ($p < 0.03$) and when the unaffected limb was supporting ($p < 0.04$) compared to healthy controls. Comparisons of the duration of postural (standing upright prior to gait initiation) and monopodal (support on one limb or the other during step) support revealed that, on the one hand, when the affected limb was supporting, the postural phase was significantly increased ($p < 0.05$) compared to the control group, whereas the monopodal phase duration was the same as the control group (Viton et al., 2000). On the other hand, when the unaffected limb was supporting, the duration of the postural phase was the same as the control group but the monopodal phase duration was increased ($p < 0.04$). The double-support phase was prolonged when both the affected limb and unaffected limbs were supporting (Viton et al., 2000). These authors concluded that when comparing KOA subjects to healthy controls, total step duration and double-support duration were longer and the length of the first step was shorter whatever the side of the pathological limb with respect to the supporting side (Viton et al., 2000).

Another study investigated inter-limb spatiotemporal gait asymmetry in 16 subjects with unilateral KOA before and after surgery compared to 91 age-matched (55 to 89 years) healthy controls during self-paced walking (Berman, Zarro, Bosacco & Israelite, 1987). These authors used an unspecified instrumented gait mat to estimate parameter estimates of spatiotemporal variables including: gait speed, step length, stance time, swing time, single- and double-support time. Berman et al. (1987) reported that values were similar pre-operatively between affected and unaffected limbs in subjects with unilateral KOA. The results of pre-operative unilateral KOA subjects were compared to the healthy controls using a value indicating the percentage of the normal control group. The authors reported that comparisons suggest reduced gait speed (63% of normal) and step length (80% of normal) and increased time spent in stance (144% of normal), swing (115% of normal), single- and double-support (137% and 189% of normal, respectively) in KOA subjects (Berman et al., 1987).

Finally, Draper et al. (2000) investigated symmetry of stance and swing phase duration in 30 individuals with unilateral KOA (ages 35 to 70 years) before and three months after a valgus knee bracing intervention. The stance and swing phase duration SI, defined as the ratio of the means of the variables of the affected limb divided by the unaffected limb (i.e., SI of 1 indicates perfect symmetry, a shift toward 1 indicates improved symmetry and a shift away from 1 indicates asymmetry), was collected during self-paced gait using a level treadmill equipped with two forces plates (Draper et al., 2000). The study findings suggested that without the valgus knee brace, subjects spent less time on the affected limb, demonstrating statistically significant ($p < 0.05$) stance and

swing phase asymmetry (stance phase ratio 0.97 ± 0.11; swing phase ratio 1.13 ± 0.32), whereas with the brace a more symmetrical gait pattern (stance 1.02 ± 0.11; swing 1.12 ± 0.29) was observed (Draper et al., 2000).

A common feature from all of these reports is that individuals with OA involving one or both knees exhibit gait asymmetry in one or more spatiotemporal variables including step length, step time, single- or double-support time, swing and stance phase time in comparison to healthy controls (Bejek et al., 2006; Berman et al., 1987; Draper et al., 2000; Lafuente et al., 2000; Viton et al., 2000). It remains unclear how much asymmetry is important in samples of individuals with and without gait pathology (Sadeghi et al., 2000; Shorter et al., 2008).

Relation between Gait Asymmetry and Disability in KOA Samples

Only two studies investigated the relationship between gait asymmetry and measures of disability in a sample of individuals with KOA. One study by Lafuente et al. (2000) reported that in the KOA subjects, increased stance phase duration asymmetry was significantly correlated ($r = -0.46$, $p < 0.001$) with decrease in physical function, on the Hospital for Special Surgery (HSS) knee score. In another study, Draper et al. (2000) found significant ($p < 0.05$) improvement in symmetry of stance and swing phase gait duration and subjects self-perceived physical function, measured on HSS knee score, with the valgus knee brace intervention compared to no bracing intervention. These authors suggested that the stance and swing phase SI had a similar capacity to detect change in physical function as the HSS knee score (Draper et al., 2000).

The Use of Outcome Measurement in KOA Samples

It has been suggested that inclusion of individuals' self-perceived pain, symptoms and function are important due to their direct links to functioning in ADLs (Maly, Costigan & Olney, 2006). Hence, clinically relevant outcome measures of perceived pain, symptoms and physical function in ADLs should be considered in studies assessing gait symmetry in individuals with KOA in order to elucidate possible indicators of symptom expression and functional impairment.

There are two main methods that exist to assess pain and physical function: Self-report measures and physical performance tests. Self-report outcome measures evaluate the individual's perceived level of pain and physical function on selected items using standardized questions (Stratford, Kennedy, Pagura & Gollish, 2003). Physical performance tests use standardized environment, test and scoring procedures to measure an individual's ability to execute a physical activity, such as walking (Finch, Brooks, Stratford & Mayo, 2002). Physical performance tests are often used in clinical practice and research to assess aspects of physical function (Bean et al., 2002; Harada, Chiu & Stewart, 1999). In MSK research no gold standard measurement exists for lower limb pain and physical function (Pua, Cowan, Wrigley & Bennell, 2009). The dilemma is that, in individuals with KOA, self-report instruments and physical performance tests have only low to moderate correlation between assessment methods (Stratford et al., 2003; Stratford & Kennedy, 2006). It has been proposed that self-report measures assess different aspects of function than do performance tests (Stratford et al., 2003; Stratford & Kennedy, 2006). The self-report measure may provide information about the individual

experience associated with performing a task while a physical performance test may reveal information about the ability to complete a task (Stratford & Kennedy, 2006). Both modes of assessment appear necessary to achieve a more representative estimate of an individual's functional status (Beattie, 2001; Stratford et al., 2003; Stratford & Kennedy, 2006). A number of self-report and physical performance measures are available. For the purposes of this study, only the two most frequently used questionnaires for each of pain, physical exertion and function and common performance tests are reviewed.

Two commonly used self-report outcome measures of pain used in KOA samples

The Numeric Pain Rating Scale (NPRS) is a single item questionnaire measuring current pain on a whole number scale from 0 "no pain" to 10 "worst possible pain". Studies have used the NPRS to assess self-reported pain in a spectrum of chronic lower limb orthopedic conditions (Farrar, Young, LaMoreaux, Werth & Poole, 2001). It has been shown that a minimally clinically important difference of at least two scale points (i.e., approximately 30%) on the NPRS was shown to be sufficient to measure demonstrable change in individual pain intensity in OA samples (Farrar et al., 2001; Salaffi, Stancati, Silvestri, Ciapetti & Grassi, 2004). The NPRS has shown moderate to substantial reliability (Landis & Koch, 1977), validity and responsiveness in studies of community-dwelling individuals with KOA undergoing rehabilitation interventions (Halket, Stratford, Kennedy, Woodhouse & Spadoni, 2008; Stratford & Spadoni, 2001; Veenhof, et al., 2006).

Another pain scale, the Visual Analog Scale (VAS) is an instrument using a line 100 mm in length, anchored by words indicating "no pain" on the left-hand end and "worst pain imaginable" on the right-hand end. The assessor measures, using a ruler in mm, the distance from the left-hand end of the scale to the point the subject marks that represents his/her perception of his/her current pain (Price, Bush, Long & Harkins, 1994). The VAS and NPRS are highly correlated (r = 0.94) with one another due to the similarities of the two scales (Williamson & Hoggart, 2005).

Two commonly used self-report outcome measures of physical exertion in KOA samples

A self-report outcome measure widely accepted as a means of estimating physical exertion and intensity during exercise and ambulation in healthy and diseased samples is the Borg Rating of Perceived Exertion (RPE) scale (Borg, 1998; Stratford et al., 2003). The Borg RPE scale measures current perception of exertion on a whole number scale from 6 "no exertion at all" to 20 "maximal exertion" (Borg, 1998). Test-retest reliability of the Borg RPE scale has been shown to reliably estimate the rating of perceived exertion during aerobic exercise, with measures of intraclass correlation coefficient (ICC) ranging from 0.75 to 0.82 for treadmill exercise (Lamb, Eston & Corns, 1999).

The fatigue VAS is another self-report outcome measure used in the KOA literature which aims to capture the current status of fatigue severity or intensity (Hewlett, Dures & Almeida, 2011; Murphy, Lyden, Phillips, Clauw & Williams, 2011). The fatigue VAS comprises a 100mm horizontal line, anchored by two statements representing extremes on a single fatigue continuum of severity or intensity (e.g. "not at all tired" to

"very tired" or "no fatigue" to "total exhaustion") (Hewlett et al., 2011). The fatigue VAS is scored in the same manner as the pain VAS. The fatigue VAS has been used in studies evaluating exercise interventions in KOA samples (Fransen, Margiotta, Crosbie & Edmonds, 1997; Yip, Sit, Wong, Chong & Chung, 2008).

Two commonly used self-report outcome measures of physical function in KOA samples

Condition-specific self-report measures of pain and physical function are widely used in samples of subjects with KOA (McConnell, Kolopack & Davis, 2001; Pua et al., 2009; Veenhof et al., 2006). The most common is the 24-item WOMAC Osteoarthritis Likert version, a condition-specific (hip or knee OA) questionnaire. There are three subscales: pain (five items, maximum score of 20), stiffness (two items, maximum score of 8) and physical function (17 items, maximum score of 68). The WOMAC applies a 5-point response scale ranging from 0 ("no symptoms") to 4 ("extreme symptoms"), with lower scores representing less pain and stiffness and greater levels of functional status (Bellamy, Buchanan, Goldsmith, Campbell & Stitt, 1988). In a study of arthroscopically assessed individuals with KOA, test-retest reliability of the WOMAC was 0.74, 0.58 and 0.92 (ICC) for pain, stiffness and physical function, respectively (Guyatt, Walter & Norman, 1987). The WOMAC demonstrated good construct validity correlating with the VAS pain scale ($r = 0.40$ to 0.70) and Short Form-36 (SF-36) physical function subscale ($r > 0.70$) (Veenhof, et al., 2006). The WOMAC has been tested in a sample with lower limb OA undergoing an exercise rehabilitation intervention and effects of larger than 12%

of baseline score (6% of maximal score) can be attained and detected as minimally clinically important change (Angst, Aeschlimann & Stucki, 2001).

The Knee Osteoarthritis Outcome Score (KOOS), a 42-item knee survey, is intended to be used for knee injury resulting from OA and assesses the individual's opinion about his/her knee and associated impairments (Roos & Toksvig-Larsen, 2003). The KOOS consists of five subscales scored separately: pain (nine items), other symptoms (seven items), function in ADLs (17 items), function in sport and recreation (five items) and knee related QoL (four items). Higher scores on the KOOS indicate better performance. The KOOS sport and recreation and QoL subscales have been shown to be more sensitive and discriminative than the three subscales of the WOMAC when studied in individuals with signs of KOA (Roos, Roos & Lohmander, 1999). Furthermore, in individuals with KOA following TKA surgery, the KOOS has shown moderate to substantial (Landis & Koch, 1981) test-retest reliability (ICC > 0.75) and high construct validity correlating with the SF-36 (bodily pain versus pain r = 0.62; physical function versus ADLs r = 0.48) and the WOMAC physical function subscale (r > 0.70) (Roos & Toksvig-Larsen, 2003; Veenhof et al., 2006). The questions regarding pain, stiffness and function from the WOMAC were included in their complete form in the KOOS questionnaire, thus WOMAC scores can be calculated from the KOOS' pain, symptoms and ADL scores (Roos et al., 1998).

Two commonly used physical performance tests in KOA samples

A widely used physical performance test in a spectrum of lower limb orthopaedic conditions, including KOA, is the Six-Minute Walk Test (SMWT). The SMWT assesses

distance travelled and gait speed over a six minute duration (Farrar et al., 2001; Halket et al., 2008; Kennedy, Stratford, Wessel, Gollish & Penney, 2005; Steffen, Hacker & Mollinger, 2002). The SMWT measures an individual's level of functional mobility and sub-maximal aerobic capacity, taking into account any limitations imposed by major body systems, such as the MSK system (Harada et al., 1999). The SMWT has demonstrated substantial reliability (Landis & Koch, 1977) for the time component of the test with an ICC of 0.94 and standard error of measurement (SEM) of 26.29 m in a sample of knee and hip OA subjects who subsequently underwent total knee or hip arthroplasty surgery (Kennedy et al., 2005). The SMWT has shown moderate factorial validity of performance-specific assessments of function (Stratford, Kennedy & Woodhouse, 2006). Therefore, the SMWT has shown moderate to substantial reliability (Landis & Koch, 1977) and psychometric measures in studies of subjects with KOA (Halket et al., 2008; Stratford & Spadoni, 2001; Veenhof et al., 2006).

The Self-Paced Walk Test (SPWT) evaluates walking performance as an indicator of functional activity in KOA samples (Finch et al., 2002). The subject is timed as he/she is required to walk 2 circuits over a 240 m indoor course, excluding the time for turning (Kennedy et al., 2005). The SPWT demonstrated high reliability and SEM for the timed component of the test (ICC 0.91 and SEM 1.73 s) in a sample of individuals with KOA awaiting TKA surgery (Halket et al., 2008). The SPWT also has substantial content validity (r = 0.60 to 0.93) correlating with the three walk items of the Lower Extremity Functional Scale (Stratford et al., 2003). Both the SPWT and the SMWT have moderate to substantial reliability and psychometric measurements.

Problem Statement

While the evidence suggests that asymmetry of some aspects of gait arise in individuals with KOA and may progressively worsen in parallel to the loss of function, a gap exists in the literature regarding the reliability of the gait SI measurement as well as its relationship to symptoms and functional impairment in KOA samples. In light of the possible use of the SI as an objective clinical gait measure, there is a need to better understand the occurrence and severity of asymmetry among ambulating individuals with unilateral KOA (Patterson et al., 2008). A reliable tool may provide clinicians with a measure to test the success of therapeutic interventions focusing on correcting asymmetry (Al-Zahrani & Bakheit, 2002; Patterson et al., 2008; Draper, 2000; Viton et al., 2000).

Study Objectives

This project investigates key factors that are necessary to clarify before gait symmetry can be reliably and feasibly utilized in future studies. In a sample of community-dwelling individuals 40 years of age and older, with and without clinical unilateral KOA, defined by clinical examination findings developed by the American College of Rheumatology (Altman et al., 1986), the specific objectives of this study were the following:

1) To determine:
    i. the feasibility of recruitment and study protocol;
    ii. test-retest reliability of the primary outcome measures (i.e., spatiotemporal gait step length, step time, stance time SIs and limb-specific variables (i.e., for the affected and unaffected limb in the KOA group and dominant and

non-dominant limb in the healthy group). It was hypothesized that the test-retest reliability (two measurement administrations, separated by a five minute interval) of the primary outcome measures would be high (anticipated reliability of ICC $\geq$ 0.90) over the testing interval.

2) To estimate differences before and after an experimental walking intervention (SMWT and treadmill time):
    i. between the two groups' primary outcome measures. It was hypothesized that a more asymmetrical gait pattern, induced by the experimental walking intervention, would be present on the affected limb compared to the unaffected limb of individuals with KOA and a more symmetrical gait pattern between the non-dominant and dominant limbs of healthy individuals.
    ii. within the two groups' primary outcome measures with measures of pain (NPRS), and perceived exertion (Borg RPE scale). It was hypothesized that differences would increase between the affected and unaffected limbs in individuals with KOA compared to the non-dominant and dominant limbs of healthy individuals.
3) To estimate the relationship between the primary outcome measures with measures of pain, perceived exertion and physical function (i.e., SMWT and treadmill time) before and after an experimental walking intervention in a sample of individuals with KOA. It was hypothesized that spatiotemporal variables would

correlate highly with changes in pain, perceived exertion and physical function over the experimental walking condition.

4) To determine the sample size requirements needed for a future fully powered study.

Materials and Methods

Participants and Recruitment

Prior to completing data capture, this study was approved by the Canadian Memorial Chiropractic College (CMCC) Research Ethics Board (see Appendix B) and the Hamilton Health Sciences/Faculty of Health Sciences Research Ethics Board (see Appendices C and D). Study participants were men and women 40 years of age or older and able to speak and comprehend written English. The study was conducted in the Biomechanics Lab at CMCC in Toronto, Ontario. Participants were recruited by the primary investigator and research coordinator from the local community and CMCC campus clinics in the Greater Toronto Area via flyers (see Appendix E) posted in the college and by word of mouth. The participants were obtained from a convenience sample of volunteers who were screened by the primary investigator to establish suitability for inclusion in the study.

Criteria for inclusion in the healthy control group included the response "no" to the questions "do you suffer from knee pain within the past month?" in the screening and intake data collection forms (see Appendix F), in addition to the exclusion criteria outlined below. Criteria for inclusion in the KOA group were: knee pain on most days of the preceding month (identified as at least 'weekly' option chosen by the individual on the KOOS pain subscale question: "How often do you experience knee pain?"), ability to ambulate without the use of a walking aid, and diagnosis of KOA by a family physician or chiropractor and verified according to the American College of Rheumatology clinical criteria for the classification of idiopathic KOA (Altman et al., 1987) (see Figure 2).

1. Knee pain for most days of the preceding month +
2. At least three of the following six: A. Age > 50 years B. Morning stiffness < 30 minute duration C. Crepitus on active joint motion D. Bony tenderness of the knee on examination E. Bony enlargement of knee on examination F. No palpable warmth of the knee on examination

Figure 2: Criteria for the classification of clinical examination of KOA. Adapted from "Development of criteria for the classification and reporting of osteoarthritis: Classification of osteoarthritis of the knee," by R. Altman et al., 1986, Arthritis and Rheumatism, 29(8), p. 104

The information used to determine the presence or absence of criteria for classification of clinical KOA (see Figure 2) was obtained from the screening form for historical presence of knee pain, anthropometric data and related medical history (see Appendix F). The primary investigator palpated the subject's knee in order to determine the presence or absence of bony tenderness (based on subject's report with palpation), apparent enlargement and relative cutaneous warmth during the clinical examination. Each subject eligible for inclusion in the KOA group required criteria 1) and any combination of at least three of the six criteria listed in 2) A-F (see Figure 2), in addition to the exclusion criteria outlined below.

Potential participants in the KOA and control group were excluded if they had: self-reported medical conditions that could be exacerbated by walking on level-ground or a treadmill such as cerebrovascular, cardiovascular or neurological disease (i.e., stroke, central nervous system dysfunction, congestive heart failure, atherosclerosis, deep vein thrombosis or paralysis of the lower limb), any history of lower limb surgery, congenital

or developmental abnormalities of the lower limbs, or inflammatory arthritis of joints of the lower limb. Participants were also excluded if, within three months prior to the study, he/she reported any disabling episode of back or lower limb injury or disease other than KOA.

Eligible participants were informed of the study and asked if they wished to participate. Participants provided written informed consent (see Appendix G). At the time of participation each participant was monetarily reimbursed $60 for his/her time and travel expense.

Study Design

An observational cohort study design (see Figure 3) was chosen to best meet the study objectives. The project was divided into two principal components: 1) test-retest reliability; and 2) pre- to post-experimental walking intervention for measures of primary spatiotemporal outcomes including step length, step time and stance time SIs and limb-specific (affected and unaffected limb of individuals with KOA and dominant and non-dominant limb of healthy individuals) variables.

The KOOS knee survey was administered to each participant prior to gait analysis to assess most recent physical function as an indicator of severity of involvement in the KOA group. The primary outcome measures identified were collected on each occasion the participant walked on the GAITRite® mat electronic walkway system (CIR Systems Inc., version 3.9, Peekskill, NY). The NPRS and Borg RPE scale were administered to participants before and after each GAITRite® mat walk, as well as following the SMWT and treadmill walk (i.e., the experimental walking intervention).

For the test-retest study component, the participants were asked to traverse the GAITRite® mat, wearing their comfortable walking shoes, at their self-selected walking speed two times. There was a five minute rest interval between the two mat walks. For the pre- to post- experimental walking intervention component, upon completion of walking on the GAITRite mat® for two separate occasions (pre-experimental walking intervention), the participants completed the SMWT (the distance travelled in metres recorded), and treadmill walk (total treadmill walk time, in minutes, recorded) which served to physically exert the participants and provide measures of physical function. Participants then walked on the GAITRite® mat for the final time (post-experimental walking intervention).

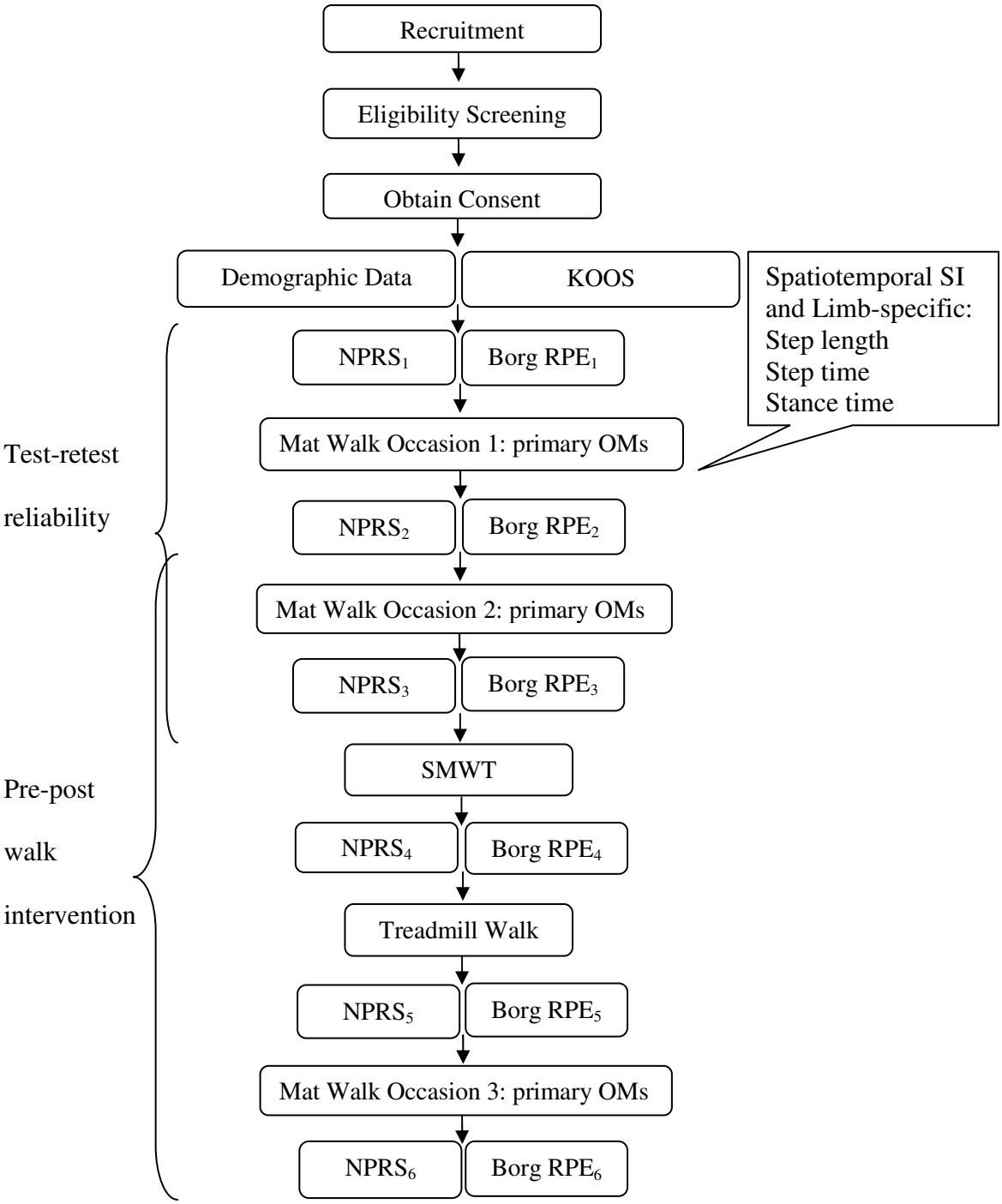


Figure 3: Study design. KOOS = Knee Osteoarthritis Outcome Score; NPRS = Numeric Pain Rating Scale; Borg RPE = Borg Rating of Perceived Exertion; OMs = outcome measures; SMWT = Six-Minute Walk Test.

Spatiotemporal Gait Measures and Analyses

Spatiotemporal gait variables were collected to characterize the different movement strategies implemented by participants while performing the functional task of walking. All participants were asked to wear their own comfortable flat-sole walking shoes and to ambulate at a self-paced speed on the GAITRite® mat. The GAITRite® is a carpeted sensor walkway system utilized to measure both spatial and temporal variables from foot-fall pressure as the participant walks over the carpet. The active area of the GAITRite® mat is approximately 6.09 m long and 0.61 m wide (GAITRite® Electronic Walkway Technical Reference, 2012). Each mat walk occasion started and ended approximately two metres from the walkway so that approximately two steps accounted for start-up acceleration and deceleration after passing the active sensor area. The GAITRite® mat sampling rate was 120 Hz in the present study with a spatial resolution of 1.27 centimetres (cm) and temporal accuracy of ± 8 milliseconds (ms) (GAITRite® Electronic Walkway Technical Reference, 2012). The GAITRite® electronic walkway system identifies a single two-dimensional footprint quadrilateral, which consists of three trapezoid sections with sensors indicating the heel, mid-foot and forefoot areas (see Figure 4) (Shores, 1980). The sensors making up each trapezoid section are isolated by the GAITRite® system to perform appropriate calculations of several spatiotemporal variables. Each spatiotemporal variable captured in this study represents the average value of respective limbs (i.e. coded footprints identified the left (black) and right (white) sides, see Appendix H) based on the total number of individual steps collected on each occasion the participant walked on the mat. Heel contact was verified through

observation, by the primary investigator, as the subject walked and by viewing the pictorial of complete bilateral footfalls on the GAITRite® output data report (see Appendix H) following each mat walk. The GAITRite® system calculates the heel centroid (see Figure 4) by averaging each sensor making up the heel trapezoid section. Averaging the sensors that make up the heel section effects the spatial resolution by canceling out the noise, generating a more accurate value of the heel centroid for each footfall.

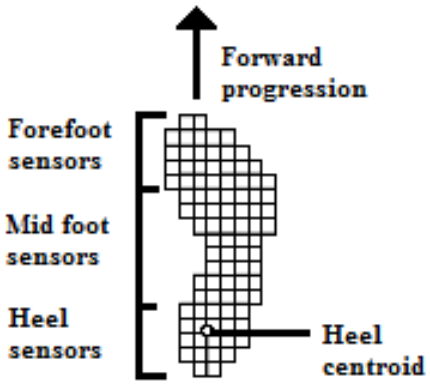


Figure 4: Footprint quadrilateral identifying heel, mid-foot and forefoot sensor trapezoid sections. From GAITRite® Electronic Walkway Technical Reference, p. 29. Copyright 2012 by CIR Systems Inc. Adapted with permission.

The variables of primary interest in this study were step length, step time and stance time, which are defined in Table 1 and depicted in Figures 5 and 6. These three variables were chosen as primary outcome measures based on the recommendations of Stanic et al. (1977) on the standardization of reporting kinematics. These authors suggested that step length, step time and stance time represent the minimum number of spatiotemporal variables necessary for quantitative gait evaluation (Stanic et al., 1977). It was also suggested by these authors that inter-limb symmetry of these three

spatiotemporal variables are the most characteristic property of able-bodied human gait (Stanic et al., 1977). Step length, step time and stance time variables have shown high test-retest reliability (ICC ranging from 0.94 to 0.97) over two consecutive measurements one week apart in a sample of healthy adults walking at their preferred walking speed (van Uden & Bresser, 2004). Studies investigating gait characteristics in healthy and diseased samples, including KOA, suggest that these variables are clinically important (Al-Zahrani & Bakheit, 2002; Bejek et al., 2006; Debi et al., 2009; Lafuente et al., 2000; Levinger, Webster, & Feller, 2008; Zeni & Higginson, 2009).

The GAITRite® system has been shown to be a valid tool for measuring both individual step and averaged spatiotemporal gait parameters in a sample of 10 subjects who had undergone TKA (Webster, Wittwer & Feller, 2005). The spatiotemporal gait variable values collected in this study were calculated by the GAITRite® walkway system as the overall average of multiple steps collected during a single GAITRite® mat walk. Individual footfalls for each mat walk were collected, however, these values were not included in the data analysis of the current study.

Table 1

Spatiotemporal Gait Variables of Interest in this Study

Spatial Variables	Units	Measured
Step length	m	from the heel centre (centroid of the heel quadrilateral) of the current footprint to the heel centre of the previous footprint on the opposite foot, along the line of progression
Temporal Variables	**Units**	**Measured**
Step time	s	as the time elapsed from first contact (first sensor activated in the heel quadrilateral) of one foot to first contact of the opposite foot
Stance time	s	as the time elapsed between the first contact and the last contact (last sensor activated in the toe quadrilateral) of two consecutive footfalls on the same foot

From GAITRite® Electronic Walkway Technical Reference. Copyright 2012 by CIR Systems Inc. Adapted with permission.

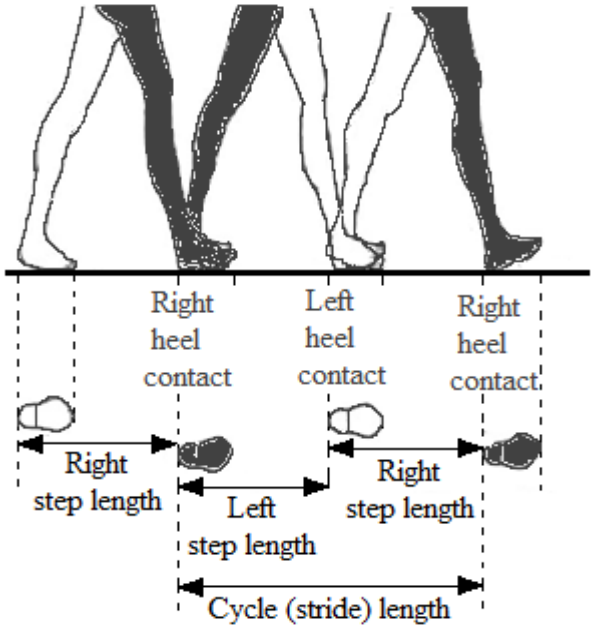


Figure 5: Step length. Black limb = right; white limb = left. Adapted from "Human Walking," by V. Inman, H. Ralston, and F. Todd, 1981, p. 26.

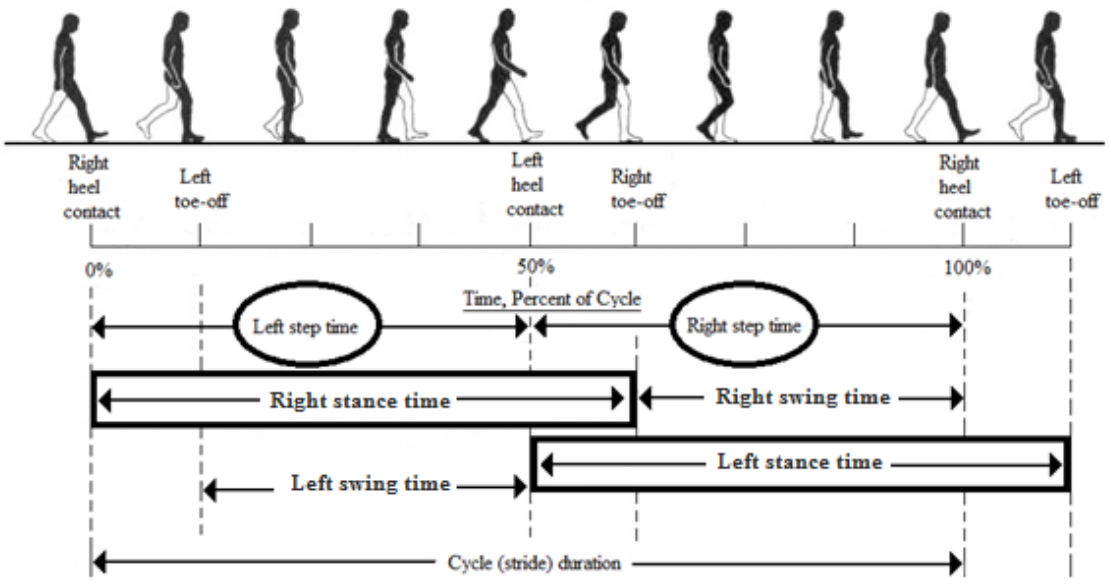


Figure 6: Step time and stance time. Black limb = right; white limb = left. From GAITRite® Electronic Walkway Technical Reference, p. 35. Copyright 2012 by CIR Systems Inc. Adapted with permission.

The primary outcome measures including step length, step time and stance time mean values were measured for the affected and unaffected limb for the KOA group and dominant and non-dominant limb for the healthy group. The participant identified the appropriate limb (left and right) as affected and unaffected, in the KOA group, or dominant and non-dominant, in the healthy group. The primary investigator verified the appropriate limb and matched the values of the appropriate coded footprint from the GAITRite® output report to the limb identified by the participant in order to ensure proper allocation for data analysis.

The SI was calculated using the following equation (Shorter et al., 2008):

$$SI\ (\%) = [(V_{A\ or\ ND} - V_{UN\ or\ D})/(0.5\ (V_{A\ or\ ND} + V_{UN\ or\ D}))] \times 100$$

Where $V_{A\ or\ ND}$ is the primary outcome measure recorded for the affected or non-dominant limb and $V_{UN\ or\ D}$ for the unaffected or dominant limb.

A SI value of zero represents perfectly symmetrical gait (Kim & Eng, 2003; Robinson et al., 1987; Teichtahl et al., 2009). A positive SI indicates that the gait variable was asymmetric with the larger magnitude on the affected or non-dominant limb, while a negative SI denotes a larger magnitude on the unaffected or dominant limb (Herzog et al., 1989; Patterson et al., 2008; Robinson et al., 1987).

Clinical Outcome Measures

There are two types of instruments used in this study: self-report outcome measures and physical performance tests. The rationale for the chosen self-report outcomes measures and physical performance tests are described in greater detail in the following sections.

Self-report outcome measure of pain – Numeric Pain Rating Scale (NPRS)

The 11-point NPRS questionnaire (see Appendix I) self-report outcome measure of pain was chosen in this study since the literature indicates that the NPRS is easier to score, using whole numbers' and does not require a ruler for measurement, avoiding measurement error associated with the VAS (Ferraz et al., 1990; Joyce, Zutshi, Hrubes & Mason, 1975; Williamson & Hoggart, 2005). The NPRS is categorical and requires an individual to choose a whole number, a possible disadvantage of this scale is that a single point change from 7 to 8 may represent a greater subjective increase in pain intensity than a change from 1 to 2 (Hughes, 2008). It has been shown, however, that a difference of at least two scale points is sufficient to measure demonstrable change in pain intensity (Farrar et al., 2001; Salaffi et al., 2004). The NPRS was administered on paper to participants before and after each GAITRite® mat walk, as well as each experimental walking intervention to measure the participants' pain level at the time of each test, to establish any change in pain over the course of the study.

Self-report outcome measure of physical exertion – Borg Rating of Perceived Exertion (RPE) Scale

The 15-point Borg RPE scale (see Appendix I) self-report outcome measure of physical exertion was chosen over the fatigue VAS since the reliability of the fatigue VAS in a KOA sample has yet to be determined and response options for the fatigue VAS are not standardized, whereas the Borg RPE scale is both reliable and standardized (Hewlett et al., 2011). The Borg RPE scale was administered on paper to participants before and after each GAITRite® mat walk, as well as the experimental walking

intervention. The Borg RPE scale was used in order to measure participants' perceived exertion rating over the course of the study.

Self-report outcome measure of physical function – Knee Osteoarthritis Outcome Score (KOOS)

The 42-item KOOS knee survey (see Appendix I) consists of five subscales: pain (nine items), other symptoms (seven items), function in ADLs (17 items), function in sport and recreation (five items) and knee related QoL (four items). A Likert scale is used and all items have five possible answer options scored from 0 (indicating no knee problems) to 4 (indicating extreme knee problems). An aggregate score is not calculated from the KOOS, instead the authors of the KOOS recommend that each subscale be analyzed and interpreted separately (Roos et al., 1998). Scores are then transformed to a scale from 0 to 100, with zero indicating extreme knee problems and 100 representing no knee problems (Roos et al., 1998). This transformed score is calculated as the sum of the total score of each subscale divided by the possible maximum score of the scale (i.e., 100 – [(actual raw score x 100)/possible raw score range]) (Roos et al., 1998).

The KOOS was chosen in this study because, unlike the WOMAC, the KOOS is easily accessible online, there is no cost to the investigator for its use and the KOOS' pain, symptoms and ADL scores can be converted to WOMAC scores. Hence, the KOOS is a practical alternative to the WOMAC for the purposes of this study. The KOOS was administered to assess physical function as an indicator of severity of KOA in this sample of participants. In accordance with instructions provided by KOOS developers, the raw scores from the pain (items five to nine), symptoms (items six to seven) and ADL (items

one to 17) subscales were used to convert these response items to the pain, stiffness and function WOMAC scores, respectively. Participant's responses for each item of the KOOS subscale and WOMAC scores were included for descriptive purposes in this study.

Physical performance tests – Six-Minute Walk Test (SMWT) and treadmill walk time

For evaluation of physical performance the SMWT was chosen over the SPWT since the former has both speed and endurance components that provide additional information for researchers and clinicians regarding aspects of physical function in individuals with KOA (Kennedy et al., 2005). For the SMWT, participants were instructed to cover as much distance (measured in metres) as possible in six minutes, while walking at their own pace back and forth, along a measured indoor level-ground corridor. Standardized prompts were given to participants when four and two minutes remained in the test to ensure consistency with prior studies (Demers, McKelvie, Negassa & Yusuf, 2001; Du, Newton, Salamonson, Carrieri-Kohlman & Davidson, 2009). The following standardized prompts were used: "You have four (or two) minutes remaining", "you are doing well", "try to cover as much distance as you can in the time remaining" (Stevens et al., 1999).

Treadmill walk time was included in this study to assess any change in gait or symptoms (as a measure of physical function), as well as a means of increasing physical exertion in order to evaluate changes in measured outcomes (spatiotemporal SI and limb-specific variables, pain and perceived exertion) before and after the experimental walking

intervention (combined SMWT and treadmill walk time). Following the SMWT, the participants were asked to walk on the treadmill to tolerance or to a cumulative total of 60 minutes combined with the SMWT. Based on the study by Waters et al. (1983), participants were asked to walk at a targeted normal distance and interval of 1.21 metres per second (m/s) treadmill speed initially, with the option to elect an increased or reduced pace or to terminate treadmill walking based on their tolerance and perception of knee pain or discomfort. Prompts were given to each participant prior to commencement of treadmill walking and included: "Walk at a speed you can tolerate, with the goal of reaching a speed of 1.2 m/s", "you have the option to increase or decrease the treadmill speed or terminate treadmill walking at any time", "treadmill walk time will be terminated when you have reached a total of 60 minutes of walking". The handle bars of the treadmill were utilized by participants for safety and were equipped with a heart rate monitor. The participants' heart rate was measured before and after treadmill walking. The total treadmill time (in minutes) for each participant was recorded.

Test-retest Interval

Studies evaluating non-surgically managed individuals with KOA chose a test-retest interval of anywhere from two minutes (Piva, Fitzgerald, Irrgang, Bouzubar & Starz, 2004) to at least 24 hours over the course of one week (Birmingham, Hunt, Jones, Jenkyn & Giffin, 2007; Faik et al., 2008). Since there does not appear to be a typical stable test-retest interval in the literature evaluating non-surgically managed KOA samples, a five minute interval between the two test administrations was arbitrarily chosen in this study.

Statistical Analyses

The Statistical Package for the Social Sciences (SPSS) for Windows Version 17.0 was used for statistical analyses. Since the purpose of this preliminary study was to inform a future fully powered study, statistical results were expressed as parameter estimates with associated 95% confidence intervals (CIs) for each research question.

Descriptive measures

Descriptive measures (mean and standard deviation (SD)) of participant characteristics including age, mass, height, body mass index (BMI), KOOS and WOMAC subscales were included to provide details on the characteristics of the study sample. These measures were tested for normality using the Kolmogorov-Smirnov test.

Descriptive measures (mean and SD) of spatiotemporal gait SIs and limb-specific variables (step length, step time and stance time primary outcome measures) and gait speed on each of the three test occasions were included to further characterize the groups gait over the course of the study protocol. As an indicator of physical function the mean and SD of the SMWT distance and treadmill walk time were included to characterize the two groups.

Test-retest reliability

One of the purposes of this study was to provide parameter estimates of the test-retest reliability (two test administrations) for spatiotemporal gait SIs and limb-specific variables in individuals with KOA and healthy controls. Test-retest reliability refers to the consistency, dependability and repeatability of a test or measurement scores or variables over repeated administrations of a test (Pagano, 2001; Weir, 2005) while trying to keep

all testing conditions the same as possible on each occasion (Portney & Watkins, 2009). A reliable test demonstrates similar scores across occasions thus implying that the instrument has the capability to assess the same attribute, variable or condition repeatedly (Beattie, 2001).

Common statistical methods used to determine reliability include determining the relative reliability coefficient, intraclass correlation coefficient (ICC); and the absolute reliability coefficient, standard error of measurement (SEM) (Shrout & Fleiss, 1979; Stratford, 2004). The ICC is a measure of relative reliability or agreement scores and is defined by the ratio of true variability to total variability (Streiner & Norman, 2008). True variability is the extent to which subjects average scores differ (Finch et al., 2002; Weir, 2005). Total variability is the sum of between-subject (δ^2_s), occasion (δ^2_o), and residual error (δ^2_e) (Streiner & Norman, 2008; Weir, 2005). Measurement error is further defined as the extent to which repeated measures within a subject differ (Finch et al., 2002).

The ICC (2,1) was calculated in this study since a two-way random effects model repeated measures analysis of variance (ANOVA) and scores in the analysis were from single scores from each subject for each trial. The ICC (2,1) was used to generate the variance values from subjects ($\delta^2_{s)}$, occasions (δ^2_o) and error ($\delta^2_{e)}$ (Shrout and Fleiss, 1979). The ICC (2, 1) determined the relative test-retest reliability of step length, step time and stance time SIs and limb-specific variables on each of two test occasions. The test-retest reliability coefficient was calculated using the following formula (Streiner & Norman, 2008):

$$ICC\ (2,1) = \delta^2_s/(\delta^2_s + \delta^2_o + \delta^2_e)$$

The ICC value ranges from 0.00 to 1.00. An ICC value closer to 1.00 indicates stronger reliability than a value closer to 0.00. To interpret the strength of agreement, the benchmark guidelines suggested by Fleiss (1981) were used: ICC < 0.40 poor, 0.40-0.75 intermediate to good, > 0.75 excellent. In this study the expected test-retest reliability ICC value of ≥ 0.90 was chosen as an acceptable reliability value to estimate the proportion of variance in a set of scores that is attributable to the true score variance (Weir, 2005). The chosen anticipated test-reliability ICC value of ≥ 0.90 was based on the recommendation by Portney & Watkins (2009) that clinical measurements with reliability coefficients equal to or exceeding 0.90 enhances the likelihood that the measurement are also reasonably valid. The upper and lower bound of the 95% confidence interval (CI) were also calculated. The ICC was presented with CIs as it is only a point estimate based on a selected sample (Eliasziw, Young, Woodbury & Fryday-Field, 1994). The CI covers the range of values that are likely to include the true population value (Eliasziw et al., 1994).

The SEM is a reliability index that indicates the amount a score can vary on repeated measurement and is used to express aspects of response stability or consistency of scores, which is an important feature of reliability assessment (Portney & Watkins, 2009; Stratford, 2004). One SEM is associated with a 68% CI that an individual's score can range between two values and the inconsistency is due to measurement error; 1.65 SEM is associated with a 90% CI and 1.96 SEM is associated with 95% CI (Stratford, 2004). The SEM was determined by calculating the square root of the mean square error term from the repeated measures ANOVA table (Stratford, 2004; Lexell & Downham, 2005). A score smaller than the SEM value is considered measurement error and does not

reflect true change (Portney & Watkins, 2009). The 95% CI associated with the SEM^2 was determined using the formula from Stratford & Goldsmith (1997):

$$SSE/\chi^2_{\alpha/2,df};\ SSE/\chi^2_{1-\alpha/2,df}$$

SSE refers to the sum of squares error. The chi-square (χ^2) value with alpha (α) = 0.05 and degrees of freedom (df) associated with the SSE of n-1 was taken from the critical value table found in statistical textbooks (Rosner, 2006).

Taking the square root of the CI values yields the 95% CI for the SEM (Stratford & Goldsmith, 1997).

The reliability values were pooled for the KOA affected and healthy non-dominant limb data as well as pooled for the KOA unaffected and healthy dominant limb data for each step length, step time and stance time SI and limb-specific variable collected in this study.

Pre- to post-experimental walking intervention

Estimate of differences between groups

In order to estimate whether observed differences exist between the two groups for step length, step time and stance time SIs and limb-specific variables over the experimental walking intervention, the following formula was used to determine parameter estimates with 95% CIs (Hazelrigg, 2009):

$$X(bar)_1 - X(bar)_2 \pm t_{cv}\ x\ \sqrt{s_1^{\,2}/n_1 + s_2^{\,2}/n_2}$$

$X(bar)_1$ and $X(bar)_2$ refer to the mean of the KOA and healthy group, respectively; s_1 and s_2 are the sample estimates of the mean difference of each group, respectively; t_{cv} the two-tailed critical t value for n-2 degrees of freedom; and n per group.

Estimate of differences within groups

To estimate whether the step length, step time and stance time SIs and limb-specific variables differ along with pain (NPRS) and perceived exertion (Borg RPE Scale) rating within the groups over the experimental walking intervention, the following equation was used to determine parameter estimates with 95% CIs (Hurlburt, 1998):

$$X(bar)_d \pm t_{cv} \times s_d/\sqrt{n}$$

$X(bar)_d$ refers to the mean of the group differences; s_d the sample estimate of the standard deviation of the differences, t_{cv} the two-tailed critical t value for n-1 degrees of freedom; and n per group.

The decision rules used to determine differences between and within the groups are based on whether the 95% CI includes zero or not. If the 95% CI includes zero than no observed differences are suggested, however, if it does not include zero than observed differences are suggested.

Correlation between outcomes in the KOA group

To test whether correlations exist in individuals with KOA before and after the experimental walking intervention for step length, step time and stance time SIs and limb-specific variables in direct proportion to change in pain, perceived exertion rating and physical function (SMWT distance and treadmill time), the Pearson correlation coefficients (r) were calculated (pairwise two-tailed test) with associated 95% CI. Pearson's r is a measure of the strength and direction of linear relationships, ranging from -1.00 to +1.00 (Cohen & Brooke Lea, 2004). A negative value of r indicates a negative correlation (i.e., as one variable increases, the other variable decreases) and a positive value of r indicates a positive correlation (i.e., as one variable increases, the other variable

increases), while a value of 0 indicates no relationship (Cohen & Brooke Lea, 2004). The strength of the relationship is indicated by how far r is above and below zero (Cohen & Brooke Lea, 2004). For linear correlations, the magnitude of the relationship was interpreted according to guidelines developed by Bartz (1999): $r < 0.20$ very low, 0.20-0.40 low, 0.40-0.60 moderate, 0.60-0.80 strong, > 0.80 very high.

Sample size estimation for a future fully powered study

Sample sizes for each research question were estimated to inform a fully powered study.

Test-retest reliability

For the test-retest reliability component the estimate of the sample size for the reliability was based on the following assumptions: null hypothesis of reliability less than or equal to 0.80, alternative hypothesis of greater than 0.80, and an expected reliability of 0.90 was proposed with one-tailed Type I error 0.05 level of significance and a Type II error of 0.20. The anticipated reliability of 0.90 was chosen based on recommendations that clinical measurements with reliability coefficients equal to or greater than 0.90 enhances the likelihood that the measurement is also reasonably valid (Portney & Watkins, 2009). Applying these assumptions to the table provided by Walter et al. (1998), the minimum total sample size required was determined for step length, step time and stance time SIs and limb-specific variables.

Pre- to post-experimental walking intervention

Estimate of differences between groups

For differences between the affected and unaffected limb of the individuals with KOA and non-dominant and dominant limb of healthy individuals, the sample size estimates were determined based on the assumptions of a two-tailed test of significance at a Type I error probability of 0.05, and a Type II error of 0.20 probability level. The following formula was used to estimate the pre- and post-experimental walking intervention sample sizes for the groups' step length, step time and stance time SIs (six sample size estimates) and limb-specific variables (12 sample size estimates) for a total of 18 sample size estimates:

$$n = 2[(Z_\alpha + Z_\beta)\, \sigma/\Delta]^2$$

Z_α refers to the Z-value for two-tailed $\alpha_{0.05} = 1.96$, Z_β refers to the Z-value for $\beta_{0.20} = 0.84$, σ refers to the pooled standard deviation (equal variances assumed), and Δ refers to the mean difference.

The n is the sample size per group, hence the value is multiplied by two in order to determine the total sample size estimate for a future study.

Estimate of differences within groups

Estimates of the sample size for differences within each groups' SIs and limb-specific variables (affected and unaffected limb in the KOA group and non-dominant and dominant limb in the healthy group) were determined. Based on the assumptions of a two-tailed test of significance at a Type I error probability of 0.05, and a Type II error of 0.20, the following formula was used to estimate the sample size in each group for step length, step time and stance time SIs (six sample size estimates) and limb-specific

variables (12 sample size estimates) as well as pain (one sample size estimate) and perceived exertion (two sample size estimates), for a total of 21 samples size estimates:

$$n = [(Z_\alpha + Z_\beta)\ \sigma\ /\Delta]^2$$

Z_α refers to the z-value for a two-tailed $\alpha_{0.05} = 1.96$, Z_β refers to the z-value for $\beta_{0.20} = 0.84$, σ refers to the standard deviation of the difference, and Δ refers to the mean difference.

Correlation between outcomes in the KOA group

The number of individuals with KOA needed to obtain a significant correlation was determined using the table provided by Machin and Campbell (1987) and applying the following assumptions: null hypothesis of correlation equal to 0, alternative hypothesis of greater than 0.80, an observed correlation of r = 0.60 with one-tailed Type I error of 0.005, Bonferroni correction applied due to multiple comparisons of interest, Type II error of 0.20. The minimum total sample size required for the correlation coefficient was determined for step length, step time and stance time SIs and limb-specific variables as well as pain, perceived exertion and physical function.

Results

Study Timeline

Upon approval from the Research Ethics Boards, the study began in February 2011. Recruitment was completed between March 2011 and August 2011. Data collection occurred between April 2011 and August 2011. Data analysis occurred between September 2011 and April 2012. Writing of the thesis began January 2012 and was completed November 2012. Figure 7 depicts the study timeline.

Year	Month	Ethics	Recruitment	Data Collection	Data Analysis	Writing
2011	February	°				
	March		°	°		
	April		°	°		
	May		°	°		
	June					
	July					
	August		°	°		
	September				°	
	October				°	
	November				°	
	December				°	
2012	January				°	°
	February	°			°	°
	March				°	°
	April				°	°
	May					°
	June					°
	July					°
	August					°
	September					°
	October					°
	November					°

Figure 7: Study timeline

Recruitment Flow

Ten participants were referred from the CMCC main campus clinic and six others heard about the study though word of mouth. Of the 16 potential participants who were approached by the primary investigator or the research coordinator, all 16 participants met inclusion and exclusion criteria, signed consent and completed data collection. The data of all 16 participants were included in this study.

Total Participant Test Protocol Duration

The total protocol test duration was a maximum of 90 minutes. The test duration varied depending on the amount of time each participant walked on the treadmill. The duration of the experimental walking intervention (combined SMWT and treadmill walk time) was capped at 60 minutes based on the protocol parameters chosen at the onset of the study. The maximum duration of the experimental walking intervention across participants was 46 minutes.

Descriptive Data

Demographic characteristics

Sixteen adults over the age of 40 years participated in this study, eight participants in each group (see Table 2). In the KOA group there were three men and five women and in the healthy control group there were four men and four women.

Table 2

Demographics and Anthropometrics of Study Participants

Characteristics		KOA (n = 8) Mean (SD)	Healthy (n = 8) Mean (SD)
Age (year)		59 (5)	57 (8)
Mass (kg)		87.8 (24.5)	71.5 (16.9)
Height (m)		1.66 (0.11)	1.62 (0.12)
BMI (kg/m^2)		31.2 (5.5)	27.1 (5.2)
KOOS	Pain	70.1 (12.5)	98.8 (1.5)
	Symptoms	71.4 (14.8)	95.7 (3.6)
	ADLs	74.2 (18.6)	99.2 (1.4)
	Sport & Rec	54.3 (25.4)	97.5 (4.6)
	QoL	52.5 (11.3)	99.2 (2.1)
WOMAC	Pain	4.8 (2.5)	0.3 (0.5)
	Stiffness	1.9 (1.7)	0.4 (0.5)
	Physical function	17.5 (12.7)	0.6 (1.1)
	Total	24.1 (15.6)	1.3 (1.4)
Gender, n	Men	3	4
	Women	5	4

Note. SD = standard deviation; BMI = body mass index; KOOS = Knee Osteoarthritis Outcome Score; ADLs = activities of daily living; Sport & Rec = sport and recreation; QoL = quality of life

Patient demographic and anthropometric data, per group, was normally distributed, based on the Kolmogorov-Smirnov test of normality for small sample sizes ($p > 0.05$). Values for self-reported outcome measures in the healthy groups' KOOS pain, ADL, QoL and sport and recreation subscales were not normally distributed. Also, in the KOA group the KOOS sport and recreation subscale was not normally distributed. Measures of physical function (i.e., SMWT and treadmill time) were normally distributed in both groups and descriptive characteristics are provided in Table 3.

Table 3

Descriptive Measures of Physical Function

	KOA (n = 8)	Healthy (n = 8)
Physical Function Measure	Mean (SD)	Mean (SD)
SMWT (m)	418.4 (70.1)	484.4 (41.7)
Treadmill time (min)	12.8 (11.2)	18.8 (13.3)

Note. SMWT = Six Minute Walk Test; m = metres; min = minutes; SD = standard deviation.

Spatiotemporal gait data

For each participant, a minimum of 7 and maximum of 11 steps were collected for a single mat walk on each of the three occasions data was collected, hence the number of steps varied per participant on each mat walk occasion.

Descriptive measures of the KOA and healthy groups' step length, step time and stance time SIs for each of the three occasions are provided in Table 4. Step length, step time and stance time limb-specific variables for the KOA and healthy groups on each of the three occasions are provided in Table 5. Gait speed for the KOA and healthy groups on each of the three test occasions are provided in Table 6.

Table 4

Group Descriptive SI (%) Variables for Each Test Occasion

	KOA (n = 8)	Healthy (n = 8)
Variable	SI (%)	SI (%)
Occasion One		
Step Length	-1.2 (6.1)	-0.7 (4.7)
Step Time	-0.3 (6.1)	1.5 (3.1)
Stance Time	-1.2 (3.1)	-1.4 (2.0)
Occasion Two		
Step Length	-0.6 (4.8)	-0.6 (4.5)
Step Time	-0.5 (3.7)	2.4 (3.0)
Stance Time	-1.6 (3.9)	-2.5 (2.5)
Occasion Three		
Step Length	-0.5 (6.6)	-2.6 (3.5)
Step Time	-1.0 (4.3)	0.8 (2.8)
Stance Time	0.2 (3.9)	-1.6 (2.1)

For the KOA group SIs over the three test occasions (see Table 4), mean step length SIs were negative suggesting an observational trend toward a larger magnitude on the unaffected limb compared to the affected limb. The mean step length SIs of the healthy group were negative suggesting an observational trend for larger magnitude on the dominant limb. For KOA step time SIs were negative suggesting a larger magnitude on the unaffected limb over the three occasions. The healthy group mean step time SIs were positive suggesting a larger magnitude on the non-dominant limb. For stance time SIs in the KOA group, the means for the first two occasions were negative suggesting a

larger magnitude on the unaffected limb. On the third occasion, however, KOA stance time SI was positive showing an observational trend toward a larger magnitude on the affected limb. For the healthy group SIs over the three test occasions (see Table 4), mean stance time SIs were found to be negative suggesting a larger magnitude on the dominant limb. The SI values for the healthy controls suggest a greater magnitude of asymmetry than individuals with KOA for step and stance time on the first two occasions and for step length and stance time on the third occasion. All other SI values suggest a greater magnitude of asymmetry in individuals with KOA compared to healthy controls.

Table 5

Group Descriptive Limb-specific Variables for Each Test Occasion

	KOA (n = 8)		Healthy (n = 8)	
Variable (unit)	A Limb	UN Limb	D Limb	ND Limb
Occasion One				
Step Length (m)	0.57 (0.1)	0.58 (0.1)	0.65 (0.1)	0.64 (0.1)
Step Time (s)	0.64 (0.1)	0.64 (0.1)	0.58 (0.1)	0.59 (0.1)
Stance Time (s)	0.85 (0.1)	0.86 (0.1)	0.75 (0.07)	0.74 (0.1)
Occasion Two				
Step Length (m)	0.59 (0.1)	0.60 (0.1)	0.65 (0.1)	0.63 (0.1)
Step Time (s)	0.62 (0.1)	0.63 (0.1)	0.57 (0.1)	0.58 (0.1)
Stance Time (s)	0.82 (0.1)	0.83 (0.1)	0.74 (0.1)	0.73 (0.1)
Occasion Three				
Step Length (m)	0.61 (0.1)	0.62 (0.1)	0.67 (0.1)	0.65 (0.1)
Step Time (s)	0.60 (0.1)	0.61 (0.1)	0.57 (0.1)	0.57 (0.1)
Stance Time (s)	0.79 (0.1)	0.78 (0.1)	0.73 (0.1)	0.71 (0.1)

Note. A = affected limb; UN = unaffected limb; D = dominant limb; ND = non-dominant limb; KOA five right and three left affected; healthy all eight right dominant

For limb-specific spatiotemporal gait measures over the three test occasions (see Table 5), individuals with KOA tended to have increased step length and time on the unaffected limb. The KOA group also tended to spend more time in stance on the unaffected limb for the first two test occasions, however, following the experimental walking intervention they tended to spend more time on the affected limb. Healthy individuals tended to increase step length and stance time on the dominant limb, while spending more time stepping with the non-dominant limb over the three test occasions.

Table 6

Gait Speed of KOA and Healthy Groups

	KOA			Healthy		
Variable (unit)	Occasion One	Occasion Two	Occasion Three	Occasion One	Occasion Two	Occasion Three
Gait speed (m/s)	0.90 (0.1)	0.96 (0.1)	1.02 (0.2)	1.08 (0.1)	1.10 (0.2)	1.13 (0.1)

In both groups, gait speed appeared to progressively increase over the three test occasions.

Test-Retest Reliability

The KOA and healthy groups reliability values were pooled together in this study.

Table 7

Reliability of the Spatiotemporal Gait SI (%) and Limb-specific (m or s) Variables of the Sample (n = 16)

Variables	Mean (SD) Trial 1	Mean (SD) Trial 2	ICC (95% CI)	SEM (95% CI)
Step Length SI (%)	-1.0 (5.2)	-0.6 (4.5)	0.85 (0.56, 0.95)	2.5 (1.9, 4.0)
Step Time SI (%)	0.6 (4.7)	0.9 (3.6)	0.87 (0.63, 0.95)	2.0 (1.5, 3.1)
Stance Time SI (%)	-1.3 (2.5)	-2.1 (3.2)	0.77 (0.37, 0.92)	1.7 (1.3, 2.7)
Step Length Affected or Non-Dominant Limb (m)	0.61 (0.1)	0.62 (0.1)	0.95 (0.85, 0.98)	2.6 (1.9, 4.0)
Step Length Unaffected or Dominant Limb (m)	0.62 (0.1)	0.63 (0.1)	0.94 (0.84, 0.98)	2.5 (1.8, 3.9)
Step Time Affected or Non-Dominant Limb (s)	0.61 (0.1)	0.60 (0.1)	0.95 (0.86, 0.98)	0.03 (0.02, 0.04)
Step Time Unaffected or Dominant Limb (s)	0.61 (0.1)	0.60 (0.1)	0.97 (0.88, 0.99)	0.03 (0.02, 0.04)

Table 7 Continued

Reliability of the Spatiotemporal Gait SI (%) and Limb-specific (m or s) Variables of the Sample (n = 16)

Variables	Mean (SD) Trial 1	Mean (SD) Trial 2	ICC (95% CI)	SEM (95% CI)
Stance Time Affected or Non-Dominant Limb (s)	0.80 (0.1)	0.78 (0.1)	0.96 (0.87, 0.99)	0.03 (0.02, 0.04)
Stance Time Unaffected or Dominant Limb (s)	0.81 (0.1)	0.79 (0.1)	0.97 (0.88, 0.99)	0.03 (0.02, 0.04)

Note. Intraclass Correlation Coefficients (ICC 2,1) with 95% confidence intervals (CI) in parentheses; SEM = standard error of measurement

Relative reliability

Reliability point estimate values for step length, step time and stance time symmetry indices (SIs) for the sample appear excellent, according to benchmark guidelines outlined by Fleiss (1981), showing an ICC (2,1) ranging from 0.77 to 0.85, however, demonstrating wide 95% CIs (see Table 7). Limb-specific measures performed more strongly (ICC ranging from 0.94 to 0.97) and the respective 95% CI widths were narrower.

Absolute reliability

The spatiotemporal gait SI variables SEM was smallest for stance time SI, followed by step time SI and the largest was for step length SI.

The absolute reliability values showed low SEM for step length of the unaffected or dominant limb compared to the affected or non-dominant limb. The 95% CI bands were narrower for step length of the unaffected or dominant limb compared to the affected or

non-dominant limb. Step and stance time of both limbs showed equally low SEM and 95% CI bands for both limbs of the group.

There is a lack of consistency in the literature as to the appropriate amount of time between test administrations required to ensure that the participants' true score is obtained. The findings in this reliability study component suggest that the test-retest interval of five minutes provided a relatively stable duration between test administrations.

Pre- to Post-Experimental Walking Intervention

Estimate of differences between groups

Table 8

Estimate of Differences Between Groups for Spatiotemporal Gait SI (%) and Limb-specific (m or s) Variables

Variables	Test Time	Mean (SD)		Mean Diff (95% CI)
		KOA	Healthy	
Step Length SI (%)	Pre	-0.9 (5.2)	-0.6 (4.2)	0.3 (-4. 8, 5.3)
	Post	-0.5 (6.6)	-2.6 (1.2)	-2.0 (-7.9, 3.8)
Step Time SI (%)	Pre	-0.4 (4.7)	1.9 (2.8)	2.3 (-1.9, 6.6)
	Post	-1.0 (4.3)	0.8 (2.8)	1.9 (-2.1, 5.8)
Stance Time SI (%)	Pre	-1.4 (3.1)	-2.0 (2.1)	-0.6 (-3.5, 2.3)
	Post	0.2 (3.9)	-1.6 (2.1)	-1.9 (-5.4, 1.6)
Step Length Affected or Non-dominant Limb (m)	Pre	0.59 (0.1)	0.65 (0.1)	0.06 (-0.0, 0.1)
	Post	0.61 (0.1)	0.65 (0.1)	0.04 (-0.0, 0.1)
Step Length Unaffected or Dominant Limb (m)	Pre	0.59 (0.1)	0.65 (0.1)	0.06 (-0.0, 0.1)
	Post	0.61 (0.1)	0.67 (0.1)	0.06 (-0.0, 0.1)
Step Time Affected or Non-dominant Limb (s)	Pre	0.63 (0.1)	0.59 (0.1)	-0.04 (-0.1, 0.0)
	Post	0.60 (0.1)	0.57 (0.1)	-0.03 (-0.1, 0.0)

Table 8 Continued

Estimate of Differences Between Groups for Spatiotemporal Gait SI (%) and Limb-specific (m or s) Variables

Variables	Test Time	Mean (SD)		Mean Diff (95% CI)
		KOA	Healthy	
Step Time Unaffected or Dominant Limb (s)	Pre	0.64 (0.1)	0.57 (0.1)	-0.07 (-0.1, 0.0)
	Post	0.61 (0.1)	0.57 (0.1)	-0.04 (-0.1, 0.0)
Stance Time Affected or Non-dominant Limb (s)	Pre	0.84 (0.1)	0.74 (0.1)	-0.10 (-0.2, 0.0)
	Post	0.79 (0.1)	0.71 (0.1)	-0.08 (-0.2, 0.0)
Stance Time Unaffected or Dominant Limb (s)	Pre	0.85 (0.1)	0.75 (0.1)	-0.10 (-0.2, 0.0)
	Post	0.78 (0.1)	0.73 (0.1)	-0.05 (-0.1, 0.0)

Note. SD = standard deviation; CI = confidence interval. Bolded values = observed differences suggested (i.e., CI do not include zero).

Based on the decision rules used to determine differences in parameter estimates between the KOA and healthy groups (i.e., if the 95% CI includes zero than no observed differences were suggested and if it does not include zero than observed differences were suggested), all three spatiotemporal gait SI variable 95% CIs contain zero (see Table 8) suggesting no observed differences before and after the experimental walking intervention. Based on the same decision rules, limb-specific spatiotemporal variable parameter estimates with associated 95% CIs also include zero (see Table 8), suggesting no observed differences between the two groups before and after the experimental walking intervention.

Estimate of differences within groups

Table 9

Differences Within the Group for Spatiotemporal Gait SI (%) and Limb-specific (m or s) Variables, Pain and Perceived Exertion

		KOA (n = 8)		Healthy (n = 8)	
Variables	Test Time	Mean (SD)	Mean Diff (95% CI)	Mean (SD)	Mean Diff (95% CI)
Step Length SI (%)	Pre-	-0.9 (5.2)	-0.4	-0.6 (4.2)	1.9
	Post-	-0.5 (6.6)	(-5.5, 4.7)	-2.5 (3.5)	(-1.1, 4.9)
Step Time SI (%)	Pre-	-0.4 (4.7)	0.6	1.9 (2.8)	1.1
	Post-	-1.0 (4.3)	(-2.4, 3.7)	0.8 (2.8)	(-1.7, 3.9)
Stance Time SI (%)	Pre-	-1.4 (3.1)	-1.6	-2.0 (2.1)	-0.4
	Post-	0.2 (3.9)	(-4.0, 0.8)	-1.6 (2.1)	(-2.4, 1.6)
Step Length Affected or Non-dominant Limb (m)	Pre-	0.59 (0.1)	-0.02	0.63 (0.1)	-0.02
	Post-	0.61 (0.1)	(-5.8, 0.4)	0.65 (0.1)	(-5.1, 1.8)
Step Length Unaffected or Dominant Limb (m)	Pre-	0.59 (0.1)	-0.02	0.65 (0.1)	-0.02
	Post-	0.61 (0.1)	(-5.4, 0.4)	0.67 (0.1)	(-4.8, 1.2)
Step Time Affected or Non-dominant Limb (s)	Pre-	0.63 (0.1)	0.03	0.59 (0.1)	0.02
	Post-	0.60 (0.1)	(0.0, 0.1)	0.57 (0.1)	(-0.0, 0.1)
Step Time Unaffected or Dominant Limb (s)	Pre-	0.64 (0.1)	0.03	0.58 (0.1)	0.02
	Post-	0.61 (0.1)	(-0.0, 0.1)	0.56 (0.1)	(-0.0, 0.1)
Stance Time Affected or Non-dominant Limb (s)	Pre-	0.84 (0.1)	0.05	0.74 (0.1)	0.03
	Post-	0.79 (0.1)	(0.0, 0.1)	0.71 (0.1)	(-0.0, 0.1)
Stance Time Unaffected or Dominant Limb (s)	Pre-	0.85 (0.1)	0.07	0.75 (0.1)	0.02
	Post-	0.78 (0.1)	(0.0, 0.1)	0.73 (0.1)	(-0.0, 0.1)
Pain Rating (NPRS)	Pre-	2.6 (2.8)	-1.7	0.0 (0.0)	N/A
	Post-	4.2 (3.2)	(-4.0, 0.7)	0.0 (0.0)	
Perceived Exertion Rating (Borg RPE Scale)	**Pre-**	**6.4 (0.8)**	**-7.4**	**6.2 (0.5)**	**-6.7**
	Post-	**13.9 (1.7)**	**(-8.5, -6.4)**	**13.0 (1.8)**	**(-8.0, -5.5)**

Note. SD = standard deviation; CI = confidence interval; NPRS = Numeric Pain Rating Scale; RPE = Rating of Perceived Exertion; N/A = Not applicable. Bolded values = observed differences suggested (i.e., CI do not include zero).

For differences within the KOA and healthy groups, the 95% CIs for all three spatiotemporal gait SI and limb-specific variables contain zero, suggesting that differences were not observed over the experimental walking intervention (see Table 9).

Pain rating in the KOA group was not observed to differ over the experimental walking intervention. Perceived exertion rating, however, was observed to differ in both groups over the experimental walking intervention (see Table 9).

Correlation between outcomes in the KOA group

The variables of interest in this study were step length, step time and stance time SIs and limb-specific variables relationship with pain, perceived exertion and physical function before and after the experimental walking intervention in individuals with KOA. Table 10 shows the Pearson r values with associated 95% CIs for all outcomes of interest (a total of 108 possible comparisons) over the course of the experimental walking intervention. The SIs and limb-specific variables correlating highly, $r > 0.75$ (Bartz, 1999), with outcomes of interest are bolded. Based on the analysis of within-group differences of individuals with KOA, no differences were suggested for SIs and limb-specific variables pre- and post-experimental walking condition. Therefore, graphical representations of Pearson correlations > 0.75 of pre-experimental walking condition SIs and limb-specific variables with outcome measures of pain and physical function are shown in Figures 8 to 11.

Table 10

Correlation Between Outcomes of Interest Over the Experimental Walking Intervention in the KOA Group

Variables	Test Time	Pain (NPRS) (95% CI) Pre	Pain (NPRS) (95% CI) Post	Perceived Exertion (Borg RPE) (95% CI) Pre	Perceived Exertion (Borg RPE) (95% CI) Post	Physical Function (SMWT) (95% CI)	Physical Function (Treadmill Time) (95% CI)
Step Length SI	Pre	0.13 (-54, 0.70)	-0.48 (-0.85, 0.21)	0.10 (-0.57, 0.69)	0.61 (-0.03, 0.90)	0.56 (-0.11, 0.88)	0.14 (-0.54, 0.71)
	Post	0.56 (-0.11, 0.88)	0.14 (-0.54, 0.71)	0.73 (0.19, 0.93)	**0.82 (0.39, 0.96)**	0.09 (-0.57, 0.68)	-0.12 (-0.70, 0.55)
Step Time SI	Pre	0.27 (-0.43, 0.77)	0.25 (-0.45, 0.76)	0.33 (-0.38, 0.79)	0.10 (-0.57, 0.69)	**-0.78 (-0.95, -0.30)**	**-0.79 (-0.95, -0.32)**
	Post	0.23 (-0.47, 0.75)	0.43 (-0.27, 0.83)	0.43 (-0.27, 0.83)	-0.10 (-0.69, 0.57)	-0.62 (-0.90, 0.02)	-0.48 (-0.85, 0.21)
Stance Time SI	Pre	-0.26 (-0.76, 0.44)	-0.28 (-0.77, 0.42)	0.03 (-0.61, 0.65)	0.26 (-0.44, 0.76)	0.54 (-0.14, 0.87)	0.32 (-0.39, 0.79)
	Post	-0.30 (-0.78, 0.41)	-0.02 (-0.64, 0.62)	0.54 (-0.14, 0.87)	0.64 (0.02, 0.90)	0.03 (-0.61, 0.65)	-0.28 (-0.77, 0.42)

Table 10 Continued

Correlation Between Outcomes of Interest Over the Experimental Walking Intervention in the KOA Group

Variables	Test Time	Pain (NPRS) (95% CI) Pre	Pain (NPRS) (95% CI) Post	Perceived Exertion (Borg RPE) (95% CI) Pre	Perceived Exertion (Borg RPE) (95% CI) Post	Physical Function (SMWT) (95% CI)	Physical Function (Treadmill Time) (95% CI)
Step Length Affected Limb	Pre	-0.45 (-0.84, 0.25)	-0.41 (-083, 0.30)	-0.21 (-0.74, 0.48)	0.05 (-0.60, 0.66)	**0.89 (0.59, 0.97)**	**0.85 (0.47, 0.96)**
	Post	-0.27 (-0.77, 0.43)	-0.36 (-0.81, 0.35)	-0.11 (-0.69, 0.56)	0.07 (-0.59, 0.67)	**0.88 (0.56, 0.97)**	**0.85 (0.47, 0.96)**
Step Length Unaffected Limb	Pre	-0.53 (-0.87, 0.15)	-0.25 (-0.76, 0.45)	-0.25 (-0.76, 0.45)	-0.16 (-0.72, 0.52)	**0.75 (0.23, 0.94)**	**0.87 (0.53, 0.97)**
	Post	-0.49 (-0.86, 0.20)	-0.42 (-0.83, 0.28)	-0.39 (-0.82, 0.32)	-0.23 (-0.75, 0.47)	**0.89 (0.59, 0.97)**	**0.93 (0.72, 0.98)**
Step Time Affected Limb	Pre	0.59 (-0.06, 0.89)	**0.76 (0.25, 0.94)**	0.66 (0.05, 0.91)	0.36 (-0.35, 0.81)	-0.13 (-0.70, 0.54)	0.11 (-0.56, 0.69)
	Post	0.29 (-0.42, 0.78)	0.69 (0.11, 0.92)	0.38 (-0.33, 0.81)	0.21 (-0.48. 0.74)	0.02 (-0.62, 0.64)	0.38 (-0.33, 0.81)
Step Time Unaffected Limb	Pre	0.30 (-0.41, 0.78)	0.47 (-0.23, 0.85)	0.45 (-0.25, 0.84)	0.21 (-0.48, 0.74)	0.25 (-0.45, 0.76)	0.45 (-0.25, 0.84)
	Post	0.12 (-0.55, 0.70)	0.38 (-0.33, 0.81)	0.11 (-0.56, 0.69)	0.20 (-0.49, 0.74)	0.29 (-0.42, 0.78)	0.52 (-0.16, 0.87)

Table 10 Continued

Correlation Between Outcomes of Interest Over the Experimental Walking Intervention in the KOA Group

Variables	Test Time	Pain (NPRS) (95% CI) Pre	Pain (NPRS) (95% CI) Post	Perceived Exertion (Borg RPE) (95% CI) Pre	Perceived Exertion (Borg RPE) (95% CI) Post	Physical Function (SMWT) (95% CI)	Physical Function (Treadmill Time) (95% CI)
Stance Time Affected Limb	Pre	0.38 (-0.33, 0.81)	0.58 (-0.08, 0.89)	0.50 (-0.19, 0.86)	0.31 (-0.40, 0.79)	0.13 (-0.54, 0.70)	0.34 (-0.37, 0.80)
	Post	0.15 (-0.53, 0.71)	0.54 (-0.14, 0.87)	0.21 (-0.48, 0.74)	0.22 (-0.48, 0.75)	0.06 (-0.59, 0.66)	0.35 (-0.36, 0.80)
Stance Time Unaffected Limb	Pre	0.53 (-0.15, 0.87)	**0.76 (0.25, 0.94)**	0.56 (-0.11, 0.88)	0.27 (-0.43, 0.77)	-0.05 (-0.66, 0.60)	0.27 (-0.43, 0.77)
	Post	0.03 (-0.61, 0.65)	0.51 (-0.18, 0.86)	0.00 (-0.63, 0.63)	-0.02 (-0.64, 0.62)	0.04 (-0.60, 0.65)	0.44 (-0.26, 0.84)

Note. NPRS = Numeric Pain Rating Scale, RPE = Rating of Perceived Exertion. Bolded values = high ($r > 0.75$) correlations observed

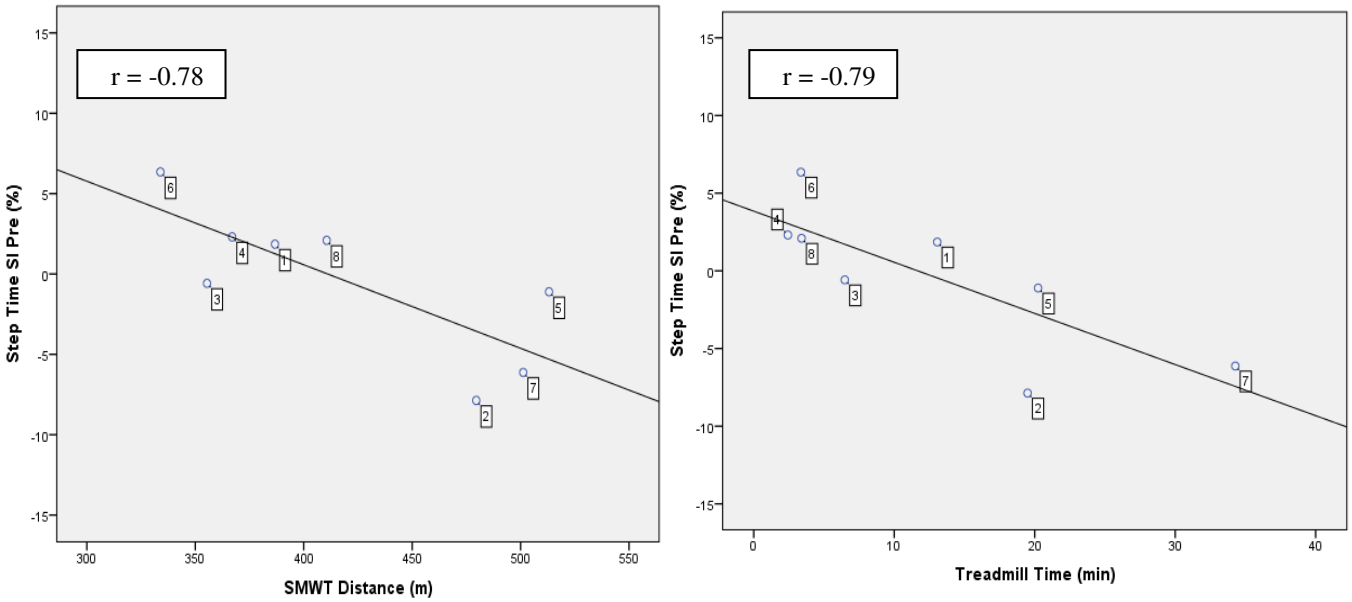


Figure 8: Correlations for spatiotemporal SI variables with outcome measures of physical function (SMWT and treadmill time) in KOA subjects. SMWT = Six Minute Walk Test; Pre = pre-experimental walking intervention.

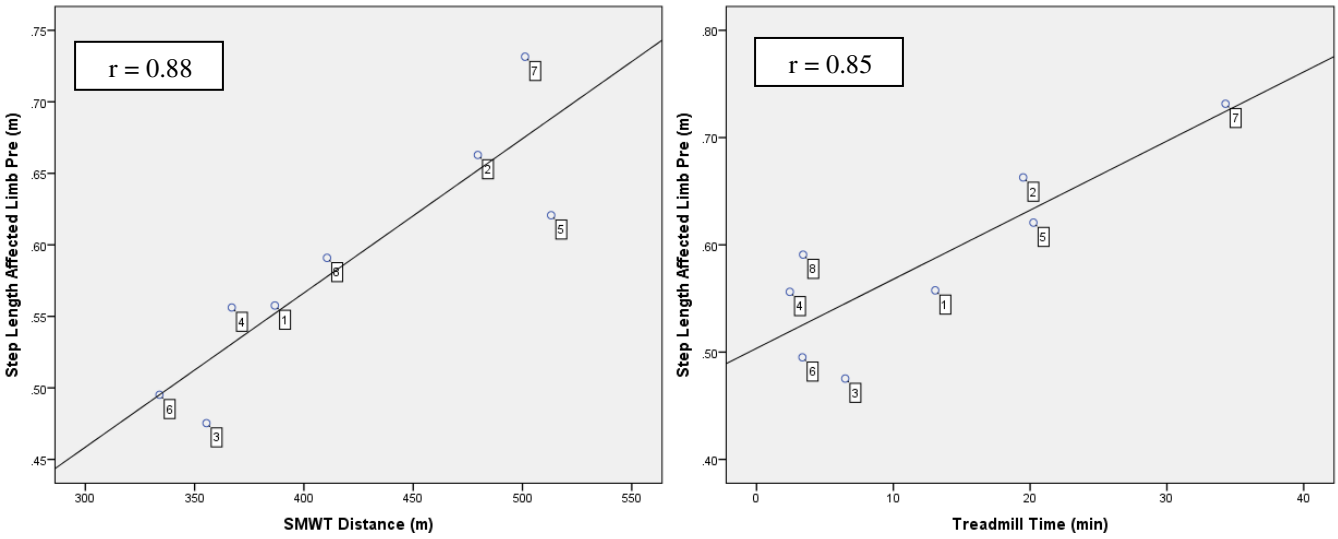


Figure 9: Correlations for step length of the affected limb with outcome measures of physical function (SMWT and treadmill time) in KOA subjects. SMWT = Six Minute Walk Test; Pre = pre-experimental walking intervention.

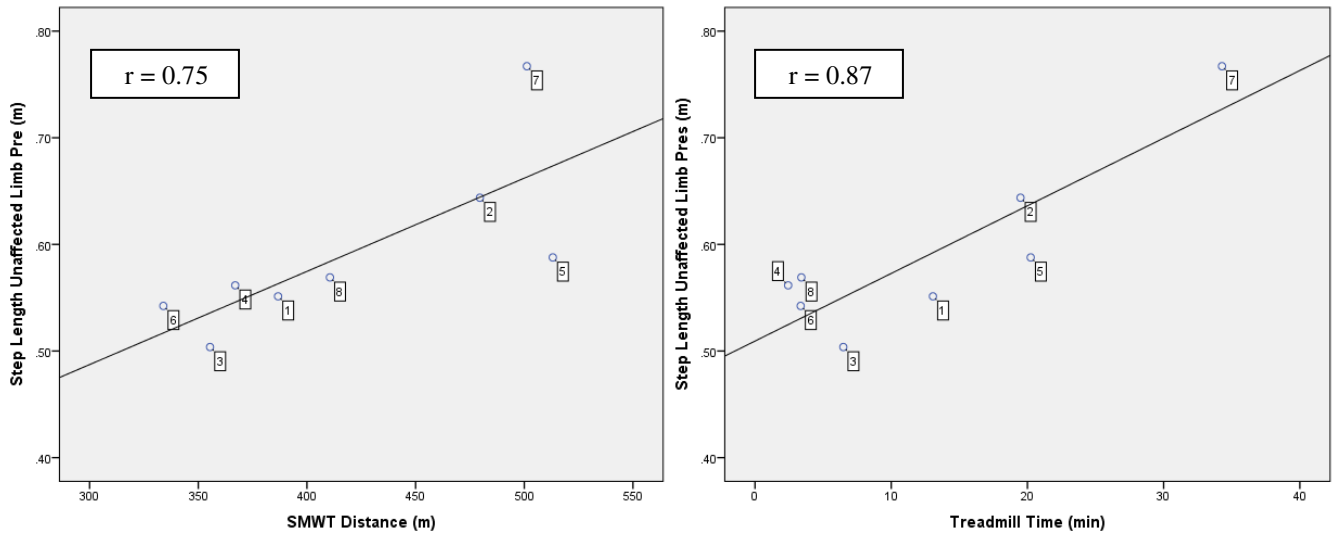


Figure 10: Correlations for step length of the unaffected limb with outcome measures of physical function (SMWT and treadmill time) in KOA subjects. SMWT = Six Minute Walk Test; Pre = pre-experimental walking intervention.

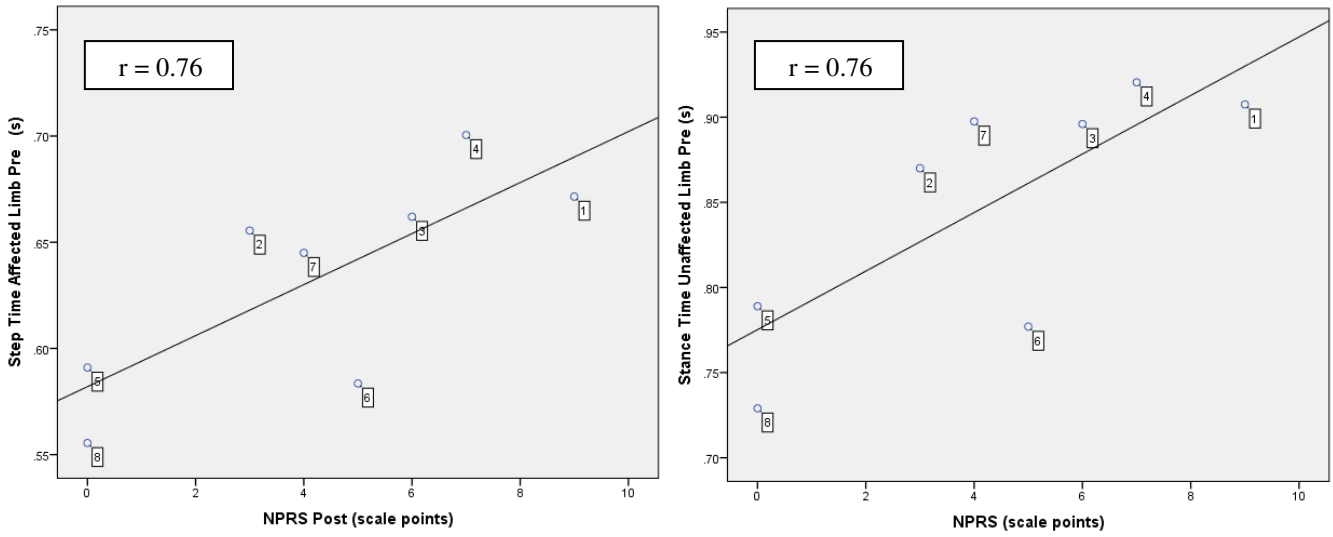


Figure 11: Correlations for step time of the affected limb and stance time of the unaffected limb with outcome measure of pain in KOA subjects. NPRS = Numeric Pain Rating Scale; Pre = pre-experimental walking intervention.

Some correlations were present for spatiotemporal SI measures (see Table 10). Step length SI following the experimental walking intervention correlated positively with perceived exertion rating following the experimental walking intervention (r = 0.82; 95% CI 0.39 to 0.96). Step time SI before the experimental walking intervention correlated negatively with SMWT distance (r = -0.78; 95% CI -0.95 to -0.30) and treadmill time (r = -0.79; 95% CI -0.99 to -0.32).

For limb-specific variables several correlations were also present (see Table 10). Step time of the affected limb before the experimental walking intervention correlated positively with pain after the experimental walking intervention (r = 0.76; 95% CI 0.25 to 0.94). Likewise, stance time of the unaffected limb before the experimental walking intervention correlated positively with pain after the experimental walking intervention (r = 0.76; 95% CI 0.25 to 0.94). Step length of the affected limb before (r = 0.89; 95% CI

0.59 to 0.97) and after (r = 0.88; 95% CI 0.56 to 0.97) the experimental walking intervention correlated positively with SMWT distance. Also, step length of the affected limb both before and after the experimental walking intervention were positively correlated with the treadmill time (r = 0.85; 95% CI 0.47 to 0.96, respectively). Likewise, step length of the unaffected limb before (r = 0.75; 95% CI 0.23 to 0.94) and after (r = 0.89; 95% CI 0.59 to 0.97) the experimental walking intervention correlated positively with SMWT distance. Step length of the unaffected limb also correlated positively with treadmill time before (r = 0.87; 95% CI 0.53 to 0.97) and after (r = 0.93; 95% CI 0.72 to 0.98) the experimental walking intervention.

Sample Size Estimation for a Future Fully Powered Study

Test-retest reliability

Based on the application of assumptions outlined in the methods section to the table provided by Walter et al. (1998), a minimum of 46 participants for the test-retest reliability component would be necessary in a future fully powered study evaluating step length, step time and stance time SIs and limb-specific variables.

Pre- to post-experimental walking intervention

Differences between groups

The sample size estimates for all 18 spatiotemporal variable SIs and limb-specific differences between the KOA and healthy groups are provided in Table 11. Calculation of the pooled standard deviation was appropriate since variation in the groups were similar. The total sample sizes ranged from 22 to 2378.

Table 11

Sample Size Estimates Differences Between Groups for Variables of Interest

Variable	Test Time	KOA Mean	Healthy Mean	Pooled SD (σ)	Total sample size estimate
Step Length SI (%)	Pre	-0.9	-0.6	5.0	974
	Post	-0.5	-2.5	5.1	84
Step Time SI (%)	Pre	-0.4	1.9	4.1	136
	Post	-1.0	0.8	3.9	708
Stance Time SI (%)	Pre	-1.4	-2.0	2.9	2378
	Post	0.2	-1.6	3.4	42
Step Length Affected or Non-dominant Limb (m)	Pre-	0.59	0.65	7.2	34
	Post-	0.61	0.65	8.4	124
Step Length Unaffected or Dominant Limb (m)	Pre-	0.59	0.65	7.5	44
	Post-	0.61	0.67	8.4	68
Step Time Affected or Non-dominant Limb (s)	Pre-	0.63	0.59	0.1	72
	Post-	0.60	0.57	0.1	126
Step Time Unaffected or Dominant Limb (s)	Pre-	0.64	0.57	0.1	24
	Post-	0.61	0.57	0.1	72
Stance Time Affected or Non-dominant Limb (s)	Pre-	0.84	0.74	0.1	26
	Post-	0.79	0.71	0.1	40
Stance Time Unaffected or Dominant Limb (s)	Pre-	0.85	0.75	0.1	22
	Post-	0.78	0.73	0.1	126

Note. SD = standard deviation.

Differences within groups

Sample size estimates for all 21 variables for differences within the two groups are provided in Table 12. The total sample sizes ranged from 6 to 1828.

Table 12

Sample Size Estimates Differences Within Groups for Variables of Interest

	KOA		Total Sample	Healthy		Total Sample
Variable	Mean	SD	Size	Mean	SD	Size
Step Length SI (%)	-0.4	6.1	1828	1.9	3.6	31
Step Time SI (%)	0.6	3. 7	301	1.1	3.4	78
Stance Time SI (%)	-1.6	2.9	28	-0.4	2.4	285
Step Length Affected or Non-dominant Limb (m)	-0.02	0.1	199	-0.02	0.1	199
Step Length Unaffected or Dominant Limb (m)	-0.02	0.1	199	-0.02	0.1	199
Step Time Affected or Non-dominant Limb (s)	0.03	0.1	90	0.02	0.1	199
Step Time Unaffected or Dominant Limb (s)	0.03	0.1	90	0.02	0.1	199
Stance Time Affected or Non-dominant Limb (s)	0.05	0.1	34	0.02	0.1	199
Stance Time Unaffected or Dominant Limb (s)	0.07	0.1	19	0.02	0.1	199
Pain (NPRS)	-1.7	2.8	24	0.0	0.0	N/A
Perceived Exertion (Borg RPE scale)	-7.4	1.2	6	-6.7	1.5	6

Note. SD = standard deviation, N/A = not applicable.

Correlation between outcomes in the KOA group

Based on the application of the assumptions outlined in the methods section to the table provided by Machin & Campbell (1987), a future correlation analysis would require a minimum of 27 participants to evaluate the relationship between step length, step time and stance time SIs and limb-specific variables with pain, perceived exertion and physical function.

Discussion

This study sought to determine the feasibility of recruitment and protocol as well as describe spatiotemporal gait characteristics during the functional task of walking in a sample of KOA and healthy participants. The primary objectives of this preliminary study were to inform a future fully powered study by first evaluating the test-retest reliability of step length, step time and stance time SIs and limb-specific variables over two test administrations. A secondary objective was to investigate the differences and associations between and within the unilateral KOA and healthy groups SIs and limb-specific variables with pain, perceived exertion and physical function before and after an experimental walking intervention.

Feasibility of Recruitment and Study Protocol

During the recruitment period, all 16 potential participants approached by the primary investigator and research coordinator agreed to complete this study. All recruited participants completed the study and all collected data was included the analysis.

The test burden per participant was a maximum of 90 minutes for a single session. The burden to the participant varied since he/she had the option to elect to terminate treadmill walk time depending on his/her tolerance, up to an upper limit of 60 minutes combined with the SMWT. Other factors contributing to test burden include the value for the participant's time invested in this study. At the time of participation, each participant was monetarily reimbursed $60 for his/her time and travel expense and informed that he/she can opt to terminate testing at any time point during the study. Therefore, the test burden may be considered reasonable.

Participant Characteristics

The inclusion of participants 40 years of age and older was chosen in this study based on large population-based studies in the United States of America (USA) and Europe. Two population-based studies found that the overall prevalence of symptomatic KOA in individuals 40 years of age and older ranged from 11% in the USA (Jordan et al., 2007) to 17% in France (Guillemin et al., 2011) with a preponderance for increasing age (Centers for Disease Control and Prevention, 2011). The lower limit of 40 years of age of the current study was chosen based on the findings of these epidemiological studies.

The sample demographics and anthropometrics (i.e., age, mass and height) of the current study were compared to that found in the literature (see Table 13).

Table 13

Comparison of Demographic and Anthropometrics of the Current Study to the Literature

	Current study		Gok et al. (2002)		Bejek et al. (2006)	
Characteristics	KOA Mean (SD)	Healthy Mean (SD)	KOA Mean (SD)	Healthy Mean (SD)	KOA Mean (SD)	Healthy Mean (SD)
Age (year) (min, max)	59 (6) (50, 66)	57 (8) (45, 66)	57 (8) (46, 60)	58 (11) (46, 60)	68 (7) (45, 93)	69 (9) (52, 84)
Mass (kg)	88 (24)	71 (17)	77 (12)	73 (11)	71 (12)	72 (12)
Height (m)	1.66 (0.11)	1.62 (0.12)	1.57 (0.07)	1.57 (0.05)	1.69 (0.11)	1.69 (0.19)

Note. SD = standard deviation

Comparison of sample age reveals that the current study is relatively similar to that of Gok et al. (2002). The sample age of Bejek et al. (2006), however, shows that the range spans greater decades than this study. Anthropometric comparisons between these studies suggest that individuals with KOA in this study appear heavier than that found in the literature, whereas height in both groups appears to be consistent with the literature.

For height there appears to be relative consistency across the studies compared, whereas for such characteristics as age and mass, relative differences are suggested. The findings associated with the current study can only be generalized to other studies of similar demographics.

All demographic and anthropometric characteristics, SMWT distance and treadmill time were normally distributed in both groups. Self-report outcome measures of physical function, however, were not normally distributed for the healthy participants KOOS Pain, ADL and QoL subscales as well as both groups' sport and recreation subscale. The distribution in the healthy groups' pain, ADL, QoL and sport and recreation subscales of the KOOS may not be normally distributed due to skewness of this groups' data as a result of extreme values in the tail of the distributions (i.e., decreased self-reported pain resulting in a negative skew and increased physical function resulting in a positive skew). The non-normal distribution of the KOA groups' sport and recreation subscale of the KOOS may be a result of two participants reporting higher function on certain items of this subscale (such as jumping, running and kneeling), presenting outliers compared to the rest of the KOA group.

Spatiotemporal Characteristics

Rationale for primary outcome measures chosen in the current study

The spatiotemporal variables described in this study included step length, step time and stance time. These three variables were chosen as primary outcome measures based on the recommendations of Stanic et al. (1977) on the standardization of reporting kinematics. These authors suggested that step length, step time and stance time present

the minimum number of spatiotemporal variables necessary for quantitative gait evaluation (Stanic et al., 1977). Inclusion of the minimum spatiotemporal gait variables was considered sufficient for quantitatively evaluating limb-specific measures of gait in this study based on the recommendations by Stanic et al. (1977).

It has also been suggested that inter-limb symmetry of the three spatiotemporal variables are the most characteristic property of able-bodied gait (Stanic et al., 1977). Quantitative SI measurements characteristic of able-bodied gait have been suggested only for stance time symmetry. Herzog et al. (1989) reported that stance time symmetry in healthy samples deviated ± 4% from zero. Some authors suggest that able-bodied gait may be naturally asymmetrical due to the different contributions of the lower limbs in propulsion or limb dominance when walking (Sadeghi et al., 2000; Singh, 1970). In this study, the healthy groups' stance time SI deviated less than ± 4% from zero which coincide with the findings of Herzog et al. (1989), suggesting symmetry. All SI measurements in each KOA and healthy group deviated less than ± 4% from zero in this study. The SI values of this preliminary study provide a basis for a future fully powered study to determine quantitative thresholds of step length, step time and stance time SIs in a similar sample.

Comparison of the current study to the literature

The spatiotemporal variable results (mean, SD and 84% CI), of the current study were compared to that found in the literature (see Table 14). It has been suggested that when comparing findings between studies, non-overlapping 84% CIs suggest statistically significant differences at an approximate alpha (α) level of 0.05, whereas overlapping

84% CIs suggest no significant differences at $\alpha = 0.05$ (Payton, Greenstone & Schenker, 2003). Three studies examined one or more of the variables of primary interest in this study (i.e., step length, step time and stance time). Berman et al. (1987) reported mean and SD for step length and stance time of the affected and unaffected limbs of 16 individuals with unilateral KOA pre-operatively and a single randomly chosen limb for each of the 91 healthy controls, which were compared to the current study. Comparisons were also made to the study by Gundersen et al. (1989) which reported mean values of each of step length, step time and stance time for the dominant and non-dominant limbs of 14 healthy adults. The study by Levinger et al. (2008) reported mean and SD for step length and step time in a sample of 19 individuals with unilateral KOA who underwent TKA surgery and the findings were included as a comparison to the current study. The data from either the first or second test occasion (before to the experimental walking intervention) of this study could be compared to the literature based on the relatively stable test-retest interval, whereas the third occasion would not be suitable as a comparison to the literature since this test followed the experimental walking intervention. As a result, the values for spatiotemporal gait variables pertaining to the first test occasion were arbitrarily chosen for comparison. Figure 12 shows graphical representations of the comparison between studies.

Table 14
Comparison of Spatiotemporal Variable Results of the Current Study to the Literature

Variable	Current study Mean (SD) (84% CI)	Berman et al. (1987) Mean (SD) (84% CI)	Levinger et al. (2008) Mean (SD) (84% CI)	Gundersen et al. (1989) Mean
KOA				
Step Length Affected Limb (m)	0.57 (0.1) (0.52, 0.62)	0.42 (0.1) (0.40, 0.46)	0.68 (0.1) (0.64, 0.71)	-
Step Length Unaffected Limb (m)	0.58 (0.1) (0.53, 0.62)	0.43 (0.1) (0.38, 0.47)	0.70 (0.1) (0.66, 0.73)	-
Step Time Affected Limb (s)	0.64 (0.1) (0.61, 0.67)	-	0.52 (0.1) (0.51, 0.53)	-
Step Time Unaffected Limb (s)	0.64 (0.1) (0.60, 0.68)	-	0.52 (0.1) (0.51, 0.53)	-
Stance Time Affected Limb (s)	0.85 (0.1) (0.80, 0.89)	1.07 (0.2) (1.0, 1.1)	-	-
Stance Time Unaffected Limb (s)	0.86 (0.1) (0.81, 0.90)	1.09 (0.2) (1.0, 1.2)	-	-
Healthy				
Step Length Dominant Limb (m)	0.65 (0.1) (0.61, 0.68)	0.53 (0.1) (0.51, 0.54)	-	0.69
Step Length Non-dominant Limb (m)	0.64 (0.1) (0.60, 0.68)	-	-	0.69
Step Time Dominant Limb (s)	0.58 (0.05) (0.55, 0.61)	-	-	0.54
Step Time Non-dominant Limb (s)	0.59 (0.05) (0.56, 0.62)	-	-	0.54
Stance Time Dominant Limb (s)	0.75 (0.07) (0.71, 0.79)	0.74 (0.02) (0.73, 0.74)	-	0.70
Stance Time Non-dominant Limb (s)	0.74 (0.08) (0.69, 0.78)	-	-	0.70

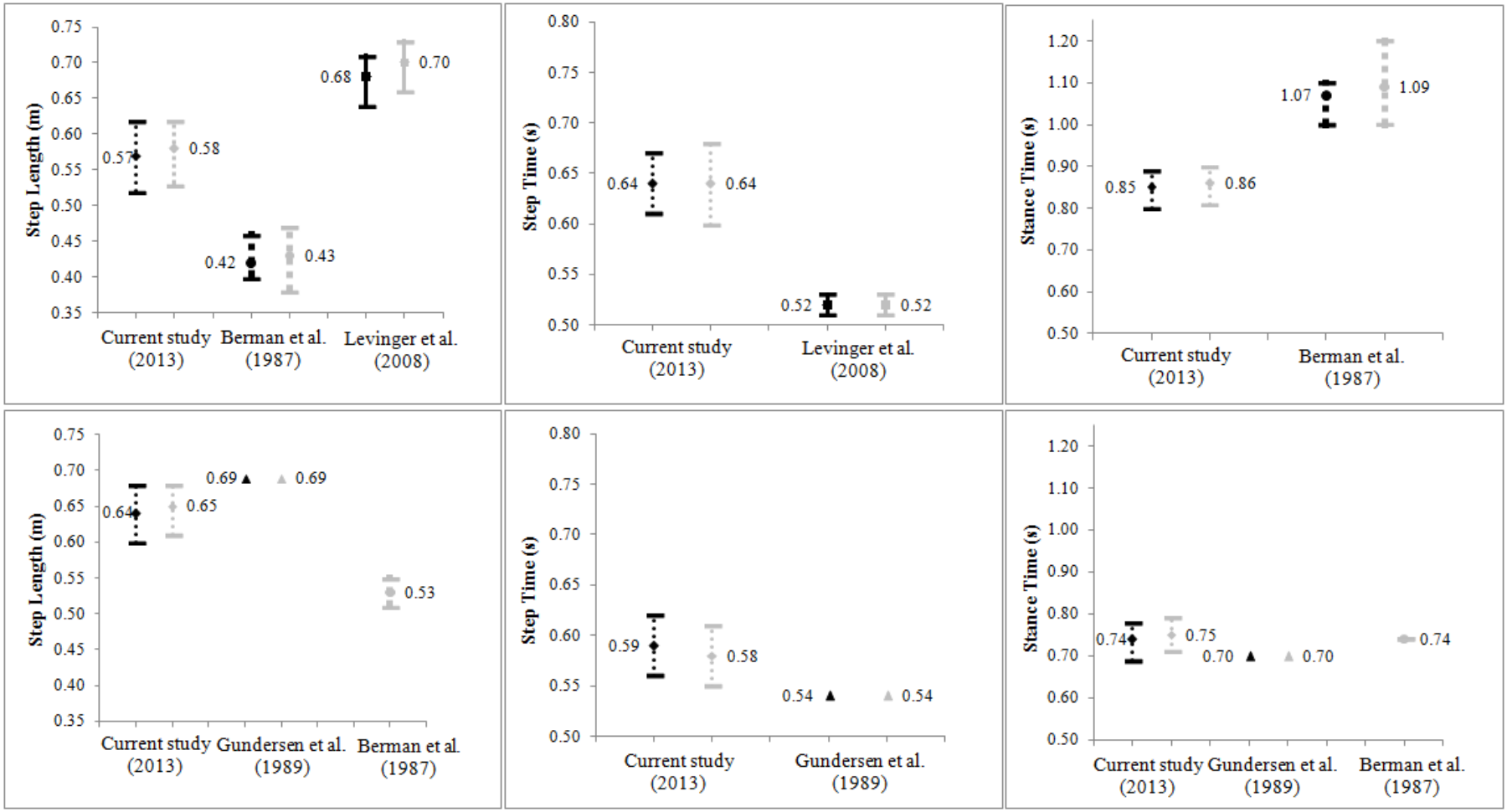


Figure 12: Comparisons of KOA (top row) and healthy controls (bottom row) step length, step time and stance time of the current study to the literature. Black bar = affected or non-dominant limb; Grey bar = unaffected or dominant limb

The findings of the current study differed (i.e., non-overlapping CIs), from previously reported data for step length, step time and stance time variables of the affected and unaffected limbs in individuals with KOA. For all spatiotemporal variables of the affected and unaffected limbs, it appears that the values in the current study fall between the comparison studies (see Figure 12). The study by Berman et al. (1987) included pre-operative individuals with unilateral KOA and Levinger et al. (2008) included post-operative individuals with unilateral KOA, whereas individuals with KOA in the current study were not scheduled for and had not undergone knee surgery. The difference in the studies compared may be due to the differences in severity of the condition of the KOA samples. The studies reported on the condition of KOA using self-report outcomes or clinical examination. The study by Berman et al. (1987) evaluated the pre-operative KOA groups' condition using the HSS and reported poor scores (60 points or less on the 100-point scale) which the authors considered moderate to severe disease. The study by Levinger et al. (2008) evaluated the condition of post-operative individuals with KOA using the American Knee Society knee score (consisting of a total score out of a 100-point scale, with a maximum of 50 points for each clinical and pain assessment section, with higher scores indicating full knee ROM and no pain) to assess outcomes one year after surgery. Levinger et al. (2008) reported that the KOA group had mild disease severity, with a mean total knee score of 92 ± 11 (47 ± 3 and 44 ± 9, for clinical and pain sections respectively). It can be hypothesized that the literature showing reduced step length and increased stance time in KOA samples compared to healthy controls may be due to increased KOA severity, such as that reported by Berman et al. (1987); whereas in

comparison, less severe KOA samples have larger values for step length, resembling able-bodied gait, much like that found by Levinger et al. (2008). The outcome measures used in this study do not permit determination of KOA disease severity. Typically, the degree of KOA severity has been quantified in the literature based on evaluation of radiographic grading systems, such as the Kellgren-Lawrence scale (Kellgren & Lawrence, 1957). Perhaps a future study could evaluate the degree of KOA severity by such grading methods to permit comparisons based on severity of the different samples.

Comparisons between the current study and the literature for stance time in healthy individuals revealed overlapping CIs, suggesting similarities across studies for this spatiotemporal variable (see Figure 12). Comparisons of healthy individuals step length and step time across the studies, however, suggest differences (see Figure 12). The study by Gundersen et al. (1989) included only mean values for spatiotemporal variables of the healthy sample, hence CIs could not be evaluated for comparison. The study by Berman et al. (1987) evaluated spatiotemporal variables, including step length and stance time, of healthy individuals comparing their findings to two other studies (Murray et al., 1969; Simon et al., 1983). Berman et al. (1987) acknowledged differences for step length from previously reported data, finding smaller step length (0.53 m) compared to larger step length (0.64 m, Simon et al. (1983) and 0.69 m, Murray et al. (1969)) of the comparison studies. Stance time in the study by Berman et al. (1987) was similar to the studies by Simon et al. (1983) and Murray et al. (1969) and is consistent with the current study. For healthy individuals, there appear to be consistencies across studies for stance time,

however, step length and step time appear to differ. These findings suggest that step length and step time variance may need to be considered in future study comparisons.

Test-Retest Reliability

This study was the first to evaluate the test-retest reliability of step length, step time and stance time SIs and limb-specific variables in a sample of individuals with KOA and healthy controls, providing preliminary information regarding reliability of these three spatiotemporal gait variables in this sample. The reliability coefficient point estimate values indicate that the three spatiotemporal gait SIs failed to reach the anticipated reliability values set out in this study (ICC $\geq$ 0.90). Limb-specific reliability point estimate values, however, exceeded the anticipated reliability values (i.e., ICC ranged from 0.94 to 0.99). The limb-specific step length, step time and stance time reliability values found in this study are similar to published test-retest reliability coefficients for the same variables in a sample of healthy adults walking at their preferred walking speed over two consecutive measurements one week apart (ICC ranging from 0.94 to 0.97) (van Uden & Bresser, 2004).

The analysis of reliability values in this study involved pooling of the KOA affected and healthy non-dominant limb data as well as pooling of the KOA unaffected and healthy dominant limb data for each spatiotemporal variable measured. Pooling the data together in the same analysis increases the number of observations, which increases the estimated reliability coefficient (Weir, 2005). This approach has implications for the magnitude of the reliability coefficients. Combining heterogeneous groups in the same analysis increases the between subjects variability, improving the ICC which can mask

poor trial-to-trial consistency (Weir, 2005). Given these implications, a future fully powered study could analyze reliability separately for each group and comparisons could be made to the literature in order to determine whether the high test-retest reliability is maintained.

The difference in reliability values between the SI and limb-specific measures found in this study may have been a consequence of the inherent error associated with the SI index calculation method which was not a factor in the limb-specific calculation method. A limitation of the SI may be that it calculates the difference divided by the bilateral average value which may filter out differences between sides (Sadeghi et al., 2000) For example, if a large asymmetry was present, the average value does not correctly reflect the performance of either limb, and for parameters that have large values but relatively small limb-specific differences would tend to lower the index and reflect symmetry (Sadeghi et al., 2000). An alternative approach to calculating symmetry which may eliminate the limitations of the ratio index could be the use of statistical approaches to quantify similarities or dissimilarities between limbs. Such analyses could include evaluating the relationship (correlation coefficients, coefficients of variation), statistical differences (paired t tests) or multivariate analysis (two-way multivariate analysis of variance) of several spatiotemporal variables in a single analysis (Sadeghi et al., 2000). The literature suggests that the SI is a valuable method in assessing symmetry of discrete variables (Sadeghi et al., 2000; Zifchock, Davis, Higginson & Royer, 2008), however, using the method proposed in this study to quantify gait variables needs to be considered in light of its limitations.

In addition, the reliability coefficient could have been affected by both random and systematic measurement error (Finch et al., 2002; Weir, 2005). Random errors are factors due to chance that can both increase and decrease test scores on repeated testing in a random manner, whereas systematic error can affect all scores equally (*constant error*) and certain scores differently than others (*bias*) (Weir, 2005). In particular, sources of error can be due to learning and fatigue effects, instrumentation, the subject and the tester (Finch et al., 2002; Weir, 2005). Measurement error can be reduced by employing such techniques as standardizing the measurement method, ensuring proper working order of the measurement tool, increasing the sample size and averaging repeated measurements (Finch et al., 2002; Weir, 2005). Minimization of measurement error in this study was reduced by ensuring the protocol was administered in the same manner by the same tester for each participant over the course of data collection (e.g. techniques employed to encourage a steady-state walk speed over the instrumented walkway, use of standardized prompts throughout the testing procedure, completion of at least one pre-trial instrumented walk test to acquaint the participants to the testing environment). Proper working order of the measurement instrument was monitored by assessing the GAITRite® application software controls for functionality and the processed raw data for adequate footfall measurement subsequent to each occasion the participants' data was collected. This study included a small sample size which can produce unstable reliability estimates of population reliability (Morrow & Jackson, 1993). For example, the ICC value associated with stance time SI (ICC = 0.78) is in the excellent range according to benchmark guidelines outlined by Fleiss (1981), however, the associated CI of 0.36 to

0.92 indicates a considerable uncertainty in the precision of the reliability estimate. The effect of small sample size could have been reduced by increasing the sample size or expanding the protocol to three or four occasions which may have improved the overall reliability. Such techniques could be employed in a future study.

The ICC cannot be easily interpreted clinically because it is a unitless value and it should be used in conjunction with the SEM (Weir, 2005). The SEM provides a method for determining absolute reliability and is expressed in the original test unit. The SEM informs the clinician about the measurement error associated with an individual's test value (Portney & Watkins, 2009; Weir, 2005). For example, if an individual with KOA has a step time SI value of 1.2%, the researcher or clinician could be 95% certain that the individual's true value falls between -2.7 and 5.1% (observed value ± 1.96 x SEM of step time SI = 2.0). It appears that the 95% SEM error margin for SIs were large and this large error variance across both groups suggests a less reliable measure. The 95% SEM for limb-specific variables, however, were narrower suggesting a more reliable measure in comparison to the SI. The measurement error may have been affected by the small sample size and inadequate power of this study. The study findings for absolute reliability measures should, therefore, be interpreted with caution.

Pre- to Post-Experimental Walking Intervention

Differences between groups

This study component set out to first investigate whether differences exist between individuals with unilateral KOA compared to healthy controls for the step length, step time and stance time SIs and limb-specific variables before and after an experimental

walking intervention. The SIs of the three variables were not observed to differ between the two groups over the experimental walking intervention. Evaluation of limb-specific spatiotemporal gait variables were included for comparison with the SI index data. Likewise, the limb-specific spatiotemporal variables were not observed to differ between the two groups. The findings of the current study differ from the literature demonstrating prolonged stance time in individuals with KOA compared to healthy controls (Astephen et al., 2008; Lafuente et al., 2000). In addition, the study findings for step time and step length were not observed to differ between the groups, however, the literature reported that step time and step length were shorter in individuals with KOA compared to healthy controls (Astephen et al., 2008; Berman et al., 1987; Chen et al., 2003; Viton et al., 2000). The discrepancies between this preliminary study's findings and the literature may be attributed to the small sample size and inadequate power of this study.

Differences within groups

Within group differences of spatiotemporal gait SIs and limb-specific variables, pain and perceived exertion before and after the experimental walking intervention were investigated. Within the healthy group, the spatiotemporal gait SI and limb-specific variables were not observed to differ. This was expected in this study and is consistent with previous literature suggesting relative gait symmetry in able-bodied individuals (Herzog et al., 1989; Liikavanio et al., 2007; Sadeghi et al., 2000). Within the KOA group, the spatiotemporal gait SI and limb-specific variables also were not observed to differ. The findings of the current study differ from previous investigations showing reduced step length (Bejek et al., 2006; Kiss, 2011) and increased stance time (Lafuente

et al, 2000; Viton et al., 2000) of the affected compared to the unaffected limb in individuals with KOA as a consequence of a compensatory antalgic gait favouring the OA limb, which is suggested to be an attempt to reduce the load on the painful knee (Al-Zahrani & Bakheit, 2002; Huang et al., 2008; McGibbon & Krebs, 2002; Stauffer et al., 1977). The discrepancy between the findings in the literature of altered gait characteristics between limbs and the current study findings may be a consequence of the small sample size and inadequate power of the study to detect such differences.

Surprisingly, pain in the KOA group did not appear to differ over the experimental walking intervention. Perhaps a more challenging task to the MSK system (e.g. stair climbing) needs to be implemented in future studies to find significant changes in pain and spatiotemporal gait measures. Researchers may also find these changes in individuals with a more severe case of KOA. These techniques may cause an increase in subjective pain and led to greater changes in spatiotemporal gait symmetry measures.

There is a lack of evidence in the literature to justify the total duration of the experimental walking intervention required to elicit fatigue and/or pain in a sample similar to this study. It was hypothesized that healthy participants could potentially tolerate a bout of 60 minutes of walking, however, individuals with KOA may not be able to tolerate the bout of 60 minutes of walking. As a result an upper limit of 60 minutes (SMWT and treadmill walk time combined), was chosen at the onset of this study as the total duration of the experimental walking intervention and each participant was given the option to elect to terminate treadmill walking at any time. None of the participants in either the KOA or healthy group walked on the treadmill for longer than 40 minutes.

Differences in perceived exertion rating were found in this study before and after the experimental walking intervention, suggesting that this intervention achieved the goal of increasing exertion in this sample of participants. As a result, an upper limit of 46 minutes (SMWT and treadmill walk time combined) may be a sufficient target walking duration.

For estimates of differences both between and within the groups, it is important to acknowledge the distinction between statistical and clinical significance. Statistical significance does not necessarily imply clinical relevance; likewise, statistically non-significant differences do not necessarily imply clinical unimportance (Luus, Muller & Meyer, 1989). A statistically significant difference may be indicative of an important difference or a small difference detected by a sensitive statistical analysis (Luus et al., 1989). If a difference between group means is statistically non-significant, it may suggest a similarity between groups or an insensitive statistical analysis which cannot detect possible important differences (Luus et al., 1989). The differences between spatiotemporal variables of one limb versus the other may be statistically significant in the literature, however, the difference may be so small that it is clinically irrelevant. Based on the review of the literature reporting differences between limbs in diseased samples, these differences were so small that they appear clinically irrelevant. For example, in stroke survivors, the paretic limb step length was 0.04 m longer than the non-paretic limb (Hsu et al., 2003). In individuals with KOA, Bejek et al. (2006) reported that step length of the affected limb was 0.51 m versus 0.55 m on the unaffected limb, a difference of 0.04 m. It is important to determine clinically relevant differences of spatiotemporal gait variables, particularly in KOA samples, which remains to be

determined. Future studies may be interested in evaluating the clinically meaningful magnitude of the differences between spatiotemporal variables in both healthy and KOA samples.

Correlation between outcome measures in the KOA group

Correlations between step length, step time and stance time SIs and limb-specific variables with pain, perceived exertion and physical function measures were assessed in the unilateral KOA group. There appear to be several correlations that exist between the spatiotemporal variables and measures of pain, perceived exertion and physical function, however, some variables intuitively depend on one another. For example, step length correlated highly and positively with SMWT, both of which are distance measures. Likewise, it is intuitive that step time of the affected limb and stance time of the unaffected limb correlated highly and positively with pain, since these gait variables appear inherently related (i.e., increased step time on one limb corresponds with increased stance time on the other limb). It appears that some relationships exist between the spatiotemporal gait variables and measures of pain and physical function, varying in magnitude and direction depending on which single limb was supporting.

In this study there were a large number of possible comparisons for correlations of spatiotemporal gait variables with self-reported pain, perceived exertion and physical function before and after the experimental walking condition. Correlation of the difference scores before and after the experimental walking condition for each outcome would reduce the number of possible comparisons, which should be considered in a future study. The level of significance for correlation analysis in a future study would still

require adjustment, using such statistical methods as the Bonferroni correction, in order to account for multiple comparisons. A future study should also consider performing stepwise multiple regression based on the results of the correlation analyses for spatiotemporal limb-specific variables in order to determine the best predictors of knee pain and physical function.

Outcome Measures to Consider for a Future Fully Powered Study

The current study findings suggest that the outcomes of interest for a future fully powered study should only include the limb-specific spatiotemporal gait variables (i.e., step length, step time and stance time of each respective limb), based on the questionable test-retest reliability of the SI ratio. The relationship of these three limb-specific variables with pain and physical function should also be considered since these outcome measures appear clinically relevant in KOA samples.

In the literature, gait speed has been shown to be reduced in KOA samples compared to able-bodied self-paced gait (Al-Zahrani & Bakheit, 2002; Bejek et al., 2006; Zeni & Higginson, 2009). The descriptive findings of this study suggest reduced gait speed in individuals with KOA compared to healthy controls, which is consistent with the literature. Several studies have investigated the influence of varying gait speed (slow and fast paced) or controlling cadence (pace set to a metronome) in healthy and KOA samples (Al-Zahrani & Bakheit, 2002; Bejek et al., 2006; Kiss, 2011; Gok et al., 2002; Zeni & Higginson, 2009). The differences between KOA and healthy individuals has also been suggested in the literature to become more pronounced as gait speed deviates (slow or fast pace) from self-paced gait (Bejek et al., 2006; Lafuente et al., 2000). In a future study

evaluation of the effects of varying gait speed on spatiotemporal variables over the study protocol may provide further insight into characteristic differences between able-bodied and KOA gait.

Sample Size Estimation for a Future Fully Powered Study

Sample sizes for each research question were estimated based on the outcome measures of interest to inform a fully powered study.

Omission of the spatiotemporal SI variables was implemented since these variables have questionable reliability coefficients based on the findings of the current study. For the test-retest reliability component, based on the assumptions outlined in the methods section, sample size estimates for step length, step time and stance time limb-specific variables were calculated and a minimum of 46 participants (pooled KOA and healthy) may be necessary for a future fully powered study.

Based on the assumptions outlined in the methods section and excluding the SI measurements, for *between* group differences taking the conservative estimate of the remaining 12 limb-specific outcomes of interest (see Table 11), a future study would require a minimum of 126 participants. For differences *within* the two groups a minimum of 199 participants would be necessary, based on the conservative estimate of the remaining 15 outcomes of interest (i.e., limb-specific variables, pain and perceived exertion) (see Table 12).

For the correlation analysis, sample size estimates for the KOA groups' step length, step time and stance time limb-specific variables with pain, perceived exertion and

physical function measures were assessed and a minimum of 27 participants would be required in a future study based on the assumptions outlined in the methods section.

The sample size estimates suggested to inform a future study were included in this study to provide a basis for outcome measures to consider in a future fully powered study. It has been suggested that using a pilot study to guide power calculations for a larger study should be interpreted with caution (Arain, Campbell, Cooper & Lancaster, 2010; Kraemer, Mintz, Noda, Tinklenberg & Yesavage, 2006). These authors suggest that sample sizes estimated on the basis of a pilot study effect size may be too small and result in a future study that is underpowered to detect the effect sizes of clinical significance (Kraemer et al., 2006; Arain et al., 2010). In order to minimize the risk of a type II error, a future study should consider capturing a larger sample.

In addition, the heterogeneity of the sample, for example pooling the KOA and healthy groups for the test-retest reliability component, has implications on the size of the sample. The more heterogeneous the sample, the larger the sample size required to obtain a given level of precision (Shoukri, Asyali & Donner, 2004). Therefore, heterogeneity of the sample should be considered when planning a future fully powered study by adopting methods such as separately analyzing test-retest reliability coefficients per group and adequately matching experimental participants for such factors as disease severity.

Implications for Future Research

This preliminary study was intended to provide information on three factors for a possible larger scale study: 1) the process, 2) the resources and 3) the management (Kraemer et al., 2006; Thabane et al., 2010). The *process* assesses the feasibility of the

sequence of steps which need to take place as part of a future fully powered study (Thabane et al., 2010). *Resource* assesses the time, equipment and measurement protocols needed to complete the study (Kraemer et al., 2006; Thabane et al., 2010). *Management* covers the personnel and data optimization issues as well as flaws in the research design (Kraemer et al., 2006; Thabane et al., 2010). All potential participants that were approached had agreed to participate in and completed the study protocol. The process, resources available and test burden per participant are considered reasonable. The findings reported, however, still need to be viewed in light of the limitations of the study.

Comparisons of participant demographic and anthropometric characteristics of the current study were made to the literature and appear relatively consistent for height, whereas other characteristics, such as age and mass, appear slightly different across studies. Some biases may have been operative in this study and must be considered prior to considering the implications of the results. A selection bias may have been present in this study. The results of this sample of convenience were not derived from a randomized sample. In this study many participants in both the KOA and healthy control groups were volunteers obtained through the CMCC main campus clinic. This clinic provides access to therapeutic management to individuals with MSK conditions. Individuals who visit the clinic and elect to accept the services provided may differ from those who do not seek services. Those participants obtained through word of mouth were individuals who lived in the local community. It is possible that these participants may not be representative of individuals from other neighbourhoods and may limit the generalizability of the study outside this jurisdiction.

In addition, an expectation bias may have been operative in this study. The primary investigator was aware of the diagnostic status of the participants who comprised both the control and experimental groups. Efforts were made to code each participant's data by assigning an independent number unrelated to his/her identification or age. This coding technique provided anonymity of each participant, however, the primary investigator coded the data from participants and hence was not blinded. Therefore, the lack of randomized sample and possible biases may have been operative in this study. Caution must be exercised in generalizing the findings of this study to any other population.

One of the purposes of a pilot study was to test a proposed methodology to answer a research question. The limitations of the study design, time and resources available make it difficult to establish any definitive conclusions. A future study, therefore, should be repeated with the following modifications summarized below based on this preliminary work:

1) adequate sample size and power
2) randomized selection of the experimental participants
3) experimental group matched for anthropometrics and disease severity
4) adequately matched control participants
5) inclusion of gait speed as a variable of interest
6) separate analysis per group for reliability coefficients
7) correlating changes scores before and after the experimental walking intervention for gait variables with pain and physical function

Additional research is needed to identify the possible compensatory gait strategies that exist in individuals with KOA. Future studies should take into consideration the aforementioned limitations and modifications in designing and implementing a fully powered study. By establishing potential compensatory strategies exhibited by such a sample of individuals with unilateral KOA, appropriate assessment and treatment interventions can be implemented for this condition.

Conclusion

The recruitment strategies and protocol of this preliminary study appear feasible. The limitations and summary of modifications proposed in this study help guide a future fully powered study. For test-retest reliability coefficients, the three (step length, step time, stance time) spatiotemporal gait SI measures, when applied to a sample similar to this study, have questionable relative reliability. Limb-specific spatiotemporal gait measures, however, show more promise. The SEM values of the three spatiotemporal gait SIs were less favourable compared to limb-specific variables. Limb-specific spatiotemporal variables appear acceptable in terms of measurement error. For differences before and after the experimental walking intervention, the findings suggest that the walk intervention implemented in this study successfully achieved the goal of increasing perceived exertion within the two groups. Absence of differences both between and within groups for spatiotemporal gait variables investigated in this study suggest that individuals with KOA adopt compensatory movement strategies compared to healthy controls over the experimental walking intervention. Lastly, the correlation between certain spatiotemporal measures and clinical measures of pain and physical function indicate their potential usefulness as biomechanical indices of gait.

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Appendices

Appendix A: Search Strategy

Database: Ovid MEDLINE® < 1966 to October 2012>

Limits: Human, English language

Keyword search terms:

1. osteoarthritis.mp
2. knee osteoarthritis.mp
3. symmetry.mp
4. asymmetry.mp
5. gait analysis.mp
6. 1 AND 2
7. 1 AND 3
8. 1 AND 4
9. 1 AND 5
10. 2 AND 5

Only articles investigating spatiotemporal variables were considered

Appendix B: Ethics Board Approval Canadian Memorial Chiropractic College (CMCC)

CMCC Certificate of REB Approval

Project Number 102027 **REB Approval** 1011X01

Principal Investigator Malik, Keshena

Faculty Supervisor Faculty Project

The project entitled Gait asymmetry in patients with minimal to moderate radiographic knee osteoarthritis.

has received CMCC REB Approval as of 04-Nov-10

This approval expires in one year. The status of the project must be reported by the faculty supervisor as of 04-Nov-11

The faculty supervisor is responsible for ensuring that the work is conducted in accordance with the CMCC's Research Policy and Procedure manual.

The faculty supervisor is responsible for notifying the ORA when this study is completed.

November 4, 2010

Mark Fillery, BA, CCRP
Research Administrator, Office of Research Administration

Appendix C: Ethics Board Approval Hamilton Health Sciences/McMaster Research

Hamilton Health Sciences McMaster University

HHS/FHS REB: Student Research Committee

Final Approval

Date:	February 9, 2011
REB Number:	10-610-S
Title of Study:	Gait asymmetry in patients with minimal to moderate radiographic knee osteoarthritis
Student PI:	Malik, Keshena
LPI:	Triano, John
Version date:	Document:
Oct 25 10	Application
Feb 8 2011	Protocol
Oct 25 10	Advertisement
Feb 8 2011	Information and Consent Form
Oct 25 10	Intake Form and Questionnaire
Oct 25 10	Screening

Dear Keshena:

We have completed our review of your study and are pleased to issue our final approval. You may now begin your study.

All recruitment and consent material must bear an REB stamp. You may pick up the stamped forms from our office.

Any changes to this study must be submitted as an amendment before they can be implemented. Amendment forms are available on our website.

This approval is effective for 12 months from the date of this letter. If you require more time to complete your study you must request an extension in writing before this approval expires. Please submit an Annual review form with your request.

Please cite the REB number in any correspondence.

Good luck with your research,

Marie Townsend BA, MBA
Chair, HHS/FHS Student Research Committee
Health Research Services, HSC 1B7, McMaster University

The HHS/FHS SRC complies with the guidelines set by the Tri-Council Policy Statement: *Ethical Conduct for Research Involving Humans* and with ICH Good Clinical Practice.

Appendix D: Amendment Ethics Board Approval Hamilton Health Sciences/McMaster Research

Hamilton Health Sciences McMaster University Health Sciences

HHS/FHS REB: Student Research Committee

Amendment Approval

Date:	April 5, 2011
REB Number:	10-610-S
Title of Study:	Gait asymmetry in patients with minimal to moderate radiographic knee osteoarthritis
Student PI:	Malik, Keshena
LPI:	Triano, John
Version date:	Document:
Apr 4 2011	Amendment Request form
Apr 4 2011	Amended Protocol
Apr 4 2011	Amended Brochure
Apr 4 2011	Amended ICF
Apr 4 2011	Amended Budget
Apr 4 2011	Newspaper advertisement

Dear Keshena:

We have completed our review of your amendment and are pleased to issue our final approval. You may now continue your study as amended.

All recruitment and consent material must bear an REB stamp. You may pick up the stamped forms from our office. If you need to make changes to any of these documents, please submit them for review as an amendment.

Please cite the REB number in any correspondence.

Good luck with your research,

Marie Townsend BA, MBA
Chair, HHS/FHS Student Research Committee
Health Research Services, HSC 1B7, McMaster University

The HHS/FHS SRC complies with the guidelines set by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and with ICH Good Clinical Practice.

Appendix E: Flyer

An Invitation to Participate in a Research Study Investigating Walking Patterns in Knee Arthritis

Are you or someone you know 40 years of age or older, a healthy person or have knee arthritis?

We are currently looking for participants to observe walking patterns

For more information please contact
Keshena Malik/Maricelle Dinulos at:
malikkk@mcmaster.ca/mdinulos@cmcc.ca
416-482-2340 x 266

Keshena/Maricelle
malikkk@mcmaster.ca
mdinulos@cmcc.ca
416-482-2340 x266

Appendix F: Data Collection Forms

Research Study Screening of Potential Participants

Please circle the answers below that best describe you:

1) Do you suffer from knee pain within the past month?

Yes No

2) Is your knee pain in one knee only?

Yes No Not applicable

If yes, which knee is painful?

Left Right

3) Do you have morning knee stiffness?

Yes No

If Yes, does the stiffness last half an hour or less?

Yes No

4) Do you have cracking or popping in your knee?

Yes No

5) Would you be willing to speak to the research coordinator about participation in a study?

Yes No

Name of Participant _____

Intake Form

Age: _____

Sex: _____

Height: _____

Weight: _____

1) Have you had knee surgery in the past?

Yes No

2) Have you had back pain in the past 3 months that has prevented you from performing your daily activities?

Yes No

3) Do you use a walking aid, such as a cane or walker?

Yes No

If Yes, please list below:

_____

4) Do you suffer from any previous medical conditions? (e.g. heart condition, high blood pressure, stroke, blood clot of the leg)

Yes No

If Yes, please list below:

_____

5) Do you have a family physician?

Yes No

If Yes, please provide the doctor's first and last name and medical practice address.

_____

Request for Study Related Information

Please circle which your option below:

Yes, I would like to hear more about knee arthritis

No, I do not want to hear more about knee arthritis

Yes, I would like to receive a summary of the study's results.
Please send them to this email address _____

Or to this mailing address
_____.

No, I do not want to receive a summary of the study's results.

Signature: _____

Name of Participant (Printed) _____

Appendix G: Information Letter/Consent

CMCC
Canadian Memorial Chiropractic College

McMaster University
Inspiring Innovation and Discover

LETTER OF INFORMATION / CONSENT

Gait Asymmetry in Patients with Minimal to Moderate Radiographic Knee Osteoarthritis

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Purpose of the Study

I am doing this research for my Master's thesis project. This study will investigate whether or not people with knee arthritis of one of their knees walk with a different pattern and speed compared to healthy people of the same age. Also, this study will evaluate whether the measures used to assess walking patterns and speed are reliable. Also, participants will be given questionnaires to assess pain and level of exertion before and after a period of treadmill walking in order to observe whether any changes in walking patterns and speed exist. The results of this study can provide valuable information about the measures used to evaluate walking patterns and speed contributes further to rehabilitation programs and treatment outcomes for people with knee arthritis. This measure of walking patterns and speed may shed light on possible screening techniques healthcare providers can use to identify people with knee arthritis early in their disease.

What will happen during the study?

You are invited to take part in this study. We will be recruiting participants during the months of January 2011 to March 2011 at the Canadian Memorial Chiropractic College Main Campus Clinic Biomechanics Laboratory.

With your permission, you will be asked to:

- Complete a brief intake form asking about your demographic information (your age, sex, weight and height). Questions will then be asked about your past history of medical conditions and pain in your bones, muscles and joints. The intake process can take approximately 10 minutes to complete.
- You will then be asked to change, in our change room, into your comfortable walking shoes (avoid heels, if applicable) and dress in loose fitting clothing.
- Once you have changed, the lab technician and I will then attach sensors to your skin, which can be easily removed. These sensors are used to record a computer image of your body movements. Outfitting parts of your lower legs can take approximately 20 minutes.
- You will then be asked to walk at your comfortable speed across a 15 meter mat. This may take approximately 10 minutes.
- After you walk on this mat, you will be offered time to rest (for up to 5 minutes).
- After you have rested, you will be asked to walk again on the same mat.
- Once you finish walking on the mat, we will provide you with a rating scale to complete: this scale asks about your current pain.
- After you finish completing the rating scale, you will be asked to walk at your own pace and cover as much distance as possible in a hallway corridor for 6 minutes. You will be asked to complete two rating scales: one scale asks about your current pain and the other asks about your level of exertion.
- You will then be asked to walk on the treadmill at a targeted normal walking speed. Before you begin walking on the treadmill you will be shown the location of the treadmill's "stop" button which turns off the treadmill when pressed by you. You will also be shown the location of the handrails on the treadmill to use for support, if needed. When walking on the treadmill you will have the opportunity to slow down your walking speed or stop walking if you feel the need to do so. This portion of treadmill walking could last up to a maximum of one hour or as long as you are able to walk. You will be afforded the opportunity to stop at any point during treadmill walking.
- Once you have completed walking on the treadmill you will be asked again to complete. After completing the rating scales, you will be asked to walk at your comfortable walking speed on the same mat you walked on at the earlier stage of testing.
- Once you have completed the walk on the mat, the lab technician and I will remove the sensors from your body and ask you to change in the change room, back into your clothes. At any point during the testing you are encouraged to let me know about any questions or concerns you may have about the testing.
- At this point, you will have completed the testing. You will be provided with the opportunity to request further information about the study once the entire study is completed, if you are interested.

Are there any risks to doing study?

The risks involved in participating in this study are minimal. You may feel uncomfortable with the sensors placed on your skin as some people can experience skin irritation or sensitivity. You may find yourself experiencing fatigue, pain or discomfort from walking on the treadmill. You will be provided with an emergency stop switch which allows you to stop the treadmill at any time while on the treadmill. You may feel off balance while walking on the treadmill. The treadmill is equipped with hand railings to minimize the risk of fall. The research investigator (Keshena Malik) will be present throughout the study period.

I describe below the steps I am taking to protect your privacy.

Are there any benefits to doing this study?

The research will not benefit you directly. I hope to contribute to research in knee arthritis which affects 3 million (1 in 10) Canadians. I hope that what is learned as a result of this study will help to better understand whether the method used to measure patterns of gait can be used in clinics by health professionals to identify people at risk for or worsening knee arthritis. I hope that what is learned from this study will help us better guide treatment for people with knee arthritis.

If you are interested, you will be given the opportunity to learn more about knee arthritis. Please let me know and I can provide further information to you.

Who will know what I said or did in the study?

Your participation in this study it will be strictly confidential. I will not use your name or any other information that would allow you to be identified. No one but me, my supervisor, my supervisory committee, the lab technician and clinical research coordinator will know whether you participated unless you choose to tell them.

The information/data recorded on paper that you provide will be kept in a locked cabinet where only I will have access to it. Information kept on a computer will be protected by a password. Once the study is complete, an archive of the data, without identifying information, will be stored in a password protected computer and information recorded on paper will be destroyed. After 10 years has passed since the study completion, all archive of data will be destroyed.

What if I change my mind about being in the study?

Your participation in this study is voluntary. It is your choice to be part of the study or not. If you decide to be part of the study, you can decide to stop, at any time, even after signing the consent form or part-way through the study. If you decide to stop, there will be no consequences to you. In case you stop, any data you have provided will be destroyed unless you indicate otherwise. If you do not want to answer some of the questions you do not have to, but you can still be in the study. Your decision whether or not to be part of the study will not affect your continuing access to services at the Canadian Memorial Chiropractic College Main Campus Clinic.

How do I find out what was learned in this study?

If you are interested, you can request a copy of the study findings upon study completion.
I expect to have the results of the study completed by approximately June 2011. If you would like to receive information about the findings of this study, please let me know and I can record your contact information on the Request for Study Information form and send you a summary of the results personally.

Questions about the Study

If you have questions or require more information about the study itself, please contact me.

This study has been reviewed by the Hamilton Health Sciences/McMaster Faculty of Health Sciences Research Ethics Board (HHS/FHS REB). The REB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call The Office of the Chair, HHS/FHS REB at 905.521.2100 x 42013.

CONSENT

I have read the information presented in the information letter about a study being conducted by Keshena Malik, of McMaster University. I have had the opportunity to ask questions about my involvement in this study and to receive additional details I requested. I understand that if I agree to participate in this study, I may withdraw from the study at any time. I have been given a copy of this form. I agree to participate in the study.

Signature: _____

Name of Participant (Printed) _____

Consent for the Release of Personal Health Information

I, _____, authorize Keshena Malik to request medical information, such as imaging or laboratory reports, concerning my diagnosis of knee arthritis.

Family Doctor Name: _____
Address: _____
Phone number: _____
Fax Number: _____

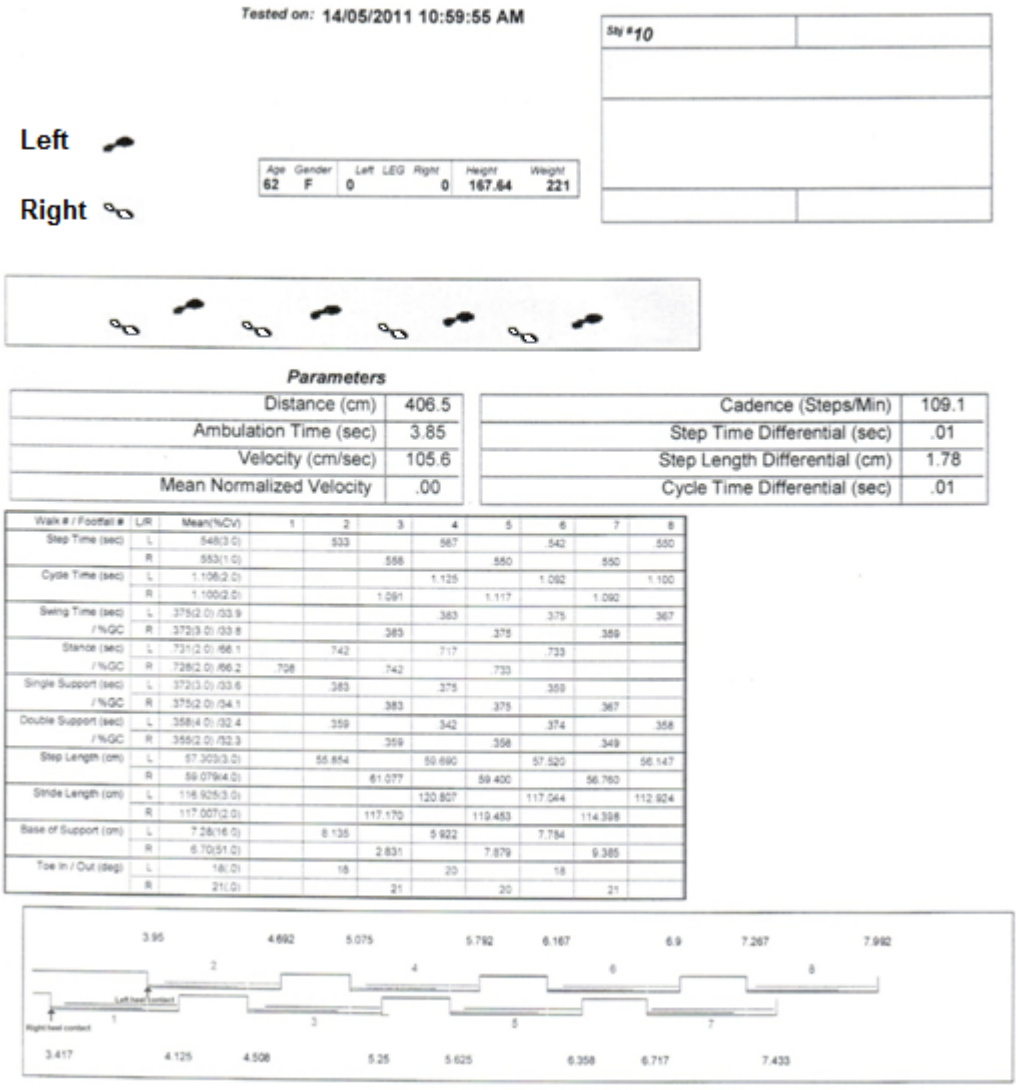
□ I understand that I may refuse to sign this form, and that my decision whether or not to be part of the study will not affect my continuing access to services at the Canadian Memorial Chiropractic College Main Campus Clinic be affected if I do sign this form.

I hereby authorize you to exchange my medical file and health information with Vitality Chiropractic to the attention of

_____ _____
Name of Participant (Printed) Signature

_____
Date

Appendix H: Example of GAITRite® Spatiotemporal Parameter Data: Single Subject on a Single Occasion

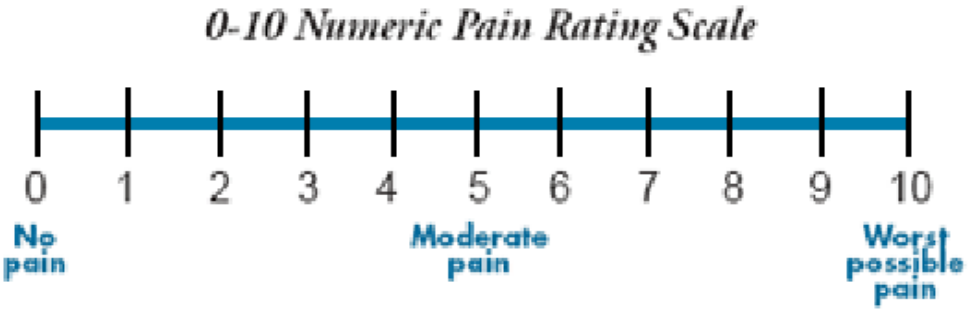


An example of the GAITRite® electronic walkway system data output. Copyright 2012 by CIR Systems Inc. Reprinted with permission.

Appendix I: Outcome Measures

Numeric Pain Rating Scale (NPRS)

The Numeric Pain Rating Scale uses whole numbers marked on a line bar varying from 0 "no pain" to 10 "worst possible pain". Please circle the number that best represents your current pain level.



From Endo Pharmaceuticals. (2010). The pain assessment tool: Using a pain rating scale. Retrieved May 20, 2010 from http://www.endo.com/Pain_Assessment.aspx

Borg Rating of Perceived Exertion (RPE) Scale

Please rate your perception of exertion by circling one of the following options:

Exertion	**RPE**
no exertion at all	6
extremely light	7
	8
very light	9
	10
light	11
	12
somewhat hard	13
	14
hard (heavy)	15
	16
very hard	17
	18
extremely hard	19
maximal exertion	20

Adapted from "Borg's perceived exertion and pain scales," by G. Borg, 1998, Human Kinetics, p. 49.

Knee Osteoarthritis Outcome Score (KOOS) Knee Survey

Knee injury and Osteoarthritis Outcome Score (KOOS), English version LK1.0

KOOS KNEE SURVEY

Today's date: _____/_____/_____ Date of birth: _____/_____/_____

Name: _____

INSTRUCTIONS: This survey asks for your view about your knee. This information will help us keep track of how you feel about your knee and how well you are able to perform your usual activities.
Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can.

Symptoms
These questions should be answered thinking of your knee symptoms during the **last week**.

S1. Do you have swelling in your knee?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S2. Do you feel grinding, hear clicking or any other type of noise when your knee moves?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S3. Does your knee catch or hang up when moving?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S4. Can you straighten your knee fully?

Always	Often	Sometimes	Rarely	Never
☐	☐	☐	☐	☐

S5. Can you bend your knee fully?

Always	Often	Sometimes	Rarely	Never
☐	☐	☐	☐	☐

Stiffness
The following questions concern the amount of joint stiffness you have experienced during the **last week** in your knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your knee joint.

S6. How severe is your knee joint stiffness after first wakening in the morning?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

S7. How severe is your knee stiffness after sitting, lying or resting **later in the day**?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Knee injury and Osteoarthritis Outcome Score (KOOS), English version LK1.0

Pain

P1. How often do you experience knee pain?

Never ☐ Monthly ☐ Weekly ☐ Daily ☐ Always ☐

What amount of knee pain have you experienced the **last week** during the following activities?

P2. Twisting/pivoting on your knee

None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme ☐

P3. Straightening knee fully

None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme ☐

P4. Bending knee fully

None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme ☐

P5. Walking on flat surface

None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme ☐

P6. Going up or down stairs

None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme ☐

P7. At night while in bed

None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme ☐

P8. Sitting or lying

None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme ☐

P9. Standing upright

None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme ☐

Function, daily living

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A1. Descending stairs

None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme ☐

A2. Ascending stairs

None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme ☐

Knee injury and Osteoarthritis Outcome Score (KOOS), English version LK1.0

For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A3. Rising from sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A4. Standing

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A5. Bending to floor/pick up an object

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A6. Walking on flat surface

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A7. Getting in/out of car

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A8. Going shopping

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A9. Putting on socks/stockings

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A10. Rising from bed

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A11. Taking off socks/stockings

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A12. Lying in bed (turning over, maintaining knee position)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A13. Getting in/out of bath

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A14. Sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A15. Getting on/off toilet

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Knee injury and Osteoarthritis Outcome Score (KOOS), English version LK1.0

For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A16. Heavy domestic duties (moving heavy boxes, scrubbing floors, etc)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A17. Light domestic duties (cooking, dusting, etc)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Function, sports and recreational activities

The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experienced during the **last week** due to your knee.

SP1. Squatting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP2. Running

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP3. Jumping

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP4. Twisting/pivoting on your injured knee

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP5. Kneeling

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Quality of Life

Q1. How often are you aware of your knee problem?

Never	Monthly	Weekly	Daily	Constantly
☐	☐	☐	☐	☐

Q2. Have you modified your life style to avoid potentially damaging activities to your knee?

Not at all	Mildly	Moderately	Severely	Totally
☐	☐	☐	☐	☐

Q3. How much are you troubled with lack of confidence in your knee?

Not at all	Mildly	Moderately	Severely	Extremely
☐	☐	☐	☐	☐

Q4. In general, how much difficulty do you have with your knee?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Thank you very much for completing all the questions in this questionnaire.

From "Questionnaires and language versions KOOS" by E. W. Roos (n.d). Retrieved from http://www.koos.nu/koos-english.pdf