

RENAN ALVES RESENDE

**EFEITOS DA PRONAÇÃO AUMENTADA SOBRE A
BIOMECÂNICA DA MARCHA DE INDIVÍDUOS
ADULTOS JOVENS SAUDÁVEIS E INDIVÍDUOS COM
OSTEOARTRITE DE JOELHO**

Belo Horizonte

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Tese apresentada ao Colegiado de Pós-Graduação em Ciências da Reabilitação da Universidade Federal de Minas Gerais como requisito parcial para obtenção do título de doutor.

Área de concentração: Desempenho Funcional Humano

Linha de pesquisa: Estudos do Desempenho Motor e Funcional Humano.

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Belo Horizonte

2014

COLEGIADO DE PÓS-GRADUAÇÃO EM CIÊNCIAS EM REABILITAÇÃO
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ATA DE NÚMERO 34 (TRINTA E QUATRO) DA SESSÃO DE ARGUIÇÃO E DEFESA
DE TESE APRESENTADA PELO CANDIDATO **RENAN ALVES RESENDE** DO
PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS DA REABILITAÇÃO.

Aos 07 (sete) dias do mês de abril do ano de dois mil e quatorze, realizou-se na Escola de Educação Física, Fisioterapia e Terapia Ocupacional, a sessão pública para apresentação e defesa da Tese de Doutorado intitulada: "**EFEITOS DA PRONAÇÃO AUMENTADA SOBRE A BIOMECÂNICA DA MARCHA DE INDIVÍDUOS ADULTOS JOVENS SAUDÁVEIS E INDIVÍDUOS COM OSTEOARTRITE DE JOELHO**". A comissão examinadora foi constituída pelos seguintes Professores Doutores: Sérgio Teixeira da Fonseca, Anamaria Siriani de Oliveira, Paula Maria Machado Arantes, Juliana de Melo Ocarino e Thales Rezende de Souza, sob a Presidência do primeiro. Os trabalhos iniciaram-se às 14h00min com apresentação oral do candidato, seguida de arguição dos membros da Comissão Examinadora. Após avaliação, os examinadores consideraram o candidato **aprovado e apto a receber o título de Doutor após a entrega da versão definitiva da Tese**. Nada mais havendo a tratar, eu, Eni da Conceição Rocha, secretária do Colegiado de Pós-Graduação em Ciências da Reabilitação dos Departamentos de Fisioterapia e de Terapia Ocupacional da Escola de Educação Física, Fisioterapia e Terapia Ocupacional, lavrei a presente Ata, que depois de lida e aprovada será assinada por mim e pelos membros da Comissão Examinadora.

Belo Horizonte, 07 de abril de 2014.

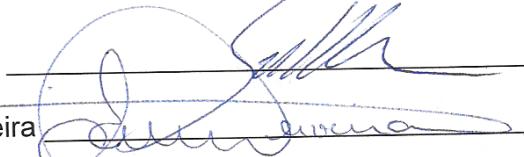
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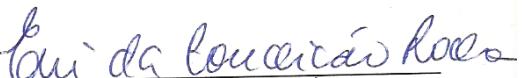
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Eni da Conceição Rocha

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DECLARAÇÃO

Declaramos para os devidos fins que, **RENAN ALVES RESENDE** defendeu a Tese de Doutorado intitulada: "**EFEITOS DA PRONAÇÃO AUMENTADA SOBRE A BIOMECÂNICA DA MARCHA DE INDIVÍDUOS ADULTOS JOVENS SAUDÁVEIS E INDIVÍDUOS COM OSTEOARTRITE DE JOELHO**" obtendo em 07/04/2014 a aprovação unânime da Banca Examinadora, junto ao Programa de Pós-Graduação em Ciências da Reabilitação, nível: Doutorado, da Universidade Federal de Minas Gerais; fazendo jus ao título de Doutor em Ciências da Reabilitação a partir da referida data.

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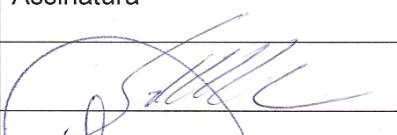
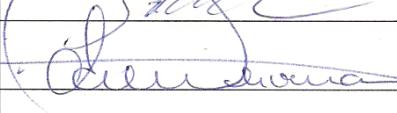
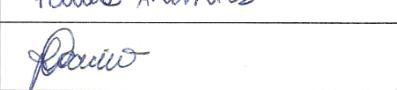
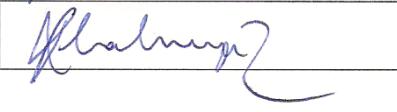
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PARECER

Considerando que a Tese de Doutorado de **RENAN ALVES RESENDE** intitulada: “**EFEITOS DA PRONAÇÃO AUMENTADA SOBRE A BIOMECÂNICA DA MARCHA DE INDIVÍDUOS ADULTOS JOVENS SAUDÁVEIS E INDIVÍDUOS COM OSTEOARTRITE DE JOELHO**”, defendida junto ao Programa de Pós-Graduação em Ciências da Reabilitação, nível: Doutorado cumpriu sua função didática, atendendo a todos os critérios científicos, a Comissão Examinadora **APROVOU** a Tese de doutorado, conferindo-lhe as seguintes indicações:

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RESUMO

Foram realizados 2 estudos com medidas repetidas. Foram utilizadas sandálias planas e sandálias com inclinação lateral para promover pronação durante a fase de apoio marcha. Os indivíduos andaram em 3 condições, as quais incluíram uma condição controle (sandálias sem inclinação) e 2 condições nas quais as sandálias aumentaram a quantidade de pronação do pé (inclinação no pé ipsilateral e inclinação no pé contralateral ao membro inferior direito no primeiro estudo e ao membro com osteoartrite de joelho no segundo estudo). A ordem de coleta dos dados foi randomizada. Um sistema de análise de movimento e 6 plataformas de força foram utilizados para a captura dos dados da marcha. A análise de componentes principais e ANOVA simples com medidas repetidas foram utilizadas para identificar diferenças entre condições nos dois estudos ($\alpha = 0,05$). No primeiro estudo, a sandália inclinada aumentou o momento evensor de tornozelo ($p<0,001$); aumentou a eversão do retropé ($p<0,001$); aumentou a rotação medial de perna ($p=0,009$); reduziu o momento rotador medial de joelho durante a fase final de apoio ($p<0,001$); aumentou e reduziu a rotação medial de joelho durante a fase de apoio inicial e apoio final, respectivamente ($p<0,001$); aumentou a rotação medial de fêmur ($p=0,005$; tamanho de efeito=0,90); reduziu o momento rotador medial de quadril durante a fase final de apoio ($p=0,001$); e aumentou a queda pélvica ipsilateral ($p=0,02$) do membro inferior ipsilateral. A utilização da sandália inclinada no membro contralateral aumentou a queda pélvica contralateral ($p=0,001$); aumentou o momento adutor de quadril ao longo de toda a fase apoio ($p=0,027$); aumentou o momento adutor de joelho durante a fase inicial de apoio ($p<0,001$); e aumentou a amplitude de movimento do joelho no plano frontal ($p=0,017$). O aumento da rotação medial de quadril causado pela sandália inclinada pode ter dificultado a ação dos músculos rotadores laterais de quadril durante a fase de apoio terminal (momento articular interno) devido ao alongamento dessa musculatura, o que resultou em menor momento rotador medial de quadril calculado a partir da força de reação do solo (momento articular externo). No segundo estudo, a sandália inclinada aumentou o momento evensor de tornozelo ($p<0,001$); aumentou a eversão de retropé ($p<0,001$); aumentou a rotação medial da perna ($p<0,001$); reduziu o momento rotador medial de joelho ($p<0,001$); aumentou e reduziu a rotação medial de joelho

durante a fase inicial de apoio e fase final de apoio, respectivamente ($p=0,004$); aumentou a rotação medial de fêmur ($p<0,001$); e reduziu o momento rotador medial de quadril ($p=0,001$) do membro inferior ipsilateral. A sandália inclinada aumentou o momento adutor de quadril ($p=0,003$); e aumentou o momento adutor de joelho ($p=0,002$) do membro inferior contralateral. O movimento do pé deve ser avaliado em indivíduos com OA de joelho e o uso de calçados com elevação lateral para reduzir o momento adutor de joelho em indivíduos com OA deve levar em consideração os possíveis efeitos deletérios sobre o plano transverso do membro ipsilateral e sobre o plano frontal do membro contralateral.

Palavras-chave: Biomecânica. Marcha. Pronação do pé. Osteoartrite de joelho.

ABSTRACT

Two repeated measures studies were implemented in the human mobility research laboratory of the Queen's University. Two types of sandals were specifically designed for the study. The individuals walked on 3 different conditions. The study had 1 control condition (flat sandals) and 2 conditions which increased foot pronation (wedged sandal on the knee OA side and wedged sandal on the knee OA contralateral side – right lower limb used as a reference for the study with the young individuals). The order of data collection was randomized. A motion analysis system and 6 force platforms were used to collect the data. After each condition, the subject was asked about his knee pain and comfort while walking with the previous pair of sandals. Principal component analysis and repeated measures one-way ANOVA were used to identify differences between conditions. The results of the first study demonstrated that on the ipsilateral side, the wedged sandal increased ankle eversion moment ($p<0.001$); rearfoot eversion ($p<0.001$); reduced knee internal rotation moment in late stance ($p<0.001$); increased and reduced knee internal rotation during early and late stance, respectively ($p<0.001$); reduced hip internal rotation moment during late stance ($p=0.001$); and increased pelvic ipsilateral drop ($p=0.02$). On the contralateral side, the laterally wedged sandal increased pelvic contralateral drop ($p=0.001$); increased hip adduction moment throughout stance ($p=0.027$); increased knee adduction moment in early stance ($p<0.001$); and increased knee frontal plane range of motion ($p=0.017$). The results of the second study demonstrated that on the ipsilateral side, the wedged sandal increased ankle eversion moment ($p<0.001$); rearfoot eversion ($p<0.001$); shank internal rotation ($p<0.001$); reduced knee internal rotation moment ($p<0.001$); increased and reduced knee internal rotation during early and late stance, respectively ($p=0.004$); increased femur internal rotation ($p<0.001$); and reduced hip internal rotation moment ($p=0.001$). On the contralateral side, the wedged sandal increased hip adduction moment ($p=0.003$); and increased knee adduction moment ($p=0.002$). The increased hip internal rotation caused by the wedged sandal may have hampered hip external rotators action in terminal stance (internal moments) resulting in smaller hip internal rotation moments computed based on the ground reaction force (external moments). The increased pelvic contralateral drop may explain the increased hip and knee

adduction moments on the contralateral lower limb. These results should be considered in individuals presenting increased foot pronation. The coupling mechanism between foot pronation and shank internal rotation also occurs in individuals with knee OA. The increased knee adduction moment on the contralateral lower limb may be a compensation for the smaller knee adduction moment on the ipsilateral lower limb. Foot motion should be evaluated in individuals with knee OA and the use of lateral wedges to reduce knee adduction moment should consider the possible deleterious effects on the transverse plane of ipsilateral lower limb and on the frontal plane of the contralateral lower limb.

Keywords: Biomechanics. Gait. Foot pronation. Knee osteoarthritis.

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1 INTRODUÇÃO

Osteoartrite (OA) é uma doença progressiva que causa incapacidade e perda de função (MCKEAN *et al.*, 2007). O risco de desenvolver OA de joelho ao longo da vida é de aproximadamente 45% (40% em homens e 47% em mulheres) (JORDAN *et al.*, 2007). A prevalência de OA sintomática de joelho em adultos acima de 45 anos varia entre 11 e 19% (JORDAN *et al.*, 2007; PEAT *et al.*, 2001). No entanto, com o envelhecimento e aumento da obesidade da população, é esperado que essa prevalência aumente, o que já foi demonstrado pelo estudo longitudinal de Framingham, o qual demonstrou que a prevalência de OA dobrou em mulheres e triplicou em homens entre 1983 e 2005 (NGUYEN *et al.*, 2011). Indivíduos em estágios avançados de OA de joelho são comumente submetidos à artroplastia total, a qual apresenta tempo médio de falha de 5,9 anos, sendo 35,3% de todas as revisões realizadas em menos de 2 anos após a cirurgia, e 60,2% em menos de 5 anos (SCHROER *et al.*, 2013). Dessa forma, medidas que contribuam para a redução da sobrecarga sobre o joelho podem retardar a necessidade de se submeter à artroplastia e assim reduzir os efeitos adversos (SCHROER *et al.*, 2013) e os custos associados à realização da mesma (LOVALD *et al.*, 2013).

Diversos fatores são apontados como possíveis preditores da progressão da OA de joelho (CHEUNG *et al.*, 2010). De maneira relativamente arbitrária, esses fatores podem ser classificados como modificáveis e não-modificáveis. Fatores não-modificáveis incluem idade avançada, presença de OA em múltiplas articulações e a deformidade em varo do joelho (CHAPPLE *et al.*, 2011). Entre os modificáveis estão o índice de massa corporal (IMC) elevado (CHAPPLE *et al.*, 2011), alimentação pobre em vitamina D (MCALINDON *et al.*, 1996) e C (MCALINDON *et al.*, 1996) e alterações da biomecânica da marcha (ANDRIACCHI *et al.*, 2004). Assim, um melhor entendimento dos fatores modificáveis, como as alterações da biomecânica articular durante a marcha, possibilitam o desenvolvimento de estratégias para a redução da sobrecarga sobre o joelho e consequentemente progressão da OA.

Durante a marcha, foi estabelecido que alterações biomecânicas no plano frontal podem sobrecarregar o joelho (LYNN *et al.*, 2007). Por exemplo, o momento de força externo adutor de joelho é foco de grande parte dos estudos, já que o aumento de 1% desse momento aumenta em 6,46 vezes o risco de progressão da

doença (MIYAZAKI *et al.*, 2002). Nesse contexto, estudos longitudinais avaliaram intervenções com o objetivo de reduzir o momento externo adutor do joelho e consequentemente a progressão da doença, como o uso de calçados com elevação lateral sob o pé (KAKIHANA *et al.*, 2005; HINMAN *et al.*, 2012). Esses estudos, no entanto, não obtiveram sucesso na redução da progressão da doença (BAKER *et al.*, 2007; BARRIOS *et al.*, 2009; BENNELL *et al.*, 2011; MAILLEFERT *et al.*, 2001; PHAM *et al.*, 2004). É possível que esses resultados sejam parcialmente explicados pelo aumento da rotação interna de tíbia causado pelo uso de elevações laterais sob o pé (SOUZA *et al.*, 2009), o que aumentaria o estresse rotacional sobre o joelho e assim contrabalancearia os efeitos positivos da redução do momento adutor de joelho. Além disso, BENNEL *et al.* (2011) demonstraram que 47% dos indivíduos avaliados reportaram desconforto com o uso de elevações laterais sob o pé, o que pode ter ocorrido devido ao aumento do momento externo evensor de tornozelo causado pelo uso de elevações laterais (KAKIHANA *et al.*, 2004). Dessa forma, apesar de o uso de elevação lateral sob o pé reduzir o momento externo adutor de joelho, os efeitos sobre outras variáveis biomecânicas, como o momento externo evensor de tornozelo e o deslocamento angular de joelho no plano transverso, também devem ser considerados.

A menor rigidez ligamentar (NOYES; GROOD, 1976; WOO *et al.*, 1991) e a menor força (JUBRIAS *et al.*, 1997) e ativação musculares (SHARMA *et al.*, 1999; STACKHOUSE *et al.*, 2001) decorrentes do envelhecimento contribuem para menor estabilidade da articulação do joelho. Assim, é provável que, com o envelhecimento, a articulação do joelho se torne mais suscetível a forças que tendem a aumentar a quantidade de movimento nos três planos. Além disso, é possível que a piora da função do ligamento cruzado anterior com o envelhecimento cause aumento da rotação interna de joelho durante a marcha (ANDRIACCHI; DYRBY, 2005; GEORGULIS *et al.*, 2003). Em indivíduos com OA de joelho, a frouxidão articular é ainda mais evidente (WADA *et al.*, 1996). Dessa forma, forças que tendem a aumentar a rotação interna de joelho potencializariam o estresse mecânico por cisalhamento sobre a cartilagem articular já deteriorada devido à OA. Utilizando métodos de modelagem específicos, ANDRIACCHI *et al.* (2006) demonstraram que o aumento de 5° de rotação interna da tíbia durante a fase de apoio inicial da marcha em joelho sem alterações degenerativas resulta em degeneração da cartilagem

articular de todo o joelho, o que sugere os efeitos deletérios de alterações no plano transverso do joelho com OA.

Durante a fase de apoio da marcha, o quadril, o joelho e o complexo tornozelo/pé constituem uma cadeia cinética fechada e, portanto, o movimento de uma articulação não ocorre de maneira isolada das demais articulações. Dessa forma, alterações na cinemática do complexo tornozelo/pé afetam diretamente a biomecânica da articulação do joelho. Por exemplo, o acoplamento entre as articulações do pé e joelho associa pronação do pé à rotação interna de tibia (NESTER *et al.*, 2000; NIGG *et al.*, 1993; SOUZA *et al.*, 2009). Assim, a pronação aumentada observada em indivíduos com OA de joelho (LEVINGER *et al.*, 2012) pode acelerar a progressão da OA por meio do aumento da rotação interna de joelho durante a marcha.

Supondo a existência de uma relação de causa-efeito simples entre fatores associados à OA de joelho, pode-se argumentar que o aumento da pronação do pé em indivíduos com OA de joelho é uma estratégia compensatória (consequência hipotética) para permitir apoio da parte medial do pé no solo em indivíduos com geno varo do joelho aumentado (causa hipotética) (LEVINGER *et al.*, 2012). Assim, a pronação aumentada não contribuiria para a progressão da OA em indivíduos com geno varo aumentado, mas seria uma mera consequência. No entanto, geno varo não prediz o desenvolvimento da doença (HUNTER *et al.*, 2007) e aumenta progressivamente em indivíduos com OA (TEICHTAHL *et al.*, 2009), o que torna questionável o argumento de que pronação aumentada seja consequência de geno varo nesses indivíduos. Além disso, desalinhamentos do pé que contribuem para o aumento da pronação (MONAGHAN *et al.*, 2013), como retropé (STRAUS, 1927; TIBERIO, 1988) e antepé varo (HUNT; BROCATO, 1988; TIBERIO, 1988), estão presentes desde a infância, o que sugere que a pronação aumentada pode contribuir para o desenvolvimento da OA de joelho.

Uma fonte potencial de estresse repetitivo sobre o joelho é o alinhamento em varo do pé. Antepé varo é um desalinhamento estrutural no plano frontal que altera a orientação do pé em relação ao solo, sendo a borda medial do antepé mais elevada que a borda lateral (TIBERIO, 1988). Estudos prévios demonstraram que o ângulo do antepé no momento do contato com o solo pode produzir torques pronatórios que resultam em aumento da magnitude e da duração da pronação (LAFORTUNE *et al.*, 1994; MONAGHAN *et al.*, 2013). Segundo esse raciocínio, SOUZA *et al.* (2009)

demonstraram que andar com elevação lateral sob o antepé aumenta a eversão do retropé e a rotação interna de perna e quadril de indivíduos adultos jovens durante a fase de apoio da marcha.

É possível que o acoplamento entre eversão do pé e rotação interna de perna também ocorra em indivíduos com OA de joelho. No entanto, devido a maior frouxidão articular de indivíduos com OA de joelho, é possível que o acoplamento entre pé e da perna não ocorra (WADA *et al.*, 1996), o que levaria à dissipação dos movimentos do pé no plano frontal na articulação talocrural. Além disso, a maior parte dos indivíduos com OA de joelho apresentam pé plano (GROSS *et al.*, 2011), o que contribui para a horizontalização do eixo da articulação subtalar e consequentemente para a redução da proporção do movimento da articulação subtalar no plano transverso. Dessa forma, a demonstração da relação entre pronação aumentada e/ou da presença de antepé varo e o aumento da rotação interna de perna em indivíduos com OA de joelho contribuiria para o melhor entendimento dos fatores biomecânicos envolvidos no desgaste da cartilagem articular do joelho. Apesar de não ter sido demonstrado relação entre mau alinhamento do pé e presença de OA no joelho, os efeitos de possuir antepé varo foram observados na articulação do quadril por Gross e colaboradores (GROSS *et al.*, 2007), os quais demonstraram que antepé varo está associado com a presença de dor e evolução para artroplastia do quadril.

Os efeitos de pronação aumentada sobre a cinemática de articulações proximais no plano transverso de indivíduos com OA de joelho podem afetar a capacidade de geração de torque em articulações proximais. Especificamente no quadril, é possível que o aumento da rotação interna causado por pronação aumentada (SOUZA *et al.*, 2009) alongue dinamicamente os músculos rotadores externos de quadril durante a fase de apoio da marcha tornando esse grupo muscular menos eficiente para a geração de momento rotador externo no quadril durante a fase de apoio (momento articular interno). De maneira cíclica, a redução do momento interno rotador externo de quadril contribuiria para a permanência do membro inferior em rotação interna durante a fase de apoio. É possível que esse mecanismo seja potencializado em indivíduos com OA de joelho, uma vez que eles apresentam fraqueza da musculatura rotadora externa de quadril (ALNAHDI *et al.*, 2012).

A dinâmica da marcha é dependente da interação entre os membros inferiores (HERR; POPOVIC, 2008). Dessa forma, é possível que pronação aumentada do lado oposto ao membro inferior com OA de joelho possa influenciar na biomecânica do membro inferior com OA. Estudos prévios demonstraram que em posição ortostática, aumento da pronação do pé aumenta a queda pélvica em direção ao mesmo lado (KHAMIS; YIZHAR, 2007; PINTO *et al.*, 2008; TATEUCHI *et al.*, 2011). Assim, se esse acoplamento entre pé e pelve também ocorrer durante a marcha, pronação aumentada do lado oposto à OA pode afetar a biomecânica do membro inferior com OA por meio da modificação do movimento pélvico. Especificamente, aumento da queda pélvica em direção ao lado oposto à OA pode aumentar o momento externo adutor do joelho com OA (TAKACS; HUNT, 2012) e consequentemente sobrecarregar essa articulação.

A demonstração dos efeitos biomecânicos de pronação aumentada em indivíduos com OA de joelho pode contribuir para o entendimento da relação entre esses fatores e a progressão da doença. É possível que os resultados do presente estudo demonstrem a importância de (1) avaliar os movimentos do pé em indivíduos com OA de joelho e, (2) nos casos nos quais alterações forem encontradas, intervir com a indicação de palmilhas específicas e estratégias para modificação das características teciduais indesejadas associadas à pronação aumentada. Além disso, é possível que nossos resultados contribuam para o melhor entendimento da influência do membro oposto sobre a biomecânica do membro inferior com OA de joelho. Finalmente, é possível que o presente estudo contribua para a discussão sobre intervenções designadas para indivíduos com OA de joelho, como o uso de elevações laterais sob o pé, as quais devem ser consideradas tendo em vista seus efeitos sobre outras variáveis que não somente o momento externo adutor do joelho com OA.

1.1 Objetivos

1.1.1 Objetivo geral

Antes da coleta de dados com os indivíduos com OA de joelho, tivemos como objetivo investigar a viabilidade do nosso estudo em indivíduos adultos jovens

saudáveis. Além disso, tínhamos como objetivo testar nossas hipóteses acerca dos efeitos da pronação aumentada em indivíduos adultos jovens para justificar a realização do estudo com os indivíduos com OA de joelho. Dessa forma, o objetivo geral do presente trabalho foi investigar os efeitos da pronação unilateralmente aumentada sobre a biomecânica de membros inferiores e pelve durante a marcha de indivíduos adultos jovens saudáveis e sobre a biomecânica de membros inferiores e pelve durante a marcha e sobre o relato de dor e conforto em indivíduos com OA de joelho. Para cumprir esse objetivo, dois estudos foram realizados.

1.1.2 Estudo 1

Os objetivos do primeiro estudo foram: a) Investigar os efeitos da indução da pronação unilateralmente aumentada sobre o momento externo inversor de tornozelo, deslocamento angular de retropé no plano frontal, deslocamento angular de perna, joelho, coxa e quadril e no momento externo de joelho e quadril no plano transverso, e deslocamento angular de pelve no plano frontal do membro ipsilateral; b) Investigar os efeitos da indução da pronação unilateralmente aumentada sobre o deslocamento angular da pelve, deslocamento angular e momento externo de quadril e joelho, momento externo de tornozelo e deslocamento angular de retropé no plano frontal do membro inferior contralateral.

1.1.3 Estudo 2

Os objetivos do segundo estudo foram: a) Investigar os efeitos da indução da pronação unilateralmente aumentada sobre o momento externo inversor de tornozelo, deslocamento angular de retropé no plano frontal, deslocamento angular de perna, joelho e coxa e no momento externo de joelho e quadril no plano transverso, e sobre o deslocamento angular de pelve no plano frontal do membro com OA de joelho; b) Investigar os efeitos da indução da pronação unilateralmente aumentada sobre o deslocamento angular da pelve, deslocamento angular e

momento externo de quadril e joelho no plano frontal do membro contralateral ao membro com OA de joelho. c) Investigar os efeitos da indução da pronação unilateralmente aumentada do lado com OA de joelho e do lado oposto ao joelho com OA sobre a dor no joelho com OA e sobre o conforto durante a marcha.

1.2 Hipóteses

1.2.1 Estudo 1

H1: A pronação aumentada aumentará o momento evensor de tornozelo, a eversão de retropé, a rotação interna de perna, joelho, fêmur e quadril e a queda ipsilateral da pelve e reduzirá os momentos rotadores internos de joelho e quadril ipsilaterais durante a fase de apoio da marcha.

H2: A pronação aumentada aumentará a queda contralateral da pelve, os momentos adutores e adução de quadril e joelho contralaterais durante a fase de apoio da marcha.

1.2.2 Estudo 2

H1: A pronação aumentada aumentará o momento evensor de tornozelo, a eversão de retropé, a rotação interna de perna, joelho e fêmur e a queda ipsilateral da pelve e reduzirá os momentos rotadores internos de joelho e quadril do membro com OA de joelho durante a fase de apoio da marcha.

H2: A pronação aumentada aumentará a queda contralateral da pelve, os momentos adutores e adução de quadril e joelho do membro contralateral ao membro com OA de joelho durante a fase de apoio da marcha.

H3: Deambular com pronação aumentada do lado com OA e do lado contralateral à OA de joelho aumentará a dor no joelho com OA e reduzirá o conforto do indivíduo durante a marcha.

2 MATERIAIS E MÉTODO

2.1 Desenho do estudo

Dois estudos de medidas repetidas foram conduzidos, um com indivíduos jovens saudáveis e um com indivíduos com OA bilateral ou unilateral de joelho em um dia de coleta no laboratório.

2.2 Aspectos éticos

O projeto foi enviado e aprovado pelo comitê de ética em pesquisa da Queen's University, Kingston (APÊNDICES A e B), Ontario, Canadá e todos os participantes assinaram um Termo de Consentimento Livre e Esclarecido de acordo com o Comitê de Ética em Pesquisa da Instituição (APÊNDICE C – primeiro estudo; APÊNDICE D – segundo estudo).

2.3 Localização

O estudo foi desenvolvido no Human Mobility Research Laboratory localizado no Hotel Dieu Hospital em Kingston, Ontário, Canadá.

2.4 Amostra do primeiro estudo

Vinte e dois indivíduos adultos jovens saudáveis (10 mulheres, 12 homens) com média de idade, massa e altura de 25 anos (DP 4,5), 71.7 kg (DP 11,3) e 175 cm (DP 8), respectivamente, participaram do primeiro estudo. Os participantes foram recrutados entre alunos de graduação e pós-graduação da Queen's University. Os critérios de inclusão foram ter entre 20 e 40 anos de idade, não possuir história de

cirurgia ou lesões nos membros inferiores ou região lombo-pélvica durante o último ano. O critério de exclusão foi o relato de qualquer desconforto durante a coleta de dados.

2.5 Amostra do segundo estudo

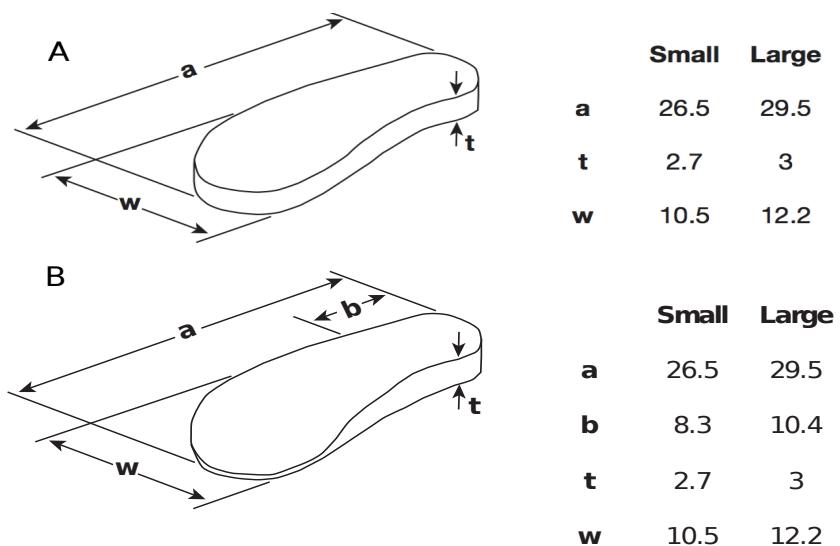
Vinte indivíduos (13 mulheres, 7 homens) com média de idade, massa e altura de 67 anos (DP 8,3), 87,9 kg (DP 18) e 170 cm (SD 8) participaram do segundo estudo. Os participantes foram recrutados por meio de contatos fornecidos por dois cirurgiões ortopédicos, os quais tinham experiência de no mínimo 10 anos com pacientes com OA de joelho. Indivíduos diagnosticados pelos cirurgiões com OA do joelho unilateral ou bilateral participaram do estudo. A classificação radiográfica da OA de joelho foi baseada nos critérios de Kellgren e Lawrence (KELLGREN; LAWRENCE, 1957) sendo incluídos indivíduos de ambos os sexos. Para evitar a influência de diferentes níveis de severidade de OA de joelho sobre os resultados do presente estudo, apenas indivíduos graus III e IV foram incluídos no presente estudo. Os critérios de inclusão foram: não ter histórico de quedas nos últimos seis meses, não necessitar de dispositivo de auxílio para andar, ser capaz de subir degraus de maneira recíproca, ou seja, com apenas um membro inferior em cada degrau, não ter histórico de trauma ou cirurgia nos últimos 6 meses, fraturas ou outras doenças afetando as articulações dos membros inferiores e não possuir doenças cardiovasculares descompensadas. Os critério de exclusão foram o relato de dor excessiva durante a coleta de dados, definida como relato de dor acima de 80 mm em uma escala visual analógica de dor de 100 mm, ou demonstração de insegurança ou desequilíbrio durante a coleta dos dados.

2.6 Modelos das Sandálias

No sentido de induzir o aumento da pronação, dois modelos de sandálias com duas numerações diferentes - pequena e grande, quatro pares no total - foram

utilizados no presente estudo como mostrado na Figura 1. As sandálias foram modeladas com espuma vinílica acetinada (EVA) de alta densidade e possuíam alças com extremidades compostas por velcro, as quais permitiam que as mesmas fossem acopladas aos pés dos participantes. A Figura 1A mostra o modelo 1 de sandália com solado plano grosso, espessura de 2,7 e 3,0 cm e largura de 10,5 e 12,2 cm nos tamanhos de sandália pequeno e grande, respectivamente. O segundo modelo de sandália (modelo 2), também nos tamanhos pequeno e grande, apresentava inclinação lateral (possuíam uma depressão medial) sob o antepé atingindo pico de 10° de depressão medial na altura da cabeça dos metatarsos (SOUZA *et al.*, 2009). O comprimento da base plana para apoio do retropé era de 8,3 cm no par de sandálias pequeno e 10,4 cm no par de sandálias grande; apenas o retropé apresentava espessura de 2,7 cm no par de sandálias pequeno e de 3,0 cm no par de sandálias grande e os dois tamanhos de sandália possuíam largura de 10,5 e 1,2 cm, respectivamente (Figura 1B). A inclinação foi utilizada apenas no antepé, uma vez que foi demonstrado que o ângulo do antepé influencia na duração e na magnitude da pronação durante a fase de apoio da marcha (MONAGHAN *et al.*, 2013). Além disso, foi utilizada uma inclinação de 10°, pois em um estudo envolvendo indivíduos idosos da amostra de coorte de OA de Framingham, o ângulo médio de antepé varo dos indivíduos foi de 9,9° (GROSS *et al.*, 2007).

Figura 1: Dimensões dos diferentes modelos de sandálias nos tamanhos pequeno e grande. Modelo 1 (A); Modelo 2 (B). Legenda: a: comprimento das sandálias; b: comprimento do retropé na sandália inclinada; t: espessura das sandálias (no caso da sandália inclinada a espessura se aplica somente ao retropé); w: largura das sandálias.



2.7 Procedimentos

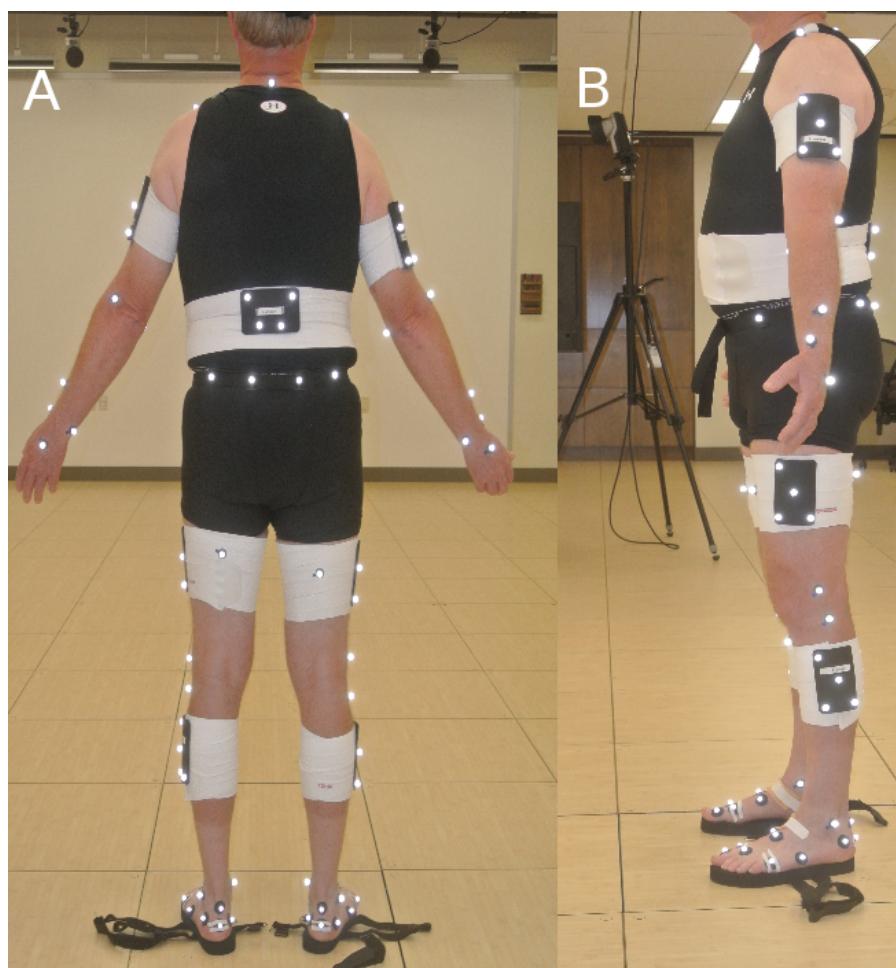
Os procedimentos implementados para coleta de dados foram em sua maior parte os mesmos para os dois estudos. Dessa forma, quando não for especificado um dos estudos, é porque aquele procedimento específico foi implementado nos dois estudos. Após receberem uma carta do cirurgião ortopédico informando sobre a existência do estudo (APÊNDICE E) com o termo de consentimento em anexo, os pacientes do segundo estudo foram contatados via ligação telefônica na qual eram informados sobre os objetivos do estudo e convidados a participarem do mesmo. No caso dos participantes do primeiro estudo o contato foi realizado de maneira direta via e-mail ou telefonema. Em caso de resposta positiva, os critérios de inclusão eram investigados e em caso de adequação do indivíduo aos mesmos, uma data para a coleta dos dados era agendada (APÊNDICE F). Com o objetivo de cobrir os gastos com transporte, estacionamento e/ou alimentação, 20 dólares canadenses foram pagos aos participantes do segundo estudo.

Ao chegar ao laboratório, os participantes foram convidados a ler e assinar o termo de consentimento livre e esclarecido. Em seguida, apenas para os participantes do segundo estudo, foram aplicados os questionários Western Ontario and McMaster Universities Arthritis Index (WOMAC) (BELLAMY *et al.*, 1988), especificamente desenvolvido e validado para avaliar dor, rigidez e função física em indivíduos com OA de joelho (ANEXO A), e a Lower Extremity Activity Scale (LEAS) (SALEH *et al.*, 2005), especificamente desenvolvida e validada para avaliar o nível de atividade física em pacientes em pré ou pós operatório de artroplastia do joelho (ANEXO B). Esses questionários foram aplicados com o objetivo de caracterizar a amostra. Os participantes dos dois estudos foram novamente questionados sobre o histórico de lesões e cirurgias e então os shorts e camisetas utilizados durante a coleta de dados foram fornecidos.

Em seguida, a massa e altura dos participantes foi obtida e os dados da marcha foram então coletados utilizando um sistema de análise de movimento composto por 12 câmeras (Oqus 4, Qualisys, Gothenburg, Suécia) sincronizado a 6 plataformas de força (Custom BP model, AMTI, Massachusetts, USA). A frequência de coleta das câmeras foi de 200 Hz e as plataformas de força registraram a força

de reação do solo a uma frequência de 1000 Hz, a qual foi subsequentemente reamostrada para 200 Hz. Marcas anatômicas e clusters com marcas de rastreamento foram utilizados para determinar o sistema de coordenadas de todo o corpo durante uma coleta estática com o indivíduo em posição anatômica (FIGURA 2). O retropé do modelo modificado de Oxford (WRIGHT *et al.*, 2011) e o modelo de pelve CODA (Charnwood Dynamics Ltd., UK) foram utilizados no presente estudo.

Figura 2: Coleta estática com o indivíduo em posição ortostática sobre as sandálias utilizadas durante a condição controle. A) Visão posterior; B) Visão lateral.



Após a coleta estática, uma coleta com o objetivo de definir o eixo funcional do quadril era realizada. O indivíduo era orientado a manter pelve e tronco estáveis enquanto realizava movimentos de flexão, abdução, extensão e circundução de quadril com o joelho estendido. Durante essa coleta, o indivíduo utilizava apoio do membro superior contralateral sobre uma estrutura rígida posicionada ao lado do participante para que mantivesse pelve e tronco estáveis. Em seguida, com as

sandálias acopladas aos pés do participante por meio de tiras e velcro, os dados cinemáticos e cinéticos foram coletados em 3 condições diferentes (FIGURA 3). No primeiro estudo, as 3 condições foram as seguintes:

- 1) Condição controle: o participante deambulou utilizando o modelo 1 de sandália (plana e grossa) (FIGURA 4A);
- 2) Condição inclinada do mesmo lado: o participante deambulou utilizando a sandália modelo 2 (inclinada) no membro inferior direito e a sandália modelo 1 (plana e grossa) do lado esquerdo (FIGURA 4B);
- 3) Condição inclinada do lado oposto: o participante utilizou a sandália modelo 2 (inclinada) no membro inferior esquerdo e a sandália modelo 1 (plana e grossa) no membro inferior direito (FIGURA 4C).

No segundo estudo, as 3 condições foram as seguintes:

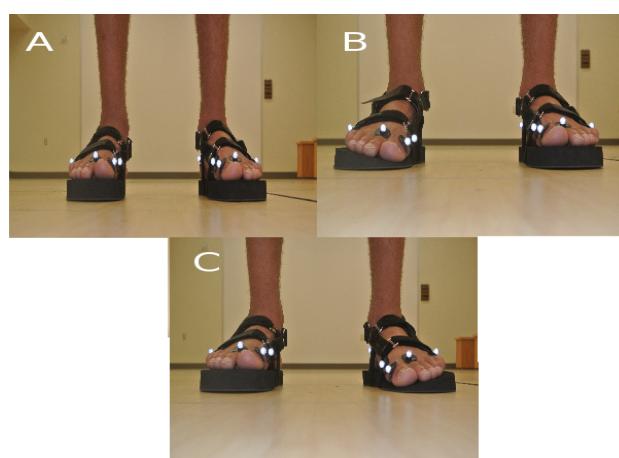
- 1) Condição controle: o participante deambulou utilizando o modelo 1 de sandália (plana e grossa) (FIGURA 4A);
- 2) Condição inclinada do lado com OA: o participante deambulou utilizando a sandália modelo 2 (inclinada) no membro inferior com OA e a sandália modelo 1 (plana e grossa) do lado oposto (FIGURA 4B);
- 3) Condição inclinada do lado oposto à OA: o participante utilizou a sandália modelo 2 (inclinada) do lado oposto ao membro inferior com OA e a sandália modelo 1 (plana e grossa) no membro inferior com OA (FIGURA 4C);

Figura 3: Alças com velcros utilizados para acoplar as sandálias aos pés dos participantes após a realização da coleta estática.



Apesar de termos coletado dados de todo o corpo, apenas os dados do membro inferior direito para o primeiro estudo e do membro inferior com OA de joelho para o segundo estudo foram analisados para todas as condições. Nos casos de indivíduos com OA bilateral, o joelho com maior relato de dor na sub-escala dor do questionário WOMAC foi o joelho escolhido para análise.

Figura 4: Diferentes condições dos dois estudos, especificamente para o segundo estudo a figura simula um indivíduo com osteoartrite (OA) de joelho no lado direito (D). A) Condição controle – modelo 1 de sandália; B) Condição inclinada do mesmo lado – sandália modelo 2 do lado D e sandália modelo 1 do lado esquerdo (E); C) Condição inclinada do lado oposto – sandália modelo 1 do lado D e sandália modelo 2 do lado E.



Os participantes andaram em sua velocidade normal auto-selecionada por pelo menos 5 vezes por condição ao longo de uma distância de 15 metros (Figura 5). A ordem de coleta de dados por condição foi aleatorizada. Antes do início da coleta de dados em cada condição, os participantes andaram por aproximadamente 1 minuto para familiarização com o par de sandálias. Especificamente no segundo estudo, entre condições, o sujeito descansava por aproximadamente 2 minutos em um dispositivo para apoio parcial de carga (Figura 6). Durante esse período de repouso, o participante foi questionado acerca do conforto ao andar com o par de sandálias utilizados na condição anterior (MILLS *et al.*, 2010) e a respeito da dor no joelho com OA naquele momento (WANG *et al.*, 2010) por meio de uma escala visual analógica de dor e uma escala visual analógica de conforto de 100 mm cada (ANEXO C). A escala visual analógica de conforto foi ancorada com os termos “*not comfortable at all*” e “*most comfortable imaginable*” e a escala de dor foi ancorada com os termos “*no pain*” e “*pain as bad as it could possible be*”. Não foi permitido que os participantes vissem escalas preenchidas referentes a condições anteriores quando estavam preenchendo novas escalas de conforto e dor. Durante o primeiro estudo, não foi oferecido período de descanso entre condições para os participantes. Nos dois estudos, após a coleta de dados nas 3 condições, os indivíduos foram solicitados a deambular descalços em sua velocidade normal auto-selecionada. Os dados cinemáticos e cinéticos coletados com o indivíduo deambulando descalço foram posteriormente comparados com os dados das condições controle de cada estudo com o objetivo de investigar se as sandálias utilizadas na condição controle modificaram o padrão de marcha usual dos participantes.

Figura 5: Coleta dos dados do indivíduo andando em velocidade normal auto-selecionada.



Figura 6: Dispositivo utilizado para que o participante descansasse entre as condições sem movimentação dos marcadores.



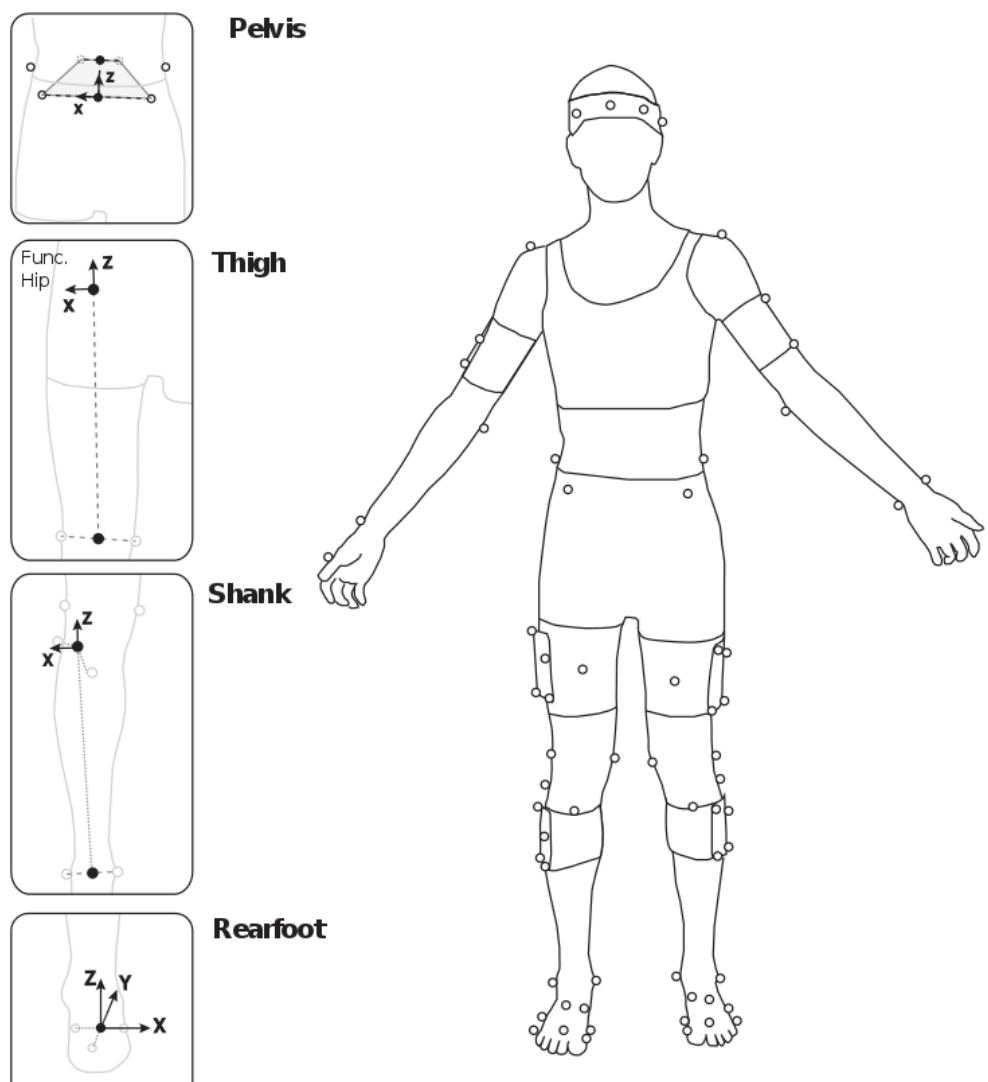
2.8 Redução dos dados

2.8.1 Filtros e definição da fase de apoio da marcha

Os dados cinemáticos e cinéticos sincronizados foram processados utilizando o *software* Visual 3D (C-motion, Inc., Rockville, USA) (FIGURA 7). Para o segundo estudo, nos casos em que o indivíduo possuía OA bilateralmente, o lado com o

maior escore na subescala dor do questionário WOMAC foi escolhido para a análise dos dados (CHANG *et al.*, 2005; MAGALHÃES *et al.*, 2013; SLED *et al.*, 2010). As trajetórias dos marcadores e os dados de força fornecidos pelas plataformas de força foram filtrados utilizando filtros passa-baixa Butterworth de quarta ordem com frequências de corte de 6 Hz (WINTER, 1990) e 18 Hz, respectivamente. O contato inicial e a retirada do pé do solo foram determinados automaticamente no Visual 3D utilizando o componente vertical da força de reação do solo com um limiar de 20 N. Os valores médios de pelo menos 5 fases de apoio, para cada participante em cada condição, foram considerados para a análise.

Figura 7: Sistemas de coordenadas utilizados para os segmentos pelve, coxa, perna e retropé para os dois estudos.



2.8.2 Variáveis dependentes

O deslocamento angular do antepé no plano frontal (eixo anteroposterior) em relação ao retropé foi calculado com o objetivo de verificar se a sandália com inclinação lateral aumentou eversão de antepé durante a fase de apoio da marcha. As seguintes variáveis cinemáticas da marcha foram calculadas: (1) inversão-eversão do retropé (eixo anteroposterior) em relação à perna; (2) rotação interna de perna (eixo longitudinal), representada pelo movimento da perna em relação ao laboratório; (3) rotação interna-externa (eixo longitudinal) e adução-abdução (eixo anteroposterior) de joelho, representadas pelo movimento da perna em relação à coxa; (4) rotação interna de coxa (eixo longitudinal), representada pelo movimento da coxa em relação ao laboratório; (5) rotação interna-externa (eixo longitudinal) e adução-abdução (eixo anteroposterior) de quadril, representadas pelo movimento da coxa em relação à pelve; (6) queda pélvica ipsilateral e contralateral (eixo anteroposterior) em relação ao laboratório – queda pélvica contralateral foi definida como o ângulo negativo de obliquidade pélvica (TAKACS; HUNT, 2012). Variáveis cinéticas incluíram momentos de inversão do tornozelo e de rotação interna e adução de joelho e quadril. Os dados cinemáticos e cinéticos foram calculados baseados na sequência de Cardan x, y e z (KADABA; RAMAKRISHNAN; WOOTTEN, 1990). Para os dois estudos, os momentos articulares foram calculados utilizando os procedimentos da dinâmica inversa, normalizados pela massa corporal (kg), e reportados em Nm/kg. Momentos articulares externos foram reportados ao longo dos dois estudos. As variáveis da marcha foram normalizadas em 101 pontos, um para cada porcentagem da fase de apoio da marcha.

2.9 Análise dos dados

2.9.1 Justificativa para o uso da Análise de Componentes Principais (ACP)

A maior parte das variáveis dependentes do presente estudo (deslocamento angular e momento externo de força) é representada por curvas ou séries temporais. Esses dados apresentam características específicas, entre elas: a)

multidimensionalidade, se representarmos as curvas de rotação interna de joelho durante a fase de apoio de cada um dos indivíduos em cada uma das condições do primeiro estudo em cada porcentagem da fase de apoio da marcha (de 0 a 100%), então teremos: 22 participantes X 3 condições x 101 = 6.666 pontos de dados; b) existe um formato geral das curvas de dados, um padrão subjacente dos dados que as curvas geralmente seguem. Para uma dada curva, um valor específico é relacionado aos valores vizinhos na mesma curva de dados e também aos valores das outras curvas. A força da relação entre os valores das curvas pode ser descrita como colinearidade e pode ser referida como a estrutura de correlação presente nos dados. c) Existe grande variabilidade nos dados. Parte dessa variabilidade está presente dentro de cada condição, e está relacionada a diferenças na rotação interna de joelho entre sujeitos (variação sujeito a sujeito). Outra parte da variação é consequente a diferenças em rotação interna de joelho entre as 3 condições (variação entre grupos ou condições) e é nessa variação que estamos interessados a medida que ela se relaciona com o objetivo da nossa análise biomecânica: detectar e interpretar diferenças nas curvas de dados das 3 condições de interesse.

Para alcançar esse objetivo, considerando a grande quantidade de dados sendo avaliados, devemos encontrar as características mais salientes do conjunto de dados, retendo as características mais importantes, sem perder informação discriminatória importante. Tradicionalmente, esse objetivo tem sido alcançado por meio da extração de parâmetros discretos da curva de dados (por exemplo, pico ou valor mínimo). Apesar de essa estratégia resultar em um menor número de parâmetros que podem ser comparados entre sujeitos, grande parte da informação temporal presente nos dados é perdida. Essas abordagens causam reduções drásticas dos dados originais e informações importantes são descartadas, o que torna essas abordagens insatisfatórias (DONÀ *et al.*, 2009; DONOGHUE *et al.*, 2008). Nesse contexto, o fato de estudos diferentes utilizarem definições de parâmetros discretos distintas (por exemplo, média durante uma fase específica ou valor em um evento temporal específico) tem sido sugerida como uma das causas para conclusões inconsistentes na literatura (O'CONNOR; BOTTUM, 2009). Além disso, a definição de parâmetros discretos pode ser difícil, particularmente no estudo de movimento de indivíduos com disfunções. Em alguns casos, as curvas de dados de alguns indivíduos podem não exibir uma característica específica. Em um estudo avaliando o momento externo adutor de joelho em indivíduos assintomáticos e em

indivíduos com OA de joelho, Hurwitz *et al.* (2002) reconheceram que 52% dos indivíduos com OA de joelho não apresentavam um segundo pico de momento externo adutor comparado com 29% dos indivíduos assintomáticos. Dessa forma, optamos por utilizar a ACP na tentativa de capturar informação a respeito do formato das curvas de deslocamento angular e momento externo e reter informação temporal.

2.9.2 ACP

A ACP é uma técnica de decomposição ortogonal resultando, portanto, em componentes principais (CP) os quais são independentes uns dos outros. Matematicamente, a ACP é uma transformação ortogonal que converte um número de variáveis correlacionadas em um número menor de variáveis não-correlacionadas e independentes chamadas CP. Idealmente, ACP é indicada para redução e interpretação de dados e tem sido utilizada de maneira efetiva para analisar diversos tipos de curvas de dados temporais incluindo marcha (KIRKWOOD *et al.*, 2011; LANDRY *et al.*, 2007; MUNIZ; NADAL, 2009; RESENDE *et al.*, 2012), equilíbrio (PINTER *et al.*, 2008), ergonomia (WRIGLEY *et al.*, 2006) e eletromiografia de superfície (HUBLEY-KOZEEY *et al.*, 2006; PEREZ; NUSSBAUM, 2003; WOOTTEN *et al.*, 1990).

Existe uma analogia direta entre a análise de Fourier e a ACP de curvas temporais. Na análise de Fourier, um sinal que varia ao longo do tempo é representado por uma combinação de sinusóides em várias frequências e mudanças de fases. Na análise de Fourier, as sinusóides utilizadas para representar as curvas de dados temporais podem ser entendidas como funções base, e uma curva específica é associada a um conjunto específico de coeficientes das funções base, conhecidos nesse caso como os coeficientes de Fourier. No entanto, dados temporais também podem ser representados por outras funções base que não aquelas encontradas a partir da análise de Fourier. Em vários casos, sinusóides não se ajustam de maneira adequada às curvas de dados originais, e um melhor conjunto de funções base pode ser obtido a partir das próprias curvas de dados

originais. Quando aplicada a curvas de dados originais, ACP computa e extrai um conjunto único de funções base das curvas tendo como base a variação que está presente nas curvas de dados originais. Essas funções base são conhecidas como CP, e estão relacionadas ao formato da curva e, em particular, aos modos de variação presente nos dados. As 3 maiores vantagens da ACP são: (i) os CP são independentes uns dos outros; (ii) somente alguns CP são necessários para representar de maneira adequada as curvas de dados originais; e (iii) os escores obtidos a partir da análise podem ser utilizados em análise subsequentes (por exemplo, como variáveis dependentes ao se testar hipóteses, análise discriminante, análise de *cluster*, etc.) para detectar e interpretar diferenças no formato das curvas entre indivíduos.

2.9.3 Procedimentos da ACP

ACP foi implementada no presente estudo com o objetivo de re-expressar os 101 pontos ou variáveis originais compondo cada curva de dados como um conjunto reduzido de variáveis não-correlacionadas chamadas CPs. Cada CP identificado expressa uma relação única entre as amostras temporais das variáveis biomecânicas que capturam a sua variância ao longo da fase de apoio da marcha e entre os participantes de maneira otimizada. Esses CPs podem ser considerados elementos constituintes únicos (ou características) das curvas de dados biomecânicos computados originalmente. A seguir será descrito de maneira breve os procedimentos utilizados para extração dos CPs e as estratégias utilizadas para interpretá-los - para uma descrição mais detalhada consultar Astephen & Deluzio (2009).

ACP de curvas foi aplicada às variáveis da marcha separadamente (25 variáveis da marcha no total, 13 para o primeiro estudo e 12 para o segundo estudo). Para o primeiro estudo, os dados da marcha foram organizados em 13 matrizes de dados 66_101 (22 sujeitos x 3 condições_101 pontos de dados por fase de apoio) para o procedimento da ACP. Para o segundo estudo, os dados da marcha foram organizados em 12 matrizes de dados 60 x 101 (20 sujeitos x 3 condições x 101 pontos de dados por fase de apoio) para o procedimento da ACP.

Considerando uma matriz de dados específica de dados originais X , como por exemplo a matriz com os dados de rotação interna de joelho durante a fase de apoio da marcha (Figura 8A), a análise se inicia pela subtração da média de todos os participantes de cada amostra temporal, criando, dessa forma, **escores centrados** das variáveis originais – a ACP é feita nas colunas da matriz X . Subsequentemente, a matriz de covariância de X (S) é computada (Figura 8b). Os termos fora da diagonal de S capturam a covariância entre todos os pares possíveis de amostras de rotação interna de joelho, refletindo a redundância no conjunto de dados X . Os termos na diagonal de S capturam a variância em cada amostra temporal de rotação interna de joelho, refletindo a estrutura relevante em X (FIGURA 8B).

Figura 8: A) Matriz com os dados originais. Cada coluna representa um percentual da fase de apoio da marcha. B) Matriz de covariância dos dados originais. Elementos da diagonal representam a variância em cada amostra temporal e elementos fora da diagonal representam a covariância entre todos os pares possíveis de amostras temporais.

Grupo	Quad/sag	0	1	2	3	...	100
0	AH01	-0,063814	-0,098866	-0,040995	0,029454	...	0,04538
0	AH05	0,386174	0,406571	0,43414	0,439001	...	0,391358
0	AH10	-0,362664	-0,263899	-0,170283	-0,108503	...	-0,298724
0	AH12	0,016555	-0,020316	-0,044748	-0,04449	...	0,09427
0	AH13	-0,31744	-0,323972	-0,337701	-0,345882	...	-0,337096
0	AH14	0,179522	0,338279	0,507686	0,607476	...	0,034023
0	AH16	0,036935	0,041397	0,067307	0,065625	...	0,208566
0	AH17	0,128017	0,20941	0,292452	0,345374	...	0,074155
0	AH19	-0,17282	-0,235783	-0,27219	-0,279137	...	-0,021098
...
1	AH79	0,041415	0,035788	0,058046	0,102482	...	0,050665
1	AH80	-0,054556	-0,042936	-0,078839	-0,05061	...	-0,143307
1	AH82	-0,767428	-0,282732	0,188957	0,57978	...	0,085932

$$S = \begin{bmatrix} S_{11} & S_{12} & \cdots & S_{1p} \\ S_{21} & S_{22} & \cdots & S_{2p} \\ \vdots & \vdots & \ddots & \vdots \\ S_{p1} & S_{p2} & \cdots & S_{pp} \end{bmatrix}$$

De maneira geral, os elementos fora da diagonal de S são diferentes de 0, o que significa que as colunas das matrizes de dados originais são correlacionadas (relação linear entre as variáveis). No entanto, os CPs não podem ser correlacionados e, dessa forma, devem ser associados a uma matriz de covariância que possua todos os elementos fora da diagonal iguais a 0. Para tal, a matriz de covariância de X é transformada na matriz D de covariância dos CPs por meio do processo conhecido como diagonalização ou decomposição ortogonal, o qual realinha os dados originais em um novo sistema de coordenadas (FIGURA 9A). As novas coordenadas são os CPs e eles são alinhados de acordo com a direção de variação presente nos dados, da maior para a menor.

Durante o processo de diagonalização, além da matriz D é criada a matriz U (FIGURA 9B), sendo as colunas da matriz U as cargas vetoriais (descrições características) da matriz de covariância de X e os elementos da diagonal da matriz D os autovalores (medidas de variação associadas aos autovetores). Dessa forma, os CPs são o conjunto de vetores lineares ortogonais (ou cargas vetoriais) $C\{c_1, \dots, c_{101}\}$ que transformam S com o objetivo de maximizar os seus componentes de variância (estrutura) e minimizar os seus componentes de covariância (redundância).

Figura 9: A) Matriz D : é uma matriz diagonal de covariância na qual os elementos da diagonal são os autovalores – valores característicos associados aos autovetores. B) Matriz U : suas colunas são os autovetores (descrição característica) da matriz S .

	1	2	3	4	5	6	7	8		1	2	3	4	5	6	7	8
1	-763,88	0	0	0	0	0	0	0	1	1,00	0	0	0	0	0	0	0
2	0	-282,87	0	0	0	0	0	0	2	0	0,95	0,30	0,12	0	0	0	0
3	0	0	-264,30	0	0	0	0	0	3	0	-0,31	0,94	0,14	0	0	0	0
4	0	0	0	-231,72	0	0	0	0	4	0	-0,07	-0,17	0,98	0	0	0	0
5	0	0	0	0	228,95	0	0	0	5	0	0	0	0	0,99	0,06	0,13	0
6	0	0	0	0	0	258,26	0	0	6	0	0	0	0	-0,11	0,92	0,37	0
7	0	0	0	0	0	0	276,67	0	7	0	0	0	0	-0,10	-0,38	0,92	0
8	0	0	0	0	0	0	0	778,88	8	0	0	0	0	0	0	0	1,00

Matematicamente, as cargas vetoriais (ou CPs) são os autovetores de S . Os autovetores constituem um sistema de coordenadas ótimo para representar o conjunto de dados pois eles são alinhados com as direções de máxima variância nas amostras temporais de rotação interna de joelho. Na prática, a carga vetorial definindo um CP contém os coeficientes que são combinados (ou multiplicados) com a curva original de dados para computar os escores naquele CP para cada curva de cada participante em cada condição. Explicitamente, o escore de um CP foi calculado como a soma dos produtos dos **escores centrados** de cada amostra temporal de rotação interna de joelho f_i ($i = 1$ a 101) e o coeficiente correspondente c_i ($i = 1$ a 101) na carga vetorial do CP. Alternativamente, os escores podem ser entendidos como indicadores da distância que a curva de cada indivíduo em cada condição está do CP.

Os CPs extraídos são ordenados em função da quantidade de variância que eles explicam (indexada pelos seus autovalores) e o número máximo de CPs é igual ao número de variáveis originais. Devido à alta covariação existente entre as amostras temporais das medidas biomecânicas obtidas durante a marcha

(particularmente entre valores próximos uns dos outros durante a fase de apoio da marcha), a maior parte da variância é usualmente explicada pelos primeiros CPs, e esses normalmente contêm a informação mais relevante dos dados originais (DELUZIO; ASTEPHEN, 2007; KIRKWOOD *et al.*, 2011). Os componentes restantes frequentemente podem ser descartados sem perda de informação importante, reduzindo assim a dimensionalidade do conjunto de dados. Um critério de 90% da variabilidade dos dados explicada foi utilizado para determinar o número de CPs a serem retidos para a análise (BRANDON *et al.*, 2013).

Para o primeiro estudo, os escores dos CPs selecionados para representar as curvas de dados originais foram comparados entre as condições controle, inclinada do mesmo lado e inclinada do lado oposto utilizando modelos de análise de variância (ANOVA) simples para medidas repetidas com contrastes pré-planejados entre a condição controle e a condição inclinada do mesmo lado para as seguintes variáveis dependentes: (1) ângulos de inversão de retropé; (2) momento inversor de tornozelo; (3) ângulos de rotação interna de perna, joelho, coxa e quadril; (4) momento rotador interno de joelho e quadril; (5) queda pélvica ipsilateral. Contrastess pré-planejados também foram realizados entre a condição controle e a condição inclinada do lado oposto para as seguintes variáveis dependentes: (1) queda pélvica ipsilateral; (2) momento adutor de quadril e joelho; (3) ângulos de adução de quadril e joelho.

Para o segundo estudo, os escores dos CPs selecionados para representar as curvas de dados originais foram comparados entre as condições controle, inclinada do lado com OA e inclinada do lado oposto à OA utilizando modelos de análise de variância (ANOVA) simples para medidas repetidas com contrastes pré-planejados entre a condição controle e a condição inclinada do lado com OA para as seguintes variáveis dependentes: (1) ângulos de inversão de retropé; (2) momento inversor de tornozelo; (3) ângulos de rotação interna de perna, joelho, coxa e quadril; (4) momento rotador interno de joelho e quadril; (5) queda pélvica ipsilateral. Contrastess pré-planejados também foram realizados entre a condição controle e a condição inclinada do lado oposto à OA para as seguintes variáveis dependentes: (1) queda pélvica ipsilateral; (2) momento adutor de quadril e joelho; e (3) ângulos de adução de quadril e joelho.

Para os dois estudos, significância foi definida utilizando $\alpha = 0,05$ exceto para as duas comparações pré-planejadas de queda pélvica ipsilateral, nos quais, de acordo com a correção de Bonferroni, α foi definida a 0,025.

2.9.3.1 Interpretação dos CPs

A interpretação dos CPs selecionados é o processo de identificar as características das curvas originais que eles capturam. O objetivo desse processo é entender as diferenças nos escores dos CPs que observamos entre as diferentes condições. Neste estudo, a interpretação dos CPs se baseia na seguinte pergunta: o que um escore alto ou baixo em um CP significa em termos do padrão da variável original durante a fase de apoio da marcha?

Responder a essa questão requer um processo com dois passos. O primeiro passo é examinar as magnitudes das cargas vetoriais qualificando um CP específico, o que define a sua relação com a curva de dados original. Especificamente, se os coeficientes estão próximos de zero para algumas amostras temporais específicas, significa que essas amostras temporais contribuem muito pouco para o escore do CP. Dessa forma, um CP específico captura a variância nas amostras temporais da variável original relacionadas aos coeficientes da carga vetorial que possuem alta magnitude. No entanto, examinar somente a carga vetorial representando um CP não é suficiente para entender o que um escore alto ou baixo significa pois os escores dos CPs dependem também dos **escores centrados** das amostras temporais das variáveis originais. Assim, o segundo passo é examinar as curvas dos dados originais correspondentes a escores alto e baixo no CP de interesse para entender as características de variação temporal na variável original que os distinguem. Por ser desafiador selecionar curvas de dados originais que diferem somente em relação ao CP sendo interpretado, nós reconstruímos a curva de dados originais multiplicando a sua carga vetorial por um escore baixo do CP (1 desvio padrão abaixo da média) e por um escore alto do CP (1 desvio padrão acima da média) (BRANDON *et al.*, 2013). O padrão de desvio entre as curvas correspondentes aos escores baixo e alto do CP forma a base para interpretar as diferenças nos escores dos CPs observadas entre condições. Em suma,

interpretação dos CPs no presente estudo foi baseada na avaliação dos gráficos capturando (1) a magnitude dos coeficientes da carga vetorial, e (2) o padrão de duas curvas dos dados originais correspondentes a escores alto e baixo do CP sendo reportados somente os padrões das curvas correspondentes a escores alto e baixo na no CP.

2.9.4 Escalas visuais de dor e conforto (segundo estudo)

As distâncias entre os inícios das escalas visuais analógicas de dor e conforto e os pontos nos quais os indivíduos com OA de joelho identificaram o nível de dor no joelho com OA e o conforto ao andar com o par de sandálias foram mensuradas em milímetros (mm). Os valores encontrados nas condições controle, inclinada do lado com OA e inclinada do lado oposto à OA foram comparados por meio de ANOVA com medidas repetidas e com contrastes pré-planejados com $\alpha = 0,05$.

2.9.5 WOMAC e LEAS

Com o objetivo de caracterizar a amostra do segundo estudo, os escores dos participantes nas subescalas do questionário WOMAC dor, rigidez articular e função física foram calculados por uma escala de cinco pontos de Likert (0, 1, 2, 3, 4), onde escores menores indicam melhor condição naquele domínio (KIRKWOOD *et al.*, 2011). Os escores dos participantes na LEAS foram avaliados variando de 1 a 18, sendo maiores escores indicativo de melhor nível de atividade física. Estatística descritiva foi utilizada para caracterizar esses dados.

2.9.6 Características dos participantes e dados temporais e espaciais da marcha

Foi realizada uma análise descritiva dos aspectos demográficos e clínicos dos

participantes. A velocidade da marcha foi computada e comparada entre as condições de cada estudo por meio de ANOVA simples com medidas repetidas utilizando $\alpha = 0,05$.

3 ARTIGO 1

Increased unilateral foot pronation affects lower limbs and pelvic biomechanics during walking¹

Abstract

Increased foot pronation causes functional changes at the lower limbs resulting in overuse injuries. The purpose of this study was to investigate the effects of increased unilateral foot pronation on the biomechanics of both lower limbs and pelvis during gait. Kinematic and kinetic data of twenty-two participants were collected while the participants walked wearing flat sandals and unilaterally wedged sandals (10° medially inclined on the forefoot). Principal Component Analysis was used to compare differences between conditions. On the ipsilateral side, the laterally wedged sandal increased ankle eversion moment ($p<0.001$; effect size=0.97); rearfoot eversion ($p<0.001$; effect size=0.76); shank internal rotation ($p=0.009$; effect size=0.53); reduced knee internal rotation moment in late stance ($p<0.001$; effect size=0.87); increased and reduced knee internal rotation during early and late stance, respectively ($p<0.001$; effect size=0.89); increased femur internal rotation ($p=0.005$; effect size=0.90); reduced hip internal rotation moment during late stance ($p=0.001$; effect size=0.68); and increased pelvic ipsilateral drop ($p=0.02$; effect size=0.48). On the contralateral side, the laterally wedged sandal increased pelvic contralateral drop ($p=0.001$; effect size=0.63); increased hip adduction moment throughout stance ($p=0.027$; effect size=0.46); increased knee adduction moment in early stance ($p<0.001$; effect size=0.79); and increased knee frontal plane range of motion ($p=0.017$; effect size=0.49). The increased hip internal rotation caused by the wedged sandal may have hampered hip external rotators action in terminal stance

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(internal moments) resulting in smaller hip internal rotation moments (external moments). The increased pelvic contralateral drop may explain the increased hip and knee adduction moments on the contralateral lower limb. These results should be considered in individuals presenting increased foot pronation.

1. Introduction

Increased foot pronation causes functional changes at the lower limbs, which results in overuse injuries at the proximal joints [1]. Previous studies demonstrated that inadequate forefoot alignment at ground contact can produce large pronation torques that result in increased magnitude and duration of pronation [2]. Following this rationale, Souza et al. [3] demonstrated that walking using lateral wedges under the forefoot increases rearfoot eversion and shank and hip internal rotation during the stance phase. Our work builds on these insights by examining the effects of increased foot pronation on knee and hip transverse plane moments and pelvic kinematics with the goal of further understanding the relationship between increased foot pronation and the occurrence of injuries.

Walking dynamics is dependent on the interaction between the lower limbs [4]. Therefore, it is logical to hypothesize that increased unilateral foot pronation may also influence the biomechanics of the opposite lower limb. Previous studies demonstrated that during quiet standing, foot pronation increases pelvic ipsilateral drop [5]. If that coupling mechanism remains true for walking, increased foot pronation may affect the biomechanics of the opposite lower limb through modification of pelvic motion. Specifically, increased pelvic drop may increase contralateral hip and knee adduction moments [6] and consequently increase the load on these joints during the stance phase of gait.

In order to investigate the effects of foot pronation during gait, different strategies such as shoes [7], foot orthosis [8] and sandals [9] have been implemented. Specifically for studies using segmented foot models, the use of sandals seems to be the most appropriate, since it was demonstrated that markers placed on shoes overestimate foot segments motion [10]. Regardless of the methods chosen, it is usual to make assumptions about the effects of foot pronation based on a small set of biomechanical variables, such as ipsilateral knee adduction moment

[11]. However, considering that influence of foot pronation on pelvic kinematics may also affect the biomechanics of the contralateral lower limb [6], more detailed information about the effects of foot pronation on the mechanics of the lower limbs is necessary.

Therefore, the purpose of this study was to investigate the effects of increased unilateral foot pronation on the biomechanics of the lower limbs during the stance phase of gait. We hypothesized that increased unilateral foot pronation will increase ipsilateral lower limb internal rotation angles and ipsilateral pelvic drop and reduce internal rotation moments during the stance phase of gait. On the contralateral lower limb, lateral wedges will increase knee and hip adduction angles and moments during early stance.

2. Methods

2.1. Participants

Twenty-two subjects (10 females, 12 males) with an average age, mass and height of 25 years (SD 4.5), 71.7 kg (SD 11.3) and 175 cm (SD 8), respectively, participated in the study. The inclusion criteria were age between 20 and 40 years, no history of surgery or injuries to the lower limbs or to the lumbar-pelvic complex in the last year. The exclusion criterion was the report of any discomfort during data collection. Each participant signed a consent form approved by the university's Ethics Research Committee.

2.2. Procedures

Initially, the heights and masses of the participants were measured. Subsequently, gait data were recorded at 200 Hz using 12-camera motion capture system (Oqus 4, Qualisys, Gothenburg, Sweden) and six tandem force platforms (Custom BP model, AMTI, Massachusetts, USA). The force platforms registered ground reaction force data at a frequency of 1000 Hz, which was subsequently resampled to 200 Hz.

Anatomical markers and clusters of tracking markers were used to determine the coordinates of the whole body using data obtained with the participant in a standing position (static trials) (Fig. 1a). The kinematic and kinetic data were collected in 3 different conditions: 1) control condition: the participant walked wearing

flat sandals (Fig. 1b); 2) ipsilateral side inclined condition: flat sandal on the left and a wedged sandal on the right foot (Fig. 1c); 3) contralateral side inclined condition: flat sandal on the right and a wedged sandal on the left foot (Fig. 1d). Only the right lower limb data was analyzed for the 3 conditions. Following the methods used by Souza et al.[3], the wedged sandals were flat at the rearfoot and laterally wedged (medially depressed) under the forefoot (Fig. 1c and d) to simulate a forefoot varus deformity, which has been shown to affect the duration and amplitude of pronation during walking [2]. We had 2 sizes of sandals for each condition with the metrics described in the supplementary figure 1. The sandals' bases were made of high-density ethylene vinyl acetate and were attached to the participants' feet with velcro. The participants walked at their self-selected normal speed, performing six trials per condition along a 15-m distance. The order of data collection was randomized. Before data collection in each condition, the participants walked for approximately one minute for familiarization with the pair of sandals.

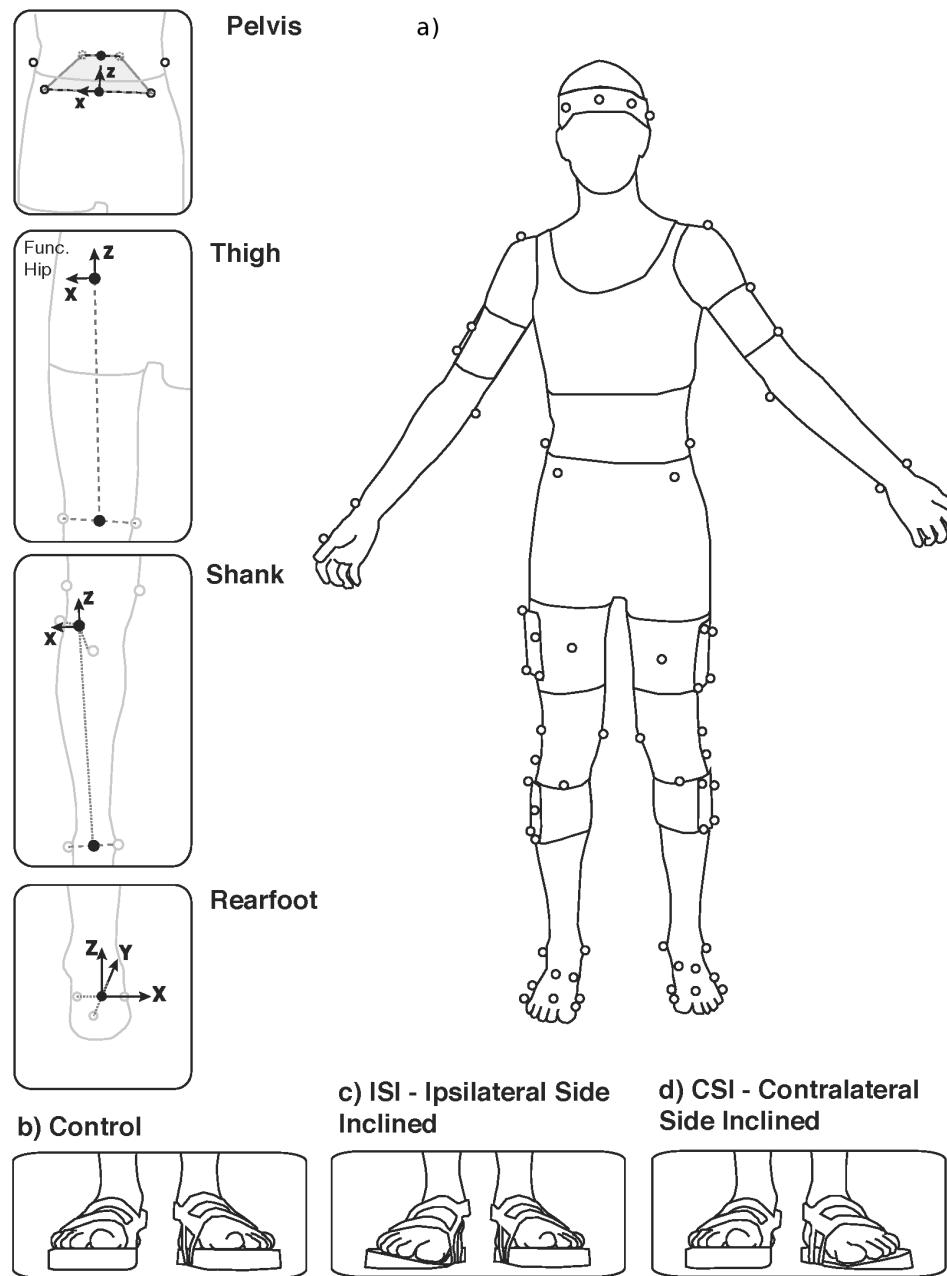


Fig. 1: Marker placement and segments coordinate systems (a); control (b), ipsilateral side inclined (c) and contralateral side inclined (d) conditions.

After data collection on the 3 conditions, gait data were obtained as the participants walked barefoot. These data were subsequently compared to the data collected while the participants walked wearing flat sandals in order to investigate if the flat sandals affected the participants' normal gait pattern.

2.3. Data reduction

Synchronized raw kinematic and kinetic signals were processed using Visual

3D (C-motion, Inc., Rockville, USA). Raw kinematic and force data were filtered using a low-pass fourth order Butterworth filter with a cut-off frequency set at 6 Hz [12] and 18 Hz, respectively. Heel contact and toe-off were determined automatically in Visual 3D using the vertical ground reaction force (GRF) and a threshold of 20 N. Forefoot inversion-eversion with respect to the rearfoot was calculated to ensure that the wedged sandal increased forefoot eversion. The following kinematic gait measures were calculated: (1) rearfoot inversion-eversion (antero-posterior axis) with respect to the shank; (2) shank internal-external rotation (longitudinal axis) represented by the motion of the shank relative to the lab; (3) femur internal-external rotation, represented by the motion of the thigh relative to the lab; (4) knee adduction-abduction (antero-posterior axis) and internal-external rotation, represented by the motion of the shank relative to the thigh; (5) hip adduction-abduction and internal-external rotation, represented by the motion of the thigh relative to the pelvis; (4) pelvic ipsilateral-contralateral drop (antero-posterior axis) with respect to the lab – contralateral pelvic drop was denoted as a negative pelvic obliquity angle [6]. Kinetic data included ankle inversion moment and knee and hip adduction and internal rotation moments (external joint moments). Kinematic and kinetic data were calculated based on the Cardan sequence x, y and z [13]. Joint moments were calculated using inverse dynamic procedures, normalized to body mass (kg), and reported in Nm/kg. Gait measures were normalized to 101 data points, one for each percentage of the stance phase.

2.3. Data analysis

2.4.1. Principal Component Analysis (PCA)

PCA was applied to 13 gait measures arranged in 13 separate 66×101 data matrices (22 subjects \times 3 conditions \times 101 time points per stance phase). The resulted principal components (PCs) are computed to represent the maximal amount of variance using the fewest possible parameters [14]. A criteria of 90% of variance explained was used to determine the number of principal components (PCs) to retain for data analysis [15, 16]. When two or more PCs, retained for analysis, demonstrated differences for a specific gait measure, only the PC describing the largest amount of variance was reported.

2.4.2. Interpretation of PCs

In order to interpret the biomechanical meaning of a single PC, the goal is to isolate the variance captured by the PC of interest. This can be visualized on a single figure by plotting two waveforms, \hat{x}_H and \hat{x}_L , representing waveform corresponding to a high and low value of the PC by adding and subtracting a scalar multiple of the loading vector, u_R , to the average waveform, \bar{x} . A convenient scalar multiple is one standard deviation (SD) of the corresponding PC scores, $SD(\vec{z}_i)$. The high and low PC waveforms differ only in the feature captured by a single PC [14]. Thus, high and low PC waveforms that include only the contribution of the R th PC, denoted PC_R , can be computed:

$$\hat{x}_H = \bar{x} + u_R * SD(\vec{z}_i) \quad (1)$$

$$\hat{x}_L = \bar{x} - u_R * SD(\vec{z}_i) \quad (2)$$

where \hat{x}_H is the reconstructed high waveform for PC_R ; \hat{x}_L the reconstructed low waveform for PC_R ; \bar{x} is the mean temporal waveform for all subjects; u_R the pattern of variance, or loading vector, for PC_R ; $SD(\vec{z}_i)$ is the SD of the PC_R scores.

The scores of the PCs selected to represent the gait measures were compared between conditions using one-way repeated measures analysis of variance (ANOVA) with pre-planned contrasts between the control condition and the ipsilateral side inclined condition for the following gait measures: (1) ankle inversion moment; (2) rearfoot inversion angle; (3) shank and femur internal rotation angles; (4) knee and hip internal rotation moments and angles; (5) pelvic ipsilateral drop. Pre-planned contrasts were also performed between the control and the contralateral side inclined conditions for the following gait measures: (1) pelvic ipsilateral drop; (2) knee and hip adduction moments and angles. Significance was set as $\alpha = 0.05$ except for the pre-planned comparisons of the pelvic ipsilateral drop that α was set at 0.025. The effect sizes (e.g. *rcontrast*) of the contrasts with statistically significant differences were also calculated [17].

3. Results

3.1. Gait speed and forefoot eversion

The conditions control, ipsilateral side inclined and contralateral side inclined showed an average gait speed of 1.44 m/s (SD 0.15), 1.45 m/s (SD 0.16) and 1.45 m/s (SD 0.16), respectively, and these differences were not statistically significant ($p=0.69$). The condition ipsilateral side inclined demonstrated increased forefoot eversion in 5.27° (SD 0.42) throughout the stance phase ($p<0.001$) when compared to the control condition.

3.2. Gait measures

The results of ANOVA demonstrated 12 PCs that were statistically significant different between the 3 conditions: ankle inversion moment ($F=356.7$; $p<0.001$); rearfoot inversion angle ($F=17.7$; $p<0.001$); shank internal rotation angle ($F=5.8$; $p=0.006$); knee adduction moment ($F=18.6$; $p<0.001$); knee internal rotation moment ($F=24.2$; $p<0.001$); knee adduction angle ($F=13.4$; $p<0.001$); knee internal rotation angle ($F=26.6$; $p<0.001$); femur internal rotation ($F=7.7$; $p=0.005$); hip adduction moment ($F=4.2$; $p=0.022$); hip internal rotation moment ($F=9.6$; $p<0.001$); hip internal rotation angle ($F=3.7$; $p=0.032$); and pelvic ipsilateral drop ($F=7.5$; $p=0.002$). Analysis of the control versus barefoot data showed significantly differences in the hip internal rotation angle during late stance.

3.2 Effects of the wedged sandal on the ipsilateral side

The pre-planned comparisons between ipsilateral side inclined and control identified 9 PCs statistically different (Table 1). Gait waveforms represented by high (+ 1SD) and low (- 1SD) PC scores for each PC are shown in Fig. 2. The wedged sandal increased ankle eversion moment between 15 and 90% of the stance phase ($F=387.7$; $p<0.001$; Fig. 2a); increased rearfoot eversion angle throughout stance ($F=29.3$; $p<0.001$; Fig. 2b); increased shank internal rotation angle throughout stance ($F=8.3$; $p=0.009$; Fig. 2c); reduced knee internal rotation moment during late stance ($F=66.5$; $p<0.001$; Fig. 2d); increased knee internal rotation angle during early stance and reduced knee internal rotation angle during late stance ($F=83.0$; $p<0.001$; Fig. 2e); increased femur internal rotation throughout stance ($F=9.7$; $p=0.005$; Fig. 2f); reduced hip internal rotation moment during late stance ($F=18.3$; $p<0.001$; Fig. 2g); increased hip internal rotation angle throughout stance ($F=5.4$; $p=0.031$; Fig. 2h); and

increased pelvic ipsilateral drop during late stance ($F=6.4$; $p=0.02$; Fig. 2i).

Table 1: Principal components (PCs) with at least moderate effect sizes for the differences between ipsilateral side inclined and control conditions. Percentage of variance explained and an interpretation of each PC are also provided.

Measure	PC	Variance explained (%)	p-value	Effect size	Interpretation based on the effects of the ipsilateral side inclined condition
Ankle inversion-eversion moment	1	87.6	<0.001	0.97	Had greater ankle eversion moment between 15 and 90% of stance.
Rearfoot inversion-eversion angle	1	70.8	<0.001	0.76	Had greater rearfoot eversion throughout stance.
Shank internal-external rotation angle	1	78.8	0.009	0.53	Had greater shank internal rotation throughout stance
Knee internal-external rotation moment	1	62.4	<0.001	0.87	Had smaller knee internal rotation moment in late stance.
Knee internal-external rotation angle	2	13.5	<0.001	0.89	Had greater knee internal rotation in early stance and reduced knee internal rotation in late stance.
Femur internal-external rotation	1	69.8	0.005	0.90	Had greater femur internal rotation throughout stance.
Hip internal-external rotation moment	2	23.9	0.001	0.68	Had smaller hip internal rotation moment in late stance.
Hip internal-external rotation angle	1	63.4	0.031	0.45	Had greater hip internal rotation throughout stance phase.
Pelvic ipsilateral-contralateral drop	2	27.3	0.02	0.48	Had greater ipsilateral pelvic drop in late stance.

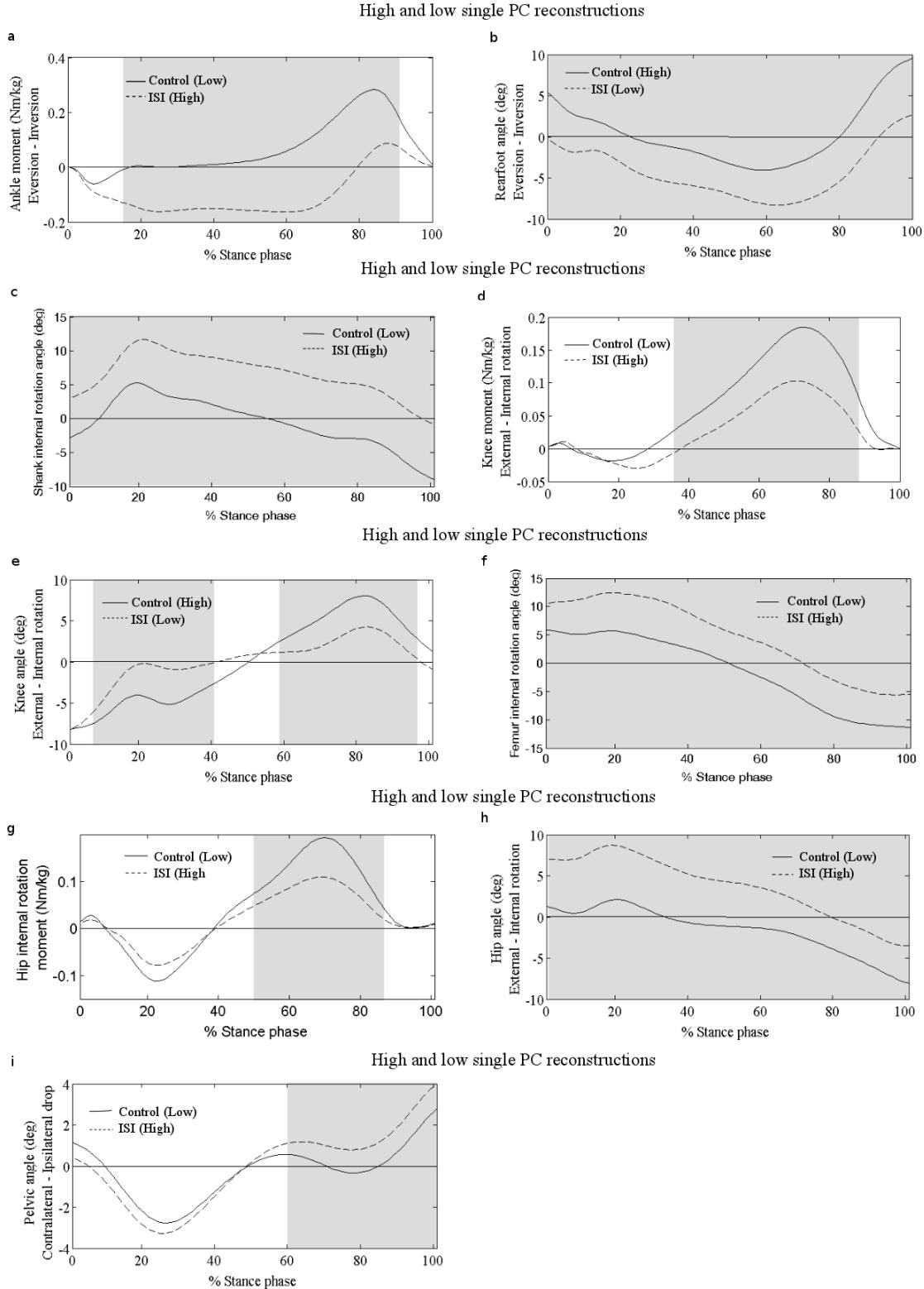


Fig. 2: Control and ipsilateral side inclined conditions differences demonstrated by the ANOVA. Shown in the figures are the waveforms that represent high and low principal component (PC) scores for the indicated measure and PC. In all cases, the waveform that represents the direction (i.e. high or low PC) that characterizes the ipsilateral side inclined condition is shown as a dashed line; the solid line indicates the control condition direction. The shaded areas demonstrate the portions of the stance phase where the differences occurred, which was demonstrated based on the magnitudes of the loading vectors. The ankle inversion moment PC1 (a); rearfoot inversion angle PC1 (b); shank internal rotation PC1 (c); knee internal rotation moment PC1 (d); knee internal rotation angle PC2 (e); femur internal rotation PC1 (f); hip internal rotation moment PC2 (g); hip internal rotation angle PC1 (h); pelvic ipsilateral drop PC2 (i). /SI: Ipsilateral side inclined condition

3.3. Effects of the wedged sandal on the contralateral side

The pre-planned comparisons between contralateral side inclined and control conditions identified 4 PCs statistically different (Table 2). Waveforms that represent high and low PC scores for each PC are shown in Fig 3. The wedged sandal increased pelvic contralateral drop ($F=13.7$; $p=0.001$; Fig. 3a); increased hip adduction moment throughout stance phase ($F=5.7$; $p=0.027$; Fig. 3b); increased knee adduction moment during early stance and reduced knee adduction moment during late stance ($F=35.9$; $p<0.001$; Fig. 3c); and increased knee adduction-abduction range of motion ($F=6.7$; $p=0.017$; Fig. 3d).

Table 2: Principal components (PCs) with at least moderate effect sizes for the differences between contralateral side inclined and control conditions. Percentage of variance explained and an interpretation of each PC are also provided.

Measure	PC	Variance explained (%)	P-value	Effect size	Interpretation based on the effects of the contralateral side inclined condition
Pelvic ipsilateral-contralateral drop	1	64.3	0.001	0.63	Had greater pelvic contralateral drop during early stance.
Hip adduction-abduction moment	1	50.4	0.027	0.46	Had greater hip adduction moment during early and late stance.
Knee adduction-abduction moment	2	23.2	<0.001	0.79	Had greater knee adduction moment in early stance and smaller knee adduction moment in late stance.
Knee adduction-abduction angle	2	7.3	0.017	0.49	Had greater knee range of motion in the frontal plane.

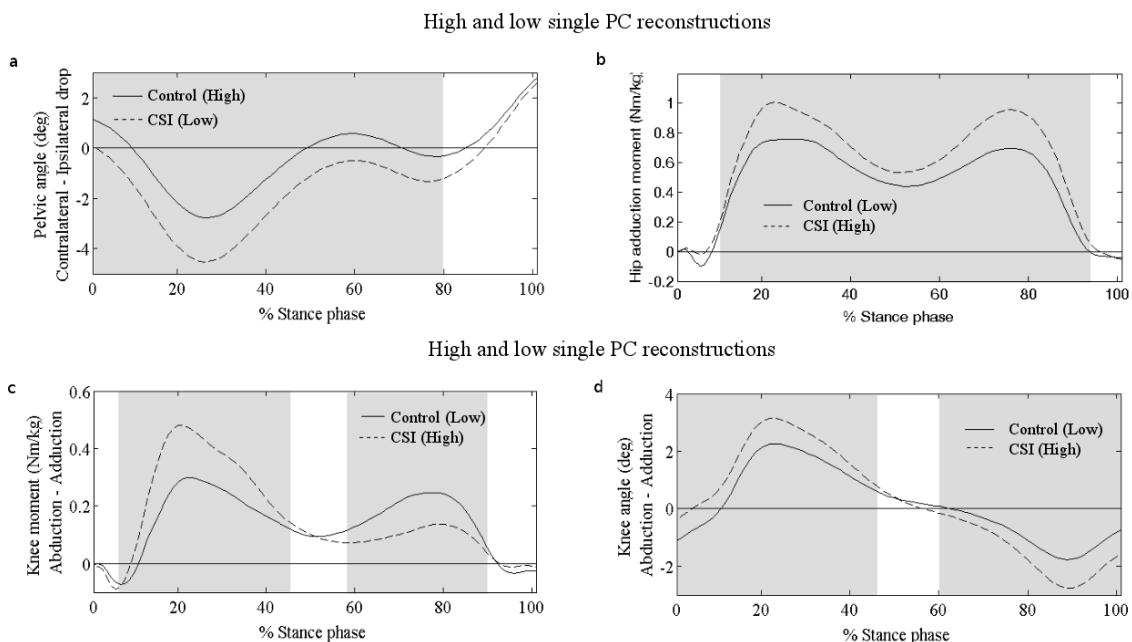


Fig. 3: Control and contralateral side inclined conditions differences demonstrated by the ANOVA. Shown in the figures are the waveforms that represent high and low principal component (PC) scores for the indicated measure and PC. In all cases, the waveform that represents the direction (i.e. high or low PC) that characterizes the contralateral side inclined condition is shown as a dashed line; the solid

line indicates the control condition direction. The shaded areas demonstrate the portions of the stance phase where the differences occurred, which was defined based on the magnitudes of the loading vectors. The pelvic ipsilateral drop PC1 (a); hip external adduction moment PC1 (b); knee external adduction moment PC2 (c); knee adduction angle PC2 (d). CSI: Contralateral side inclined condition.

4. Discussion

The results of this study demonstrated that unilateral foot pronation affects the biomechanics of the lower limbs during walking. The increased shank and femur internal rotation angles and smaller knee and hip internal rotation moments caused by the lateral wedge supports the existence of the coupling mechanism between rearfoot eversion and lower limb internal rotation [3], [9]. In addition, the increased pelvic ipsilateral drop caused by the lateral wedge reinforces the assumption that foot pronation dynamically shortens the lower limb [1]. On the contralateral lower limb, increased foot pronation increased hip and knee adduction moments. These effects were probably due to the increased pelvic contralateral drop caused by the use of the lateral wedge on the contralateral lower limb, since it increases knee and hip adduction moments during single limb standing [6].

The increased ankle eversion moment and rearfoot eversion angle caused by the wedged sandal were accompanied by increased shank and femur internal rotation angle throughout stance. The orientation of the subtalar joint axis links rearfoot eversion with lower limb internal rotation [18], and this relationship has been demonstrated by previous studies [3], [9]. Although the wedged sandal increased knee internal rotation angle during early stance, smaller knee internal rotation was observed during late stance. The knee range of motion in the transverse plane is smaller than the hip. Therefore, it is possible that during late stance the knee is already maximally internally rotated and compensation occurs at the hip, which is reinforced by the increased hip internal rotation throughout stance and by the greater effect size of the increase in femur internal rotation when compared to the increase in shank internal rotation. This is supported by the findings of Lafortune et al. [19]. Using bone-anchored markers they demonstrated that induced foot eversion increases tibial internal rotation without change in the pattern of knee transverse plane motion, indicating rotation transference between tibia and femur.

The wedged sandal reduced ipsilateral knee and hip internal rotation moments during late stance. The relationship between the GRF and the hip and knee joint

centers may help to explain these findings. During late stance, the GRF is antero-lateral and antero-medial to the hip and knee joint centers, respectively, pointing postero-medially relative to both joint centers [20]. Because walking with lateral wedges laterally shifts and vertically aligns the GRF [21], shortening of the knee and hip GRF lever arms occurs [21]. This fact may have contributed to the smaller knee and hip internal rotation moments observed in the present study. Alternatively, it is possible that the increased hip internal rotation caused by the wedged sandal hampered the action of the hip external rotators muscles through muscular stretching during mid to terminal stance. Therefore, smaller hip external rotation moments would be generated by the participants (e.g. internal joint moments) and consequently reduce the hip internal rotation moments computed based on the GRF (e.g. external joint moments).

The wedged sandal increased ipsilateral pelvic drop during late stance. This is consistent with the assumption that foot pronation reduces lower limb functional length [22]. The occurrence of leg length reduction due to foot pronation is reinforced by the demonstration that rearfoot eversion increases pelvic ipsilateral drop in standing position [1]. Therefore, in the present study, increased foot pronation produced by the wedged sandal dynamically shortened the ipsilateral lower limb during gait leading to increased ipsilateral pelvic drop. Increased pelvic drop may contribute to the development of lower back pain [23], scoliosis and other pathological conditions in the lumbar spine [22], [24], which suggests the possible deleterious effects of increased foot pronation.

As expected, the wedged sandal increased hip and knee adduction moments of the contralateral lower limb. The greater contralateral pelvic drop during the contralateral side inclined condition helps to explain these findings. Contralateral pelvic drop increases knee and hip adduction moments during single limb standing [6]. Our results show that this relationship also happens during gait. The assumption that pelvic contralateral drop influences knee adduction moment is reinforced by the findings of Lin et al [25], which demonstrated that pelvic motion in the frontal plane is the gait measure that most significantly contribute to the medio-lateral displacement of the body center of mass during gait. Increased knee and hip adduction moments are related to the development and progression of lower limb injuries [26]. Therefore, increased foot pronation of the opposite lower limb may help to explain increased knee and hip adduction moments in individuals with lower limb injuries, such as knee

osteoarthritis [27] and iliotibial band syndrome [28].

Forefoot angle influences the duration and amplitude of foot pronation during gait [2]. Because the wedged sandal on the forefoot simulates the effects of forefoot varus alignment [3], individuals with different forefoot alignment may have been an additional source of variability in the present study. However, because we used a repeated measures design, possible differences in individuals' forefoot alignment affected all conditions, and therefore did not influence the differences observed among conditions. In addition, the results of the present study were focused on the immediate effects of unilateral increased foot pronation. It is possible that the long-term effects of unilateral increased foot pronation or the effects of bilateral increased foot pronation are different. However, these effects are outside the scope of the present study.

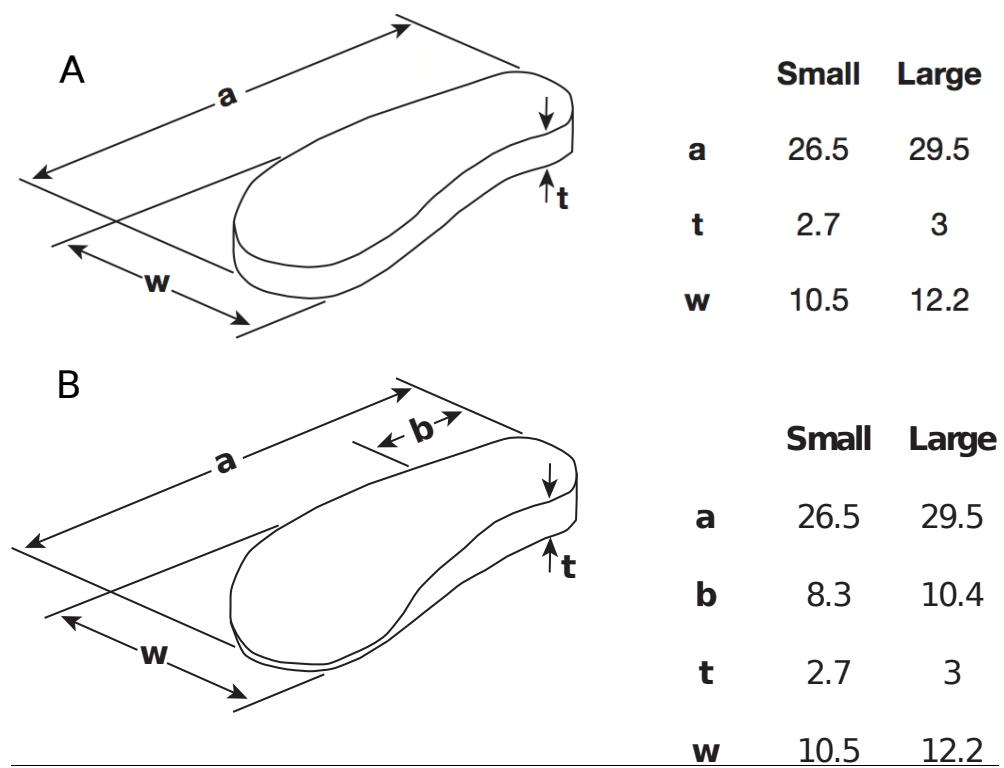
The findings of this study demonstrated that increased unilateral foot pronation caused by the use of wedged sandals affects the biomechanics of lower limbs during gait. In summary, increased foot pronation increased the ipsilateral lower limb internal rotation angles and reduced knee and hip internal rotation moments with increased pelvic ipsilateral drop. On the contralateral lower limb, foot pronation increased the knee and hip adduction moments, which may be explained by the increased contralateral pelvic drop caused by the lateral wedge on the contralateral lower limb. These results should be considered when examining individuals demonstrating increased foot pronation. In addition, strategies to manipulate foot motion, such as the use of lateral wedges [11], should be cautiously implemented in light of the possible deleterious effects on the transverse plane biomechanics of the ipsilateral lower limb and on the frontal plane biomechanics of the contralateral lower limb.

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Supplementary Figure 1: Dimensions of the small and large pair of sandals: flat sandals (A); and laterally wedged sandal (B).

4 ARTIGO 2

Ipsilateral and contralateral increased foot pronation affects lower limb mechanics of individuals with knee osteoarthritis during gait²

Background: Foot pronation may increase knee internal rotation of the ipsilateral side and knee adduction moment of the contralateral side in individuals with knee osteoarthritis (OA). This study investigated the effects of unilateral foot pronation on the biomechanics of lower limbs during gait of individuals with knee OA.

Methods: Biomechanical data of twenty individuals with knee OA were collected while they walked wearing flat sandals and wedged sandals on the forefoot. Principal Component Analysis was used to compare differences between conditions. Knee pain and comfort were compared between conditions.

Findings: On the ipsilateral side, the wedged sandal increased ankle eversion moment ($p<0.001$; effect size=0.98); rearfoot eversion ($p<0.001$; effect size=0.79); shank internal rotation ($p<0.001$; effect size=0.70); reduced knee internal rotation moment ($p<0.001$; effect size=0.83); increased and reduced knee internal rotation during early and late stance, respectively ($p=0.004$; effect size=0.61); increased femur internal rotation ($p<0.001$; effect size=0.74); and reduced hip internal rotation moment ($p=0.001$; effect size=0.66). On the contralateral side, the wedged sandal increased hip adduction moment ($p=0.003$; effect size=0.61); and increased knee adduction moment ($p=0.002$; effect size=0.63).

Interpretation: The coupling mechanism between foot pronation and shank internal rotation occurs in individuals with knee OA. The increased knee adduction moment on the contralateral lower limb may be a compensation for the smaller knee adduction moment on the ipsilateral lower limb. Foot motion should be evaluated in individuals with knee OA and the use of lateral wedges to reduce knee adduction moment should consider the possible deleterious effects on the contralateral lower limb.

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1. Introduction

Osteoarthritis (OA) is a progressive disease that causes significant disability and loss of function (McKean et al., 2007). The lifetime risk of developing symptomatic knee OA is estimated to be 45% (40% in men and 47% in women) (Murphy et al., 2008). Approximately 11 to 19% of individuals over 45 years have symptomatic knee OA (Jordan et al., 2007; Peat, et al., 2001). With aging of the population and increasing obesity, the prevalence of knee OA is expected to rise. Indeed, an increase in prevalence of symptomatic knee OA over the past 20 years has been noted in the Framingham cohort, rising by 4.1% and 6% among women and men, respectively (Nguyen et al., 2011). Individuals with severe knee OA will eventually need total knee replacement, procedure that has been demonstrating mean failure time of 5.9 years (Schroer et al., 2013). In this context, walking is the activity most commonly performed by individuals with knee OA. Therefore, better understanding of the mechanisms that overload the knee during walking may contribute to the development of strategies to slow knee OA progression and consequently postpone knee replacement (Schroer et al., 2013).

Knee kinematics during walking influences the tibial and femoral cartilage thickness (Koo, et al., 2011). Using a finite-element model derived from subject specific three-dimensional cartilage volumes, Andriacchi et al. (2006) demonstrated that an increase of 5° of shank internal rotation during the stance phase of gait increased cartilage thinning at the knee. During the stance phase of gait, shank internal rotation is coupled with foot pronation (Nester et al., 2000; Souza et al., 2009). Therefore, increased foot pronation demonstrated by individuals with knee OA (Levinger et al., 2012) may contribute to knee cartilage thinning by means of increasing shank internal rotation during the stance phase.

Previous studies demonstrated that although walking with lateral wedges insoles reduces knee adduction moment (Kerrigan et al., 2002) and pain (Keating et al., 1993; Wolfe and Brueckmann, 1991), it does not slow down knee OA progression as expected (Baker et al., 2007; Barrios et al., 2009; Bennell et al., 2011; Pham et al., 2004; Miyazaki et al., 2002). These results could be partially explained by the finding that using lateral wedges increases shank internal rotation (Souza et al.,

2009), which would contribute to knee cartilage thinning (Andriacchi et al., 2006) and therefore counterbalance the positive effects of lateral wedges insoles on knee adduction moment. In addition, it is possible that the reduction in knee adduction moment caused by lateral wedges insoles is compensated by increased knee adduction moment of the contralateral lower limb in order to balance the internal energy content resulting from the applied ground reaction force (GRF).

Therefore, the purpose of this study was to investigate the effects of increased ipsilateral and contralateral foot pronation on the lower limb kinetics and kinematics of individuals with knee OA, during the stance phase of gait. We hypothesized that increased foot pronation will increase ipsilateral lower limb internal rotation angles and ipsilateral pelvic drop and reduce internal rotation moments during the stance phase of gait. In addition, increased foot pronation will increase contralateral knee and hip adduction angles and moments in individuals with knee OA, during early stance.

2. Methods

2.1. Participants

Twenty participants diagnosed with knee OA of one or both knees by an orthopaedic surgeon (13 females, 7 males) with an average age, mass and height of 67 years (SD 8.3), 87.9 kg (SD 18) and 170 cm (SD 8), respectively, participated in the study. In order to prevent the effects of different severity levels of OA on the results, only participants with knee OA classified as moderate or severe (grades 3 and 4) were included in the study. The radiographic classification was based on the Kellgren and Lawrence criteria (Kellgren and Lawrence, 1957). The inclusion criteria were no history of falls, surgery or injury to either lower extremity in the past six months, no history of stroke or any other form of arthritis, neuromuscular or cardiovascular disorder, no need of assistive device for walking and being able to walk a city block and climb stairs in a reciprocal fashion. The exclusion criterion was the report of pain over 80 mm on a 100 mm visual analog scale or walking unsteadiness during data collection. Each participant signed a consent form approved by the university's Ethics Research Committee.

2.2. Procedures

In order to characterize the sample, the participants answered the Western Ontario and McMaster Universities Arthritis Index (WOMAC) (Bellamy et al., 1988) and the Lower Extremity Activity Scale (LEAS) (Saleh et al., 2005). The scores of the WOMAC subscales were calculated by a 5-point Likert scale (0, 1, 2, 3, 4), where lower scores indicate better condition in that domain. Then, the heights and masses of the participants were measured. Subsequently, gait data were recorded at 200 Hz using 12-camera motion capture system (Oqus 4, Qualisys, Gothenburg, Sweden) and six tandem force platforms (Custom BP model, AMTI, Massachusetts, USA). The force platforms registered ground reaction force data at a frequency of 1000 Hz, which was subsequently resampled to 200 Hz.

Anatomical markers and clusters of tracking markers were used to determine the coordinates of the whole body using data obtained with the participant in a relaxed standing position (static trials) (Fig. 1a). The kinematic and kinetic data were collected in three different conditions: 1) control condition: the participant walked wearing flat sandals (Fig. 1b); 2) ipsilateral side inclined condition: the participant walked wearing a sandal with a 10° lateral wedge on the knee OA side and a flat sandal on the contralateral side (Fig. 1c); 3) contralateral side inclined condition: the participant walked wearing a flat sandal on the knee OA side and a sandal with a 10° lateral wedge on the contralateral side (Fig. 1d). Although we collected data from both lower limbs, only the knee OA lower limb data were analyzed for the three conditions. In subjects with bilateral knee OA, the lower limb with the highest score in the WOMAC pain subscale (i.e. worse pain) was analyzed. Following the methods used by Souza et al. (2009), the wedged sandals were flat at the rearfoot and 10° laterally wedged (medially depressed) under the forefoot (Fig. 2b) to simulate a forefoot varus deformity, which has been shown to affect the duration and amplitude of pronation during walking (Monaghan et al., 2013). According to a study from the Framingham OA cohort, the mean forefoot varus angle in elderly subjects was 9.9° (Gross et al., 2007). We had 2 sizes of sandals for each condition with the specific dimensions described in fig. 2. The sandals' bases were made of high-density ethylene vinyl acetate and were attached to the participants' feet with velcro. The participants walked at their self-selected normal speed, performing five trials per condition along a 15-m distance. The order of data collection was randomized. Before data collection in each condition, the participants walked for approximately one minute to familiarize with the sandals.

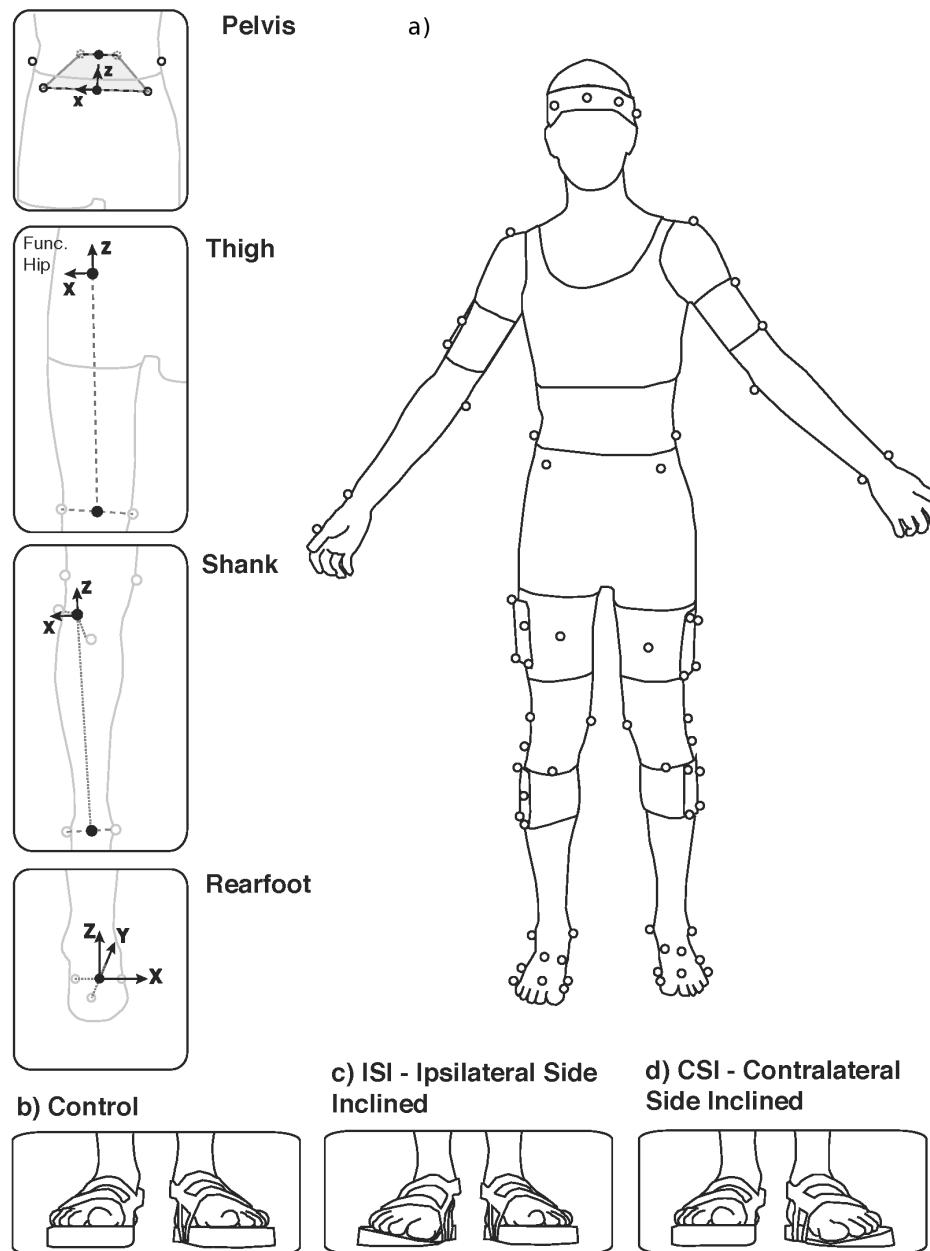


Fig. 1: Marker placement, segments coordinate systems (a), and the 3 different conditions considering a participant with knee osteoarthritis on the right side: control (b), ipsilateral side inclined (c) and contralateral side inclined (d).

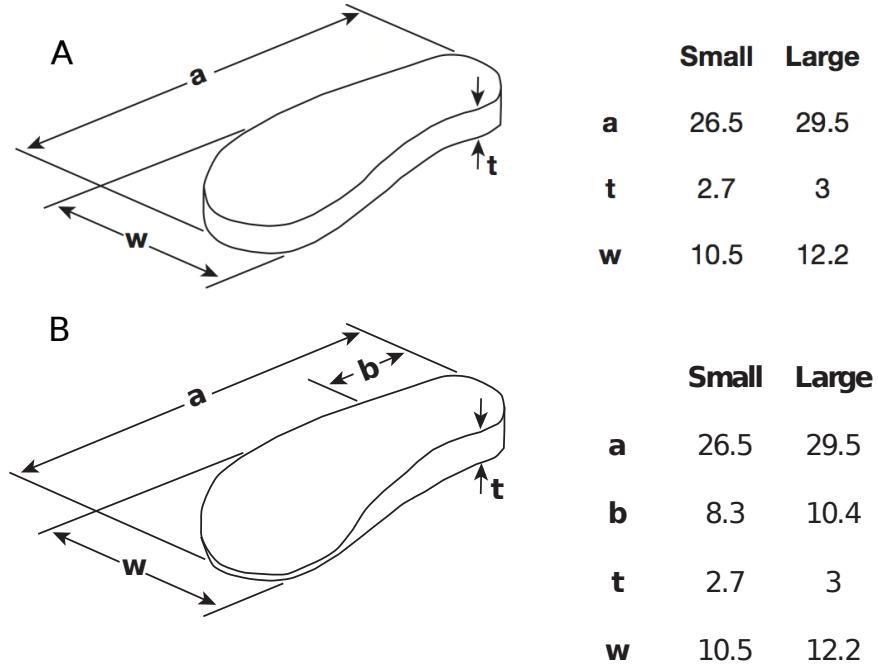


Fig. 2: Dimensions of the small and large pair of sandals: flat sandals (A) and laterally wedged sandal (B).

Between data collections in each condition, the participants rested for 2 minutes in a semi-seated position. During this resting period, the participants used visual analog scales in order to rate the knee pain and the comfort level of walking with the previous pair of sandals. The pain visual analog scale was a 100 mm horizontal line with "no pain" at one end and "worst pain imaginable" at the other (Wessel, 1995). The comfort visual analog scale was also a 100 mm horizontal line but anchored with the terms "not comfortable at all" to "most comfortable imaginable" (Mills et al., 2010). The outcome measure for both visual analog scales was the distance in mm of the participant's mark on the line. Participants were not allowed to see completed scales from previous conditions when making new pain and comfort ratings.

After data collection on the three conditions, kinematics and kinetics data were collected as the participants walked barefoot in their self-selected normal speed. These data were subsequently compared to the data collected while the participants walked wearing flat sandals (i.e. control condition) in order to investigate if the flat sandals affected the participants' normal gait pattern.

2.3. Data reduction

Synchronized raw kinematic and kinetic signals were processed using Visual

3D (C-motion, Inc., Rockville, USA). Raw kinematic and force data were filtered using a low-pass fourth order Butterworth filter with a cut-off frequency set at 6 Hz (Winter, 1990) and 18 Hz, respectively. Heel contact and toe-off were determined automatically in Visual 3D using the vertical GRF and a threshold of 20 N. Forefoot inversion-eversion (antero-posterior axis) with respect to the rearfoot was calculated to ensure that the lateral wedge increased forefoot eversion. The following joint kinematics were calculated: (1) rearfoot inversion-eversion (antero-posterior axis) with respect to the shank; (2) shank internal-external rotation (longitudinal axis), represented by the motion of the shank relative to the lab; (3) femur internal-external rotation (longitudinal axis), represented by the motion of the femur relative to the lab; (4) knee adduction-abduction (antero-posterior axis) and internal-external rotation (longitudinal axis), represented by the motion of the shank relative to the thigh; (5) hip adduction-abduction (antero-posterior axis), represented by the motion of the thigh relative to the pelvis; (6) pelvic ipsilateral-contralateral drop (antero-posterior axis) with respect to the lab – contralateral pelvic drop was denoted as a negative pelvic obliquity angle (Takacs and Hunt, 2012). Kinetic data included ankle inversion moment and knee and hip adduction and internal rotation moments. Kinematic and kinetic data were calculated based on the Cardan sequence x, y and z (Kadaba et al., 1990). Joint moments were calculated using inverse dynamic procedures, normalized to body mass (kg), and reported in Nm/kg. External joint moments were reported through the text. Kinematics and kinetics data were normalized to 101 data points, one for each percentage of the stance phase.

2.4. Data analysis

2.4.1. Principal Component Analysis (PCA)

PCA was applied to the gait measures separately (12 gait measures in total). Gait data were arranged in 12 separate 60×101 data matrices (20 subjects \times 3 conditions \times 101 time points per stance phase) for the PCA procedure. PCA results in principal components (PCs), which are computed to represent the maximal amount of variance using the fewest possible parameters (Ramsay and Silverman, 1997). For a single PC, each subject's waveform receives a PC-score, representing the degree to which the subject expresses the specific pattern of variance, or PC loading vector. Because the PCs are orthogonal, the PCA estimate of the dataset can be expressed as a linear combination of PCs (Jackson, 1991):

$$\hat{x}_i = \bar{x} + u_1 * z_{1i} + u_2 * z_{2i} + \dots + u_k * z_{ki} \quad (1)$$

where \hat{x}_i is the (1×101) estimated waveform for subject i ; \bar{x} the (1×101) mean temporal waveform for all subjects; u_j the (1×101) pattern of variance, or loading vector, for PC j ; z_{ji} is the PC-score for subject i , PC j ; k is the number of PCs retained in the model ($k \ll 101$).

A criteria of 90% of variance explained was used to determine the number of principal components (PCs) to retain for data analysis (Kirkwood et al., 2011; McKean et al., 2007). Thus, instead of comparing raw waveforms described by n correlated variables, PCA consider the estimated waveforms from Eq. (1), which are described by k orthogonal PCs (Jackson, 1991).

2.4.2. Interpretation of PCs

In order to interpret the biomechanical meaning of a single PC, the goal is to isolate the variance captured by the PC of interest. This can be visualized on a single figure by plotting two waveforms, \hat{x}_H and \hat{x}_L , representing waveforms corresponding to a high and low value of the PC by adding and subtracting a scalar multiple of the loading vector, u_R , to the average waveform, \bar{x} . A convenient scalar multiple is one standard deviation (SD) of the corresponding PC scores, $SD(\vec{z}_i)$. The high and low PC waveforms differ only in the feature captured by a single PC (Ramsay and Silverman, 1997). According to Eq. (1), the PCA model is a linear combination of the mean waveform and the PCs; thus, high and low PC waveforms that include only the contribution of the R th PC, denoted PC_R , can be computed by simply discarding all other confounding PCs from the linear model to yield:

$$\hat{x}_H = \bar{x} + u_R * SD(\vec{z}_i) \quad (2)$$

$$\hat{x}_L = \bar{x} - u_R * SD(\vec{z}_i) \quad (3)$$

where \hat{x}_H is the reconstructed high waveform for PC_R ; \hat{x}_L the reconstructed low waveform for PC_R ; \bar{x} is the mean temporal waveform for all subjects; u_R the pattern of variance, or loading vector, for PC_R ; $SD(\vec{z}_i)$ is the SD of the PC_R scores.

The scores of the PCs selected to represent the gait measures were compared between conditions using one-way repeated measures analysis of variance (ANOVA) with pre-planned contrasts between the control condition and the ipsilateral side inclined condition for the following gait measures: (1) rearfoot

inversion-eversion; (2) shank and femur internal-external rotation; (3) knee internal-external rotation; (4) pelvic ipsilateral-contralateral drop; (5) ankle inversion moment; (6) and knee and hip internal rotation moments. Pre-planned contrasts were also performed between the control and the contralateral side inclined conditions for the following gait measures: (1) knee and hip adduction moments; (2) knee and hip adduction-abduction angles; (3) and pelvic ipsilateral-contralateral drop. Significance was set as $\alpha = 0.05$ except for the two pre-planned comparisons of the pelvic ipsilateral-contralateral drop, in which α was set at 0.025. The effect sizes of the contrasts with statistically significant differences were calculated (Morris and DeShon, 2002) with differences reported only if they achieved at least a moderate effect size (i.e. $r\text{-contrast} > .3$) (Field, 2006).

2.4.3 Pain and comfort VAS

Differences in the pain and comfort visual analog scales were examined by means of one-way, repeated measures ANOVA with pre-planned contrasts between the control and the other two conditions. Significance was set as $\alpha = 0.05$ for the main effect and as $\alpha = 0.025$ for the pre-planned comparisons.

3. Results

3.1. Characterization of the participants (WOMAC and LEAS)

Regarding the WOMAC questionnaire, the participants demonstrated 7.4 (SD 4.0) in the pain, 3.4 (SD 1.4) in the stiffness and 23.15 (SD 9.5) in the physical function domains, with a total score of 34 (SD 13.5). For the LEAS, the participants demonstrated mean score of 11.3 (SD 3.2). The score 11 in the LEAS means: “*I am up and about at my will in my house and outside. I also work outside the house in a moderately active job*”.

3.2. Gait speed and forefoot inversion-eversion angle

The control, ipsilateral side inclined and contralateral side inclined conditions had an average gait speed of 1.11 m/s (SD 0.18), 1.10 m/s (SD 0.15) and 1.11 m/s (SD 0.16), respectively, and the differences were not statistically significant ($p=0.39$). The sandal with the lateral wedge increased the forefoot eversion in 4.15° (SD 0.54) throughout the stance phase ($p<0.001$) when compared to the flat sandal.

3.3. Gait measures

The results of ANOVA demonstrated 9 PCs in which there were statistically significant differences between conditions: ankle inversion moment ($F=236.2$; $p<0.001$), rearfoot inversion angle ($F=19.8$; $p<0.001$), shank internal rotation ($F=26.4$; $p<0.001$), knee adduction moment ($F=10.2$; $p<0.001$), knee internal rotation moment ($F=31.7$; $p<0.001$), knee internal rotation angle ($F=7.9$; $p=0.001$), femur internal rotation ($F=16.7$; $p<0.001$), hip adduction moment ($F=10.3$; $p<0.001$) and hip internal rotation moment ($F=18.4$; $p<0.001$). The comparisons between barefoot and control condition gait data did not demonstrate any differences in the gait measures evaluated in this study.

3.3.1. Effects of the ipsilateral inclined sandal

The pre-planned comparisons between ipsilateral side inclined and control conditions' PC scores identified 7 PCs in which there were significant differences (Table 1). Gait waveforms that represent high (+ 1SD) and low (- 1SD) PC scores for each PC of all measures are shown in Fig. 3. In the ipsilateral side inclined condition it was observed greater ankle eversion moment during late stance ($F=360$; $p<0.001$; Fig. 3a), increased rearfoot eversion throughout stance ($F=30.6$; $p<0.001$; Fig. 3b), increased shank internal rotation during late stance ($F=18.7$; $p<0.001$; Fig. 3c), smaller knee internal rotation moment during late stance ($F=43.5$; $p<0.001$; Fig. 3d), increased knee internal rotation during early stance and reduced knee internal rotation during late stance ($F=11.1$; $p=0.004$; Fig. 3e), reduced femur internal rotation during early stance ($F=21.5$; $p<0.001$; Fig. 3f) and increased femur internal rotation during late stance and smaller hip external rotation moment during early stance and internal rotation moment during late stance ($F=15.1$; $p=0.001$; Fig. 2g).

Table 1: Principal components (PCs) that demonstrated differences between ipsilateral side inclined and control conditions. Percentage of variance explained and an interpretation of each PC are also provided.

Measure	PC	Variance explained (%)	p-value	Effect size	Interpretation based on the effects of the ipsilateral side inclined condition
Ankle inversion-eversion moment	1	91.8	<0.001	0.98	Had greater ankle eversion moment in late stance.
Rearfoot inversion-eversion angle	1	78.9	<0.001	0.79	Had greater rearfoot eversion throughout stance.
Shank internal-external rotation angle	2	3.6	<0.001	0.70	Had greater shank internal rotation during late stance.

Knee internal-external rotation moment	1	86.5	<0.001	0.83	Had smaller knee internal rotation moment in late stance.
Knee internal-external rotation angle	2	17.1	0.004	0.61	Had greater knee internal rotation in early stance and smaller knee internal rotation in late stance.
Femur internal-external rotation angle	2	12.1	<0.001	0.74	Had smaller femur internal rotation in early stance and greater femur internal rotation during late stance.
Hip internal-external rotation moment	2	17.4	0.001	0.66	Had smaller hip external rotation moment in early stance and smaller hip internal rotation moment in late stance.

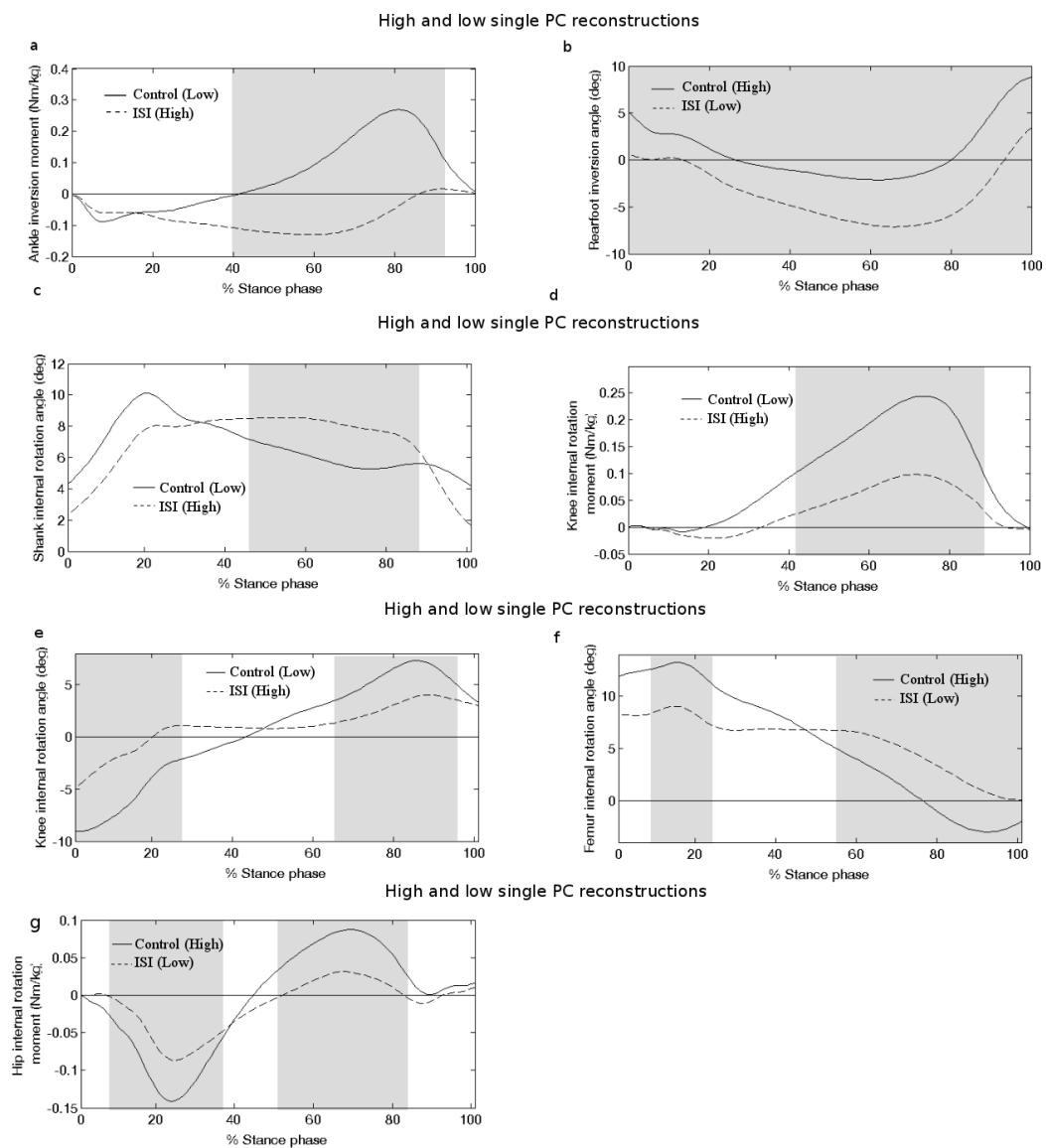


Fig. 3: Control and ipsilateral side inclined conditions differences demonstrated by the ANOVA. Shown in the figures are the waveforms that represent high and low principal component (PC) scores for the indicated measure and PC. In all cases, the waveform that represents the direction (i.e. high or low PC) that characterizes the ipsilateral side inclined condition is shown as a dashed line; the solid line indicates the control condition direction. The shaded areas demonstrate the portions of the stance phase where the differences occurred, which was defined based on the magnitudes of the loading vector. The ankle inversion moment PC1 (a); rearfoot inversion PC1 (b); shank internal rotation (c);

knee internal rotation moment PC1 (d); knee internal rotation angle PC2 (e); femur internal rotation PC2 (f); and hip internal rotation moment PC2 (g). *ISI*: Ipsilateral side inclined condition.

3.3.2. Effects of the contralateral wedged sandal

The pre-planned comparisons between contralateral side inclined and control conditions' PC scores identified 2 PCs in which there were significant differences (Table 2). Waveforms that represent high and low PC scores for each PC of the variables measured are shown in Fig 4. Contralateral side wedge increased hip adduction moment throughout stance phase ($F=11.5$; $p=0.003$; Fig. 4a) and increased knee adduction moment during early stance ($F=12.4$; $p=0.002$; Fig. 4b).

Table 2: Principal components (PCs) the differences between contralateral side inclined and control conditions. Percentage of variance explained and an interpretation of each PC are also provided.

Measure	PC	Variance explained (%)	P-value	Effect size	Interpretation based on the effects of the contralateral side inclined condition
Hip adduction-adduction moment	1	74.4	0.003	0.61	Had greater hip adduction moment throughout stance.
Knee adduction-adduction moment	3	8.0	0.002	0.63	Had greater knee adduction moment in early stance.

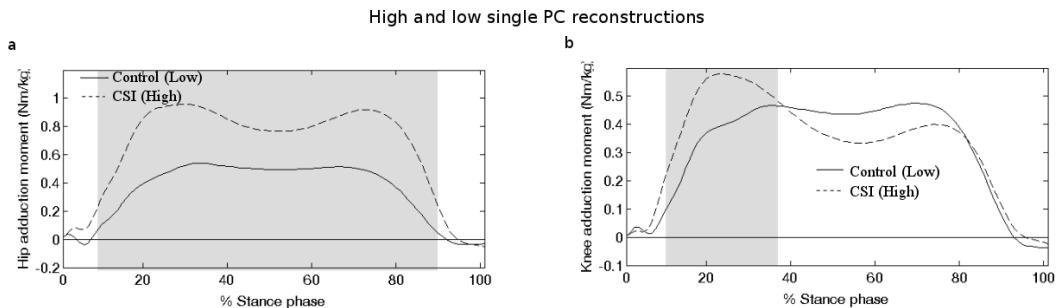


Fig. 4: Control and contralateral side inclined conditions differences demonstrated by the ANOVA. Shown in the figures are the waveforms that represent high and low principal component (PC) scores for the indicated measure and PC. In all cases, the waveform that represents the direction (i.e. high or low PC) that characterizes the contralateral side inclined condition is shown as a dashed line; the solid line indicates the control condition direction. The shaded areas demonstrate the portions of the stance phase where the differences occurred; which was defined based on the magnitudes of the loading vector. *CSI*: Contralateral side inclined condition.

3.3. Effects of the lateral wedge on the knee pain and comfort

There were no differences in knee pain intensity between conditions ($p=0.91$). On the other hand, participants reported greater comfort walking with the flat sandals in comparison to walking with the laterally wedged sandal on the knee OA side ($p=0.021$) and with walking with the laterally wedged sandal on the contralateral side

to the knee OA ($p=0.004$). The control, ipsilateral side inclined and contralateral side inclined conditions demonstrated 70.45 (SD 20.5), 52.2 (SD 34.0) and 47.85 mm (SD 30.2) on the comfort visual analog scale, respectively. The differences between the control condition and the ipsilateral and contralateral side inclined conditions were clinically meaningful, since they were greater than 10.2 mm (Mills et al., 2010).

4. Discussion

The findings of this study demonstrated that ipsilateral and contralateral foot pronation affects lower limb mechanics of individuals with knee OA, during walking, with no interference on the intensity of knee pain level. The increased rearfoot eversion throughout stance and shank and femur internal rotation in late stance during the ipsilateral side inclined condition suggests that increased foot pronation is also coupled with lower limb internal rotation in individuals with knee OA. In addition, the increased knee and hip adduction moments during the contralateral side inclined condition demonstrates the effects of foot pronation on the contralateral lower limb mechanics of individuals with knee OA.

The laterally wedged sandal increased ankle eversion moment, rearfoot eversion and knee internal rotation angles during early stance and shank and femur internal rotation angles during late stance of the ipsilateral lower limb. The increased ankle eversion moment and rearfoot eversion may help to explain why some individuals with knee OA complained of decreased comfort and even stopped wearing lateral wedges due to pain in the ankle/subtalar joint complex in previous studies (Bennell et al., 2011; Kakihana et al., 2004). Andriacchi et al. (2006) demonstrated that increased shank internal rotation causes knee cartilage thinning. Therefore, increased foot pronation may be deleterious to individuals with knee OA due to modification of knee transverse plane motion, which reinforces the need of evaluating and treating increased foot pronation in individuals with knee OA. In addition, these results contribute to a better understanding of the effects of laterally wedged insoles in individuals with knee OA, since this intervention has been shown not to slow down disease progression (Baker et al., 2007; Barrios et al., 2009; Bennell et al., 2011).

The laterally wedged sandal increased knee and hip adduction moments of the contralateral lower limb. Previous studies demonstrated that walking with laterally wedged insoles reduces knee adduction moment of the ipsilateral lower limb in

individuals with knee OA (Kerrigan et al., 2002). This has been also demonstrated by our results ($F=30.6$; $p<0.001$). Considering that walking with the laterally wedged sandal did not reduce the GRF ($p=0.80$), the smaller ipsilateral knee adduction moment caused by the wedged sandal must be compensated in other joints. Therefore, it is possible that the greater hip and knee adduction moments of the contralateral lower limb are compensations to the smaller ipsilateral knee adduction moment. The greater knee adduction moment of the contralateral lower limb suggests the deleterious effects of increased unilateral foot pronation on knee OA and demonstrates a side-effect of prescribing laterally wedged insoles for individuals with knee OA, since the contralateral knee is at a high risk of concurrent or later OA (Felson et al., 1995; Mont et al., 1995).

The participants reported less comfort walking with the laterally wedged sandals. This self-reported discomfort may have two reasons: i) the biomechanical consequences of walking with laterally wedged sandals (e.g. increased ankle eversion moment) (Kakihana et al., 2004); ii) and/or asymmetry resulting from walking with different sandals. This finding is in accordance to the findings of Bennell et al. (2011), which demonstrated that 47% of individuals reported discomfort with lateral wedge insoles. Considering that the asymmetry between lower limbs contributed to decrease the comfort level, this finding should be considered when designing interventions, since most of the studies that investigated the effects of lateral wedges in individuals with knee OA implemented unilateral wedges (Baker et al., 2007). There were no differences in knee pain intensity between conditions. This result is contrary to those of previous studies (Keating et al., 1993; Wolfe and Brueckmann, 1991), which demonstrated reduced pain level with lateral heel wedges. The fact that we used lateral forefoot wedges and that individuals walked only for 5 trials in each condition may partly explain the different results. In addition, our participants had moderate and severe knee OA levels, which mean that most of them had already knee pain before the beginning of data collection.

The effects of walking with laterally wedged sandals may be different for subjects with unilateral or bilateral knee OA. In the present study, we recruited individuals with unilateral and with bilateral knee OA, which may be a limitation of this study. However, finding subjects with only unilateral knee OA is very difficult. Therefore, we applied the same categorization as other studies (Magalhães et al., 2013; Sled et al., 2010), by assigning “unaffected” status to the limb with the lower

WOMAC pain subscore, and “affected” to the limb with the higher pain subscore. In addition, we did not exclude individuals with forefoot varus alignment (Gross et al., 2007). Because the lateral wedge on the forefoot simulates the effects of having forefoot varus alignment (Souza et al., 2009), individuals with different forefoot alignment may have been an additional source of variability in the present study. However, because we used a repeated measures design, possible differences in individuals’ forefoot alignment affected all conditions, and therefore did not influence the differences observed among conditions.

The findings demonstrated that increased foot pronation affects ipsilateral and contralateral lower limb mechanics during the stance phase of walking of individuals with knee OA. In summary, increased foot pronation increased shank and femur internal rotation during late stance and reduced knee and hip internal rotation moments during late stance of the ipsilateral lower limb. The increased foot pronation also increased knee and hip adduction moments of the contralateral lower limb without interference with knee pain intensity level. These results suggest the importance of evaluating and treating excessive foot pronation in individuals with knee OA. In addition, the use of laterally wedged insoles by individuals with knee OA should be cautiously implemented, considering the possible deleterious effects on the lower limb frontal and transverse plane mechanics.

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5 CONSIDERAÇÕES FINAIS

Os resultados do presente trabalho reforçam a importância da avaliação dos movimentos do pé durante a marcha e tratamento dos mecanismos causais de possíveis alterações encontradas, como pronação unilateral aumentada, em indivíduos adultos jovens saudáveis e indivíduos idosos com osteoartrite (OA) de joelho. Além disso, nossos resultados sugerem que intervenções comumente utilizadas para o tratamento de indivíduos com OA de joelho, como o uso de palmilhas com elevação lateral, sejam repensadas levando em consideração os efeitos deletérios sobre a mecânica no plano transverso do membro ipsilateral à palmilha e sobre a mecânica no plano frontal do membro contralateral à palmilha.

A demonstração dos efeitos da pronação unilateral aumentada sobre articulações proximais e sobre o membro inferior oposto em indivíduos adultos jovens reforça a suposição de que disfunções em articulações proximais, como quadril e coluna lombar podem ser decorrentes de alterações distais como a pronação aumentada. Em indivíduos com dor na região lombar ou na região do quadril, por exemplo, é possível que o aumento da rotação interna de quadril e queda pélvica ipsilateral durante a marcha causadas por pronação aumentada possam contribuir para o desenvolvimento de disfunções nessas regiões. Considerando os efeitos sobre articulações proximais foram demonstrados com aumento de apenas 5,27° de eversão do antepé em relação ao retropé, é provável que em indivíduos com maiores magnitudes de pronação, os mesmos efeitos sobre articulações proximais e sobre o membro inferior oposto sejam ainda mais relevantes.

Apesar de o presente trabalho não ter realizado uma comparação dos efeitos da pronação unilateral aumentada com os efeitos da pronação aumentada bilateralmente, os resultados demonstram os efeitos deletérios da assimetria causada por pronação unilateral aumentada, o que pode ser especialmente prejudicial para regiões como a coluna lombar e a pelve. Considerando o número de passos dados por dia, é possível que os efeitos de pequenas alterações biomecânicas a longo prazo, como o aumento da rotação interna de membro inferior e o aumento do momento externo adutor de quadril contribuam para o desenvolvimento de disfunções.

Especificamente para os indivíduos com OA de joelho, é possível que a devido às alterações estruturais já estabelecidas, o potencial para correção dos fatores associados à pronação aumentada unilateral seja reduzido, o que no entanto ainda precisa ser investigado por meio de estudos experimentais. Independentemente do potencial de adaptação de indivíduos com OA de joelho, a indicação do uso de calçados ou palmilhas com elevação lateral de maneira inespecífica deve ser descontinuada tendo como base os resultados demonstrados, especialmente quando realizada de maneira assimétrica.

Diversas alterações podem contribuir para que o indivíduo apresente pronação aumentada. Entre elas estão as alterações de alinhamento dos segmentos do pé, como antepé e retropé varo, hipermobilidade do primeiro raio, limitação da amplitude de dorsiflexão de tornozelo passiva e fraqueza e/ou baixa rigidez da musculatura rotadora externa de quadril. A maior parte dessas alterações são modificáveis a partir da avaliação e intervenção fisioterapêutica. Como exemplos de intervenções possíveis, temos a indicação de palmilhas para as alterações de alinhamento do pé, as mobilizações e alongamento e fortalecimento de flexores plantares na posição alongada para a limitação de dorsiflexão de tornozelo e fortalecimento de músculos rotadores externos de quadril com ênfase na posição encurtada para a baixa rigidez de rotadores externos de quadril.

Finalmente, o presente trabalho está inserido no modelo de atuação do fisioterapeuta, no qual o diagnóstico de uma doença ou patologia não define o tipo de intervenção a ser utilizada, já que a mesma doença pode e frequentemente possui diferentes fatores causais em diferentes indivíduos. Nesse contexto, a prescrição do uso de calçados ou palmilhas com elevações laterais de maneira arbitrária para indivíduos com diagnóstico de OA de joelho pode ser prejudicial, o que foi reforçado pelos resultados do presente estudo.

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APÊNDICE A



**QUEEN'S UNIVERSITY HEALTH SCIENCES & AFFILIATED TEACHING
HOSPITALS RESEARCH ETHICS BOARD-DELEGATED REVIEW**

November 02, 2012

Dr. Gavin Wood
Department of Surgery
Kingston General Hospital

Dear Dr. Wood

Study Title: SURG-265-12 Effects of the use of lateral wedges under the forefoot on the kinematics and kinetics of the knee during gait.

File # 6007495

Co-Investigators: Dr. Kevin Deluzio

I am writing to acknowledge receipt of your recent ethics submission. We have examined the protocol, information/invitation letter, revised consent form – Normals and the revised consent form – Knee Osteoarthritis participants for your project (as stated above) and consider it to be ethically acceptable. This approval is valid for one year from the date of the Chair's signature below. This approval will be reported to the Research Ethics Board. Please attend carefully to the following listing of ethics requirements you must fulfill over the course of your study:

Reporting of Amendments: If there are any changes to your study (e.g. consent, protocol, study procedures, etc.), you must submit an amendment to the Research Ethics Board for approval. Please use event form: HSREB Multi-Use Amendment/Full Board Renewal Form associated with your post review file # **6007495** in your Researcher Portal (https://eservices.queensu.ca/romeo_researcher/)

Reporting of Serious Adverse Events: Any unexpected serious adverse event occurring locally must be reported within 2 working days or earlier if required by the study sponsor. All other serious adverse events must be reported within 15 days after becoming aware of the information. Serious Adverse Event forms are located with your post-review file **6007495** in your Researcher Portal (https://eservices.queensu.ca/romeo_researcher/)

Reporting of Complaints: Any complaints made by participants or persons acting on behalf of participants must be reported to the Research Ethics Board within 7 days of becoming aware of the complaint. Note: All documents supplied to participants must have the contact information for the Research Ethics Board.

Annual Renewal: Prior to the expiration of your approval (which is one year from the date of the Chair's signature below), you will be reminded to submit your renewal form along with any new changes or amendments you wish to make to your study. If there have been no major changes to your protocol, your approval may be renewed for another year.

Yours sincerely,

Albert J. Clark.
Chair, Research Ethics Board
November 02, 2012

Investigators please note that if your trial is registered by the sponsor, you must take responsibility to ensure that the registration information is accurate and complete



QUEEN'S UNIVERSITY HEALTH SCIENCES & AFFILIATED TEACHING HOSPITALS RESEARCH ETHICS BOARD

The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards and operates in compliance with the Tri-Council Policy Statement; Part C Division 5 of the Food and Drug Regulations, OHRP, and U.S. DHHS Code of Federal Regulations Title 45, Part 46 and carries out its functions in a manner consistent with Good Clinical Practices.

Federalwide Assurance Number: #FWA00004184, #IRB00001173

Current 2012 membership of the Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board:

Dr. A.F. Clark, Emeritus Professor, Department of Biochemistry, Faculty of Health Sciences, Queen's University (Chair)

Dr. H. Abdollah, Professor, Department of Medicine, Queen's University

Dr. R. Brison, Professor, Department of Emergency Medicine, Queen's University

Dr. C. Cline, Assistant Professor, Department of Medicine, Director, Office of Bioethics, Queen's University, Clinical Ethicist, Kingston General Hospital

Dr. M. Evans, Community Member

Dr. S. Horgan, Manager, Program Evaluation & Health Services Development, Geriatric Psychiatry Service, Providence Care, Mental Health Services, Assistant Professor, Department of Psychiatry

Ms. J. Hudacik, Community Member

Dr. B. Kisilevsky, Professor, School of Nursing, Departments of Psychology and Obstetrics and Gynaecology, Queen's University

Dr. J. MacKenzie, Pediatric Geneticist, Department of Paediatrics, Queen's University

Mr. D. McNaughton, Community Member

Ms. P. Newman, Pharmacist, Clinical Care Specialist and Clinical Lead, Quality and Safety, Pharmacy Services, Kingston General Hospital

Ms. S. Rohland, Privacy Officer, ICES-Queen's Health Services Research Facility, Research Associate, Division of Cancer Care and Epidemiology, Queen's Cancer Research Institute

Dr. B. Simchison, Assistant Professor, Department of Anesthesiology and Perioperative Medicine, Queen's University

Dr. J. Tang, Medical Resident, Department of Emergency Medicine, Queen's University

APÊNDICE B



Amendment Acknowledgment/Approval Letter

June 07, 2013

Dr. Gavin Wood
Department of Surgery
Queen's University

RE: File #6007495 SURG-265-12 Effects of the use of lateral wedges under the forefoot on the kinematics and kinetics of the knee during gait.

Dear Dr. Wood:

I am writing to acknowledge receipt of the following:

- Notification that participants will be reimbursed for parking costs
- A copy of the revised consent form V2 05/13

I have reviewed these amendments and hereby give my approval. Receipt of these amendments will be reported to the Health Sciences Research Ethics Board.

Yours sincerely,

Albert L. Clark.

Albert Clark, Ph.D.
Chair
Research Ethics Board

APÉNDICE C

Human Mobility Research Center



CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE: Effects of the use of lateral wedges under the forefoot on the kinematics and kinetics of the knee during gait.

INVESTIGATORS: Gavin Wood, MD; Kevin Deluzio, Ph.D.; Renan Resende, MSc.; Amy Morton, MSc.

PURPOSE OF THE RESEARCH: The purpose of this study is to better understand the movements of the forefoot and its effects on the knee during walking. We will be investigating this relationship in individuals with knee osteoarthritis and healthy individuals. As a participant in the study, your joint and limb motions, forces, and muscle activity will be measured while you walk with three different types of sandals at two different self-selected speeds.

BACKGROUND: During gait, motions at the foot and knee are coupled. Therefore, modifications in the movement of the foot may contribute to changes in the movement of the knee. Excessive foot rotation has been linked to excessive knee rotation, which may overload parts of your knee joint. In addition, alterations in the movement of the foot of the opposite limb may increase knee forces during the early phase of the walking cycle, which may contribute to knee osteoarthritis progression. Excessive foot pronation has also been linked to the presence of mal-alignment in the forefoot. It is necessary to collect the same walking information from healthy individuals without knee osteoarthritis in order to have comparison information.

INCLUSION CRITERIA: You have been asked to participate in this study because:

- You are between the ages of 20-40.
- You are healthy and recreationally active and have no neuromuscular, musculoskeletal, or metabolic impairments that prevent from engaging in most forms of casual physical activity.
- You are not currently taking medications for any neurological, cardiovascular, or metabolic disorders.
- You have not had any injuries or surgeries that have impaired your walking ability in the last year.

If you do not meet one or more of these criteria, please inform the researchers. If you meet all of the inclusion criteria, you will be asked to participate in this study.

DESCRIPTION OF PARTICIPATION: This study will take place in the gait lab at Hotel Dieu Hospital. Your height and weight will first be measured, and you will be asked to report your age and level of physical activity (e.g. exercise habits). You will be asked to change into spandex shorts, a sleeveless shirt, and a pair of sandals

supplied by the lab so that a set of small reflective markers can be secured to your arms, legs, and trunk by tape and Velcro wraps. These markers allow the researchers to measure the positions of your limbs while you walk. A set of small sensors will be taped to your leg on the surface of several major muscles. The sensors allow the researchers to record the magnitude and timing of your muscle activity while you walk. The sensors are purely a measurement device. They do not and cannot deliver any sort of stimulus or electrical “shock” to your muscles.

With the markers and sensors in place, you will walk down a 20-foot walkway. At the center of the walkway are several platforms that measure the forces applied to your foot by the ground. You will perform five successful trials of walking at each of three different sandals conditions:

- Flat sandals on both feet
- Flat sandals on the left foot and a laterally wedged sandal on the right foot
- Flat sandals on the right foot and a laterally wedged sandal on the left foot

Each condition will be performed in your normal and comfortable walking speed and in your fast walking speed. You will select the speeds yourself.

The data collection session is expected to last approximately one hour, depending on how many trials are required for you to hit the force platforms successfully.

POSSIBLE RISKS: There are no major risks associated with the protocols outside of those you encounter during walking about in your daily life.

BENEFITS: You will receive no direct benefits from participation in the study. The data collected from you may ultimately lead to a better understanding of factors contributing to knee osteoarthritis progression from a biomechanical perspective, and may be useful in improving evaluation and treatment of people with knee osteoarthritis.

WITHDRAWAL: Even if you sign this document, you are free to withdraw your consent and no longer participate in the study at any time. Withdrawing from this study will not influence your ability to participate in other studies at HDH or Queen's.

CONFIDENTIALITY: The data collected from you will be identified only by an alphanumeric code (e.g. Participant A1) and the dates on which the data were collected. Your name, initials, and personal characteristics will not be used. Digital data will be collected and stored on secure (password-protected and encrypted) servers at the Human Mobility Research Centre on Queen's campus. When the data are presented at conferences or in journal articles, your identity will not be used at any stage. The cameras used in the first data collection session do not take any photographs of you personally. They only record the motion of the reflective markers in space.

INJURY: If you experience any discomfort during or following the data collection that you believe is related to the procedures you performed, please contact the study's

point contact person immediately (Renan Resende; 613-547-8898; 12rr22@queensu.ca). You do not waive any of your legal rights concerning any health issues by signing this form.

INFORMATION: Please feel free to ask any questions about the study at any time during your participation. We are happy to provide any information we can. You may direct any questions to Renan Resende at 613-547-8898 or 12rr22@queensu.ca. You may reach his supervisor, Kevin Deluzio, at 613-533-2578 - deluzio@me.queensu.ca, or Amy Morton, research assistant: MPL.HDH@gmail.com. If you have any questions regarding your rights as a research subject you may contact Dr. Albert Clark, Chair, Research Ethics Board at 613-533-6081. All protocols for this study were reviewed by the Health Sciences Research Ethics Board at Queen's University.

HUMAN SUBJECTS TRAINING: All investigators have undergone training in the ethical treatment of human subjects and design of scientific studies involving live human subjects as required by Queen's University and Hotel Dieu Hospital.

STATEMENT: "I, the participant, have read and understood this informed consent document. The researchers have adequately addressed my questions concerning my participation. I hereby give my consent to participate in this study. I understand that I may withdraw from the study at any time without incurring any penalties."

Participant Name: _____

Participant Signature: _____

Date: _____

Investigator Name: _____

Investigator Signature: _____

Date: _____

The investigators will retain the original copy of this document for their records. You will be given a copy of the document if you would like one.

APÉNDICE D



Human Mobility Research Center



KG+I KINGSTON GENERAL HOSPITAL

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE: Effects of the use of lateral wedges under the forefoot on the kinematics and kinetics of the knee during gait.

INVESTIGATORS: Gavin Wood, MD; Kevin Deluzio, Ph.D.; Renan Resende, MSc.; Amy Morton, MSc.

PURPOSE OF THE RESEARCH: The purpose of this study is to better understand the movements of the forefoot and its effects on the knee during walking. We will be investigating this relationship in individuals with knee osteoarthritis and healthy individuals. As a participant in the study, your joint and limb motions, forces, and muscle activity will be measured while you walk with three different types of sandals at two different self-selected speeds.

BACKGROUND: During gait, motions at the foot and knee are coupled. Therefore, modifications in the movement of the foot may contribute to changes in the movement of the knee. Excessive foot rotation has been linked to excessive knee rotation, which may overload parts of your knee joint. In addition, alterations in the movement of the foot of the opposite limb may increase knee forces during the early phase of the walking cycle, which may contribute to knee osteoarthritis progression. Excessive foot pronation has also been linked to the presence of mal-alignment in the forefoot.

INCLUSION CRITERIA: You have been asked to participate in this study because:

- You have knee osteoarthritis.
- You have no other neuromuscular, musculoskeletal, or metabolic conditions that impair your walking.
- You are not currently taking medications for any neurological, cardiovascular, or metabolic disorders.
- You have not had any injuries or surgeries that have impaired your walking ability in the last year.

If you do not meet one or more of these criteria, please inform the researchers. If you meet all of the inclusion criteria, you will be asked to participate in this study.

DESCRIPTION OF PARTICIPATION: This study will take place in the human performance lab at Hotel Dieu Hospital. You will be reimbursed for your parking. Your height and weight will first be measured, and you will be asked to report your age and level of physical activity (e.g. exercise habits). A questionnaire that asks questions related to your knee osteoarthritis pain and your physical activity level will

be completed. You will be asked to change into spandex shorts, a sleeveless shirt, and a pair of sandals supplied by us so that a set of small reflective markers can be secured to your arms, legs, and trunk by tape and Velcro wraps. These markers allow the researchers to measure the positions of your limbs while you walk. A set of small sensors will be taped to your leg on the surface of several major muscles. The sensors allow the researchers to record the magnitude and timing of your muscle activity while you walk. The sensors are purely a measurement device. They do not and cannot deliver any sort of stimulus or electrical “shock” to your muscles.

With the markers and sensors in place, you will walk down a 20-foot walkway. At the center of the walkway are several platforms that measure the forces applied to your foot by the ground. You will perform five successful trials of walking at each of three different sandals conditions:

- Flat sandals on both feet
- Flat sandals on the left foot and a laterally wedged sandal on the right foot
- Flat sandals on the right foot and a laterally wedged sandal on the left foot

Each condition will be performed in your normal and comfortable walking speed and in your fast walking speed. You will select the speeds yourself.

The data collection session is expected to last approximately one hour, depending on how many trials are required for you to hit the force platforms successfully.

POSSIBLE RISKS: There are no major risks associated with the protocols outside of those you encounter during walking about in your daily life.

BENEFITS: You will receive no direct benefits from participation in the study. The data collected from you may ultimately lead to a better understanding of factors contributing to knee osteoarthritis progression from a biomechanical perspective, and may be useful in improving evaluation and treatment of people with knee osteoarthritis.

WITHDRAWAL: Even if you sign this document, you are free to withdraw your consent and no longer participate in the study at any time. Withdrawing from this study will not influence your ability to participate in other studies at HDH or Queen's, nor will it affect your current or future medical care.

CONFIDENTIALITY: The data collected from you will be identified only by an alphanumeric code (e.g. Participant A1) and the dates on which the data were collected. Your name, initials, and personal characteristics will not be used. Digital data will be collected and stored on secure (password-protected and encrypted) servers at the Human Mobility Research Centre on Queen's campus. When the data are presented at conferences or in journal articles, your identity will not be used at any stage. The cameras used in the first data collection session do not take any photographs of you personally. They only record the motion of the reflective markers in space.

INJURY: If you experience any discomfort during or following the data collection that you believe is related to the procedures you performed, please contact the study's point contact person immediately (Renan Resende; 613-547-8898; 12rr22@queensu.ca). You do not waive any of your legal rights concerning any health issues by signing this form.

INFORMATION: Please feel free to ask any questions about the study at any time during your participation. We are happy to provide any information we can. You may direct any questions to Renan Resende at 613-547-8898 or 12rr22@queensu.ca. You may reach his supervisor, Kevin Deluzio, at 613-533-2578 - deluzio@me.queensu.ca, or Amy Morton, research assistant: MPL.HDH@gmail.com. If you have any questions regarding your rights as a research subject you may contact Dr. Albert Clark, Chair, Research Ethics Board at 613-533-6081. All protocols for this study were reviewed by the Health Sciences Research Ethics Board at Queen's University.

HUMAN SUBJECTS TRAINING: All investigators have undergone training in the ethical treatment of human subjects and design of scientific studies involving live human subjects as required by Queen's University and Hotel Dieu Hospital.

STATEMENT: "I, the participant, have read and understood this informed consent document. The researchers have adequately addressed my questions concerning my participation. I hereby give my consent to participate in this study. I understand that I may withdraw from the study at any time without incurring any penalties."

Participant Name: _____

Participant Signature: _____

Date: _____

Investigator Name: _____

Investigator Signature: _____

Date: _____

APÊNDICE E



Human Mobility Research Centre

Syl and Molly Apps Research Centre
Kingston General Hospital
Kingston, Ontario K7L 2V7

T: (613) 548-2430 F: (613) 549-2529

Date

Dear Mr/Mrs.

I am writing today to *invite* you to participate in an upcoming research study that my colleagues and I are planning. You have been selected for consideration because you have osteoarthritis in one of your knees.

Please read the following attached consent form that tells you about the research study. My co-investigator, Renan Resende, MSc. will be telephoning you in the near future to enquire if you are interested in participating. If you agree to participate, I ask that you sign the consent form and bring it with you to your testing appointment that Renan will book for you. If at anytime you have questions relating to the study, you may contact Dr. Kevin Deluzio from the Human Mobility Research Lab at the Hotel Dieu Hospital. His contact information is located on the bottom of the consent form.

I would like to take this opportunity to inform you that your participation in any research study is strictly **voluntary**. A decision not to participate, or to withdraw at any time will not affect the standard of medical care you receive now or in the future.

Thank you for your consideration.

Sincerely,

Dr. Gavin Wood, MD.

APÊNDICE F

Sandals Study

SCRIPT (OA)

Introduction

My name is Renan Resende, I'm calling from the Hotel Dieu Hospital. I'm the PhD student conducting the study coordinated by Dr. Kevin Deluzio in collaboration with your orthopaedic surgeon Dr. Rudan. I am wondering if you have had a chance to read the letter sent to you by Dr. Rudan about our walking study?

- If yes “would you be interested in taking part in our study?”

If yes continue.

If no thank them for their time.

- If no “would you like me to call back at a later date after you have had a chance to read the letter.”

If yes ask when would be a good time _____.

If no thank them for their time.

Study involvement

The study will require you to make one visit to the Human Motion Laboratory at the Hotel Dieu Hospital and you will be asked to walk at a normal speed on a 10 meter walkway wearing 5 different pair of sandals while your motion is being recorded. It will take approximately 2 hours.

Do you think you might be interested?

If yes continue.

If “no” thank them for their time.

Questions

In order to ensure your safety and to determine whether or not you meet the criteria for our sample could I ask you a series of questions mostly about your general health that should take about 5 minutes: Yes continue. If “no” thank them for their time.

Please answer the questions as accurately as possible. You may however discontinue answering the questions at any time and terminate this phone conversation.

Question	Desire d Answe r	Given Answer/Comment s	
Have you had any surgery to either lower extremity in the past 6 months?	N		
Have you had any injury to either lower extremity in the past six months?	N		
Do you have any breathing difficulties or any heart problem that interfere with your day to day activities?	N		
Do you have any other form of arthritis (e.g. Rheumatoid, psoriatic)?	N		
Do you have any neuromuscular disorders (e.g. Parkinson's, Multiple Sclerosis)?	N		
Do you have any prior history of stroke?	N		
Are you able to walk a city block and climb stairs in a reciprocal fashion (i.e. climb with each foot)?	Y		

You meet the inclusion criteria, would you be interested in making an appointment? Yes Continue. . If “no” thank them for their time.

You meet the criteria, are you interested in setting a time for an appointment.

Yes Continue.

No Thank you for your time.

Time of appointment _____

Details of Visit

- I'll be waiting for you at the main entrance of the Hotel Dieu Hospital.

Required to:

- Walk along a 10 meter walkway at your normal speed wearing 5 different pairs of sandals.

We will:

- Monitor your motion to measure characteristics of the way you walk.
- Tape small markers on your upper arms, trunk, thigh, calf and foot. Specialized cameras can detect these markers and determine their position in the room with great accuracy.

→ Total experiment time, from the time you arrive to the time you leave the lab: 2 hours.

→ Compensation: \$20 for taking part in the study.

Dress: We will provide spandex-type shorts and shirt.

If for any reason you have to cancel your appointment, please contact me at 343-364-9515.

Do you have any questions or concerns?

ANEXO A

Your Full Name: _____
 _____ / _____ / _____

Today's Date:

Month Day Year

WOMAC OSTEOARTHRITIS INDEX

1. The following questions concern the amount of pain you are currently experiencing in your knees. For each situation, please enter the amount of pain you have experienced in the past 48 hours.

	None	mild	moderate	severe	extreme
A. Walking on a flat surface	A. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B. Going up or down stairs	B. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C. At night while in bed	C. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D. Sitting or lying	D. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E. Standing upright	E. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Please describe the level of pain you have experienced in the past 48 hours for each one of your knees.

	None	mild	moderate	severe	extreme
A. Right knee	A. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B. Left knee	B. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. How severe is your stiffness after first awakening in the morning?

None	mild	moderate	severe	extreme
<input type="checkbox"/>				

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

None	mild	moderate	severe	extreme
<input type="checkbox"/>				

5. 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 48 hours, in your knees.

What degree of difficulty do you have with:

	None	mild	moderate	severe	extreme
A. Descending (going down) stairs	A. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B. Ascending (going up) stairs	B. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C. Rising from sitting	C. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D. Standing	D. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E. Bending to floor	E. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F. Walking on a flat surface	F. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
G. Getting in/out of car	G. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H. Going shopping	H. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I. Putting on socks/stockings	I. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
J. Rising from bed	J. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
K. Taking off socks/stockings	K. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L. Lying in bed	L. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
M. Getting in/out of bath	M. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
N. Sitting	N. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
O. Getting on/off toilet	O. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P. Heavy domestic duties (mowing the lawn, lifting heavy grocery bags)	P. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q. Light domestic duties (such as tidying a room, dusting, cooking)	Q. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

ANEXO B

Patient _____

Date ____/____/20____

Lower Extremity Activity Scale (LEAS)

Baseline 6 weeks 12 weeks 26 weeks 52 weeks _____ years

Please read through each description given below. Pick the ONE description that best describes your regular daily activity and put a check in that box (Check only one box).

- A. I am confined to bed all day. (1)
- B. I am confined to bed most of the day except for minimal transfer activities (going to the bathroom, etc.). (2)
- C. I am either in bed or sitting in a chair most of the day. (3)
- D. I sit most of the day, except for minimal transfer activities, no walking or standing (4).
- E. I sit most of the day, but I stand occasionally and walk a minimal amount in my house. (I may rarely leave the house for an appointment and may require the use of a wheelchair or scooter for transportation.) (5)
- F. I walk around my house to a moderate degree but I don't leave the house on a regular basis. I may leave the house occasionally for an appointment. (6)
- G. I walk around my house and go outside at will, walking one or two blocks at a time. (7)
- H. I walk around my house, go outside at will and walk several blocks at a time without any assistance (weather permitting). (8)
- I. I am up and about at will in my house and can go out and walk as much as I would like with no restrictions (weather permitting). (9)
- J. I am up and about at will in my house and outside. I also work outside the house in a:
 - Minimally (10)
 - Moderately (11)
 - Extremely active job (12)
 (Please check the best description of your work level.)
- K. I am up and about at will in my house and outside. I also participate in relaxed physical activity such as jogging, dancing, cycling, swimming:
 - Occasionally (2-3 times per month) (13)
 - 2-3 times per week (14)
 - Daily (15)
 (Please check the best description of how often you participate in this activity.)
- L. I am up and about at will in my house and outside. I also participate in vigorous physical activity such as competitive level sports:
 - Occasionally (2-3 times per month) (16)
 - 2-3 times per week (17)
 - Daily (18)
 (Please check the best description of how often you participate in this activity.)

ANEXO C

With regard to the present moment, please rate the following by placing a single vertical line on the scale.

1. With regard to your knee pain

No pain

Pain as bad as it
could possibly be

With regard to the present moment, please rate the following by placing a single vertical line on the scale.

1. With regard to your COMFORT

Not comfortable at
all

Most comfortable
imaginable