

Proximal effects of unloader bracing for medial knee osteoarthritis

Analyses of muscle activation and movement patterns of hip and trunk during walking

Freyja Hálfdanardóttir

Thesis for the degree of Master of Science
University of Iceland
Faculty of Medicine
Research Centre of Movement Science
School of Health Sciences



Áhrif álagsléttandi hnéspelku Greining á vöðvavirkni og hreyfingum bols og mjaðmaliða í göngu

Freyja Hálfdanardóttir

Ritgerð til meistaragráðu í hreyfivísindum Umsjónarkennari: Kristín Briem

Meistaranámsnefnd: Þorvaldur Ingvarsson, Dan K. Ramsey

Læknadeild

Rannsóknarstofa í hreyfivísindum Heilbrigðisvísindasvið Háskóla Íslands Febrúar 2015

Proximal effects of unloader bracing for medial knee osteoarthritis Analyses of muscle activation and movement patterns of hip and trunk during walking

Freyja Hálfdanardóttir

Thesis for the degree of Master of Science

Supervisor: Kristín Briem

Masters committee: Þorvaldur Ingvarsson, Dan K. Ramsey

Faculty of Medicine

Research Centre of Movement Science

School of Health Sciences

February 2015

Ritgerð þessi er til meistaragráðu í hreyfivísindum og er óheimilt að afrita ritgerðina á nokkurn hátt nema með leyfi rétthafa. © Freyja Hálfdanardóttir 2014 Prentun: Háskólaprent Reykjavík, Ísland 2014

Ágrip

Inngangur: Talið er að einstaklingar með slit í miðlæga hluta hnjáliðar gangi með auknum bolsveiflum til að draga úr álagi á miðlæga hluta hnjáliðarins. Slíkar uppbótarhreyfingar gætu haft áhrif á vöðvavirkni og álag á liði í ganglimum og þar með einnig haft áhrif á hættu á að slit þróist í fleiri liðamótum. Álagsléttandi hnéspelkur eru notaðar til að draga úr einkennum slitgigtar sem eingöngu er bundin við annan hluta hnjáliðarins. Engu að síður er lítið vitað um möguleg áhrif álagsléttandi hnéspelkna á lífaflfræðilega þætti í öðrum liðamótum í ganglimum og virkni í fráfærsluvöðvum mjaðmaliða sem geta haft áhrif á bolsveiflur. Hingað til hafa flestar rannsóknir á virkni spelkanna beinst að eldra fólki en mikilvægi spelkumeðferðar er væntanlega mest fyrir fólk undir 60 ára. Markmiðið með þessari rannsókn var að skoða hreyfingar bols og mjaðmaliða með lífaflfræðilegum aðferðum og greina vöðvavirkni í fráfærsluvöðvum mjaðma hjá tiltölulega ungum og virkum einstaklingum með slit í miðlæga hluta hnjáliðar. Einnig að kanna áhrif af álagsléttandi hnéspelku (UnloaderOne®) á þessa þætti.

Aðferð: Úrtak rannsóknarinnar var 17 karlar (40-60 ára) með staðfest slit í miðlæga hluta hnjáliðar (II.-III. gráðu Kellgren-Lawrence) sem höfðu fengið læknisbeiðni um álagsléttandi hnéspelku. Viðmiðunarhópur samanstóð af 14 körlum án einkenna um slitgigt í hné. Hreyfimunstur og kraftvægi voru metin með þrívíddargöngugreiningu. Rannsóknarhópurinn var mældur með og án hnéspelku innan 48 tíma frá því að þeir fengu spelkuna og aftur að 4 vikum liðnum. Jafnlengdarstyrkur fráfærsluvöðva mjaðmar var mældur og rafvirkni m. gluteus medius (Gmed) og m. tensor fasciae latae (TFL) metin með yfirborðs vöðvarafriti. Árangur meðferðar var metinn með KOOS spurningakvarða og rannsóknarhóp skipt í tvennt, responders (R) og non-responders (NR) eftir skilgreiningu OARSI á hvort klínískt martækur árangur náðist eða ekki. Í tölfræðigreiningu voru notuð fylgnipróf, t-próf og dreifnigreining fyrir endurteknar mælingar og alpha ákveðið 0,05.

Niðurstöður: Hóparnir voru sambærilegir hvað varðar aldur, líkamsþyngdarstuðul og staðlaðan styrk í fráfærsluvöðvum mjaðma. Skor á sjálfsmats kvörðum um verki og einkenni batnaði almennt hjá rannsóknarhópnum (p<0,05) en svörunin var breytileg. Bolhalli að stöðufæti mældist minni við hælslag (p=0,015) hjá báðum rannsóknarhópunum og seinkun varð á að bolhalli færðist frá stöðuhlið yfir á gagnstæða hlið, miðað við samanburðarhóp. Einnig var R hópur með stærra hreyfiútslag á bolhreyfingum í frontal plani en bæði NR og viðmiðunarhópur. Ekki mældist munur milli hópa eða hliða á liðferlum og kraftvægi um mjaðmaliði og engar breytingar fundust á þessum þáttum að 4 vikum liðnum. Í upphafi rannsóknar mældist ekki marktækur munur milli hópa eða hliða á hámarks virkni í Gmed án spelku og hámarks virkni TFL var meiri hjá R en viðmiðunarhóp (p<0,001) og NR (p<0,001). Meiri vöðvavirkni mældist í Gmed hjá R hóp við að nota spelkuna (p<0,01).

Ályktun: Þrátt fyrir almenna hækkun á skori á sjálfsmatskvörðum svöruðu ekki allir þátttakendur spelkumeðferð. Hreyfiútslag bols í frontal plani minnkaði lítillega en þó tölfræðilega marktækt milli mælinga sem gæti haft áhrif á kraftvægi um hné vegna þess hve stór vogararmur bolsins er. Þeir sem náðu árangri með álagsléttandi hnéspelku á 4 vikum virtust beita mjaðmavöðvum ólíkt þeim sem ekki náðu árangri. Hugsanlega náðu þeir að nýta vöðvana á einhvern hátt til að hafa áhrif á álag og einkenni í hné. Með stærri rannsókn mætti hugsanlega greina mælanlega þætti sem gætu spáð fyrir um hvaða sjúklingar eru líklegir til að hafa gagn af meðferð með álagsléttandi spelku.

Abstract

Introduction: Persons with medial knee osteoarthritis (OA) are thought to adopt increased frontal plane trunk sway to reduce medial compartment loading. This type of compensatory motion may affect bilateral muscle function and loading of the lower extremity joints, and thereby impact risk of developing multi-articular OA. Unloading valgus knee braces are frequently prescribed for symptomatic relief for individuals with uni-compartmental knee OA. However, little is known about their potential effect on the biomechanics of other lower extremity joints, or about their influence on hip abductor muscles that may contribute to trunk sway. Furthermore, most studies have focused on an older population while perhaps it is the <60 years who stand to gain the most from conservative therapy. The purpose of this study was therefore to assess frontal plane hip and trunk biomechanics and hip muscle function in a relatively young, active OA patient population and examine the effects of an unloading brace (UnloaderOne®) thereon.

Methods: Seventeen male patients (age 40-60 years) with symptomatic medial knee OA and confirmed Kellgren-Lawrence grade II or III radiographic scores were recruited for the study. All had received a prescription for an unloading brace. Fourteen asymptomatic males were recruited as controls and conventional gait analysis was performed to assess kinematic and kinetic patterns. OA participants were assessed both with and without the brace during an initial assessment within 48 hours of brace fitting and again 4 weeks later. Isometric hip abductor strength was measured and activation levels of Gluteus medius (Gmed) and tensor fasciae latae (TFL) muscles were monitored with surface electromyography (EMG). OA participants were stratified into responders (R) and non-responders (NR) according to OARSI – OMERACT criteria. Alpha was set at 0.05 for statistical analyses, which included correlations, t-tests and repeated measures analysis of variance.

Results: No group differences were found for age, BMI, or normalized hip abductor muscle strength. Overall, self-report scores of OA participants improved (p<0.05), but great variability was seen in the response. OA participants demonstrated less trunk lean to stance side at initial contact (IC) (p=0.015), and a delay in transition of trunk lean from stance to contralateral side, compared to CTRLs. Rs also had greater frontal plane trunk excursion (p=0.034) than CTRLs and NRs. No intergroup or interlimb differences were found for hip adduction moments or angles and no changes were detected over time for those parameters. No significant group or interlimb differences were found for peak muscle activation levels of Gmed at baseline but peak activation levels of TFL were significantly higher for R than CTRLs (p<0.001) and NRs (p<0.001). Rs demonstrated an increase in Gmed peak muscle activation level when wearing the brace (p<0.01).

Conclusions: Overall, self-report scores improved significantly with brace use, while frontal plane angles or moments at the hip were not affected. A slight but statistically significant decrease in frontal plane trunk excursion was detected over time, which may affect knee adduction moment via the large lever arm of the trunk. There appear to be differences in muscle activation intensity between those who respond to unloader bracing treatment after 4 week treatment and those who don't. A larger study could possibly identify measurable baseline factors that could predict which patient is likely to benefit from using an unloading brace.

Acknowledgements

The research was conducted in the Research Center of Movement Science in the University of Iceland.

First I would like to express my gratitude to my supervisor and mentor, Kristín Briem. I would like to thank her for the inspiration she gave me and all her guidance and positive input through the learning process of this Master's thesis. This paper would not have been accomplished without her assistance and dedicated involvement in every step throughout the process.

I would also like to thank the other members of my masters committee, Þorvaldur Ingvarsson and Dan K. Ramsey for their valuable input.

Thanks to Þórarinn Sveinsson for EMG processing and statistical advice. Thanks to Einfríður Árnadóttir, radiologist at Röntgen Orkuhúsið and those orthopaedic surgeons at Orkuhúsið who participated in recruiting patients for the project. Thanks to Atli Ingvarsson, prosthesist at Össur, Rakel Óskarsdóttir, Micah Nicholls and other staff members at Össur. Thanks to Finnur Malmquist for help with EMG processing, and Benedikt Hálfdanarson and David McDonald for proofreading.

Thanks to all the participants in the study.

Last but not least I would like to thank my wonderful husband and children for all their patience and endless support during this process.

The following supported the research:

Research fund of Félag sjúkraþjálfara (Icelandic physiotherapy association)

Félagsstofnun stúdenta

Table of contents

Ág	rip		3
Ab	strac	zt	4
Ac	knov	vledgements	5
Tal	ole o	f contentsf	6
Lis	t of f	figures	8
Lis	t of t	ables	9
Lis	t of a	abbreviations	.10
1	Intro	duction	.11
	1.1	Gait	11
	1.2	The knee joint	12
	1.3	External knee adduction moment	12
	1.4	Hip abductor muscle strength	13
	1.5	Gait in medial knee OA	13
		1.5.1 Knee joint kinetics and kinematics	13
		1.5.2 Frontal plane hip and trunk kinematics in medial knee OA	14
		1.5.3 Frontal plane hip kinetics in medial knee OA	15
		1.5.4 EMG of hip abductor muscles in medial knee OA	15
	1.6	Effects of unloading braces on gait	15
		1.6.1 Frontal plane hip kinematics and kinetics and bracing	16
2	Purn	oose	17
-	•	Research questions	
		Hypotheses	
		Rationale	
3	Meth	nods	
	3.1		
		Procedure overview	
	3.3	Participants	20
	3.4	Intervention	20
	3.5	Equipment	
		3.5.1 Self-report measures of pain and function	
		3.5.2 Brace use compliance	
		3.5.3 Motion analysis	
		Data management and processing	
	3.7	Statistical methods	26
4	Resu	ults	.27
	4.1	OA responders and non-responders vs controls at baseline	27
		4.1.1 Demographics	
		4.1.2 Knee range of motion and hip abductor strength at baseline	28
		4.1.3 Self-report measures at baseline	29
		4.1.4 Kinematics at baseline	
		4.1.5 Kinetics at baseline	34
		4.1.6 Electromyography	35

	4.2	Bracing effects on responders vs non-responders	37
		4.2.1 Self-report measures and demographics	37
		4.2.2 Kinematics – pre-to-post bracing	
		4.2.3 Kinetics – pre-to-post bracing	
		4.2.4 Electromyography	40
		4.2.5 Brace use	
5	Disc	cussion	44
	5.1	Trunk movements	44
	5.2	EMG	45
	5.3	Hip joint kinetics and kinematics	46
		Function, pain, brace use	
	5.5	Study limitations	49
	5.6	Study strengths	49
		Future directions	
6	Con	clusion	50
Re	eferer	nces	51
Αŗ	pend	dix	56

List of figures

Figure 1. The phases of the gait cycle	12
Figure 2. Effect of gait adaptation on knee adduction moment	14
Figure 3. The function of a valgus unloading knee brace and UnloaderOne brace	16
Figure 4. DS1922L iButton thermocron temperature logger	22
Figure 5. Motion analysis lab at the Research Centre of Movement Sciences	23
Figure 6. Marker placement, frontal view at standing calibration, from QTM	23
Figure 7. A 12 channel KinePro EMG unit and a wireless pre-amplified transmitter	24
Figure 8. Strength measurement of hip abductors	25
Figure 9. Passive knee flexion range of motion at baseline	28
Figure 10. Passive knee extension range of motion at baseline	28
Figure 11. Hip abductor muscle strength at baseline	29
Figure 12. Group mean curves for frontal plane trunk lean at baseline	30
Figure 13. Frontal plane trunk lean towards stance limb at IC (baseline)	31
Figure 14. Maximum frontal plane trunk lean towards stance limb (baseline)	31
Figure 15. Frontal plane trunk lean excursion at baseline	32
Figure 16. Frontal plane hip joint angles of involved limb	32
Figure 17. Frontal plane hip joint angles of uninvolved limb	33
Figure 18. Hip joint adduction angle at initial contact	33
Figure 19. Mean frontal plane excursion of hip joint during weight acceptance	34
Figure 20. Group mean curves of hip adduction moment, involved side at baseline	34
Figure 21. Group mean curves of hip adduction moment, uninvolved side at baseline	35
Figure 22. Mean amplitude of standardized RMS of gluteus medius	36
Figure 23. Mean amplitude of standardized RMS of tensor fasciae latae	36
Figure 24. Mean curves for frontal plane trunk lean before and after treatment	38
Figure 25. Frontal plane trunk lean towards stance limb at IC	38
Figure 26. Frontal plane trunk excursion	39
Figure 27. Maximum hip joint adduction angle during weight acceptance of stance, mean (SE)	39
Figure 28. Effect of UnloderOne knee brace on EMG activity of gluteus medius	40
Figure 29. EMG activity of gluteus medius before and after brace treatment	41
Figure 30. EMG activity of tensor fasciae latae	41
Figure 31. Mean brace use time	42
Figure 32. iButton temperature chart for regular brace use	43
Figure 33. iButton temperature chart for irregular brace use	43

List of tables

Table 1. Subject demographics, mean (SD)	27
Table 2. Grades of radiographic changes in the medial compartment of the tibiofemoral joint	27
Table 3. NPAQ categories of employment	27
Table 4. KOOS scores of Control, responder and non-responder groups at baseline, mean (SD).	29
Table 5. KOS-ADLS scores of Non-responders, Responders and Control groups at baseline, mean (SD)	30
Table 6. Absolute change on KOOS subscales over time, mean (SD)	37
Table 7. Absolute change on KOS-ADLS subscales over time, mean (SD)	37
Table 8. Baseline and follow up correlations of EMG values and strength measures	42

List of abbreviations

ANOVA Analysis of variance

CI Confidence interval

CTRL Control group

GC Gait cycle

Gmed Gluteus medius

GRF Ground reaction force

HAM Hip adduction moment

IC Initial contact

KAM Knee adduction moment

KL grade Kellgren-Lawrence grade

KOOS Knee injury and osteoarthritis score

KOS-ADLS Knee outcome survey, activities of daily living scale

MVIC Maximal voluntary isometric contraction

MVPA Moderate-to-vigorous physical activity

NPAQ Nordic physical activity questionnaire

NR Non-responders

OA Osteoarthritis

PF Patellofemoral

PHAM1 First peak of hip adduction moment

PHAM2 Second peak of hip adduction moment

PKAM1 First peak of knee adduction moment

PKAM2 Second peak of knee adduction moment

PKF Peak knee flexion

R Responders

RMS Root mean square
ROM Range of motion

sEMG Surface electromyography

TF Tibiofemoral

TFL Tensor fasciae latae

VPA Vigorous physical activity

WA Weight acceptance

1 Introduction

Osteoarthritis (OA), knee OA in particular, is a large and growing public health problem and one of the most common musculoskeletal causes of disability (1). While estimates of incidence among the Icelandic population are unavailable, projected numbers from the USA indicate that by 2030, nearly one-third of adults ages 45–64 years will have arthritis (1). Given knee OA is a degenerative disease with no known cure, the demand for joint replacement surgeries in the USA is projected to grow by 673% from 2005 to 2030 (2). Patients who have knee joint replacement surgery younger than 60 years have a higher risk of early revision surgery compared with patients who are older than 60 years (3, 4) making it even more important to place major emphasis on conservative management of young patients with early-stage OA and to develop treatment strategies that reverse or slow down progression of disease.

Dynamic loading of the knee refers to loading during physiologic activity such as walking, as opposed to static loading, which occurs when standing still. The wear and tear process in OA may occur during normal ambulation as it is the most common dynamic loading activity. A non-random pattern of evolution of multi-articular OA of the lower extremities has been demonstrated. As for persons who have developed knee OA, the contralateral knee and hip joints are specifically at risk (5) which is thought to stem from abnormal biomechanical loading of those joints (6, 7). This abnormal loading of the contralateral knee persists at least 12 months after successful knee arthroplasty and is proposed to be due to a persistence of a learned compensatory movement and muscular recruitment patterns of the lower extremity, a "chronic osteoarthritis" gait pattern (8).

Effects of non-operative conservative treatment need to be considered on a broader level since the lower extremity acts as an integrated kinematic chain composed of rigid segments and moving joints. Changes at one level can thus have profound effects on joint loading at other levels during the stance phase of gait. Yet surprisingly little reseach has examined whether conservative interventions intended to slow knee OA progression influence other weight-bearing structures. Only the work by Toriyama et al. demonstrated external hip adduction moments were reduced bilaterally when wearing an unloader brace (9) yet it remains unknown whether these effects are long-term or whether bracing influences hip muscle activity. Such knowledge would increase understanding of the effects of the unloader braces on a broader level.

1.1 Gait

Walking is a sequence of events where one limb functions as a mobile base while the other swings forward to a new support site, and is then repeated reciprocally as needed until the intended destination is reached. A single gait cycle (GC) is defined as the series of events from initial heel contact to the next initial contact of the same foot (Figure 1). The GC is divided into two phases, the stance phase where the foot is on the ground, and the swing phase of the same leg where the foot is in the air and swings forward. The stance phase is further divided into 5 sub-phases with different functional roles, 1) initial contact (IC), 2) loading response, 3) mid stance, 4) terminal stance and 5) pre-swing. Initial contact and loading response together comprise weight acceptance (WA) (10).

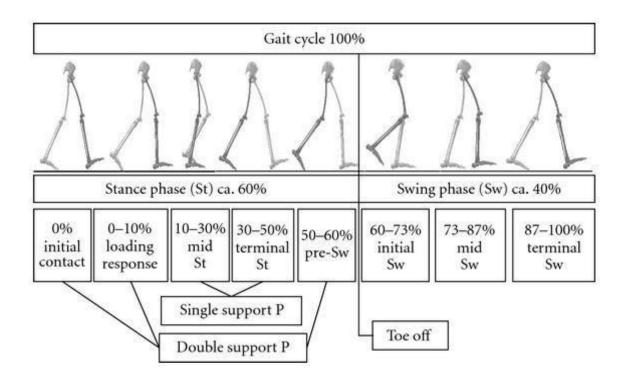


Figure 1. The phases of the gait cycle.

1.2 The knee joint

The knee joint is the largest synovial joint in the body and has to withstand great demands regarding both stability and mobility. The knee has two functional joints within one joint capsule; the patellofemoral (PF) and tibiofemoral (TF) joints. Knee alignment is knee position in reference to the hip and ankle and it influences load distribution at the knee joint. In a varus aligned knee the weight bearing line from the mid femoral head to mid ankle passes medially to the TF joint and creates an adduction moment arm which increases force loading on the medial TF joint compartment. Sharma et al. demonstrated that the risk of medial OA progression increases with varus alignment and that valgus alignment increases the risk of lateral compartment OA progression (11). The medial compartment of the TF joint is more commonly affected by OA than the lateral compartment or the PF joint (12). In medial compartment OA the medial joint space of the TF joint narrows as a result of articular cartilage degeneration and increases varus alignment of the knee, which can cause an even greater adduction moment on the knee (11).

1.3 External knee adduction moment

Direct measurement of knee load is impossible without invasive procedures. A common outcome measure in knee OA studies which is considered to be a valid proxy is the external adduction (varus) moment of the knee. It is inferred from gait analysis and inverse dynamics and represents a varus torque on the knee joint which affects dynamic load distribution in the knee during stance phase of gait (6). The magnitude of the knee adduction moment (KAM) is determined by the magnitude of the

ground reaction force vector (GRF) and its perpendicular distance from the knee joint center of rotation (6). In normal gait an external adduction moment acts on the knee joint throughout most of the stance phase (13, 14) causing a greater load on the medial compartment than on the lateral. The adduction moment typically has a biphasic pattern with two distinct peaks, the first peak knee adduction moment (PKAM1) occurs shortly after IC, the second peak knee adduction moment (PKAM2) occurring during late stance. It is widely believed that disproportionate loading of the medial compartment of the TF joint contributes to progression of medial compartment OA.

1.4 Hip abductor muscle strength

Hip musculature of people with knee OA has been found to be weaker than in asymptomatic controls, but it is not clear if hip weakness precedes knee OA onset or occurs as a consequence of disease (15). It has been proposed that hip abductor muscles might influence knee joint loading by their frontal plane control of the pelvis during stance phase, as weak hip abductors in the stance limb may cause increased pelvic drop to the contralateral swing limb (16-18). This would increase forces across the medial TF compartment of the swing limb by shifting the body's center of mass toward the swing limb. Hip abductor strengthening programs for knee OA patients have resulted in improvements in hip abductor strength (19, 20), measures of pain (19, 20) and physical function (19) without any apparent changes in PKAM1 (19, 20). A recent study examined the relationship between hip abductor muscle strength and activation and KAM characteristics during gait in individuals with knee OA and found that despite a positive association between hip abductor strength and the PKAM it only explained a small portion of the variance in PKAM (21). This would perhaps explain in part why hip abductor strengthening has not been shown to alter PKAM.

1.5 Gait in medial knee OA

Gait patterns of persons with medial knee OA have been shown to differ from those of healthy or asymptomatic individuals. The focus has until recently mostly been on kinematic and kinetic variables and muscular activity around the osteoarthritic knee joint itself without regard for the rest of the kinematic chain of the lower limb or the contralateral side.

1.5.1 Knee joint kinetics and kinematics

At initial contact (IC) OA patients exhibit a more extended knee on their involved side, compared to an asymptomatic, age, height and weight matched control group (17) and lower peak knee flexion (PKF) compared to their uninvolved side (22). In the frontal plane the involved knee demonstrates a larger adduction angle at IC and at the first peak of the knee adduction moment (PKAM1) compared to the uninvolved side (22, 23). The PKAM1 has been shown to be significantly greater in subjects with radiographic evidence of medial compartment cartilage damage than in normal subjects (14, 20, 24, 25), and the same has been demonstrated for PKAM2 (14). PKAM1 at the osteoarthritic knee has also been demostrated to be higher than at the asymptomatic contralateral knee joint (14, 26).

1.5.2 Frontal plane hip and trunk kinematics in medial knee OA

It has been found that patients with medial knee OA have less adduction of the involved side hip joint at IC compared to the uninvolved side (22) and to a control group (23), and that the hip adduction angle remains smaller at PKAM1 (22) than on the uninvolved side.

Frontal plane movements of the trunk have received increasing attention in recent years, as these potentially influence lower limb loading. An increased lean towards the stance limb, bilaterally in medial knee OA patients, compared to asymptomatic controls (23, 27) is proposed to be a compensatory response to the disease. Patients with more severe OA tend to have a larger peak trunk lean towards the involved limb than those with less severe OA (23) and patients with greater pain tend to have greater trunk lean (27). Trunk lean has been shown to be consistently different between individuals with medial compartment OA and symptomless control group during prolonged (30min) walking (27). It has been speculated that persons with medial knee OA adopt increased frontal plane trunk lean (Figure 2) to redistribute knee load off the medial compartment (evident by lower external knee adduction moments). This compensatory strategy would serve to decrease pain and could be the cause for lower ipsilateral hip adduction moment and result in weakening of hip musculature (17, 22). A small change in frontal plane trunk lean could affect lower extremity joint loads greatly through the large lever arm of the trunk. Mündermann et al. even tested the theory that increasing mediolateral trunk lean could have an effect on KAM during ambulation in healthy subjects and found that by increasing lateral trunk lean the KAM was reduced up to 65% without significant differences in lateral ground reaction forces and axial loading rates at the ankle, knee and hip (28).

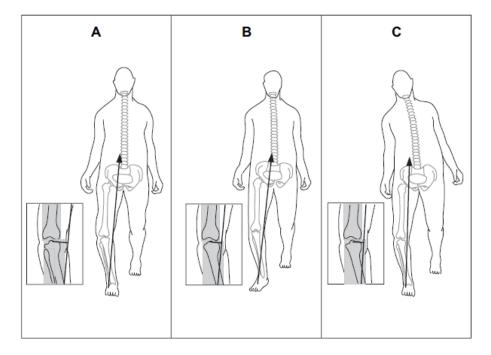


Figure 2. Effect of gait adaptation on knee adduction moment.

A) The magnitude of the knee adduction moment (KAM) is mainly determined by the ground reaction force (GRF) vector and its lever arm on the knee joint. By either B) increased toe-out angle or C) increased lateral trunk lean over the stance limb the GRF lever arm distance at the knee will be decreased thereby lowering the KAM (29).

1.5.3 Frontal plane hip kinetics in medial knee OA

The hip adduction moment typically has a biphasic pattern with two distinct peaks; the first peak hip adduction moment (PHAM1) occurs shortly after IC, with the second peak hip adduction moment (PHAM2) occurring during late stance. The ipsilateral external hip adduction moment (HAM) of patients with medial knee OA has been reported to be lower than at the contralateral hip joint during early stance (22) and lower than among healthy controls (13, 22). A higher external HAM during mid stance compared to a control group was found in another study involving patients with medial knee OA (7). A greater internal hip abduction moment (equivelent to external HAM) at baseline is proposed to be protective against progression of ipsilateral medial knee OA as measured 18 months later (16). A 50% reduction in the likelihood of medial compartment OA progression per unit of hip abduction moment was demonstrated.

1.5.4 EMG of hip abductor muscles in medial knee OA

Little is known on hip abductor muscle function in medial knee OA. A search of the literature turned up one recent study, examining the relationship between hip abductor muscle function and KAM characteristics during gait in individuals with knee OA. A higher sustained Gluteus medius (Gmed) activation during stance and a positive relationship between overall Gmed activation and KAM magnitudes during mid-stance were demonstrated (21). Another study explored whether people with early OA have neuromuscular adaptations or altered gait parameters (30). No significant differences were found in gait parameters such as the PKAM1 when early OA subjects were compared to an age and gender matched control group. However, they had increased postural sway bilaterally during ipsilateral single leg standing, as well as an increase in Gmed activity bilaterally during single leg standing and quiet standing.

1.6 Effects of unloading braces on gait

In theory, reducing medial load should slow the rate of medial OA progression. Several biomechanical interventions, such as orthotic shoe inserts, unloading braces, and joint realignment surgery, aim to slow structural damage by decreasing load on articular cartilage (6, 31).

Unloading knee braces apply an external valgus (abduction) moment to the knee joint which should in theory lower the external adduction moment (Figure 3). Studies demonstrate decreased pain (32-35), improved function (33, 34), symmetrical gait patterns (35), and improved functional stability (36). Unloader braces are reportedly cost-effective (37).

To date, biomechanical research examining the effects of unloading braces has primarily focused on knee joint kinematics and kinetics. Unloading braces reportedly lower the external adduction moment of the knee which in theory attenuates focal overload on the medial compartment (33, 34). They also reportedly increase medial condylar separation during weight acceptance (38), decrease antagonist muscular co-activation around the knee (36), and improve knee joint proprioception (39).

Very little is known on optimal wear time for unloading braces and wear time prescription may thus vary greatly between clinicians and in different studies. There appears to be a dose-response relationship in a way that greater brace use may positively affect physical activity level, but without having a negative effect on muscle strength (40).

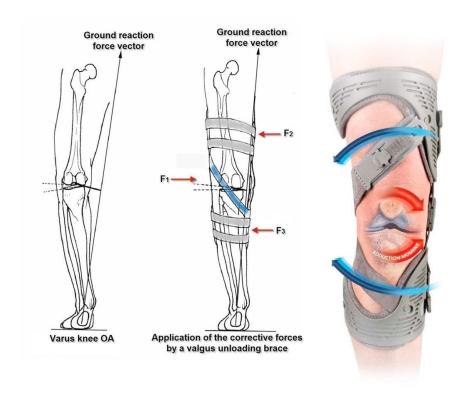


Figure 3. The function of a valgus unloading knee brace and UnloaderOne brace.

1.6.1 Frontal plane hip kinematics and kinetics and bracing

A search of the literature revealed only one study that specifically investigated effects of unloader braces on hip joint function. Toriyama et al. found that an unloading knee brace for patients with medial compartment OA had kinematic and kinetic effects on other joints during the stance phase. A reduction in ipsilateral hip joint abduction angle (a relatively more adducted hip joint) and a lower PHAM2 was found with bracing, both changing toward greater interlimb symmetry. A lower PHAM1 was found at the contralateral hip (9).

No research was found on whether unloader brace treatment for medial knee OA has any impact on frontal plane trunk lean or hip abductor EMG function.

2 Purpose

The purpose of this study was to investigate hip abductor muscle activity and frontal plane kinematic and kinetic variables at the hip and trunk during gait in patients with medial compartment OA, as well as to:

- compare outcomes to a symptomless control group.
- assess immediate and short term (4 weeks) effects of an unloader brace on those parameters.

2.1 Research questions

Are there any differences during stance phase of gait between patients with medial compartment knee OA and a symptomless control group regarding:

- frontal plane trunk movements?
- frontal plane hip joint kinematics and kinetics?
- activity levels of hip abductor muscles (Gluteus medius and tensor fasciae latae)?

Are there any immediate or short term (4 weeks) effects of applying an unloading knee brace on:

- frontal plane trunk movements?
- frontal plane hip joint kinematics and kinetics?
- levels of activity of hip abductor muscles (Gluteus medius and tensor fasciae latae)?

2.2 Hypotheses

- The OA group will have less adduction of the hip joint at IC and a lower external hip adduction moment compared to the control group.
- The OA group will have a greater trunk lean than the control group.
- The external adduction moment and adduction angle at both hip joints during stance will increase over time in the OA group.
- Hip abductor musculature activity will increase after 4 weeks of wearing the unloading brace compared to baseline.
- Trunk lean towards the stance leg will decrease over time.

2.3 Rationale

It has been proposed that patients with medial compartment knee OA try to shift loads away from the medial compartment (thereby lowering the external knee joint adduction moment) by increasing mediolateral trunk lean. This would be achieved by leaning further over the stance leg than normal and this compensatory strategy could result in lower ipsilateral external hip adduction moments (17, 22). Unloading braces have been shown to decrease the external knee joint adduction moment which may also be reflected in the hip adduction angle and external hip adduction moment. Little is known about the EMG activity of hip abductor musculature of medial knee OA patients, but a more ab- or adducted hip joint in stance might affect external joint moments and thereby abductor muscle activity to keep the net external and internal joint moments in balance. It is also unclear what role hip abductor muscles play in controlling trunk motion via the pelvis.

3 Methods

3.1 Research design

The research was designed as a prospective case control study that consisted of two groups, *i*) male patients with a diagnosis of medial compartment knee osteoarthritis (OA group) and *ii*) a control group comprised of healthy age, height and weight matched subjects. The study protocol was approved by the review board at the National Bioethics Committee (VSNb2011100025/03.07) and announced to the Data Protection Authority.

3.2 Procedure overview

All testing was conducted at the Research Centre of Movement Science, Department of Physical Therapy, Faculty of Medicine, School of Health Sciences, University of Iceland, Reykjavík, Iceland. The study period was from January 2012 to February 2014.

Participants fulfilling inclusion criteria (described later) received an introductory letter (Appendix 1) followed by a phone interview screening for possible exclusion criteria (as detailed below). When eligible OA group participants were identified, they were referred to a certified orthotist for brace fitting. Within 48 hours of brace fitting they came to the gait analysis lab, for their baseline data collection session, which lasted approximately 1.5 – 2 hours.

At the initial gait assessment, participants signed an informed consent form (Appendix 2) and completed self-report questionnaires on pain, function and activity. Information regarding any other musculoskeletal ailments, current physiotherapy, prior arthroscopy or viscosupplementation therapy was documented, as was current use of pain medication.

The methods used to collect biomechanical data are summarized below, with the specifics presented later. The same protocol was used for both the initial assessment and the follow up for the OA group 4 week later. In brief, participants changed into their own shorts, mass, height and passive knee range of motion (ROM) goniometric measurements were recorded, and the degree of knee joint effusion was noted. Prior to motion capture measurements, surface electrodes were applied over the superficial hip abductor muscles and participants performed maximal voluntary isometric muscle contraction (MVIC) of hip abductors. Strength output was registered and electromyographic (sEMG) data simultaneously collected for normalization purposes. Retro-reflective markers for 3D motion analysis were then applied over bony landmarks. Electrode and marker placement, as well as MVIC testing, were all done by the same experienced physical therapist (FH). Gait assessment included synchronized collection of three-dimensional kinematic data, ground reaction forces and sEMG measurements as subjects walked across the lab floor at a brisk pace (without and then with the brace for the OA group) wearing their own comfortable low top walking shoes (Figure 5). Data were collected until three successful sEMG recordings and five successful foot strikes per foot on the force plate were obtained.

3.3 Participants

Seventeen male patients (age 40-60 years) with confirmed medial knee osteoarthritis, Kellgren Lawrence grade (KL grade) 2 or 3 radiographic changes (41) of the medial compartment of the TF joint, and clinical history of pain and functional disability, were recruited through the Orkuhúsið orthopaedic center in Reykjavík. Patients receiving a prescription for an unloading brace, who fulfilled the inclusion criteria of the study, received an introductory letter (Appendix 1) inviting them to participate in the study. Existing weightbearing radiographs (from within 6 months of study inclusion) were scored by an experienced radiologist (Einfríður Árnadóttir at Orkuhúsið, Reykjavík). In cases where bilateral medial compartment knee OA was diagnosed, the more symptomatic knee (for which the brace was prescribed) was defined as the affected one.

Patients were excluded if they had previously used an unloading brace, if they had history of orthopaedic surgery such as joint replacement surgery or osteotomy, knee ligament reconstruction, arthroscopic surgery to any of the lower limb joints within 6 months of the study, or history of periarticular fracture to the knee. Exclusion criteria also included radiologically confirmed OA in the ankle or hip joints, intra-articular corticosteroid or visco-supplementation injection to either knee joint within 3 months of study participation, and any musculoskeletal or neurological impairment, dermatological or circulatory problems in the lower extremities that might affect ambulation or brace use. Only participants with a body mass index (BMI) lower than 35 kg/m2 were included to ensure greater quality of sEMG data.

A control group (CTRL) was formed by a convenience sample of 14 male subjects recruited from the university community. They were asymptomatic, without any knee pain or OA in any of their weight bearing joints in either limb, and adhered to the same exclusion criteria as OA participants. They were age (± 5 years), weight (± 5 kilograms), and height (± 5 centimeters) matched to the OA cohort. For convenience the left limb of the CTRL group served as comparator to the involved side of OA participants. Although the intention was to match all 17 OA participants, it proved impossible to properly match three of the OA participants within the timeframe of the study.

3.4 Intervention

OA group participants were fitted for an UnloaderOne (Össur, Reykjavík, Iceland) brace, an off-the-shelf, light-weight knee brace which applies an abduction moment on the TF joint by a 3-point leverage. Fitting of all braces was done by the same certified and experienced orthotist at Össur who also gave standard instructions on donning the brace. Current recommendations regarding brace use time are to use the brace as much as possible throughout the day and whenever the participant feels the need for it.

Baseline data collection of OA group participants was undertaken within 48 hours of brace fitting followed by a second assessment 4 weeks later. A follow-up e-mail was sent 2 weeks into the study to monitor how participants were coping with brace use. Participants were encouraged to contact the investigators by phone or e-mail with concerns or questions regarding the brace at any time during the study.

3.5 Equipment

3.5.1 Self-report measures of pain and function

3.5.1.1 KOOS

Pain and functional status for the week preceding each testing session were assessed by the Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire (42) which consists of 5 subscales assessing knee pain (KOOS $_{pain}$) and symptoms (KOOS $_{symptoms}$), function in daily living (KOOS $_{ADL}$) and during sport/recreation (KOOS $_{SR}$), and knee related quality of life (KOOS $_{QOL}$). The questionnaire has been widely used to evaluate the course of knee injury and the effects of treatment. Questions are scored from 0 to 4 and a normalized score is calculated for each subscale (100 for no symptoms and 0 for extreme symptoms). The Icelandic version of the KOOS questionnaire (Appendix 3) has been shown to be a reliable and valid tool that may be used as an outcome measure assessing knee symptoms, pain and function of individuals with impaired knee function (43).

3.5.1.2 KOS-ADLS

The Icelandic version of the Knee Outcome Survey, Activities of Daily Living Scale (KOS-ADLS) (44), was also used to assess function (Appendix 4). The KOS-ADLS is a reliable, valid, and responsive patient-reported measure of functional limitations caused by pathological disorders and impairments of the knee (45). It includes items related to symptoms and functional limitations experienced during activities of daily living. The KOS-ADLS is a 14 item scale which questions patients about how their knee symptoms affect their level of daily activities (KOS_{Symptoms}, 6 items) as well as how their knee condition affects their ability to perform specific functional tasks (KOS_{Function}, 8 items). Each item is scored 0-5 points with 0 representing "unable to perform" and 5 indicating "no difficulty". The highest possible score is 70. The sum of all items are divided by 70 and then multiplied by 100 to give an overall ADLS percent rating (KOS_{Overall}). Higher percentages reflect higher levels of functional ability with 100 indicating no limitations/symptoms and 0 indicating extreme limitations/symptoms. A global rating of function is also on a 0–100 scale, with100 being the level of knee function prior to injury and 0 being the inability to perform any usual daily activity (45).

3.5.1.3 NPAQ

Physical activity was investigated using questions from the Icelandic version (46) of the Nordic Physical Activity Questionnaire (NPAQ), (Appendix 5). Participants were asked which of 4 groups of activity at work and in leisure time best described their activity within the last week. Participants were also asked how many hours (or minutes) they spent on moderate-to-vigorous intensity physical activity (MVPA) outside of work during the last week, and how many hours (or minutes) of this activity was vigorous physical activity (VPA).

3.5.2 Brace use compliance

Brace use compliance of the first 13 OA participants was monitored by DS1922L iButton thermocron temperature loggers (Maxim Integrated Products, Sunnyvale, US). These are small data recorders (approximately 17 mm in diameter and 6 mm thick) that accurately measure and record temperature and time at regular intervals (Figure 4). They have been shown to be a valid method to monitor

thoracolumbosacral orthosis wear time (47). The loggers are property of Össur and were not available for the last four OA participants. The sensors were mounted into the silicone calf liner of the brace and set to measure temperature at the skin-brace interface at regular intervals (every 20 minutes) for 28 consecutive days. Participants were informed about the sensors and instructed to try to keep the brace dry and at room temperature (avoid direct sunlight, heating elements etc.) when not wearing it. The sensors were set to start logging at the beginning of the study and removed from the lining at the second measurement session. After retrieval from brace, iButton data text files were extracted and converted into Microsoft Excel format and average daily brace use in hours (hrs./day) was calculated. The estimate of wear time relies on the brace being warmer when it is on the knee than when it is off. An algorithm developed by Benish et al. (47) for finding a cutoff temperature to determine whether the brace was on or off the participant's knee was used.

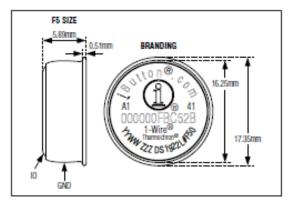




Figure 4. The DS1922L iButton thermocron temperature logger.

The DS1922L iButton thermocron temperature logger was used to monitor brace use during the study period.

3.5.3 Motion analysis

3.5.3.1 Kinematic and kinetic measurements

Kinematic measurements were recorded using 8 Oquus 300 infrared cameras (QualisysAB, Gothenburg, Sweden). Two AMTI force plates (American Management Technology, Inc.), embedded into the lab floor and synchronized to the motion capture system were used to acquire ground reaction forces. Qualisys track manager (QTM) software simultaneously recorded motion and force plate data (Figure 5).

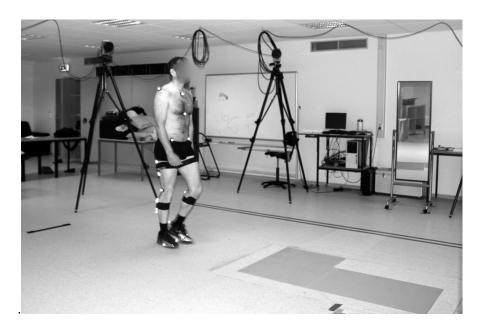


Figure 5. Motion analysis lab at the Research Centre of Movement Sciences.

Diagonal view of marker setup, force plates and infrared cameras.

Camera and force plate sampling rate was set at 100Hz and each trial was 4 seconds long. Retroreflective markers were placed according to C-Motion marker placement guidelines (48) by the same
experienced physical therapist (FH). Anatomical markers defined the proximal and distal ends of
respective segments (trunk and pelvis as well as feet, shanks and thighs of both lower limbs). Clusters
of 4-5 markers were used to track each segment during dynamic trials, secured with Velcro straps
and/or tape to avoid movement of the cluster of markers (Appendix 6). An initial static trial (Figure 6)
was recorded and the data used to determine body mass and relative marker orientation, and to
define segments and their local reference systems as well as joint centers for the model. Both static
and dynamic measurements were captured within a pre-calibrated area.

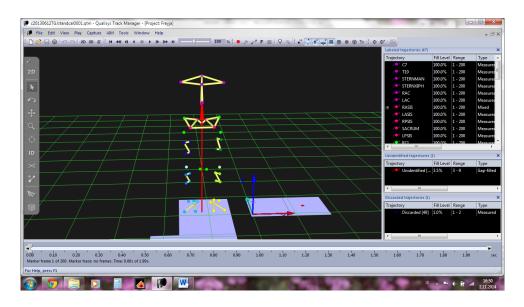


Figure 6. Marker placement, frontal view at standing calibration, from QTM.

3.5.3.2 Electromyographic recordings

Surface electromyographic activity of Gmed and tensor fasciae latae (TFL) was recorded using a wireless 12 channel EMG system (KinePro, Hafnarfjörður, Iceland) and KinePro software set to trigger simultaneous recording of the QTM motion capture system (Figure 7). The default sampling frequency of the manufacturer was set at 1600 Hz with a signal bandwidth of 16-500 Hz.

The skin was cleansed with isopropyl alcohol before electrode application. Self-adhesive disposable surface electrodes with an inter-electrode distance of 20 mm and snap-on pre-amplified wireless transmitters were used to collect data from target muscles. They were positioned parallel to the muscle fibers of the muscle bellies of Gmed and TFL bilaterally according to SENIAM recommendations (49). Palpation during muscle contraction was also performed in order to identify the optimal position.

After securing electrodes and verifying proper position by visually inspecting signal strength and quality from a short walking trial, isometric abductor muscle testing was performed and sEMG activity during a maximal voluntary isometric contraction (MVIC) recorded for normalizing the data during the walking trials.



Figure 7. A 12 channel EMG unit and a wireless pre-amplified transmitter.

3.5.3.3 Hip abductor muscle strength

The strength of the hip abductors was tested with participants in the supine position, with both hips maintained in neutral ab-/adduction and rotation according to the method described by Pua et al. (50). Stabilization belts were applied across the pelvis and the contralateral distal thigh to stabilize the pelvis and to restrain contralateral hip abduction. Muscle strength was measured during the MVIC trial by applying a hand-held dynamometer (Lafayette Manual Muscle Tester Model 01163) 5 cm proximal to the lateral femoral condyle (Figure 8). Strength measures were recorded in kilograms (kg) and then normalized to body mass index (BMI) and presented as kg/BMI. A change from the Pua et al. protocol was to apply an extra stabilization belt from the bench and around the tested leg; the dynamometer was then placed between the belt and the distal thigh. Before testing, participants were instructed to push maximally against the dynamometer with the hip in neutral rotation and verbal encouragement given during testing. After a single, submaximal trial, participants performed three trials of MVIC, each of 5 s duration, separated by 15 s of rest, recording the sEMG activity during the last one (19).



Figure 8. Strength measurement of the hip abductors.

A change from the Pua et al. (50) protocol was to apply an extra stabilization belt from the bench and around the tested leg, the dynamometer was then placed between the belt and the distal thigh.

3.6 Data management and processing

Commercial software (Visual3D™,C-Motion, Germantown, USA) was used to process the raw motion and force plate data. Marker and ground reaction force data were low-pass filtered with a Butterworth filter with a cut-off frequency at 6 and 15Hz, respectively. Three dimensional knee, hip and trunk angles were calculated using rigid body analysis and Euler angles with reference to the model and coordinate systems created from the static measurement. A local coordinate system was defined for the trunk segment, from which trunk lean was defined as a two dimensional frontal plane rotation of the trunk segment relative to the vertical axis of the frontal plane of the lab coordinate system. Joint moments for the lower limbs were derived by inverse dynamics and normalized to body mass (Nm/mass). Stance was time normalized to 100% and an ensemble average was derived across the three trials for each condition (brace vs. no-brace). Data were exported and Microsoft Excel and SPSS statistical software used for further analysis.

Raw EMG data were processed by applying a 25Hz high pass 7th order Butterworth filter, after which the signal was smoothed by calculating the root mean square (RMS) using a 250 ms moving window. Peak EMG values during a single stance phase of each of three gait trials were identified and then averaged for each limb per condition.

3.7 Statistical methods

In addition to evaluating differences between the OA and CTRL groups, the OA group was further assessed according to treatment response. Participants were stratified as responders (R) and non-responders (NR) according to Omeract-OARSI responder criteria for clinical trials (51) based on changes in KOOS and KOS-ADLS scores. A subject was classified as a responder if pain and self-reported function improved by \geq 50% relative change and an absolute change of \geq 20 points as evaluated by KOS_{Overall} scores. If they did not meet this criterion, subjects needed to improve in at least two out of three of the following:

- Improvements in pain scores by ≥20% and an absolute change of ≥10 percentage points on the KOOS_{Pain} subscale.
- Improvements in functional scores by≥20% and an absolute change of ≥10 percentage points on the KOOS_{ADL} subscale.
- Improvements in the patient's global assessment of their knee function by ≥20% and an absolute change of ≥10 percentage points.

In order to compare baseline measures between the three groups with respect to demographics and self-reported data, one-way analyses of variance (ANOVA) were used, and Tukey's HSD for post hoc comparisons. Repeated measures ANOVAs were used for hip abductor strength, knee ROM, kinematic, kinetic and EMG measures, followed by Tukey's HSD where differences were found. Repeated measures ANOVA was also used for statistical analysis of limb differences and the effect of bracing thereon (within-subjects factors), as well as differences between groups. Pearson's correlation analyses were performed to determine the relationships between hip-abductor strength and peak muscle activation. Alpha was set at 0.05.

4 Results

4.1 OA responders and non-responders vs controls at baseline

4.1.1 Demographics

No differences were found for mean age, height, mass, BMI and physical activity levels between the three groups as shown in Table 1. KL grades of radiographic changes are shown in Table 2 and type of employment according to the NPAQ categories is shown in Table 3.

Table 1. Subject demographics, mean (SD).

	CTRL (n=14)	R (n=8)	NR (n=9)	р
Age (years)	49.8 (7.2)	49.8 (7.6)	51.0 (5.1)	NS
Height (m)	1.83 (0.06)	1.80 (0.07)	1.82 (0.04)	NS
Mass (kg)	91.6 (10.1)	93.7 (10.9)	92.2 (13.5)	NS
BMI (kg/m²)	27.4 (3.2)	28.8 (2.2)	27.8 (3.8)	NS
MVPA (min)	285 (233)	367 (284)	376 (413)	NS
VPA (min)	105 (148)	64 (104)	136 (203)	NS

MVPA =Moderate-to-vigorous intensity physical activity. VPA =Vigorous physical activity. NS = Nonsignificant.

Table 2. Grades of radiographic changes in the medial compartment of the tibiofemoral joint.

	NR		R	
	Involved	Uninvolved	Involved	Uninvolved
KL°1	0	1	0	2
KL°2	3	1	4	0
KL°3	6	0	4	2
Lateral	0	1	0	0
Unilateral involvement		6		4
Bilateral involvement		3		4

KL grade of radiographic changes of the medial compartment of the knee joint

Table 3. NPAQ categories of employment.

Type of work	CTRL	R	NR	Total
0	0	1	1	2
1	7	3	3	13
2	3	2	5	10
3	2	1	0	3
4	2	1	0	3
Total	14	8	9	31

NPAQ type of work categories: 0=No work or school, 1=Mostly sedentary work like office work. 2= Work that requires a lot of walking like teaching. 3= Work that requires a lot of walking and lifting. 4=Heavy manual labour like heavy construction

4.1.2 Knee range of motion and hip abductor strength at baseline

A significant group by leg interaction (p=0.05) was found for passive knee flexion range of motion (ROM) due to interlimb symmetry in CTRLs in contrast to asymmetry in both OA groups (Figure 9). Post hoc tests revealed that the CTRL group had on average 10° greater knee flexion than the Rs (p<0.01) and 5.6°greater knee flexion than the NRs (n.s.). The Rs and NRs had less knee flexion on the involved side than the uninvolved (p<0.01). A significant group by leg interaction was also found for passive knee extension ROM (p<0.01) as seen in Figure 10, with the uninvolved knee of all groups having a similar hyperextension but an extension deficit for involved knee of both R and NR groups (1.0° and 1.4° respectively). No group or interlimb differences were found for strength measures (Figure 11).

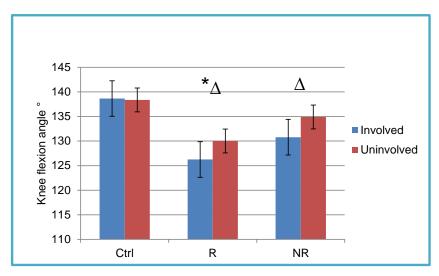


Figure 9. Passive knee flexion range of motion at baseline.

Passive knee flexion angle, mean (SE), goniometric measurement for control (CTRL), responder (R) and non-responder (NR) groups. * = Different from CTRL group; p< 0.01. Δ = Interlimb difference; p<0.01.

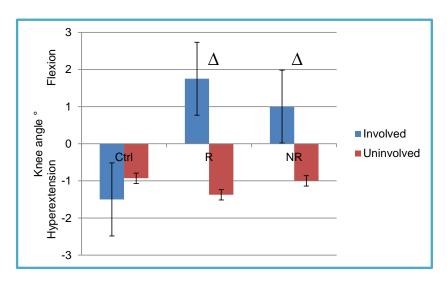


Figure 10. Passive knee extension range of motion at baseline.

Passive knee extension angle, goniometric measurement, mean (SE) for control (CTRL), responder (R) and non-responder (NR) groups. Δ = interlimb difference; (p<0.01).

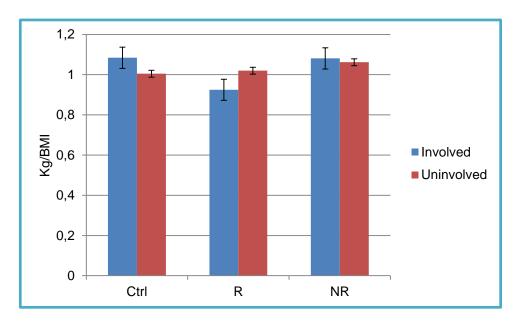


Figure 11. Hip abductor muscle strength at baseline.

Mean (SE) hip abductor muscle strength normalized to body mass index (kg/BMI), for control (CTRL), responder (R) and non-responder (NR) groups. No group or interlimb differences were found.

4.1.3 Self-report measures at baseline

4.1.3.1 KOOS

The CTRL group had higher scores than NR and R groups (Table 4) on all KOOS subscales at baseline (p<0.001) and Rs scored lower on average than NRs on KOOS_{pain}, (p<0.001), KOOS_{symptoms} (p<0.05) and KOOS_{ADL} (p<0.001) subscales.

Table 4. KOOS scores of Control, responder and non-responder groups at baseline, mean (SD).

	CTRL (n=14)	R (n=8)	NR (n=9)	р
KOOS _{Pain}	98.9 (2.2)	52.3 (13.1)*	74.6 (11.8)*†	<0.001
KOOS _{Symptoms}	95.3 (6.2)	60.6 (16.3)*	75.1 (12.2)*‡	<0.001
KOOS _{ADL}	99.4 (1.1)	60.3 (17.1)*	82.0 (17.1)*†	<0.001
KOOS _{SR}	98.9 (2.1)	22.5 (13.3)*	39.4 (25.9)*	<0.001
KOOS _{QOL}	96.9 (6.3)	36.1 (9.9)*	40.3 (20.9)*	<0.001

CTRL= Control group. R= Responders. NR= Non-responders * = different from Ctrl (p<0.001) † =different from R (p<0.001) ‡ =different from R (p<0.05)

4.1.3.2 KOS-ADLS

CTRL group participants had higher scores than Rs and NRs of the OA group (p<0.001) on all KOS-ADLS subscales at baseline (Table 5) and Rs had lower scores than NRs on KOS_{Function} (p<0.001), KOS_{Overall} (p<0.001) and Global score (p<0.05).

Table 5. KOS-ADLS scores of Non-responders, Responders and Control groups at baseline, mean (SD).

	CTRL (n=14)	R (n=8)	NR (n=8)	р
KOS _{Symptoms}	99.3 (1.4)	59.8 (22.3)*	75.3 (20)**	<0.001
KOS _{Function}	98 (2.8)	51.3 (12.9)*	70.6 (12.9)*†	<0.001
KOS _{Overall}	98.6 (2.2)	54.8 (15.4)*	72.6(15.4)*†	<0.001
Global	98.8 (2.7)	52.9 (24.3)*	74.4 (17.2)**‡	<0.001

CTRL= Control group. R= Responders. NR= Non-responders *= different from Ctrl (p<0.001), *= different from Ctrl (p<0.005), †= different from R (p<0.001), ‡= different from R (p<0.05)

4.1.4 Kinematics at baseline

4.1.4.1 Frontal plane trunk lean

During stance phase the CTRL group made an earlier transition from leaning the trunk towards the stance limb back towards the contralateral limb (Figure 12) than the Rs (p<0.05) and the NRs (p<0.05). A main effect of group was found for frontal plane trunk lean at IC (p=0.015) but no interlimb differences or interaction (Figure 13). Post hoc tests revealed that the CTRL group had greater trunk lean towards the stance limb at IC than both the Rs (P=0.03) and the NRs (p=0.05) but no difference was found between the Rs and NRs of the OA group. No difference was found between groups for maximum frontal plane trunk lean towards stance limb and no interlimb differences were found (Figure 14). Trunk lean excursion in the frontal plane differed between the CTRL group and the Rs (p=0.034) but no interlimb differences were found (Figure 15).

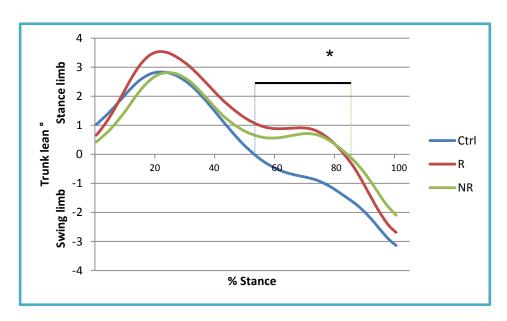


Figure 12. Group mean curves for frontal plane trunk lean at baseline.

Group mean curves for frontal plane trunk lean across the stance phase of gait of involved limb for control (CTRL), responder (R) and non-responder (NR) groups. Stance phase time normalized to 100%. Rs and NRs switch from trunk lean towards stance limb to trunk lean towards swing limb significantly later than CTRLs. * = Significantly different from CTRLs; p< 0.05.

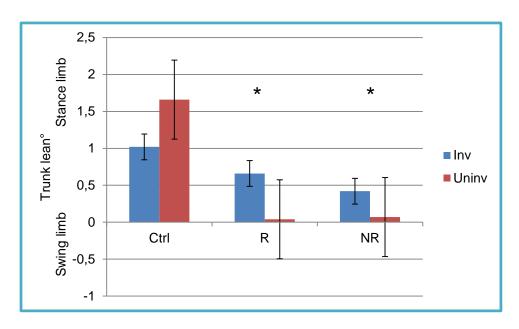


Figure 13. Frontal plane trunk lean towards stance limb at IC (baseline).

Mean (SE) of frontal plane trunk lean (°) towards stance limb at initial contact for involved (Inv) and uninvolved (Uninv) sides of control (CTRL), responder (R) and non-responder (NR) groups * = Significantly different from CTRL group; p= 0.015.

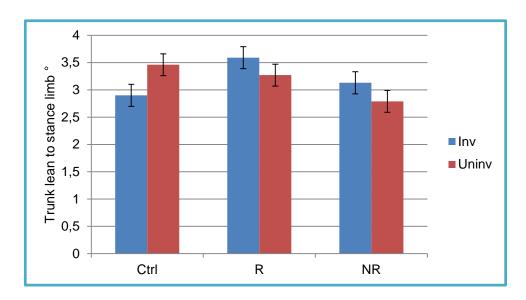


Figure 14. Maximum frontal plane trunk lean towards stance limb (baseline).

Mean (SE) for involved (Inv) and uninvolved (Uninv) sides of control (CTRL), responder (R) and non-responder (NR) groups.

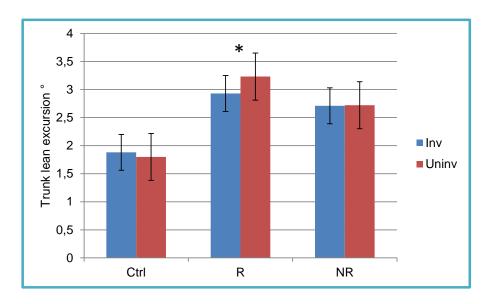


Figure 15. Frontal plane trunk lean excursion at baseline.

Mean (SE) of frontal plane trunk lean excursion (°) for involved (Inv) and uninvolved (Uninv) sides of control (CTRL), responder (R) and non-responder (NR) groups. * = Significantly different from CTRLs; p< 0.05.

4.1.4.2 Frontal plane hip joint kinematics

No statistically significant group or interlimb differences were found for hip joint adduction angle at initial contact or maximum hip adduction angle during weight acceptance. Group mean curves across the stance phase of gait are shown in Figure 16 and Figure 17. A non-significant trend (p=0.07) for a group by leg interaction was seen at IC as Rs and NRs abducted the hip of the involved side at IC while the uninvolved hip of Rs and NRs and both hips of the CTRL group were slightly adducted (Figure 18). No intergroup or interlimb differences were found for hip joint excursion during WA as demonstrated in Figure 19.

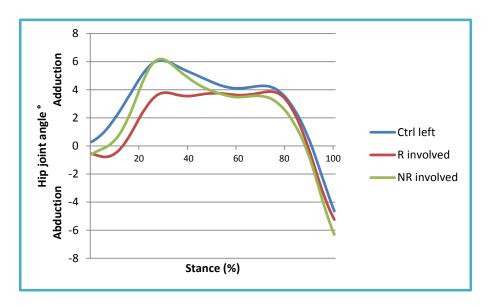


Figure 16. Frontal plane hip joint angles of involved limb.

Group mean curves across the stance phase of gait for frontal plane hip joint angles of involved limb.

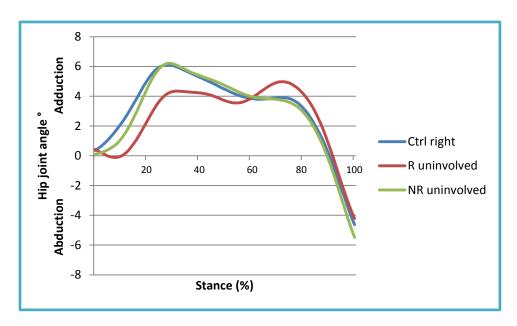


Figure 17. Frontal plane hip joint angles of uninvolved limb.

Group mean curves across the stance phase of gait for frontal plane hip joint angles of uninvolved limb.

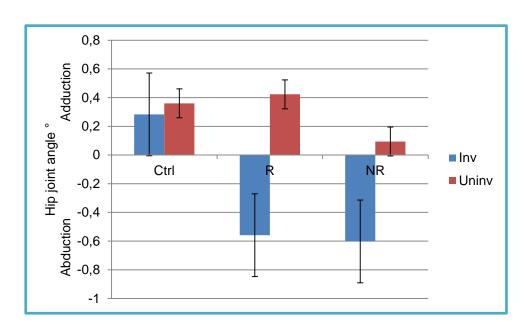


Figure 18. Hip joint adduction angle at initial contact.

Mean (SE) hip joint adduction angle of involved (Inv) and uninvolved (Uninv) side at initial contact (IC). A non-significant group by leg interaction is seen, responders (R) and non-responders (NR) abduct the hip of the involved side at IC while the hip of the uninvolved side of Rs and NRs and both sides of CTRLs are adducted.

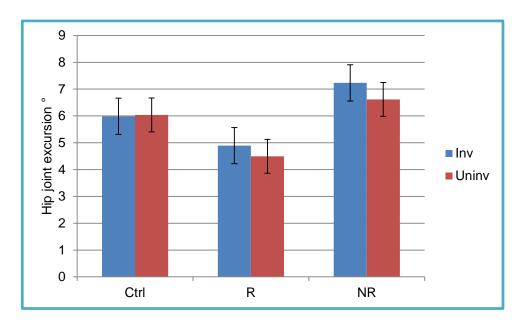


Figure 19. Mean frontal plane excursion of hip joint during weight acceptance.

Mean (SE) frontal plane excursion of hip joint from IC to maximum adduction during weight acceptance (first 50% of stance phase).

4.1.5 Kinetics at baseline

When examining hip joint frontal plane kinetics, no group or interlimb differences were found for PHAM1 or PHAM2 as shown in Figure 20 and Figure 21.

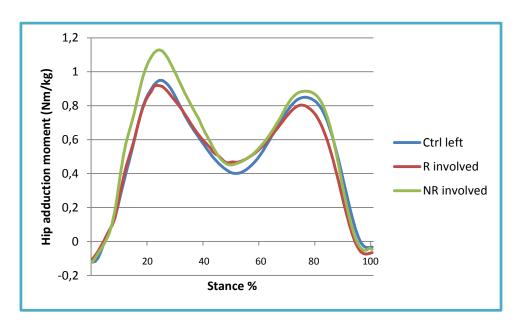


Figure 20. Group mean curves of hip adduction moment, involved side at baseline.

Group mean curves of hip adduction moment across the stance phase of the involved limb for control (CTRL), responder (R) and non-responder (NR) groups. Positive values reflect adduction moment.

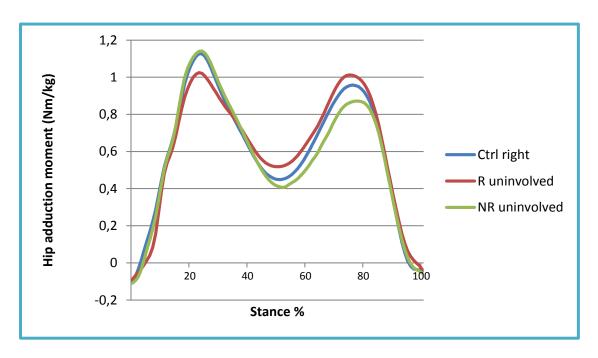


Figure 21. Group mean curves of hip adduction moment, uninvolved side at baseline.

Group mean curves of hip adduction moment across the stance phase of the uninvolved limb for control (CTRL), responder (R) and non-responder (NR) groups. Positive values reflect adduction moment.

4.1.6 Electromyography

No significant group or interlimb differences were found for mean values of the peak EMG signal from Gmed (Figure 22) although R and NR groups tended to have a greater signal amplitude from the involved compared to uninvolved side Gmed. For TFL (Figure 23), the Rs showed significantly greater activation than the CTRLs (p<0.001) and the NRs (p<0.001). There was a non-significant trend for greater activation of involved side TFL (p=0.091 compared to uninvolved side). CTRLs and Rs showed a strong positive correlation for abductor muscle strength bilaterally (r = 0.787; p=0.001 for CTRLs and r = 0.754; p=0.031 for R) reflecting symmetry in hip abductor strength that was not found in the NRs.

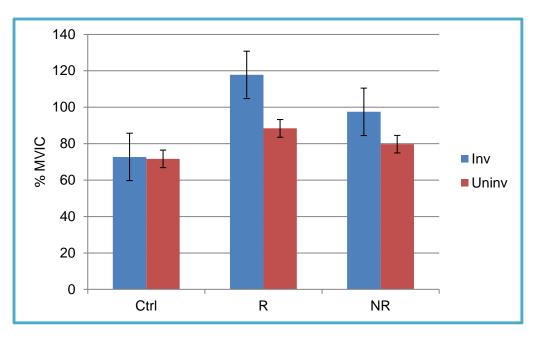


Figure 22. Mean amplitude of standardized RMS of gluteus medius.

Mean (SE) amplitude of standardized RMS of Gmed of involved (Inv) and uninvolved (Uninv) sides of control (CTRL), responder (R) and non-responder (NR) groups.

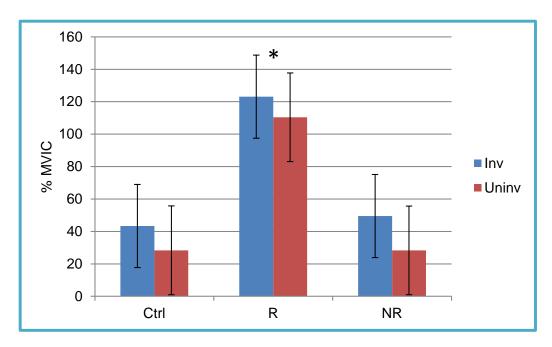


Figure 23. Mean amplitude of standardized RMS of tensor fasciae latae.

Mean (SE) amplitude of standardized RMS of TFL of involved (Inv) and uninvolved (Uninv) sides of control (CTRL), responder (R) and non-responder (NR) groups. * = Different from CTRL and NR groups; p< 0.001.

4.2 Bracing effects on responders vs non-responders

4.2.1 Self-report measures and demographics

Measured strength of hip abductor muscles increased slightly overall during the study period, increasing from 1.02 Nm/kg to 1.15 Nm/kg which was bordering on being a significant increase (CI of difference -0.001 to 0.250; p=0.051). No changes were found for passive knee flexion or extension ROM over the treatment period. An overall 151min increase in MVPA for both Rs and NRs was statistically non-significant (p=0.252).

4.2.1.1 KOOS

An overall improvement on all subscales of KOOS was seen over time (p<0.05). Due to the groups' stratification process an expected significant group*time interaction was seen as Rs improved significantly more than NRs over time on all subscales of KOOS except the KOOS_{QOL} (Table 6).

Table 6. Absolute change on KOOS subscales over time, mean (SD).

	R (n=8)	NR (n=9)	p =
KOOS _{Pain}	19.9 (9.7)	-0.3 (7.5)	0.000
KOOS _{Symptoms}	16.1 (14.1)	0.3 (11.1)	0.021
KOOS _{ADL}	18.9 (11.7)	0.7 (8.3)	0.002
KOOS _{SR}	33.1 (8.8)	13.3 (10.3)	0.001
KOOS _{QOL}	8 (17)	9.0 (10.0)	0.883

Mean (SD) absolute change on KOOS subscales for responders (R) and nonresponders (NR) over the 4 week study period.

4.2.1.2 KOS-ADLS

No change was seen in $KOS_{Symptoms}$ subscale over time but a significant interaction of time*group was found as the Rs improved markedly on $KOS_{Function}$ (p<0.05), $KOS_{Overall}$ (p<0.05) and Global scores (p<0.01) while the NRs did not (Table 7).

Table 7. Absolute change on KOS-ADLS subscales over time, mean (SD).

	R (n=8)	NR (n=8)	P =
KOS _{Symptoms}	14.3 (24.2)	0.0 (15.6)	0.183
KOS _{Function}	17.5 (16.2)	2.5 (5.4)	0.026
KOS _{Overall}	15.9 (17.8)	1.6 (9.2)	0.064
KOS _{Global}	27.4 (20.7)	-2.5 (7.6)	0.002

Mean (SD) absolute change on KOS-ADLS subscales for responders (R) and nonresponders (NR) over the 4 week study period.

4.2.2 Kinematics – pre-to-post bracing

4.2.2.1 Frontal plane trunk lean

A trend (p=0.054) was found for the OA groups' timing of transition (trunk lean from toward the stance back towards the contralateral limb), as this occurred slightly earlier during stance after 4 weeks of brace use (Figure 24). No main effect of group or bracing or any interaction was found for trunk lean

angle at IC but a significant main effect of time was found (p=0.021) where both Rs and NRs increased their trunk lean at IC after 4 weeks (Figure 25). No differences were found for maximum trunk lean angle over time and bracing had no effect thereon either. Trunk excursion from IC to maximum trunk lean decreased over time (p<0.01) but no group difference due to bracing or any interaction was found (Figure 26).

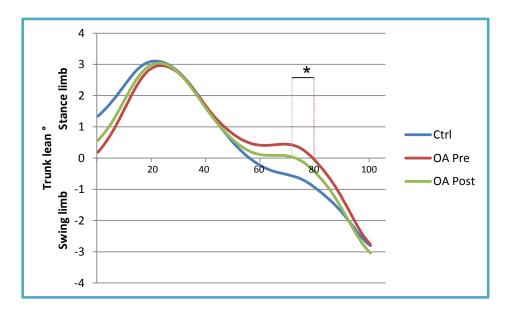


Figure 24. Mean curves for frontal plane trunk lean before and after treatment.

Curves are shown for all OA participants before (OA Pre) and after (OA Post) brace treatment and control (CTRL) subjects for comparison. Stance phase time normalized to 100%. * = Approaching significant difference from OA Pre; p= 0.054.

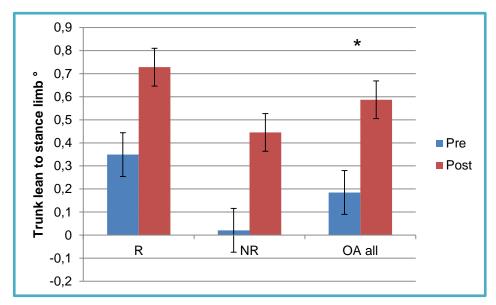


Figure 25. Frontal plane trunk lean towards stance limb at IC.

Mean (SE) frontal plane trunk lean towards stance limb at IC, showing values for responders (R), non-responders (NR) and all osteoarthritic participants (OA all) before and after 4 week bracing treatment. *= significant difference from pre values (p<0.05).

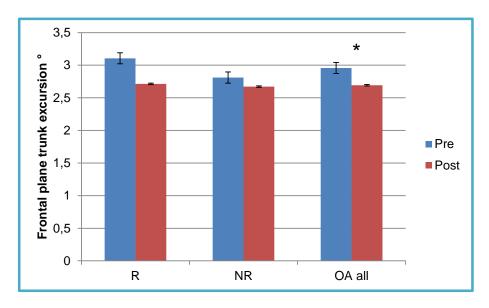


Figure 26. Frontal plane trunk excursion.

Mean (SE) frontal plane trunk excursion for responders (R), Non-responders (NR) and all OA participants before (Pre) and after (Post) 4 weeks use of brace. * = significant difference between time points; p<0.01.

4.2.2.2 Frontal plane hip joint kinematics

No changes were found for hip adduction angle at IC or frontal plane hip joint excursion during weight acceptance over time and no immediate effects of bracing thereon. A trend for a leg*time interaction was seen for maximum hip adduction during WA (Figure 27) as hip adduction of the involved side decreased over time but increased on the uninvolved side (p=0.057).

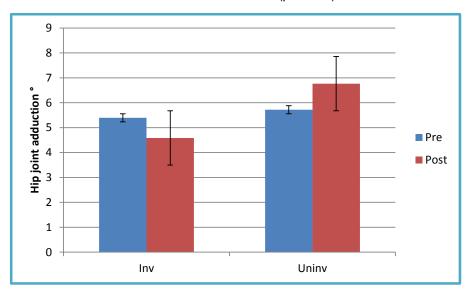


Figure 27. Maximum hip joint adduction angle during weight acceptance of stance, mean (SE).

Inv = Involved side; Uninv = Uninvolved side; Pre = Baseline; Post = after 4 week brace treatment. Mean (SE) of all OA subjects before (Pre) and after (Post) 4 week brace treatment. Leg*time interaction is non-significant, p= 0.057.

4.2.3 Kinetics – pre-to-post bracing

No changes were seen on PHAM1 or PHAM2 over time and no bracing effects on those parameters.

4.2.4 Electromyography

A significant interaction of bracing condition and response group was found across both limbs and time-points for Gmed peak activity during stance (Figure 28). Participants identified as Rs generally had higher normalized peaks during stance than NRs, but wearing the brace led to even greater mean peak EMG activity of Rs Gmed while no change was seen for the NRs. A further interaction of Leg * Time * Condition * RESPONSEgroup for Gmed activity was found. Increased activation with bracing was further enhanced in the uninvolved limb of Rs at re-evaluation, while NRs showed greater or less activation levels with bracing between limbs over time (p<0.01) (Figure 29).

A main effect of response group was seen for TFL peak activity at baseline (Figure 23) but no changes were found for TFL peak activity over time and bracing had no effect either (Figure 30). Baseline and follow-up correlations of muscle activation levels, as shown in Table 8, demonstrate symmetry in muscle strength and activation for CTRLs and asymmetry for Rs and NRs at baseline and a more symmetrical function at follow up.

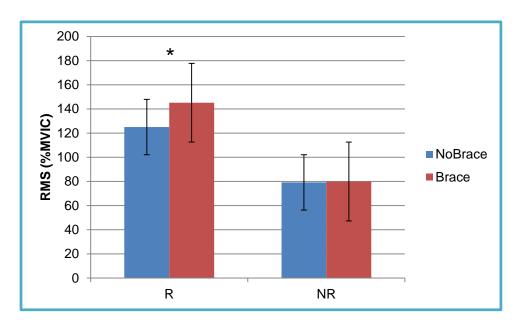


Figure 28. Effect of UnloaderOne knee brace on EMG activity of gluteus medius.

Responders (R) showed a greater mean (SE) EMG activity of Gmed while wearing the brace but no change was seen for the non-responders. * = statistically significant difference between bracing conditions (p<0.01).

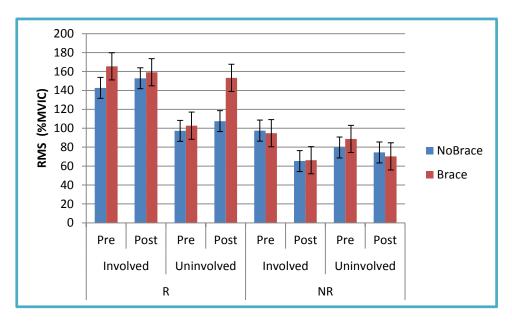


Figure 29. EMG activity of gluteus medius before and after brace treatment.

Comparison of mean (SE) EMG activity of gluteus medius (Gmed) between groups, sides, before and after treatment and with or without brace. A significant interaction was found with increased activity of uninvolved side Gmed during bracing condition after a 4 week treatment with an unloader brace (p<0.01).

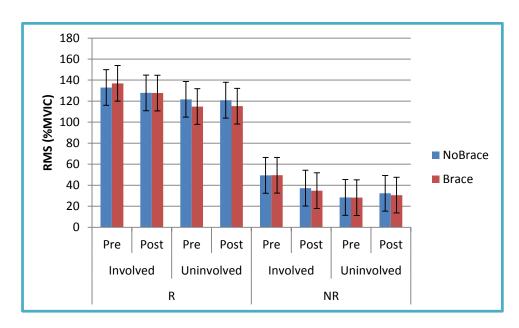


Figure 30. EMG activity of tensor fasciae latae.

Comparison of mean (SE) EMG activity of TFL between groups, sides, before and after treatment and with or without brace.

Table 8. Baseline and follow up correlations of EMG values and strength measures.

		Baselin	Baseline (r)			Follow up (r)		
		CTRL	OA _{AII}	R	NR	OA _{AII}	R	NR
EMG _{Gmed} Inv	EMG _{Gmed} Uninv	0.724*	NS	NS	NS	0.879**	0.934**	NS
EMG _{TFL} Inv	EMG _{TFL} Uninv	0.849**	0.591*	NS	NS	0.794**	NS	NS
Strength _{Hip} Inv	Strength _{Hip} Uninv	0.787**	NS	0.754*	NS	0.918**	0.829*	0.946**
EMG _{Gmed} Inv	EMG _{TFL} Inv	0.698*	0.60*	0.706 ^T	NS	0.799**	NS	NS
EMG _{Gmed} Uninv	EMG _{TFL} Uninv	0.661*	NS	NS	NS	NS	NS	NS
Strength _{Hip} Inv	EMG _{Gmed} Inv	-0.717*	NS	NS	NS	-0.529*	NS	-0.663 ^T
Strength _{Hip} Uninv	EMG _{Gmed} Uninv	NS	NS	NS	NS	NS	NS	-0.699*

EMG_{Gmed} Inv = Activation level of involved side gluteus medius; EMG_{Gmed} Uninv = Activation level of uninvolved side gluteus medius; EMG_{TFL} Inv = Activation level of involved side tensor fascia lata; EMG_{TFL} Uninv = Activation level of uninvolved side tensor fascia lata; Strength_{HipAbd} Inv = Strength of hip abductors of involved side; Strength_{HipAbd} Uninv = Strength of hip abductors of uninvolved side; $r = Pearson \ s \ r; \ s = p < 0.05; \ s = p < 0.01; \ s = p < 0.05$

4.2.5 Brace use

Thirteen participants had iButton thermocrons embedded in the lining of the brace during the 4 week study period. Rs wore the brace for 6.8 hrs./day on average (CI for mean 3.1 - 10.4) and NRs wore it for 3.5 hrs./day (CI for mean 0.5 - 6.5), but the difference did not reach significance (p=0.164) (Figure 31). Brace use varied from 0.5 hrs./day to 13.4 hrs./day, samples of high wear and low wear are shown in Figure 32 and Figure 33 respectively.

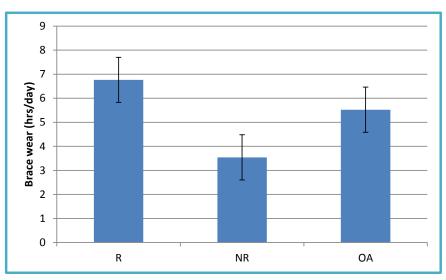


Figure 31. Mean brace use time.

Mean (SE) daily brace use measured with iButton thermocrons over the 4 week study period. Responders (R), non-responders (NR) and OA_{average}. No significant difference was found between R and NR groups for brace use time (p=0.164).

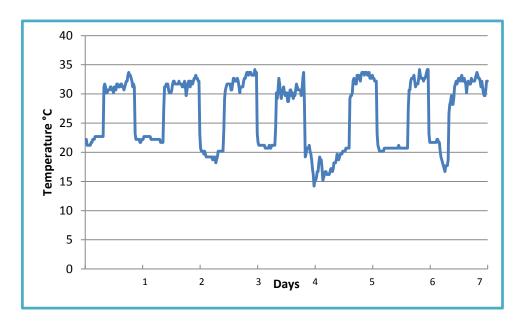


Figure 32. iButton temperature chart for regular brace use.

A sample of iButton temperature readings over one week for an individual with average daily wear time of 13.4 hrs./day.

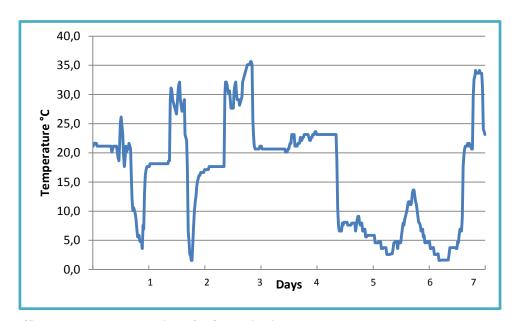


Figure 33. iButton temperature chart for irregular brace use.

A sample of iButton temperature readings over one week for an individual with average daily wear time of 2 hrs./day.

5 Discussion

The main purpose of this study was to investigate the effects of an unloading brace treatment on frontal plane hip joint moments and excursions and frontal plane trunk lean in a relatively young and active male OA sample. The study also attempted to shed a light on the biomechanical relationship of frontal plane trunk and hip movements and EMG activity of hip abductor muscles and how these factors relate to self-reported knee outcomes.

Although an overall improvement was detected on all KOOS subscale scores over time there was great variability in the response to the brace over the 4 week period, as measured by the self-reported knee outcome questionnaires. The OA group was thus stratified into responders and non-responders according to OARSI criteria for clinically significant changes.

The main findings with respect to frontal plane trunk lean at baseline showed differences between the CTRLs and the OA patients (regardless of treatment response). Those in the OA group had less of a trunk lean towards the stance side at IC, resulting in greater total excursion of trunk motion towards the ipsilateral side during stance. This was the case for both the involved and uninvolved side during the stance phase of gait. The timing of the transition as the trunk moved from leaning towards the stance limb over to the contralateral side also happened later in the stance phase for OA participants than for the CTRLs. With respect to the OA group and their response to a 4 week period of brace treatment, an overall greater trunk lean position towards the stance limb was seen at IC resulting in a smaller excursion of trunk motion during stance. Moreover, a trend (p=0.054) for an earlier transition of trunk motion from the stance over to the contralateral side was seen. These changes would seem to reflect a more normal trunk movement pattern, approximating that demonstrated by the CTRL group. Concurrent changes in HAM were not found but this could theoretically have an effect on KAM.

Differences were also found in hip muscle activation levels at baseline, with Rs showing higher activation levels of TFL than both CTRLs and NRs. On the other hand there were no baseline differences to be found in Gmed activation levels. Across both measurements, the R group showed a general increase in bilateral gluteal peak activation when wearing the brace, while the NR group demonstrated subtle changes that were dissimilar between limbs and time points.

Frontal plane hip joint kinematics and kinetics did not differ significantly between groups at baseline although there was a non-significant trend for OA participants to have a less adducted hip joint on the involved side at IC compared to the CTRL group.

5.1 Trunk movements

The results show that male patients with moderate medial compartment knee OA demonstrated different frontal plane trunk movements compared to asymptomatic subjects. The OA group swayed the trunk less towards the stance side at IC and this was further reflected in greater excursion in Rs compared to CTRLs, with no difference in maximum trunk lean. There was a significant delay in transition of trunk motion from the stance to the contralateral side lean for both OA groups compared to CTRLs. This could reflect a strategy to avoid pain by trying to shorten the period of time in single stance during which the GRF vector passes more medially to the medial compartment of the TF joint.

After a 4 week off-loading treatment period they showed an increase in trunk lean to stance limb at IC and lower total excursion of trunk but no changes in maximal lean. There was a trend for all OA participants to make an earlier transition from leaning towards the stance limb and over to the contralateral side, so short term effects of unloading bracing appear to help to normalize trunk lean. The change in trunk lean at IC was statistically significant but very small (0.4°). Nevertheless this could have an impact on loading of joints lower in the kinematic chain for some participants through the large lever arm of the trunk and could thus possibly counteract any changes on lower joint moments due to the brace. Mündermann et al. demonstrated a 65% and 57% lower knee and hip moments (respectively) by having the subjects walk with an increase (10±5°) in frontal plane trunk lean(17). Part of the reason previous studies using gait analysis have shown such contradicting results regarding the effect various interventions have on the KAM and HAM in knee OA is that trunk motion is rarely accounted for, despite its apparent importance.

5.2 EMG

There is limited work in the literature on neuromuscular adaptations in the early stages of medial compartment OA. Duffell et al. found increased Gmed activity during quiet standing and one-leg standing on both involved and uninvolved sides in an early OA cohort compared to controls (30).

In the present study, baseline data showed no significant interlimb or intergroup differences in peak Gmed activity levels during stance, although Rs and NRs tended to show a higher activation of the involved side Gmed compared to CTRLs. The Gmed signal magnitude of the CTRLs (72.2±10.0 %MVIC) is similar to what Rutherford and Hubley-Kozey found in their study of Gmed activity during walking in 22 healthy individuals (52). A consistent bracing effect was seen on Gmed activity for Rs but not NRs, where peak activity was altered in different ways across limbs over time.

There appear to be differences in the magnitude of peak muscle activation between those who respond to unloader bracing treatment after 4 week treatment and those who do not. Responders had a greater activation of TFL at baseline compared to the CTRLs and at both evaluations compared to the NRs. No effect of time or bracing was seen on TFL activity. A search of the literature revealed no previous work on TFL muscle activity during gait in medial knee OA. The TFL muscle functions as a hip flexor as well as hip abductor in synergy with Gmed and so it would act to stabilize the pelvis in the frontal plane (53). During stance it tautens the iliotibial band which inserts on the lateral condyle of the tibia and in a way, braces the knee while the knee is extended but may also impart rotatory forces at the hip and knee. The higher neuromuscular activation of the TFL in the R group could reflect a stabilizing strategy. Former work on neuromuscular activity around the knee in patients with medial compartment knee OA has revealed prolonged activation (54) and increased co-contraction of antagonistic muscle pairs (vastus lateralis-hamstrings and tibialis anterior-gastrocnemius) in the lower extremity (54). Bracing has been shown to decrease the level of lateral co-contraction, possibly due to greater joint stability (36). In addition to generally high activation levels of TFL, the Rs further demonstrated greater Gmed activity across both time-points when wearing the brace. The significance of this is uncertain but it may suggest there were some differences in motor control or neuromuscular strategies adopted by Rs compared to NRs. How this all fits together needs further clarification, but neuromuscular activity of hip abductors potentially has an effect at the knee (via the iliotibial band) and warrants further exploration in the same context as that of the agonist and antagonist muscle pairs that cross the knee joint.

Correlations for hip abductor strength and activation levels of Gmed and TFL demonstrated a more symmetrical function of the CTRLs than the Rs and NRs as well as a more symmetric function of both Rs and NRs after a 4 week bracing treatment.

There were no interlimb or group differences in measured abductor strength. A strong negative correlation was found between strength and normalized peak activity of Gmed during gait in CTRLs, indicating that stronger CTRL participants tended to have lower activation of Gmed during gait and vice versa. This relationship was not found for the OA participants, perhaps reflecting different movement strategies. Similarly, symmetry in inter- and intra-limb patterns of muscle activation of the TFL and Gmed were found in CTRL participants demonstrated in the strong associations found. Again, weaker or no associations were found in the OA group, indicating that their strategies during gait vary, in particular within the NR group. Early neuromuscular adaptations need to be given more attention as they can be targeted by exercise. Therapeutic intervention to delay OA progression warrants further exploration.

5.3 Hip joint kinetics and kinematics

Previous studies have demonstrated that during gait, persons with medial knee OA generally maintain their hip joint more abducted on the involved side at IC compared to the contralateral hip (22) and to an asymptomatic control group (23). Although possible strategies involving the trunk were discussed, the degree to which the abducted hip reflected trunk position in those studies was not clear. Significant interlimb or intergroup differences regarding hip joint adduction angle at IC were not found in this study, but a trend for a more abducted hip on the OA side at IC was seen, accompanied by less frontal plane excursion. The KL grade stated in Briem and Snyder-Mackler's report (22) was the same as in our study (KL 2 and 3) but the sample size was larger (n=32), which gave them greater statistical power to detect differences. Hunt et al. (23) compared groups with different grades of medial compartment OA to a control group and found a smaller hip adduction angle at IC in those with a more severe OA when compared to the control group, as well as a lower peak hip adduction angle during stance (23). Those with more severe OA had a more varus aligned knee which might functionally result in a more abducted hip joint during stance and, in part, explain some of the differences seen. Duffell et al. (30), on the other hand found no differences in hip adduction angle at IC between their study group of persons with early stage medial knee OA and a control group, thus indicating that changes in hip adduction angle at IC are not detectable for the early stages of OA. It has to be noted though, that their sample size was, as ours, quite small (n=18). When examining the group mean curves of frontal plane hip joint angles (Figure 16 and Figure 17) in our study it would appear that Rs tended to use less hip adduction on both sides during the first 50% of stance, but no statistically significant differences were found, perhaps due to the small sample size.

No significant interlimb or intergroup differences were found for PHAM1 or PHAM2 in our study. This appears to contrast with Briem and Snyder-Mackler's study where a lower hip adduction moment

of the involved side hip was demonstrated at PKAM1. It has to be noted though that they measured HAM at PKAM1 while we calculated PHAM1, so the data might not be obtained at the exact same point in time. On the other hand, Hunt et al. (23), found no significant differences in PHAM1 or PHAM2 between controls and OA samples of differing OA grades, which is in accordance with the results of the present study.

For OA participants, no significant changes were seen in hip joint angles or moments, neither as an immediate effect of bracing nor over time. However, a trend was noted for an interaction of leg*time as the hip of the involved side became less adducted and the uninvolved side more adducted at maximum hip adduction (Figure 27). This differs from the results of Toriyama et al. where an increase in hip adduction angle of the involved side when wearing the brace was demonstrated, as well as a lower PHAM2 on the involved side and a lower PHAM1 on the uninvolved side. The demographics of their study sample, however, were quite different from those of the present study, as on average their patients were older, with a lower BMI, and mainly female (17 vs 2 males).

5.4 Function, pain, brace use

Despite an overall improvement on all KOOS mean subscale scores over time there was great variability in the response to the brace over the 4 week period, as assessed by the questionnaires. Variability in treatment response, despite significant mean improvement, is a reality that is clinically important to acknowledge and the OA group was thus divided into responders and non-responders according to OARSI criteria for clinical significant changes. An attempt was then made to identify any baseline parameters predicting response, or differences in other variables over time between those who did and didn't respond favorably to the brace. The results indicated that the R group participants had lower self-report scores at baseline. This also meant that NRs had less room for improvement to begin with, which may have introduced a ceiling effect for at least one of the NR subjects. At the 4 week follow up the R group had improved significantly and, on average, scored on par with the NRs at that point. This variability in response to treatment serves as a reminder that in the clinical environment as in research, treatment approaches may need to be considered on a patient to patient basis. It also reflects a recognized limitation in clinical research as a treatment effect that is only represented as the study group's mean can be diluted due to variability of baseline data and treatment response.

With respect to brace studies, brace use time prescription is not well understood and long term compliance tends to be low. A recent study showed that two years after brace prescription only 25% were still using it on a regular basis (twice per week, an hour at a time or more) (32). The results of the present study showed no significant difference in average daily brace use between Rs (6.8hrs) and NRs (3.5hrs), but the Cl's were quite large due to the variability of the data. All participants but one in our study chose to continue brace treatment at the end of the study period, even though only half of them experienced what is considered a clinically significant improvement over the period according to OARSI criteria. Given that the users had to pay a fee if they chose to purchase the brace, one might surmise that these users found the brace useful. No significant difference was found in average daily

brace use between Rs and NRs (3.5hrs). Again, although the difference in the average use was large, the Cl's were quite large due to the variability of the data.

In a recent study, Skou et al. (55) demonstrated that lower knee confidence (as measured by a self-report questionnaire) was associated with worse self-reported knee instability, greater varus-valgus knee joint movement during gait, higher pain intensity and lower quadriceps strength. Lower knee confidence has also been shown to be a potential predictor of functional decline in knee OA (56) and therefore it appears that tackling these symptoms could be of great importance. Bracing and neuromuscular training would appear to be a sensible starting point for research on that matter.

Different lifestyles and jobs have different physical demands, likely impacting the individual's need for unloading a weight-bearing joint such as the knee. Of this study's relatively young and active patient population, 9 out of 17 claimed that their job demands required them to stand a lot. Unloading the medial compartment might be of greater importance for them, as opposed to those whose jobs are of a more sedentary nature.

OA treatments commonly target pain relief and seek to improve function that way. Hurwitz et al. (57) studied the effect of pain relief on knee joint loads during walking in patients suffering from painful knee joint OA and found that decreased pain was related to increased joint loading of the osteoarthritic part of the joint. Pain relief alone could prove detrimental for those who have to place high loads on the knee joint daily such as half of the patient sample of this study has to do, and biomechanical interventions to mediate joint loading may be of particular importance in these cases. An overall (but non-significant) 151min increase in self-reported MVPA at the end of the study for both Rs and NRs might imply that they find physical activity easier than before which is also reflected in improved KOOS_{SR} scores. It has been demonstrated that vigorous, not moderate physical activity is associated with a greater risk of progression on cartilage lesions (58), so bracing may be an important option for those who either choose to participate in vigorous activity, or need to do so because of their job demands. Whether this patient group reaps any benefits from unloader bracing beyond that demonstrated for the general population has yet to be researched (59) but Brouwer et al. reported a better treatment response in patients younger than 60 years (32).

There is a certain treatment gap for those under 60 years old for which arthroplastic surgery is not yet indicated because of higher risk of revision surgery. Non-surgical load-modifying interventions are an appealing solution for this patient subgroup because there are fewer inherent risks and lower costs than in surgical interventions. Because OA is progressive in nature younger patients in the moderate stage are likely have the greatest potential to benefit from bracing or other conservative treatment options that aim to slow down progression via biomechanical solutions. Clinically, it has been noted that unloader braces only help some patients, they can make a great deal of difference or have no effect. Better understanding of baseline factors which may influence whether patients are probable candidates for successful brace treatment is needed. In this study it was evident that the Rs had a different neuromuscular reaction to the brace, showing an immediate increase in Gmed activity when using the brace. This needs further exploration. Bracing is a somewhat costly treatment and therefore identifying those who are likely to adhere and respond to bracing treatment, considering age, motivation and activity levels, could prove valuable.

Increased joint loads in the contralateral knee and hip in persons with medial compartment OA are thought to be a compensation to avoid painful movements. These changes seem to become deeply grooved into the motor program and do not seem to normalize even 12 months after successful knee arthroplasty (8). Most studies to date have focused on people with advanced knee OA so there is less information at hand on gait characteristics in the earlier stages of the disease. Parameters related to motor control in the early stages are relatively unknown, but it has been indicated that early cartilage defects can be partially reversible in a younger population (60). An earlier intervention with neuromuscular training and biomechanical solutions are treatment areas which should be explored in the future.

5.5 Study limitations

The main study limitation is the small sample size, resulting in a low statistical power for detecting interlimb and intergroup differences at baseline as well as possible effects of the brace treatment.

The study period was only 4 weeks, and so the results cannot be extrapolated for long term effects, so further research is needed on that matter.

Strength measurement was done during a single MVIC for both Gmed and TFL with the participants in a supine position. It may be argued that a dynamic measure may be considered more appropriate for EMG during gait analysis. But this was a standardized measurement and can easily be replicated.

Control group was not radiologically screened for OA but they were screened clinically for signs and symptoms of knee OA.

Gait speed was not accounted for.

The iButton thermocrons have not been validated for measuring knee brace use time but a high degree of accuracy was found for monitoring thoracolumbosacral orthosis wear time (47).

5.6 Study strengths

Attempt to decrease heterogeneity of study group by limiting participation to 40-60 year old males with moderate (KL grades 2-3) medial compartment.

A control group of age, height and weight matched subjects was recruited and there was a 100% compliance of study group to finish both study sessions.

Combining biomechanic, EMG and strength measures into one study.

5.7 Future directions

A further analysis of hip and trunk kinetics and kinematics of OA patients, with a larger study sample, would be a logical step towards greater understanding of gait biomechanics in OA. For hip joint kinematics and kinetics the effect sizes are quite small so a larger group might show statistical difference since the small group in the current study was bordering on significance for several factors.

Validating the iButtons for measuring knee brace use, as has been done previously for thoracolumbar orthosis. This would appear to be a useful solution for objectively measuring brace use in studies as it has been shown to be no less reliable than a diary for monitoring lumbar orthosis wear time.

6 Conclusion

This study investigated hip abductor muscle activity and frontal plane kinematic and kinetic variables at the hip and trunk during gait in patients with medial compartment OA with the intent to i)compare outcomes to a symptomless control group and ii) assess immediate and short term (4 weeks) effects of an unloader brace on those parameters.

Participants with medial compartment OA displayed less trunk lean at IC and greater frontal plane trunk excursion as well as a delay in the transition of trunk lean from stance side to the contralateral side when compared to CTRLs. After 4 weeks of unloader bracing treatment, however, there was a shift of those measured parameters towards measures found in the CTRL group. Frontal plane hip joint kinematics and kinetics of OA participants did not differ significantly from CTRLs at baseline and unloader bracing had no significant effect on those measures. The differences involving the trunk involved both excursion and timing of its lateral shift and, although small, seem to represent a compensatory mechanism which the brace appeared to affect over time. The significance of this, with respect to knee joint loading or progression of multi-articular OA is, however, unclear and further studies are warranted.

Muscle activation patterns of the hip abductors differed between CTRLs and OA participants, and there also appeared to be differences between those who respond to unloader bracing treatment after 4 weeks and those who didn't. The OA group lacked the intra- and inter-limb symmetry demonstrated by CTRLs in peak activation levels of the two hip abductor muscles, which may be expected given the difference in kinematic measures noted above. Rs had greater activation of TFL at baseline and demonstrated an increase in Gmed activation as a result of putting and unloading brace on the knee at both time points in the study. The significance of this strategy is unclear, as is its relation to the difference in treatment response or long term consequences and further studies should be undertaken to shed a light on this.

References

- 1. Hootman JM, Helmick CG. Projections of US prevalence of arthritis and associated activity limitations. Arthritis and Rheumatism. 2006;54(1):226-9.
- 2. Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. Journal of Bone and Joint Surgery-American Volume. 2007;89A(4):780-5.
- 3. Harrysson OLA, Robertsson O, Nayfeh JF. Higher cumulative revision rate of knee arthroplasties in younger patients with osteoarthritis. Clinical Orthopaedics and Related Research. 2004(421):162-8.
- 4. Furnes O, Espehaug B, Lie SA, Vollset SE, Engesaeter LB, Havelin LI. Early failures among 7,174 primary total knee replacements: a follow-up study from the Norwegian Arthroplasty Register 1994-2000. Acta Orthop Scand. 2002;73(2):117-29.
- 5. Shakoor N, Block JA, Shott S, Case JP. Nonrandom evolution of end-stage osteoarthritis of the lower limbs. Arthritis Rheum. 2002;46(12):3185-9.
- 6. Block JA, Shakoor N. Lower limb osteoarthritis: biomechanical alterations and implications for therapy. Curr Opin Rheumatol. 2010;22(5):544-50.
- Metcalfe AJ, Stewart C, Postans N, Dodds AL, Holt CA, Roberts AP. The effect of osteoarthritis of the knee on the biomechanics of other joints in the lower limbs. Bone & Joint Journal. 2013;95B(3):348-53.
- 8. Metcalfe A, Stewart C, Postans N, Barlow D, Dodds A, Holt C, Whatling G, Roberts A. Abnormal loading of the major joints in knee osteoarthritis and the response to knee replacement. Gait & Posture. 2013;37(1):32-6.
- 9. Toriyama M, Deie M, Shimada N, Otani T, Shidahara H, Maejima H, Moriyama H, Shibuya H, Okuhara A, Ochi M. Effects of unloading bracing on knee and hip joints for patients with medial compartment knee osteoarthritis. Clin Biomech (Bristol, Avon). 2011.
- 10. Perry J, Burnfield JM. Gait analysis: normal and pathological function. 2nd ed. ed. Thorofare, N.J.: SLACK; 2010.
- 11. Sharma L, Song J, Felson DT, Cahue S, Shamiyeh E, Dunlop DD. The role of knee alignment in disease progression and functional decline in knee osteoarthritis. Jama-Journal of the American Medical Association. 2001;286(2):188-95.
- 12. Felson DT, Lawrence RC, Dieppe PA, Hirsch R, Helmick CG, Jordan JM, Kington RS, Lane NE, Nevitt MC, Zhang YQ, Sowers M, McAlindon T, Spector TD, Poole AR, Yanovski SZ, Ateshian G, Sharma L, Buckwalter JA, Brandt KD, Fries JF. Osteoarthritis: New Insights. Part 1: The Disease and Its Risk Factors. Annals of Internal Medicine. 2000;133(8):635-46.
- 13. Astephen JL, Deluzio KJ, Caldwell GE, Dunbar MJ. Biomechanical changes at the hip, knee, and ankle joints during gait are associated with knee osteoarthritis severity. J Orthop Res. 2008;26(3):332-41.

- 14. Linley HS, Sled EA, Culham EG, Deluzio KJ. A biomechanical analysis of trunk and pelvis motion during gait in subjects with knee osteoarthritis compared to control subjects. Clin Biomech (Bristol, Avon). 2010;25(10):1003-10.
- Hinman RS, Hunt MA, Creaby MW, Wrigley TV, McManus FJ, Bennell KL. Hip Muscle Weakness in Individuals With Medial Knee Osteoarthritis. Arthritis Care & Research. 2010;62(8):1190-3.
- 16. Chang A, Hayes K, Dunlop D, Song J, Hurwitz D, Cahue S, Sharma L. Hip abduction moment and protection against medial tibiofemoral osteoarthritis progression. Arthritis and Rheumatism. 2005;52(11):3515-9.
- 17. Mündermann A, Dyrby CO, Andriacchi TP. Secondary gait changes in patients with medial compartment knee osteoarthritis: increased load at the ankle, knee, and hip during walking. Arthritis Rheum. 2005;52(9):2835-44.
- 18. Sharma L, Kapoor D, Issa S. Epidemiology of osteoarthritis: an update. Current Opinion in Rheumatology. 2006;18(2):147-56.
- 19. Bennell KL, Hunt MA, Wrigley TV, Hunter DJ, McManus FJ, Hodges PW, Li L, Hinman RS. Hip strengthening reduces symptoms but not knee load in people with medial knee osteoarthritis and varus malalignment: a randomised controlled trial. Osteoarthritis and Cartilage. 2010;18(5):621-8.
- 20. Sled EA, Khoja L, Deluzio KJ, Olney SJ, Culham EG. Effect of a Home Program of Hip Abductor Exercises on Knee Joint Loading, Strength, Function, and Pain in People With Knee Osteoarthritis: A Clinical Trial. Physical Therapy. 2010;90(6):895-904.
- 21. Rutherford DJ, Hubley-Kozey C, Stanish W. Hip abductor function in individuals with medial knee osteoarthritis: Implications for medial compartment loading during gait. Clinical Biomechanics. 2014;29(5):545-50.
- 22. Briem K, Snyder-Mackler L. Proximal gait adaptations in medial knee OA. J Orthop Res. 2009;27(1):78-83.
- 23. Hunt MA, Wrigley TV, Hinman RS, Bennell KL. Individuals With Severe Knee Osteoarthritis (OA) Exhibit Altered Proximal Walking Mechanics Compared With Individuals With Less Severe OA and Those Without Knee Pain. Arthritis Care & Research. 2010;62(10):1426-32.
- 24. Baliunas AJ, Hurwitz DE, Ryals AB, Karrar A, Case JP, Block JA, Andriacchi TP. Increased knee joint loads during walking are present in subjects with knee osteoarthritis. Osteoarthritis and Cartilage. 2002;10(7):573-9.
- 25. Kaufman KR, Hughes C, Morrey BF, Morrey M, An KN. Gait characteristics of patients with knee osteoarthritis. Journal of Biomechanics. 2001;34(7):907-15.
- 26. Hunt MA, Birmingham TB, Giffin JR, Jenkyn TR. Associations among knee adduction moment, frontal plane ground reaction force, and lever arm during walking in patients with knee osteoarthritis. Journal of Biomechanics. 2006;39(12):2213-20.

- 27. Bechard DJ, Birmingham TB, Zecevic AA, Jones IC, Giffin JR, Jenkyn TR. Toe-out, lateral trunk lean, and pelvic obliquity during prolonged walking in patients with medial compartment knee osteoarthritis and healthy controls. Arthritis Care & Research. 2012;64(4):525-32.
- 28. Mündermann A, Asay JL, Mundermann L, Andriacchi TP. Implications of increased medio-lateral trunk sway for ambulatory mechanics. J Biomech. 2008;41(1):165-70.
- 29. Hunt MA, Birmingham TB, Bryant D, Jones I, Giffin JR, Jenkyn TR, Vandervoort AA. Lateral trunk lean explains variation in dynamic knee joint load in patients with medial compartment knee osteoarthritis. Osteoarthritis and Cartilage. 2008;16(5):591-9.
- 30. Duffell LD, Southgate DFL, Gulati V, McGregor AH. Balance and gait adaptations in patients with early knee osteoarthritis. Gait & Posture. 2014;39(4):1057-61.
- 31. Waller C, Hayes D, Block JE, London NJ. Unload it: the key to the treatment of knee osteoarthritis. Knee Surg Sports Traumatol Arthrosc. 2011.
- 32. Brouwer RW, van Raaij TM, Verhaar JAN, Coene L, Bierma-Zeinstra SMA. Brace treatment for osteoarthritis of the knee: a prospective randomized multi-centre trial. Osteoarthritis and Cartilage. 2006;14(8):777-83.
- 33. Pollo FE, Otis JC, Backus SI, Warren RF, Wickiewicz TL. Reduction of medial compartment loads with valgus bracing of the osteoarthritic knee. American Journal of Sports Medicine. 2002;30(3):414-21.
- 34. Gaasbeek RDA, Groen BE, Hampsink B, van Heerwaarden RJ, Duysens J. Valgus bracing in patients with medial compartment osteoarthritis of the knee A gait analysis study of a new brace. Gait & Posture. 2007;26(1):3-10.
- 35. Draper ERC, Cable JM, Sanchez-Ballester J, Hunt N, Robinson JR, Strachan RK. Improvement in function after valgus bracing of the knee An analysis of gait symmetry. Journal of Bone and Joint Surgery-British Volume. 2000;82B(7):1001-5.
- 36. Ramsey DK, Briem K, Axe MJ, Snyder-Mackler L. A mechanical theory for the effectiveness of bracing for medial compartment osteoarthritis of the knee. Journal of Bone and Joint Surgery-American Volume. 2007;89(11):2398-407.
- 37. Segal L, Day SE, Chapman AB, Osborne RH. Can we reduce disease burden from osteoarthritis? Med J Aust. 2004;180(5 Suppl):S11-7.
- 38. Ramsey DK, Russell ME. Unloader braces for medial compartment knee osteoarthritis: Implications on mediating progression. Sports Health. 2009;1(5):416-26.
- 39. Birmingham TB, Kramer JF, Kirkley A, Inglis JT, Spaulding SJ, Vandervoort AA. Knee bracing for medial compartment osteoarthritis: effects on proprioception and postural control. Rheumatology. 2001;40(3):285-9.
- 40. Hurley ST, Murdock GLH, Stanish WD, Hubley-Kozey CL. Is There a Dose Response for Valgus Unloader Brace Usage on Knee Pain, Function, and Muscle Strength? Archives of Physical Medicine and Rehabilitation. 2012;93(3):496-502.
- 41. Kellgren JH, Lawrence JS. Radiological assessment of osteo-arthrosis. Annals of the rheumatic diseases. 1957;16(4):494-502.

- 42. Roos EM, Roos HP, Lohmander LS, Ekdahl C, Beynnon BD. Knee injury and osteoarthritis outcome score (KOOS) Development of a self-administered outcome measure. Journal of Orthopaedic & Sports Physical Therapy. 1998;28(2):88-96.
- 43. Briem K. Reliability, validity and responsiveness of the Icelandic version of the knee injury and osteoarthritis outcome score (KOOS). Laeknabladid. 2012;98(7-8):403-7.
- 44. Briem K. Réttmæti og áreiðanleiki íslenskra þýðinga á KOOS- og KOS-ADLS-spurningalistunum. Laeknabladid. 2012;98(Suppl.69):E-28.
- 45. Irrgang JJ, Snyder-Mackler L, Wainner RS, Fu FH, Harner CD. Development of a patient-reported measure of function of the knee. Journal of Bone and Joint Surgery-American Volume. 1998;80A(8):1132-45.
- Sveinsson T. Validation of the Nordic Physical Activity Questionnaire (NPAQ) comparing results with a reference method (accelerometer). 10th Nordic Nutrition Conference; Reykjavík. 2012.
- 47. Benish BM, Smith KJ, Schwartz MH. Validation of a Miniature Thermochron for Monitoring Thoracolumbosacral Orthosis Wear Time. Spine. 2012;37(4):309-15.
- 48. Wu G, Siegler S, Allard P, Kirtley C, Leardini A, Rosenbaum D, Whittle M, D'Lima DD, Cristofolini L, Witte H, Schmid O, Stokes H. ISB recommendation on definitions of joint coordinate system of various joints for the reporting of human joint motion part 1: ankle, hip, and spine. Journal of Biomechanics. 2002;35(4):543-8.
- 49. Hermens HJ, Freriks B, Disselhorst-Klug C, Rau G. Development of recommendations for SEMG sensors and sensor placement procedures. Journal of Electromyography and Kinesiology. 2000;10(5):361-74.
- 50. Pua Y-H, Wrigley TW, Cowan SM, Bennell KL. Intrarater test-retest reliability of hip range of motion and hip muscle strength measurements in persons with hip osteoarthritis. Archives of Physical Medicine and Rehabilitation. 2008;89(6):1146-54.
- 51. Pham T, van der Heijde D, Altman RD, Anderson JJ, Bellamy N, Hochberg M, Simon L, Strand V, Woodworth T, Dougados M. OMERACT-OARSI Initiative: Osteoarthritis Research Society International set of responder criteria for osteoarthritis clinical trials revisited. Osteoarthritis and Cartilage. 2004;12(5):389-99.
- 52. Rutherford DJ, Hubley-Kozey C. Explaining the hip adduction moment variability during gait: Implications for hip abductor strengthening. Clinical Biomechanics. 2009;24(3):267-73.
- 53. Moore KL. Clinically oriented anatomy. 3rd ed. ed. Baltimore, Md; London: Williams & Wilkins; 1992.
- 54. Childs JD, Sparto PJ, Fitzgerald GK, Bizzini M, Irrgang JJ. Alterations in lower extremity movement and muscle activation patterns in individuals with knee osteoarthritis. Clinical Biomechanics. 2004;19(1):44-9.
- 55. Skou ST, Wrigley TV, Metcalf BR, Hinman RS, Bennell KL. Association of Knee Confidence With Pain, Knee Instability, Muscle Strength, and Dynamic Varus-Valgus Joint Motion in Knee Osteoarthritis. Arthritis Care & Research. 2014;66(5):695-701.

- 56. Colbert CJ, Song J, Dunlop D, Chmiel JS, Hayes KW, Cahue S, Moisio KC, Chang AH, Sharma L. Knee confidence as it relates to physical function outcome in persons with or at high risk of knee osteoarthritis in the osteoarthritis initiative. Arthritis and Rheumatism. 2012;64(5):1437-46.
- 57. Hurwitz DE, Ryals AR, Block JA, Sharma L, Schnitzer TJ, Andriacchi TP. Knee pain and joint loading in subjects with osteoarthritis of the knee. Journal of Orthopaedic Research. 2000;18(4):572-9.
- 58. Kumar D, Nardo L, Calixto NE, Singh J, Link TM, Majumdar S. VIGOROUS BUT NOT MODERATE PHYSICAL ACTIVITY IS RELATED TO STRUCTURAL PROGRESSION OF KNEE OSTEOARTHRITIS OVER ONE YEAR. Osteoarthritis and Cartilage. 2014;22:S20-S.
- 59. Briem K, Ramsey DK. The Role of Bracing. Sports Medicine and Arthroscopy Review. 2013;21(1):11-7.
- 60. Ding CH, Jones G, Wluka AE, Cicuttini F. What can we learn about osteoarthritis by studying a healthy person against a person with early onset of disease? Current Opinion in Rheumatology. 2010;22(5):520-7.

Appendix

Appendix 1: Letter of introduction	57
Appendix 2: Informed consent	59
Appendix 3: KOOS questionnaire Icelandic version	60
Appendix 4: KOS-ADLS questionnaire Icelandic version	64
Appendix 5: NPAQ questionnaire Icelandic version	66
Appendix 6: Marker set	68

Appendix 1: Letter of introduction

Lífaflfræðileg áhrif Unloader hnéspelku á mjaðmaliði – greining á vöðvavirkni og hreyfimynstrum mjaðmaliða í göngu

Tilgangur þessa bréfs er að óska eftir þátttöku þinni og jafnframt að kynna fyrir þér rannsóknina "Lífaflfræðileg áhrif Unloader hnéspelku á mjaðmaliði – greining á vöðvavirkni og hreyfimynstrum mjaðmaliða í göngu". Rannsóknin er meistaraverkefni Freyju Hálfdanardóttur sjúkraþjálfara, í hreyfivísindum við Læknadeild Háskóla Íslands.

Ábyrgðarmaður rannsóknarinnar: Dr.Kristín Briem, lektor við námsbraut í sjúkraþjálfun, Háskóli Íslands, Stapi við Hringbraut. Vinnusími: 525-4096, tölvupóstur: kbriem@hi.is **Rannsakandi:** Freyja Hálfdanardóttir, sími: 867-8572, tölvupóstur: freyja@sjukratjalfun.is

Inngangur:

Slitgigt í hnjáliðum er vaxandi heilbrigðisvandamál og algeng orsök færniskerðingar og örorku. Tengsl virðast vera milli slits í hnjálið og þróunar á sliti í öðrum þungaberandi liðum, þar virðast gagnstæður mjaðmarliður og hitt hnéð vera sérstaklega í áhættu. Rannsóknir hafa því í vaxandi mæli beinst að áhrifum lífaflfræðilegra þátta á þróun slitsins. Í hreyfirannsóknum hefur greinst munur á slitgigtarsjúklingum og heilbrigðum hvað varðar hreyfingu, álag og vöðvavirkni umhverfis hnén, en einnig virðist vera munur milli þessara hópa á hreyfingu og álagi á mjaðmaliði. Unloading hnéspelkur eru notaðar til að breyta álagi á liðbrjósk í hnjálið þegar aðeins er slit í hluta hans. Meðferð með slíkum spelkum getur dregið úr verkjum, bætt starfræna getu og aukið lífsgæði, einnig hafa þær áhrif á hreyfiferla og vöðvavirkni umhverfis hnéð.

Tilgangur og markmið rannsóknarinnar:

Lítið er vitað um hvaða áhrif spelkurnar hafa á álag, hreyfimynstur og vöðvavirkni kring um mjaðmaliði. Tilgangur rannsóknarinnar er að kanna áhrif UnloaderOne hnéspelku á vöðvavirkni og afl- og hreyfifræðilega þætti kring um mjaðmarliði í göngu eftir að notkun spelkunnar hefst og eftir 4 vikna notkun hennar. Niðurstöður munu auka skilning okkar á álagi mjaðmaliða hjá einstaklingum með slitgigt í hné og hvort hnéspelka hafi áhrif þar á.

Þátttökuskilyrði:

Karlmönnum á aldrinum 40-60 ára sem greindir eru með slitgigt í miðlæga hluta hnjáliðar verður boðin þátttaka. Til samanburðar verður einnig leitað eftir þátttöku einstaklinga með heilbrigð hné og sömu aldurs-, hæðar-, þyngdardreifingu og rannsóknarhópurinn.

Ekki er hægt að bjóða þeim einstaklingum að taka þátt í rannsókninni sem:

- eru með gervilið í einhverjum lið í neðri útlim eða þekkt slit í mjaðmaliðum
- eru með slitin liðbönd í hnjám eða hafa brotnað inn í hnjálið
- hafa farið í stærri hnjáaðgerðir eins og t.d. krossbandsaðgerð
- eru með sykursýki, taugasjúkdóma sem hafa áhrif á göngulag, ofurviðkvæma húð eða blóðrásarvandamál í ganglimum eða líkamsþyngdarstuðul (BMI) >35.0
- fengu sterasprautu eða hyaluranon meðferð í hnéð fyrir minna en þremur mánuðum
- fóru í speglun á hné fyrir minna en sex mánuðum

Þátttaka í rannsókninni felur í sér:

Pátttakendur í rannsóknarhóp fá UnloaderOne hnéspelku frá Össuri lánaða til notkunar í 4 vikur (http://ossur.is/thjonusta/spelkur-og-hlifar/unloaderone) þeir þurfa að mæta tvisvar í mælingar, við upphaf rannsóknar og að 4 vikum liðnum, en sérstakur nemi í spelkunni mælir hversu mikið spelkan er notuð á tímabilinu. Þátttakendur í samanburðarhóp mæta einu sinni í áþekka mælingu. Mælingar fara fram í Rannsóknarstofu í hreyfivísindum, Stapa við Hringbraut, Háskóla Íslands og tekur hver mæling um 2 klukkustundir. Endurskinskúlur verða festar með teygju eða límbandi á ganglimi og bol þátttakenda og hreyfingar kúlnanna teknar upp þegar gengið er stuttan spöl (8m) eftir sléttu gólfi rannsóknarstofunnar. Bakvöðvar og vöðvar utanvert á mjöðmum verða styrkprófaðir og vöðvarit tekið af þeim með þráðlausum elektróðum. Hver þátttakandi þarf að ganga 5-10 skipti eftir gólfinu og einnig að svara spurningarlista um virkni, verki og starfræna getu. Aldur, hæð og þyngd þátttakenda verður einnig skráð.

Ávinningur/áhætta af þátttöku:

Þátttakandi fær UnloaderOne hnéspelku frá Össuri lánaða til notkunar í 4 vikur. Ekki verður greitt fyrir þátttöku. Áhætta af þátttöku er lítil, einstaka notendur spelkunnar hafa fundið fyrir óþægindum vegna þrýstings eða núnings en slíkt er sjaldgæft. Eins er hugsanlegt að einstaklingar með viðkvæma húð finni fyrir tímabundinni ertingu undan elektróðum eða límbandi sem notað er til að festa endurskinskúlur á húð. Þátttakendur eru ekki sérstaklega tryggðir gegn óhöppum, enda engin áhætta sem felst í þátttöku utan þeirrar sem tengist göngu.

Trúnaður og gagnaöryggi:

Rannsakandi heitir fullum trúnaði við þátttakendur. Því til staðfestingar skrifar hann ásamt þátttakanda undir upplýst samþykki. Gagnaúrvinnsla fer fram í tölvu, gögn sem auðkennd eru einungis með númeri eru geymd þar undir lykilorði sem rannsakandi hefur einn aðgang að. Spurningalistar, auðkenndir með númeri, verða geymdir í læstri hirslu.

Pátttakendur geta hætt þátttöku í rannsókninni á hvaða stigi hennar sem er án skýringa eða eftirmála. Vakni einhverjar spurningar má leita til starfsfólks rannsóknarinnar eftir nánari upplýsingum, eða til vísindasiðanefndar (sjá neðanmáls).

Niðurstöður rannsóknarinnar verða birtar í mastersritgerð Freyju Hálfdanardóttur, einnig er stefnt að því að birta grein í erlendu fagtimariti. Persónugreinanlegar upplýsingar munu hvergi koma fram opinberlega.

Kær kveðja, með von um góðar undirtektir	
 Ábyrgðarmaður	Rannsakandi
Dr. Kristín Briem, lektor	Freyja Hálfdanardóttir, meistaranemi

Appendix 2: Informed consent

Lífaflfræðileg áhrif unloader hnéspelku á mjaðmaliði – greining á vöðvavirkni og hreyfimynstrum mjaðmaliða í göngu

Samþykkisyfirlýsing fyrir þátttakendur

Markmið rannsóknarinnar er að kanna áhrif UnloaderOne hnéspelku á vöðvavirkni og hreyfimynstur umhverfis mjaðmir eftir að notkun spelkunar hefst og eftir 4 vikna notkun. Niðurstöður munu auka skilning okkar á álagi mjaðmaliða hjá einstaklingum með slitgigt í hné og hvort hnéspelka hafi áhrif þar á.

Þátttakendur samþykkja að mæta í mælingar þar sem ganga þarf 5-10 ferðir eftir um 8 m sléttu gólfi rannsóknarstofunnar. Teknar verða upp hreyfingar endurskinskúlna sem festar verða á líkamann, sem og merki frá vöðvum í mjöðmum/baki. Þetta tekur um 1,5-2 klst.

Ég staðfesti hér með undirskrift minni að ég hef lesið upplýsingarnar um rannsóknina sem mér voru afhentar, hef fengið tækifæri til að spyrja spurninga um rannsóknina og fengið fullnægjandi svör og útskýringar á atriðum sem mér voru óljós. Ég hef af fúsum og frjálsum vilja ákveðið að taka þátt í rannsókninni. Mér er ljóst, að þó ég hafi skrifað undir þessa samstarfsyfirlýsingu, get ég stöðvað þátttöku mína hvenær sem er án útskýringa og án afleiðinga.

Mér er ljóst að rannsóknargögnum verður eytt að rannsókn lokinni og eigi síðar en 5 árum frá úrvinnslu rannsóknargagna. Mér hefur verið skýrt frá fyrirkomulagi trygginga fyrir þátttakendur í rannsókninni. Upplýsingabréf og samþykki fyrir þessari rannsókn eru í tvíriti og þátttakandi mun halda eftir eintaki af hvoru tveggja.

Dagsetning	Nafn þátttakanda
,	arinnar, staðfestir hér með að hafa veitt upplýsingar um mræmi við lög og reglur um vísindarannsóknir.
 Nafn þess sem leggur samþykkisyfirl	 ýsinguna fyrir

Appendix 3: KOOS questionnaire Icelandic version

KOOS hnékönnun

Dagsetning: /		Nafn/au	ðkenni <u>:</u>		
	,				
_	-			garnar munu hjálpa	
fylgjast með líðan	þinni í hnénu og h	versu vel þér gengu	r að framkvæma	venjubundnar athaf	nir.
Svaraðu <u>sérhverri</u> :	<u>spurningu</u> með þv	í að merkja í viðeiga	ındi reit, aðeins sl	kal merkja í <u>einn</u> rei	t fyrir
hverja spurningu. I	Ef þú ert óviss um	svar við spurningu,	reyndu vinsamle	gast að velja besta s	varið.
Einkenni					
Þessum spurningu	m skal svara með	einkenni síðastliðin	nar viku í huga.		
S1. Er bólga í hnén	u?				
Aldrei	Sjaldan	Stundum	Oft	Alltaf	
S2. Finnurðu fyrir r	marri, heyrir smell	i eða eitthvert anna	ð hljóð þegar þú	hreyfir hnéð?	
Aldrei	Sjaldan	Stundum	Oft	Alltaf	
S3. Læsist hnéð eð	ia festist við hreyfi	ngu?			
Aldrei	Sjaldan	Stundum	Oft	Alltaf	
S4. Geturðu rétt ú	r hnénu til fullnust	:u?			
Alltaf	Oft	Stundum	Sjaldan	Aldrei	
S5. Geturðu beygt	hnéð til fullnustu:)			
Alltaf	Oft	Stundum	Sjaldan	Aldrei	
Stirðleiki					
	ngar varða hversu	miklum stirðleika h	ú hefur fundið fyl	rir í hnélið þínum síð	ňastliňna
•	_	:öðu gegn hreyfingu		•	, astilolia
áreynslulaus.					
S6. Hversu mikill e	r stirðleikinn í hné	nu fyrst eftir að þú	vaknar á morgnar	na?	
Enginn	Svolítill	Þó nokkur	Mjög mikill	Gríðarlegur	
S7. Hversu mikill e	r stirðleikinn í hné	nu eftir að þú situr	um stund, leggur	þig eða hvílir seinna	a um
daginn?	_	,	, 55		
Enginn	Svolítill	Þó nokkur	Mjög mikill	Gríðarlegur	

Sársauki P1. Hversu oft finnurðu fyrir sársauka í hné? Alltaf Vikulega Aldrei Mánaðarlega Daglega Hversu miklum sársauka hefurðu fundið fyrir í hnénu síðastliðna viku við eftirfarandi athafnir? P2. Vinda/snúa upp á hnéð Engum Svolitlum Þó nokkrum Mjög miklum Gríðarlegum П P3. Rétta úr hnénu til fullnustu Engum Svolitlum Þó nokkrum Mjög miklum Gríðarlegum П П П P4. Beygja hnéð til fullnustu Engum Svolitlum Þó nokkrum Mjög miklum Gríðarlegum P5. Ganga á jafnsléttu Engum Svolitlum Þó nokkrum Mjög miklum Gríðarlegum P6. Ganga upp eða niður stiga Svolitlum Þó nokkrum Mjög miklum Gríðarlegum Engum P7. Rúmliggjandi að nóttu til Engum Svolitlum Þó nokkrum Mjög miklum Gríðarlegum P8. Sitjandi eða liggjandi Svolitlum Engum Þó nokkrum Mjög miklum Gríðarlegum P9. Standandi upprétt Þó nokkrum Engum Svolitlum Mjög miklum Gríðarlegum Geta til daglegra athafna. Eftirfarandi spurningar varða líkamlega starfræna færni. Með því er átt við getu þína til að hreyfa þig og sjá um sjálfa(n) þig. Fyrir <u>sérhverja athöfn</u> sem hér fer á eftir, vinsamlegast gefðu til kynna hversu miklum erfiðleikum þú hefur orðið fyrir síðastliðna viku vegna hnés þíns. A1. Ganga niður stiga Engum Svolitlum Þó nokkrum Mjög miklum Gríðarlegum

Mjög miklum

Gríðarlegum

Þó nokkrum

A2. Ganga upp stiga Engum

Svolitlum

A3.	Rísa upp úr stól					
	Engum	Svolitlum	Þó nokkrum	Mjög miklum		Gríðarlegum
Δ4	Standa					
, , , , ,	Engum	Svolitlum	Þó nokkrum	Mjög miklum		Gríðarlegum
	_	_	_	_		_
A5.	Beygja þig niður að	_	•	N 4: 2 : I - I		C(*
	Engum	Svolitlum	Þó nokkrum	Mjög miklum		Gríðarlegum
A6.	Ganga á jafnsléttu					
	Engum	Svolitlum	Þó nokkrum	Mjög miklum		Gríðarlegum
A7.	Setjast inn í/stíga ປ	ít úr bíl				
	Engum	Svolitlum	Þó nokkrum	Mjög miklum		Gríðarlegum
A8.	Fara í búðir					
	Engum	Svolitlum	Þó nokkrum	Mjög miklum		Gríðarlegum
۸۵	Klæða þig í sokka					
ΑЭ.	Engum	Svolitlum	Þó nokkrum	Mjög miklum		Gríðarlegum
	П	П	П			
	_	_				_
A10	. Fara fram úr rúm		5 ()	NATE OF THE CO.		C /3 - 1
	Engum	Svolitlum	Þó nokkrum	Mjög miklum		Gríðarlegum
A11	. Fara úr sokkum					
	Engum	Svolitlum	Þó nokkrum	Mjög miklum		Gríðarlegum
A12	. Liggja í rúminu (si	núa þér, viðhald	la stöðu á hné)			
	Engum	Svolitlum	Þó nokkrum	Mjög miklum		Gríðarlegum
A13	. Stíga ofan í baðka	ar/komast upp ú	ír			
	Engum	Svolitlum	Þó nokkrum	Mjög miklum		Gríðarlegum
Δ14	. Sitja					
, <u>, , , , , , , , , , , , , , , , , , </u>	Engum	Svolitlum	Þó nokkrum	Mjög miklum		Gríðarlegum
			П	П		
			J	_		_
A15	. Setjast á klósettið		há nakkeum	Miöa mildum		Críðarlagum
П	Engum	Svolitlum	Þó nokkrum	Mjög miklum	П	Gríðarlegum
			ı			

A16. Erfiðari heim	nilisstörf (flytja til þu	ınga hluti, skrúbba	gólf, o.s.frv.)		
Engum	Svolitlum	Þó nokkrum	Mjög miklum	Gríðarlegum	
A17. Léttari heim	ilisstörf (elda mat, þ	urrka af, o.s.frv.)			
Engum	Svolitlum	Þó nokkrum	Mjög miklum	Gríðarlegum	
Starfræn geta, í	þróttir, tómstund	argaman			
Eftirfarandi spurn	ingar varða líkamle _l	ga færni við erfiða	ri athafnir. Fyrir <u>sér</u>	<u>hverja athöfn</u> sem h	ér fer á
_	st gefðu til kynna hv	ersu miklum erfiðl	eikum þú hefur orð	ið fyrir síðastliðna v	'iku
vegna hnés þíns.					
SP1. Setjast á hæ	kjur þér				
Engum	Svolitlum	Þó nokkrum	Mjög miklum	Gríðarlegum	
SP2. Hlaupa					
Engum	Svolitlum	Þó nokkrum	Mjög miklum	Gríðarlegum	
SP3. Hoppa					
Engum	Svolitlum	Þó nokkrum	Mjög miklum	Gríðarlegum	
SP4. Snúa/vinda ι	upp á veika hnéð				
Engum	Svolitlum	Þó nokkrum	Mjög miklum	Gríðarlegum	
SP5. Krjúpa á kné					
Engum	Svolitlum	Þó nokkrum	Mjög miklum	Gríðarlegum	
Lífsgæði					
•	rðurðu var/vör við l	nnévandamálið þit	t?		
Aldrei	Mánaðarlega	Vikulega	Daglega	Stöðugt	
Q2. Hefurðu aðla	gað lífsstíl þinn til að	ð forðast athafnir s	sem mögulega skað	a hnéð?	
Alls ekki	Svolítið	Þó nokkuð	Mjög mikið	Algerlega	
Q3. Hversu mikla	r áhyggjur hefurðu v	vegna þess að þú v	antreystir hnénu?		
Engar	Svolitlar	Þó nokkrar	Mjög miklar	Gríðarlegar	
Q4. Hversu miklu	m vanda veldur hné	ð þér yfirleitt?			
Engum	Svolitlum	Þó nokkrum	Mjög miklum	Gríðarlegum	

Þakka þér kærlega fyrir að svara öllum spurningum þessa spurningalista.

Appendix 4: KOS-ADLS questionnaire Icelandic version

Leiðbeiningar:

Þessi spurningalisti er hannaður til að ákvarða einkenni og hömlur sem hnéð veldur þér við þínar <u>venjulegu daglegu athafnir</u>. Vinsamlegast svaraðu sérhverri spurningu með því að <u>merkja við þá einu staðhæfingu sem lýsir best þínu ástandi undanfarna 1-2 daga</u>. Vinsamlega merkið <u>einungis</u> við það svar sem best lýsir þér við hefðbundin dagleg störf, þó svo að fleiri en ein staðhæfing gæti svarað spurningunni.

Dagsetning:	Nafn:
• • • • • • • • • • • • • • • • • • • •	

Einkenni

Að hve miklu leyti hefur hvert eftirfarandi einkenna áhrif á getu þína til daglegra athafna? (Merkið við <u>eitt svar</u> við hverri spurningu)

	Ég hef ekki þetta einkenni	Ég hef þetta einkenni – en það hefur ekki áhrif á athafnir mínar	Þetta einkenni hefur svolítil áhrif á athafnir mínar	Þetta einkenni hefur þó nokkur áhrif á athafnir mínar	Þetta einkenni hefur mjög mikil áhrif á athafnir mínar	Þetta einkenni kemur í veg fyrir þátttöku mína í öllum daglegum athöfnum
Sársauki						
Stirðleiki						
Bólgur						
Hné hliðrast til - lætur undan						
Kraftleysi						
Helti						

Hömlur við daglegar athafnir:

Hvaða áhrif hefur hnéð á getu þína til að ... (Merkið aðeins við eitt svar í hverri línu)

	Athöfnin er ekki erfið	Athöfnin veldur sáralitlum erfiðleikum	Athöfnin er dálítið erfið	Athöfnin er þó nokkuð erfið	Athöfnin er mjög erfið	um að framkvæma þessa athöfn	
Ganga?							
Ganga upp stiga?							
Ganga niður stiga?							
Standa?							
Krjúpa á hné þitt?							
Sitja á hækjum þér?							
Sitja með hnéð bogið?							
Rísa upp úr stól?							
Veldu tölustaf á bilinu 0 til 100 sem lýsir því hversu vel þú getur notað hnéð við þín <u>venjulegu daglegu störf</u> . 100 lýsir færni í hné fyrir áverka og 0 lýsir alls engri getu til að sinna þínum daglegum störfum. Svar:							
	lir þú meta <u>alm</u> ið <u>eitt</u> svar sem		<u>né</u> við þín venju	bundnu dagleg	u störf? (vinsaı	mlegast	
 □ Eðlileg □ Nærri eðlileg □ Óeðlileg □ Mjög óeðlileg 							
Hvernig mundirðu meta <u>núverandi getu þína til daglegra athafna</u> í kjölfar hnéáverkans? (vinsamlegast merktu við það <u>eina</u> svar sem lýsir þér best) □ Eðlileg □ Nærri eðlileg							
□ Óeðli	leg						

Appendix 5: NPAQ questionnaire Icelandic version

Dagsetning: Auðkenni:						
Hreyfing í vinnu Ert þú í vinnu eða str	ındar skóla?	Já	Nei			
Ef svo er, hver af eft skólatíma? (Ekki tak			oinni atvinnu eða þínum a skóla)			
	[] Að mestu leyti kyrrsetuvinna eins og skrifstofuvinna (gjaldkeri í búð eða í banka, og létt líkamleg vinna)					
	Vinna, sem krefst mikillar göngu eins og starf grunnskólakennara (aðstoðarmanneskja í verslun, létt iðnaðarvinna)					
	em krefst mikillar g naðarmannavinna)	öngu og lyft	inga eins og starf sjúkraliða			
	camleg vinna eins o erfið skórækt)	g erfið bygg	ingavinna (erfið vinna til			
Mažalaz aufžhua	C ~-					

Meðal og erfið hreyfing

Hversu miklum tíma samtals síðustu sjö daga, eyddir þú í líkamlega hreyfingu í frítíma þínum þar sem *líkamleg áreynsla var í meðallagi eða erfiðari* og stóð yfir í *að minnsta kosti tíu mínútur í hvert skipti*? Þess háttar hreyfing eykur hjartslátt og öndun. Dæmi eru rösk ganga, skokk og erfið garðvinna, en spurt er um alla líkamlega hreyfingu í frítíma þínum og við virkan ferðamáta (t.d. til og frá vinnu eða skóla; taktu með líkamlega hreyfingu við allar útréttingar). Áætlaðu að næstu þrjátíu mínútum.

Erfið hreyfing

Hér er spurt um hversu mikið af þeirri hreyfingu sem þú gafst upp í síðustu spurningu var *erfið*? Hversu miklum tíma samtals síðustu sjö daga eyddir þú í *erfiða hreyfingu* í frítíma þínum sem stóð yfir í *að minnsta kosti tíu mínútur í hvert skipti*? Þess háttar hreyfing orsakar töluverða aukningu á hjartslætti og svita, og hraðari öndun sem gerir fólki erfitt að tala. Dæmi eru hlaup og spila fótbolta. Áætlaðu að næstu þrjátíu mínútum.

Flokkun á líkamlegri hreyfingu í frítíma

Veldu <u>eina</u> af eftirfarandi lýsingum sem passar best athöfnum þínum í frítíma, síðustu sjö daga.

[]	Lestur, sjónvarpsáhorf eða önnur kyrrseta?
[]	Ganga, hjólreiðar eða önnur tegund af léttri áreynslu í að minnsta kosti fjórar klukkustundir síðustu sjö daga. Teldu með göngu eða hjólreiðar til og frá vinnu, sunnudagsgöngu og þess háttar.
[]	Þátttaka í íþróttum í tómstundum, erfið garðyrkja og þess háttar, þar sem tímalengd hreyfingar er að minnsta kosti fjórar klukkustundir síðustu sjö daga.
[]	Þátttaka í erfiðri þjálfun eða íþróttkeppni, reglulega nokkrum sinnum síðustu sjö daga.

Appendix 6: Marker set

Anatomic and tracking markers

Location	Name		Number
First metatarsal	TOE1	Bilaterally	2
Fifth metatarsal	TOE5	Bilaterally	2
Medial malleoli	MMAL	Bilaterally	2
Lateral malleoli	LMAL	Bilaterally	2
Upper calcaneus	HEELH	Bilaterally	2
Lower calcaneus	HEELL	Bilaterally	2
Medial epicondyle of femur	MK	Bilaterally	2
Lateral epicondyle of femur	LK	Bilaterally	2
Trochanter major	GT	Bilaterally	2
Anterior superior iliac spine	ASIS	Bilaterally	2
Posterior superior iliac spine	PSIS	Bilaterally	2
Iliac crest	CI	Bilaterally	2
Sacrum	SACRUM		1
Acromion	AC	Bilaterally	2
Manubrium of sternum	STERNMAN		1
Xiphoid process	STERNXIPH		1
Cervical vertebra 7	C7		1
Thoracic vertebra 10	T10		1
Markers total			31

Marker shells

Location	Name		Number
Thigh	TH1-4 (4 markers)	Bilaterally	2
Shank	SH1-4 (4 markers)	Bilaterally	2
Markers shells total			4