

Research Update 2025

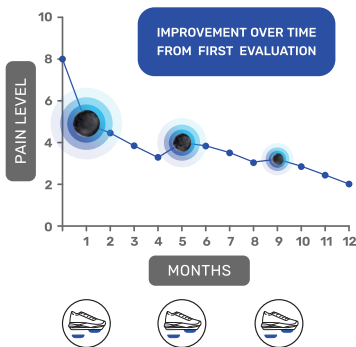


Table of contents

1] Clinical outcomes

Knee Conditions

1.1. Effect of biomechanical foot wear on knee pain in people with knee osteoarthritis. The BIOTOK randomized clinical trial	14
1.2. Avoidance of total knee replacement in a population health setting: introducing a noninvasive biomechanical intervention for patients with knee osteoarthritis	15
1.3. Surgery avoidance rates among TKR candidates following a non-invasive biomechanical intervention	16
1.4. Long-term outcomes on the rates of total knee replacement amongst patients with end-stage knee osteoarthritis who meet surgical criteria and received a non-invasive biomechanical intervention	17
1.5. Non-invasive biomechanical intervention leads to low rates of total knee replacement and reduced utilization of healthcare resources among older adults with chronic knee pain: a 5-year follow-up study	18
1.6. Utilising a non-surgical intervention in the knee osteoarthritis care pathway: a 6-year retrospective audit on NHS patients	19
1.7. Incidence of knee surgeries over 5 years among patients with knee osteoarthritis treated with a non-invasive, home-based, biomechanical intervention	20
1.8. Reduction in healthcare resource utilization following treatment with a home-based footworn device in patients with knee osteoarthritis: a retrospective claims analysis	21
1.9. Noninvasive biomechanical therapy improves objective and subjective measurements of pain and function in patients with knee osteoarthritis: a retrospective analysis	22
1.10. Effects of a customized biomechanical therapy on patients with medial compartment knee osteoarthritis	23
1.11. Long-term effects of AposTherapy in patients with osteoarthritis of the knee: a two-year followup	24
1.12. Reduction in knee adduction moment via non-invasive biomechanical training: A longitudinal gait analysis study	25
1.13. A treatment applying a biomechanical device to the feet of patients with knee osteoarthritis results in reduced pain and improved function: a prospective controlled study	26
1.14. Patients with knee osteoarthritis demonstrate improved gait pattern and reduced pain following a non-invasive biomechanical therapy: a prospective multi-center study on Singaporean population	27
1.15. The effect of treatment with a non-invasive foot worn biomechanical device on subjective and objective measures in patients with knee osteoarthritis- a retrospective analysis on a UK population	28
1.16. Alterations in sagittal plane knee kinetics in knee osteoarthritis using a biomechanical therapy device	29
1.17. Knee osteoarthritis functional classification scheme – validation of time dependent treatment effect one year follow-up of 518 patients	30
1.18. A novel self-care biomechanical treatment for obese patients with knee osteoarthritis	31
1.19. AposTherapy improves clinical measurements and gait in patients with knee osteoarthritis	32
1.20. A non-invasive, home-based biomechanical therapy for patients with spontaneous osteonecrosis of the knee	33
1.21. The outcome of a novel biomechanical therapy for patients suffering from anterior knee pain	34
1.22. A unique foot-worn device for patients with degenerative meniscal tear	35
1.23. A noninvasive biomechanical treatment as an additional tool in the rehabilitation of an acute anterior cruciate ligament tear: A case report	36
1.24. New approach for the rehabilitation of patients following total knee arthroplasty	37
1.25. A novel non-invasive adjuvant biomechanical treatment for patients with altered rehabilitation after Total Knee Arthroplasty: Results of a pilot investigation	38
1.26. A biomechanical foot-worn device improves total knee arthroplasty outcomes	39

Hip Conditions

1.27. A non-surgical foot-worn device for patients with hip osteoarthritis who meet surgical criteria for joint replacement: a retrospective audit on nhs patients. journal of novel physiotherapies 2024	40
1.28. A non-invasive biomechanical device and treatment for patients following total hip arthroplasty: results of a 6-month pilot investigation	41
1.29. Positive outcomes following gait therapy intervention for hip osteoarthritis: a longitudinal study	42
1.30. A non-invasive foot-worn biomechanical device for patients with hip osteoarthritis	43

Lower Back Conditions

1.31. Clinical outcomes of a new foot-worn non-invasive biomechanical intervention compared to traditional physical therapy in patients with chronic low back pain. A randomized controlled trial.	44
1.32. Footwear-generated dynamic biomechanical manipulation and perturbation training for chronic nonspecific low back pain	45
1.33. A novel biomechanical device improves gait pattern in patients with chronic nonspecific low back pain	46
1.34. Patients with chronic non-specific low back pain who reported reduction in pain and improvement in function	47

Ankle Conditions

- 1.35. Gait abnormalities in patients with chronic ankle instability can improve following a non-invasive biomechanical therapy: a retrospective analysis 48

2] Biomechanical alignment and perturbation

- 2.1. Control of knee coronal plane moment via modulation of center of pressure: A prospective gait analysis study 50
- 2.2. The influence of sagittal center of pressure offset on gait kinematics and kinetics 51
- 2.3. Effect of center of pressure modulation on knee adduction moment in medial compartment knee osteoarthritis 52
- 2.4. Foot center of pressure trajectory alteration by biomechanical manipulation of shoe design 53
- 2.5. Detecting and quantifying global instability during a dynamic task using kinetic and kinematic gait parameters 54
- 2.6. Reduction of frontal-plane hip joint reaction force via medio-lateral foot center of pressure manipulation: A pilot study 55
- 2.7. Alteration of the foot center of pressure trajectory by an unstable shoe design 56
- 2.8. Reduction of hip joint reaction force via medio-lateral foot center of pressure manipulation in bilateral hip osteoarthritis patients 57
- 2.9. Mechanism of reducing knee adduction moment by shortening of the knee lever arm via medio-lateral manipulation of foot center of pressure: A pilot study 58
- 2.10. The effect of unstable shoe designs on the variability of gait measures 59
- 2.11. The effect of center of pressure alteration on the ground reaction force during gait: A statistical model 60
- 2.12. Trunk kinematic, kinetic, and neuro-muscular response to foot center of pressure translation along the medio-lateral foot axis during gait- place this section c: biomechanical alignment and perturbation 61

3] Specific muscle activation

- 3.1. The effect of manipulation of the center of pressure of the foot during gait on the activation patterns of the lower limb musculature 63
- 3.2. Foot center of pressure manipulation and gait therapy influence lower limb muscle activation in patients with osteoarthritis of the knee 64
- 3.3. Neuromuscular response of hip-spanning and low back muscles to medio-lateral foot center of pressure manipulation during gait 65

4] Knee osteoarthritis functional severity classification & gait analysis

- 4.1. Novel classification of knee osteoarthritis severity based on spatiotemporal analysis 67
- 4.2. Correlation between single limb support phase and self-evaluation questionnaires in knee osteoarthritis populations 68
- 4.3. Can single limb support objectively assess the functional severity of knee osteoarthritis? 69
- 4.4. Analysis of knee flexion characteristics and how they alter with the onset of knee osteoarthritis: a case control study 70

5] Additional scientific evidence

- 5.1. Differences in gait patterns, pain, function and quality of life between males and females with knee osteoarthritis: a clinical trial 72
- 5.2. Sex and body mass index correlate with western ontario and mcmaster universities osteoarthritis index and quality of life scores in knee osteoarthritis 73
- 5.3. Differences in gait pattern parameters between medial and anterior knee pain in patients with osteoarthritis of the knee 74
- 5.4. Gait metric profile of 157 patients suffering from anterior knee pain. A controlled study 75
- 5.5. The reliability of a gait analysis mat in assessing patients with knee osteoarthritis 76
- 5.6. Gait metric profile and gender differences in hip osteoarthritis patients. A case controlled study 77
- 5.7. Clinical outcomes following ankle fracture: a cross-sectional observational study 78
- 5.8. The correlation between radiographic knee OA and clinical symptoms – do we know everything? 79
- 5.9. Deviations in gait metrics in patients with chronic ankle instability: a case control study 80
- 5.10. Gait characteristics and quality of life perception of patients following tibial plateau fracture 81
- 5.11. Lower extremity kinematic profile of gait of patients after ankle fracture: a case-control study 82
- 5.12. Gait assessment of patients with spontaneous osteonecrosis of the knee: a retrospective case controlled study retrospective case controlled study 83
- 5.13. Association between knee osteoarthritis and functional changes in ankle joint and achilles tendon 84
- 5.14. Knee osteoarthritis, degenerative meniscal lesion and osteonecrosis of the knee: Can a simple gait test direct us to a better clinical diagnosis 85
- 5.15. Correlation between gait analysis and clinical questionnaires in patients with spontaneous osteonecrosis of the knee 86
- 5.16. Using gold standard patient reported outcome measures in clinical practice – A new approach to facilitate their use 87
- 5.17. Smartphone-based inertial sensor technology – validation of a new application 88

Manuscripts

Summary of outcomes of a non-invasive biomechanical therapy for patients with knee osteoarthritis

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Osteoarthritis (OA) is the second most frequent chronic musculoskeletal (MSK) condition after low back pain and a leading cause of disability in the elderly. The number of people living with disability will continue to rise with the aging of the population. Moreover, the rapid increase in rates of surgical intervention, i.e. Total knee replacement (TKR) and revision TKRs, is expected to place an immense burden on the health care system and society. There is a call for better rehabilitation, new interventions, and disease management for patients with knee OA. The purpose of this article is to review the biomechanics of knee OA and biomechanical interventions and to summarize the current literature on a non-invasive, home-based biomechanical treatment for patients with knee OA. The evidence suggests an improvement in symptoms and biomechanical indicators after using the home-based biomechanical intervention. In the presence of value-based payment to improve efficiency and effectiveness in delivering medical care, these results are promising.

INTRODUCTION

Osteoarthritis (OA) is the second most frequent chronic musculoskeletal (MSK) condition after low back pain and a leading cause of disability in the elderly (Storheim and Zwart 2014; Endstrasser et al. 2020). The incidence of knee OA is rapidly increasing due to global demographical changes, mainly an aging population from increased life expectancy and the growing prevalence of obesity. It is esti-

mated that by 2050, 130 million people will suffer from OA worldwide, of whom the disease will severely disable 40 million (Wittenauer, Smith, and Aden 2013), leading to a gradual increase in burden for society.

Total knee replacement (TKR) is a common solution for patients with end-stage knee OA. Over the years there has been an increase in the demand for TKRs attributed to an increase in life expectancies and a decline in the average age of surgical candidates. More recently, an inactive

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lifestyle exacerbated with COVID-19 can potentially put more patients at risk for TKR (Endstrasser et al. 2020). For the above reasons, the burden of knee OA on society is on the rise (Klug et al. 2020). Existing pharmacological and non-pharmacological interventions for OA remain insufficient. These include physical therapy, biomechanical interventions, oral medications, and injections (McAlindon et al. 2014). There is an urgent need for new non-invasive interventions to effectively treat knee OA and serve as an alternative to surgical intervention.

In this review we will focus on the biomechanical aspects of knee OA and the use of biomechanical interventions to treat knee OA. In addition, we will summarize the scientific evidence of a non-invasive biomechanical intervention that aims to reduce pain and improve function by shifting loads and training neuromuscular control.

BIOMECHANICS OF KNEE OA AND BIOMECHANICAL INTERVENTIONS

Biomechanics plays an essential role in knee OA. Understanding knee biomechanics is a prerequisite for designing biomechanical knee assistive devices and optimizing rehabilitation exercises for patients with knee OA (Egloff, Hügle, and Valderrabano 2012; Zhang et al. 2020). A typical healthy knee is exposed to 3-dimensional loads (Figure 1). These include the knee adduction moment (KAM), the knee flexion moment (KFM), and the knee external rotation moment (KERM) (Al-Zahrani and Bakheit 2002; Kaufman et al. 2001; Mündermann, Dyrby, and Andriacchi 2005; Gök, Ergin, and Yavuzer 2002). Knee OA is a degenerative “wear-and-tear” disease that occurs most often in people ≥ 50 years of age and affects the biomechanics of the knee joint. The KAM, a primary biomechanical indicator for knee OA, is commonly used to assess disease severity, progression, prognosis and even predict the likelihood of developing future chronic pain in an asymptomatic population. It also correlates with early signs of knee OA, joint space narrowing, medial joint capsule loosening, and symptoms (i.e., pain and functional disability) (Sharma et al. 1998; Amin et al. 2004; Teichtahl et al. 2006; Hurwitz et al. 2002). Wear-and-tear processes also occur to the dynamic stabilizers of the knee, expressed by a deterioration of the neuromuscular control. Patients with knee OA have deteriorated muscle function, including decreased muscle strength and compromised synergy (Messier et al. 1992; Lewek, Rudolph, and Snyder-Mackler 2004). The biomechanical changes justify the use of biomechanical interventions in patients with knee OA.

Biomechanical interventions and walking aids are an integral part of the knee OA care-pathway. Amongst them are footwear, wedge insoles, orthotics, and braces. Some have been included in disease management guidelines (OARSI, ACR, NICE, AAOS) (Carlson et al. 2018; Conaghan, Dickson, and Grant 2008; Richmond et al. 2010; Schnitzer 2002), mainly because they are conservative interventions with low risk. However, in 2021, The American Academy of Orthopaedic Surgeons (AAOS) refined its recommendations on biomechanical interventions and had strongly advised against the use of lateral wedge insoles and advised with a

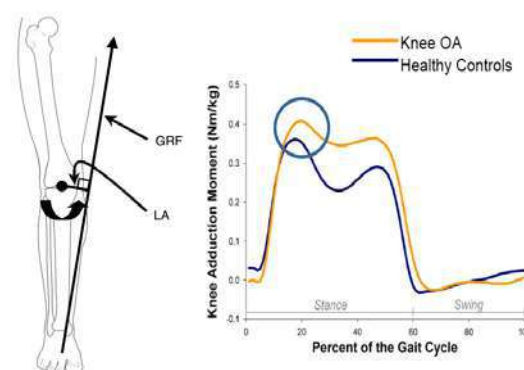


Figure 1. Knee adduction moment

moderate level of confidence on the use of canes and braces to alleviate pain and improve function and quality of life among patients with knee OA (American Academy of Orthopaedic Surgeons 2021).

Although footwear modification has not been officially reviewed and included in knee OA guidelines, there is some evidence on their ability to decrease peak external KAM and reduce pain. These include rocker-sole shoes, flexible/stiffness shoes, mobility shoes, lateral wedge insoles, conventional shoes with changing heel height, and walking with a toe-out (i.e., external rotation) gait pattern. None of the above have sufficient effect on KAM and symptoms (Radzinski, Mündermann, and Sole 2012).

The biomechanical interventions that are endorsed by the international guidelines committee are walking cane and valgus knee braces. Using a cane or a walking stick in the hand contralateral to the symptomatic knee can potentially reduce the peak KAM by 10% (Kemp et al. 2008). However, this might be a limitation when a patient suffers from a bilateral condition since holding the cane in the ipsilateral limb might cause an increase in KAM (Kemp et al. 2008). Valgus knee braces are designed to redistribute the loading in the knee by applying a valgus moment to generate an abduction moment to reduce the KAM and ultimately alleviate knee pain, yet its clinical effectiveness is inconclusive. One of the main limitations of knee braces is compliance. They are bulky, potentially uncomfortable, and might not be a practical daily solution for many patients.

BIOMECHANICAL ALTERATION OF GAIT (BMAG)

A home-based biomechanical intervention (AposHealth®, New York, US) that includes a unique foot-worn device to manipulate the center of pressure (COP) and train neuromuscular control and a home-based treatment plan has been in use for a few years. The therapy addresses the underlying biomechanical aspects of knee OA (Haim et al. 2008; Haim, Rozen, and Wolf 2010; Haim et al. 2011; Khoury et al. 2013, 2015; Solomonow-Avnon et al. 2015; Solomonow-Avnon, Herman, and Wolf 2019; Solomonow-Avnon et al. 2019; Khoury-Mireb et al. 2019; Debbi, Wolf, and Haim 2012; Goryachev, Debbi, Haim, and Wolf 2011; Goryachev, Debbi, Haim, Rozen, et al. 2011) (i.e., reducing loads by shifting the center of pressure and neuromuscular

training), while reducing pain and improving function (Goryachev, Debbi, Haim, Rozen, et al. 2011; Debbi et al. 2015; Haim et al. 2012; Bar-Ziv et al. 2010, 2013; Drexler et al. 2012; Lador et al. 2013; Elbaz et al. 2010, 2011; Elbaz, Mor, et al. 2014; Lubovsky et al. 2015; Herman et al. 2018; Reichenbach et al. 2020; Miles and Greene 2020; Barzilay et al. 2015; Elbaz et al. 2009; Lee et al. 2018; Elbaz et al. 2013; Haim et al. 2013; Atoun et al. 2016; Elbaz, Debbi, et al. 2014; Yaari et al. 2015; Debbi et al. 2019; Drexler et al. 2013; Solomonow-Avnon et al. 2017; Segal et al. 2013; Tenenbaum et al. 2017) (Figure 2). Patients are instructed to wear a personally calibrated device for 30-60 minutes a day while performing their daily activities at home or work (usage time may increase gradually, depending on progress and symptoms). The application of the treatment comprises the functional rehabilitation principle, which stresses the importance of task-specific rehabilitation with repetitive and sub-conscious activities (Levin, Weiss, and Keshner 2015; Charlton et al. 2021). The treatment has a detailed methodology. A trained clinician conducts an in-depth assessment of the patient's movement patterns and the root causes of their pain. This consultation includes questionnaires related to pain, joint function, and quality of life, an interview, computerized gait analysis, and physical examination. Once the patient has been evaluated, the clinician personalizes the Apos foot-worn device by calibrating the under-sole pods to the patient's specific needs, validates the location of the pods using subjective and objective measures, and then prescribes a personalized program for the patient (supplement video 1). For example, in medial compartment knee OA, shifting the biomechanical elements laterally causes a lateral shift of the COP that leads to a reduction in KAM (Haim et al. 2008, 2011). Furthermore, shifting the biomechanical elements anteriorly causes an anterior shift of the COP and reduces knee flexion moment (Haim, Rozen, and Wolf 2010).

Clinically, there is growing evidence on the effectiveness of this therapy in several MSK conditions, including knee OA, (Goryachev, Debbi, Haim, Rozen, et al. 2011; Debbi et al. 2015; Haim et al. 2012; Bar-Ziv et al. 2010, 2013; Drexler et al. 2012; Lador et al. 2013; Elbaz et al. 2010, 2011; Elbaz, Mor, et al. 2014; Lubovsky et al. 2015; Herman et al. 2018; Reichenbach et al. 2020; Miles and Greene 2020) low back pain (Barzilay et al. 2015; Elbaz et al. 2009; Lee et al. 2018), degenerative meniscal tear (Elbaz et al. 2013) anterior knee pain (Haim et al. 2013) spontaneous osteonecrosis of the knee (Atoun et al. 2016), total knee arthroplasty (Elbaz, Debbi, et al. 2014; Yaari et al. 2015; Debbi et al. 2019), hip OA, (Drexler et al. 2013; Solomonow-Avnon et al. 2017), total hip arthroplasty (Segal et al. 2013), and recurrent ankle sprain (Tenenbaum et al. 2017). In summary, patients report a significant reduction in pain and improved function and quality of life. In addition, a significant improvement is also seen in objective gait metrics, including spatiotemporal, kinetic, and kinematic parameters. Lastly, there are no serious adverse events related to the treatment, and patients report high compliance with the treatment program (Elbaz et al. 2013).

We classified the evidence into two main areas: prospective clinical trials, RCT, or single cohort 3D motion analysis, done in a controlled environment with a pre-defined, rel-

atively homogeneous patient population. The second one, equally important, is real-life evidence demonstrating the effectiveness in a heterogenic population suffering from multiple MSK conditions, frequently with severe comorbidities. Both methodologies complement each other and address different aspects, yet the effectiveness of the treatment on patients' symptoms was significant in both routes. Whether in a controlled environment or in real-life clinical practice, the clinical outcomes following treatment meet the gold-standard clinical significance threshold (Copay et al. 2018; Pham et al. 2004).

With respect to knee OA, studies show an improvement in biomechanical parameters and indicators of knee OA while walking with and without the device including a reduction in KAM (Haim et al. 2012), a reduction in knee flexion moment (Debbi et al. 2015), improvement in muscle activation (Goryachev, Debbi, Haim, Rozen, et al. 2011) and improvement in spatiotemporal gait patterns (Lador et al. 2013; Elbaz et al. 2010; Elbaz, Mor, et al. 2014; Lubovsky et al. 2015; Herman et al. 2018). The improvement in biomechanical indicators was associated with improved patient-reported outcome measures (PROMS), i.e., pain, functional disability, and quality of life (Bar-Ziv et al. 2010, 2013; Reichenbach et al. 2020). Recently, a double-blind RCT was published in The Journal of the American Medical Association (JAMA) (Reichenbach et al. 2020). Two hundred twenty (n=220) patients with knee OA were enrolled in a double-blind RCT that compared AposHealth to a sham device. Patients were assigned to one of two groups and were treated for six months. The primary outcome measure was the changes in pain and the secondary outcomes were function, QoL, gait patterns, and adverse events. A significant reduction in pain and improvement in function and quality of life was seen in the BMAG group with an average of 69% reduction of pain. 92% of the patients in the intervention group reported more than 30% reduction in pain, well above the minimal clinical important difference, and 83% of the reported more than 50% reduction in pain, a strong indication of the high efficacy with the number needed to treat (NNT) equal to three (Reichenbach et al. 2020). Another study evaluated the changes in KAM and symptoms of pain and functional disability in a sub-group analysis of disease severity measures by Kellgren and Lawrence (KL 2, KL 3-4) and found both groups to improve significantly. A trend towards increased improvement was seen in the more severe group (Haim et al. 2012). The treatment also seems to have a similar effect on sub-group analysis of age, BMI, and gender (Drexler et al. 2012; Lubovsky et al. 2015).

With respect to long-term data, a two-year follow-up study of patients with knee OA reported maintenance of clinical efficacy seen after 8 weeks over a 2-yr timespan (Bar-Ziv et al. 2010, 2013). Patients reported a 62% reduction in pain and a 61% improved function with a significant time-by-treatment interaction. Another retrospective study evaluated pain, function, and gait patterns at 12 months and reported a significant increase of 16% in gait velocity alongside a significant reduction of 46% in pain and 45% in functional disability (Lubovsky et al. 2015). Interestingly, BMAG was shown to have a superiority effect as a rehabilitation regimen for patients post-TKR compared to traditional PT – an important fact given the statistics that

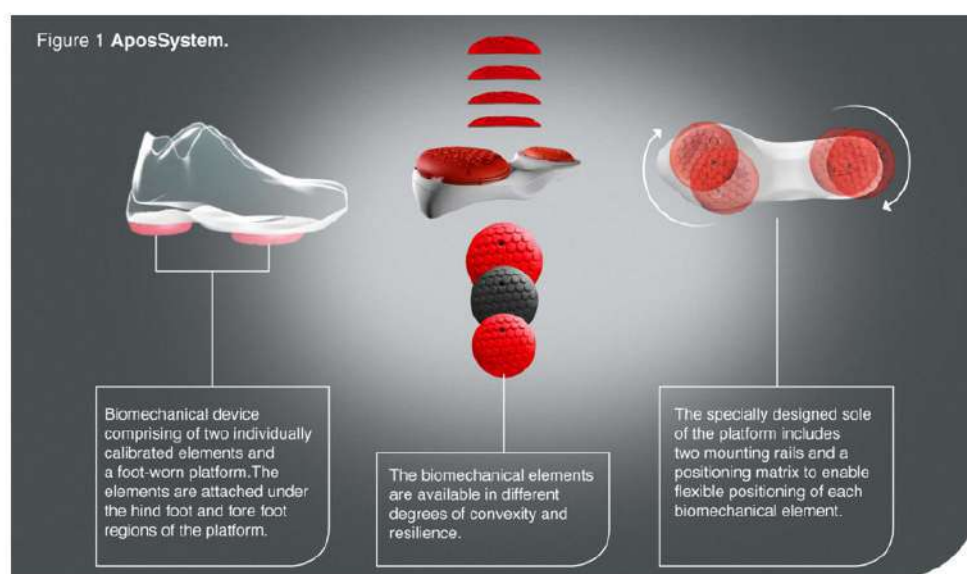


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Figure 2. The biomechanical device

suggest that 20%-30% of the post-TKR patients are with consistent pain (Yaari et al. 2015; Debbi et al. 2019; Wyld et al. 2011, 2018).

Although there is no published data on the cost-effectiveness of BMAG in knee OA population, one study showed a significant reduction of 58% in rescue medicine during a 2-month trial comparing the therapy to controls (Bar-Ziv et al. 2010). In a different study, the researchers reported that only 3% of patients with degenerative meniscal tear progressed to knee arthroscopy (Elbaz et al. 2013). One double-blind study with long-term two-year follow-up data on decay for total knee replacement reported that 2.6% of patients treated with BMAG required a TKR compared to 31% of patients in the control group, an absolute risk reduction of 28.4% (relative risk reduction of 92%), NNT = 3.5 (Bar-Ziv et al. 2013). There is a need for additional studies evaluating the cost-effectiveness of this intervention as well as the long-term (>2 yrs.) effect.

Some limitations should be acknowledged. First, this article was not aimed to perform a systematic review of non-invasive biomechanical interventions for patients with knee OA. For that reason, we did not conduct a literature review and some information might be missing. Secondly, we provided a summary of evidence of a non-invasive biomechanical intervention and relied on the available scientific evidence to date of the review. There are only two large RCTs that assessed the clinical effect of the treatment and some small-size trials looking at long-term outcomes compared to controls. Although it appears that this intervention has positive results with minimal risks, more trials are warranted to determine the long-term effect of the treatment.



Supplement: A link to a YouTube video of the before & after effect.

CONCLUSIONS

The increased prevalence of knee OA and its associated burden on the healthcare system, society, the individual, and caregivers is worrying. Moreover, the projections of annual rates of TKRs, the end-stage solution for patients with knee OA, and revision TKR are alarming. There is an urgent need for a systematic change to control these projections. In the presence of Value-Based Payment considerations to improve efficiency and effectiveness in delivering medical care, the entire healthcare system should be accountable for both quality and cost of care. With the recommendation

of improving population and policymaker awareness of the importance and benefits of managing knee OA, including new solutions for an increasing number of people living with disability associated with knee OA is warranted. The reviewed non-invasive, home-based biomechanical intervention was found to be safe and effective for patients with knee OA and we believe that it has the potential to be of value to patients.

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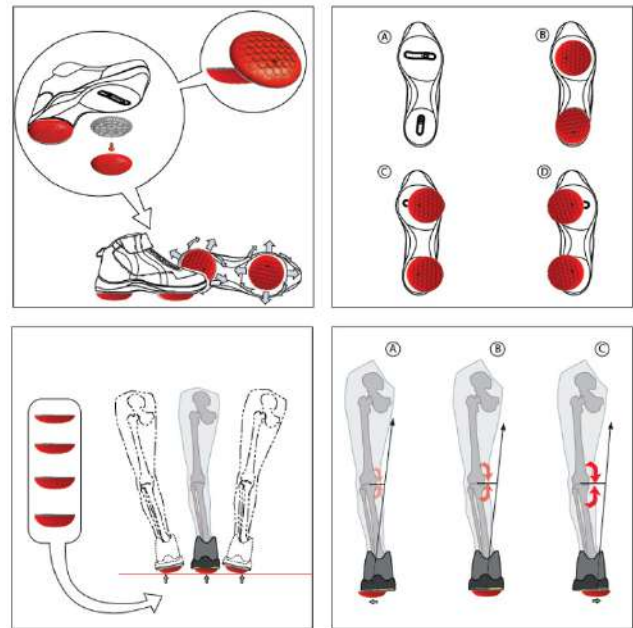


Figure 3. Mechanism of action



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1 Clinical Outcomes



JAMA | Original Investigation

Effect of Biomechanical Footwear on Knee Pain in People With Knee Osteoarthritis

The BIOTOK Randomized Clinical Trial

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IMPORTANCE Individually calibrated biomechanical footwear therapy may improve pain and physical function in people with symptomatic knee osteoarthritis, but the benefits of this therapy are unclear.

OBJECTIVE To assess the effect of a biomechanical footwear therapy vs control footwear over 24 weeks of follow-up.

DESIGN, SETTING, AND PARTICIPANTS Randomized clinical trial conducted at a Swiss university hospital. Participants (N = 220) with symptomatic, radiologically confirmed knee osteoarthritis were recruited between April 20, 2015, and January 10, 2017. The last participant visit occurred on August 15, 2017.

INTERVENTIONS Participants were randomized to biomechanical footwear involving shoes with individually adjustable external convex pods attached to the outsole (n = 111) or to control footwear (n = 109) that had visible outsole pods that were not adjustable and did not create a convex walking surface.

MAIN OUTCOMES AND MEASURES The primary outcome was knee pain at 24 weeks of follow-up assessed with the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscore standardized to range from 0 (no symptoms) to 10 (extreme symptoms). The secondary outcomes included WOMAC physical function and stiffness subscores and the WOMAC global score, all ranging from 0 (no symptoms) to 10 (extreme symptoms) at 24 weeks of follow-up, and serious adverse events.

RESULTS Among the 220 randomized participants (mean age, 65.2 years [SD, 9.3 years]; 104 women [47.3%]), 219 received the allocated treatment and 213 (96.8%) completed follow-up. At 24 weeks of follow-up, the mean standardized WOMAC pain subscore improved from 4.3 to 1.3 in the biomechanical footwear group and from 4.0 to 2.6 in the control footwear group (between-group difference in scores at 24 weeks of follow-up, -1.3 [95% CI, -1.8 to -0.9]; $P < .001$). The results were consistent for WOMAC physical function subscore (between-group difference, -1.1 [95% CI, -1.5 to -0.7]), WOMAC stiffness subscore (between-group difference, -1.4 [95% CI, -1.9 to -0.9]), and WOMAC global score (between-group difference, -1.2 [95% CI, -1.6 to -0.8]) at 24 weeks of follow-up. Three serious adverse events occurred in the biomechanical footwear group compared with 9 in the control footwear group (2.7% vs 8.3%, respectively); none were related to treatment.

CONCLUSIONS AND RELEVANCE Among participants with knee pain from osteoarthritis, use of biomechanical footwear compared with control footwear resulted in an improvement in pain at 24 weeks of follow-up that was statistically significant but of uncertain clinical importance. Further research would be needed to assess long-term efficacy and safety, as well as replication, before reaching conclusions about the clinical value of this device.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: [NCT02363712](https://clinicaltrials.gov/ct2/show/study/NCT02363712)

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Avoidance of Total Knee Replacement in a Population Health Setting: Introducing a Noninvasive Biomechanical Intervention for Patients with Knee Osteoarthritis

Ian S. Drew,¹ Marc Hoffing,² Charles Lim,² David Leece,² Matt Suess,³ and Richard Merkin⁴

Abstract

The observed increase in osteoarthritis (OA) of the knee as a result of an aging population and the obesity epidemic has led to a concomitant increase in the rates of total knee replacement (TKR), placing an additional financial and social burden on the ability of health care systems to control medical costs. Our study shows how a home-based, noninvasive biomechanical intervention reduced the rate of progression to surgery for a cohort of 237 patients with knee OA deemed eligible for TKR based on pre-established clinical selection criteria. Over the 24-month study period, 204 patients (86%) avoided surgery, with only 33 patients (14%, 95% confidence interval 82%–91%) progressing to a TKR with an average length of time to TKR of 324 days (ranging from 31 to 671 days). The application of this intervention provides health plans and provider networks managing patient care under financial risk arrangements an opportunity to realize significant cost savings without compromising quality of care or clinical outcomes.

Keywords: knee osteoarthritis, total knee replacement, nonsurgical intervention, financial risk management

Introduction

OSTEARTHRTIS (OA) RANKS AS THE 15th highest cause of the number of years lived with a disability.¹ OA is known to negatively impact the quality of life (QoL) in older adults by causing poor functional ability, pain-related distress, depression, and feelings of social isolation.² Both aging and rising rates of obesity are contributors to the increase in the prevalence of knee OA.³ In the absence of therapies that are able to reverse the pathology of OA, patients are required to live with their chronic disability and pain.

Treatments for patients with knee OA aim to alleviate symptoms, provide joint stability, and postpone disease progression.⁴ Standard treatments include arthritis education, structured land-based exercise programs, neuromus-

cular training, and dietary weight management. However, the efficacy of nonsurgical interventions for patients with knee OA is both limited and short term.⁵ As a result, patients oftentimes choose surgery to alleviate their pain, and regain functionality and QoL. Data show that over half of the US adults diagnosed with knee OA will undergo a total knee replacement (TKR) as an end-stage solution.⁶

In 2017, almost a million primary knee arthroplasties were performed in the United States⁷ with no signs that the number of arthroplasties performed will abate. A study by Singh et al in 2019 estimates that by 2040, the number of arthroplasties will rise to ~3 and a half million TKRs.⁸ At the same time, because the average age for a TKR is falling, the prevalence of revision knee surgery is also expected to rise. By 1 estimate, there will be 700,000 revision surgeries performed by 2050.⁹

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Manuscripts

Surgery avoidance rates among total knee replacement candidates following a non-invasive biomechanical intervention: A retrospective cohort study

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Keywords: Knee osteoarthritis, Pain, Function, Gait, Biomechanical treatment, TKR

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Background

Nearly twenty million people are affected by osteoarthritis (OA) across the UK. For end-stage knee OA, total knee replacement (TKR) is considered as the standard of care, but this major surgery carries high costs, long waiting lists, and risk for further revision surgeries. Health systems are therefore looking for effective alternatives to treat these cohorts, significantly delaying, and potentially avoiding joint replacement surgery altogether. The purpose of this study was to examine the 2-year surgery avoidance rate amongst TKR candidates that received a non-invasive biomechanical intervention.

Methods

A retrospective clinical audit was conducted on 365 NHS patients with end-stage knee OA patients eligible for TKR. Each patient was individually fitted with a non-invasive, shoe-like, biomechanical device, that alters the foot center of pressure, minimizes reported symptoms, and promotes neuromuscular control training using convex pods under the sole. Patients used the device for short periods during activities of daily living and were followed for two years. The primary outcome was surgery status after 2 years. Secondary outcomes were evaluated using the generalized linear mixed-models procedure and included changes in pain, function (WOMAC and Oxford Knee Score (OKS)), and spatiotemporal gait measured at 3, 6, 12, and 24 months from baseline.

Results

Of the 365 candidates for TKR, 305 (84%) avoided surgery at 2 years. Patients displayed significant clinical improvements over time. Six months after starting treatment, average pain decreased by 42%, average function improved by 39%, and average OKS increased by 7.6 points. These continued to improve over the 2 years. All spatial-temporal gait measures improved over time ($p < 0.001$).

Conclusions

The current results suggest that a non-invasive biomechanical treatment may help end-stage knee OA patients delay knee replacement surgery for at least 2 years or avoid it altogether. This treatment may provide an effective non-surgical alternative for managing these patients in the community, alleviating pain, and improving gait and function.

BACKGROUND

Osteoarthritis (OA) is a major cause of pain and disability, with 18.8 million people being affected across the UK. In England, one in five people over the age of 45 has knee OA (Versus Arthritis, n.d.) and the rates are constantly increasing due to an aging population and a rise in obesity. Knee OA leads to major social, psychological, and economical burdens with a substantial financial burden to the individual and society. Overall annual costs of OA to the healthcare system are estimated to be £10.2 billion (Woolf 2018).

Total knee replacement (TKR) is considered the most common and effective treatment for end-stage knee OA. Yet, as with any surgical intervention, TKR poses some risks including post-operative complications, persistent pain, and the need for revision surgery (Weinstein et al. 2013; Wylde et al. 2011, 2018). Furthermore, TKR carries a high cost, which is expected to rise as the demand for TKR grows, adding yet a greater burden to the healthcare system.

Interestingly, since the COVID-19 pandemic and the need to postpone a huge number of surgeries, the waiting

SHORT REPORT

Long-term outcomes on the rates of total knee replacement amongst patients with end-stage knee osteoarthritis who meet surgical criteria and received a non-invasive biomechanical intervention

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KEYWORDS

biomechanics, function, non-surgical intervention, pain, surgery avoidance, total knee replacement

1 | INTRODUCTION

In the UK, one in five people over 45 years of age have knee osteoarthritis (OA) (Felson et al., 1987). Currently, the overall annual costs of OA to the healthcare system are estimated to be £10.2 billion and are expected to increase (Woolf & Pfleger, 2003). Although total knee replacement (TKR) is considered the most common and effective treatment for end-stage knee OA, it poses some risks, including post-operative complications, persistent pain, and the need for revision surgery (Weinstein et al., 2013; Wylde et al., 2011, 2018). Conservative estimates project that by 2035 there will be 120,000 TKRs annually in the UK, while other projections suggest figures to be as high as 1.2 million TKRs annually. Either way, there is an acknowledgement of the lack of system capacity to be able to manage such rises and their significant contribution to the financial burden on the healthcare system. With the constant increase in the rates of TKR and the additional pressures that the COVID-19 pandemic has placed on elective care pathways, the healthcare systems are looking for effective non-surgical alternatives to reduce some of the burden.

In 2022, we published research that summarised the two-year outcomes of a commercial audit (Greene & Miles, 2022). An NHS Clinical Commissioning Group had been utilising a non-surgical biomechanical solution for patients with knee OA who met the criteria for orthopaedic referral for TKR between 2017 and 2019. The

service's objective was to improve knee OA patients' care and manage their condition conservatively. The Primary outcome measure was the incidence rate of TKR within 2 years since treatment inception. Secondary outcome measures looked at the clinical effect, including a reduction in pain and improvement in function using standard Patient Reported Outcome Measures and computerised gait analysis. Of the 365 patients, 306 (84%) avoided surgery at two years. Twenty-three patients (6%) had surgery during the first year, and 36 patients (10%) had surgery during their second year of treatment. Patients displayed significant clinical improvements over time. Six months after starting treatment, pain decreased by 42%, function improved by 39%, and the Oxford Knee Score (OKS) increased by 7.6 points. Clinical outcomes continued to improve over the 2 years.

The National Institute of Clinical Excellence (NICE) recently published its recommendation about this intervention finding it safe, clinically effective and cost-saving (NICE, 2022). The NICE highlighted the need for longer-term data on surgery avoidance and its impact on quality of life. With this in mind, and to provide more information on the long-term effect of this biomechanical intervention in patients with severe knee OA who meet the criteria for TKR, we conducted a follow-up study on the original research adding another year of follow-up (i.e., 3 years) on the same cohort. Patients received ongoing care and continued to use the biomechanical intervention as part of a 3-year program which allowed us to continue and monitor their outcomes over a longer time frame.

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ORIGINAL ARTICLE

Non-Invasive Biomechanical Intervention Leads to Low Rates of Total Knee Replacement and Reduced Utilization of Healthcare Resources among Older Adults with Chronic Knee Pain: A 5-Year Follow-Up Study

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Abstract

Background: Chronic knee pain, primarily associated with knee osteoarthritis (OA), is a leading cause of disability among older adults and place an immense burden on patients and healthcare systems, exceeding \$80 billion in direct medical costs annually. Current non-surgical solutions to treat chronic knee pain provide limited relief of symptoms. The present study aims to assess the long-term effect of a biomechanical, non-invasive intervention on total knee replacement (TKR) incidence and the utilization of healthcare resources over five years.

Methods: This was a retrospective study among older adults with chronic knee pain, primarily due to OA, who received the biomechanical intervention between 2014 and 2017. An independent survey institute contacted patients between August and September 2022 to confirm their surgical status and utilization of other healthcare services, covering at least five years of follow-up. During the intervention, patients were provided with a FDA-cleared shoe-like device, which includes two convex pods attached to the sole. The pods are attached to the shoe in a customized manner based on the patient's gait and pain (i.e., calibrated). The device shifts the foot's center of pressure to reduce the knee joint load and alleviate pain. The device also creates controlled perturbation that challenges gait and posture stability and creates neuromuscular training. Patients were instructed to wear the device for up to 2-3 hours a day during their daily routine and invited to follow-up sessions for treatment modifications.

Results: Four hundred and fourteen patients responded to the survey. Their mean (SD) age was 66.5 (4.2) years, 65% were women and 82% of patients were diagnosed with knee OA. At five years since inception, the TKR incidence rate

was 18.4% with 95% CI (14.6%, 22.1%). Most responders (79%) reported using other healthcare resources and services to treat their knee pain before the intervention. Of them, 64% ceased receiving intra-articular injections to the knee, 44% discontinued using pain medication and 46% stopped receiving physiotherapy.

Conclusion: This biomechanical, non-invasive intervention is a beneficial and sustainable intervention that reduces healthcare resource utilization, including avoidance of TKR and chronic knee pain. With the constant increase in the prevalence of chronic knee pain, offering this intervention to patients can help address the increasing burden on the healthcare system and society.

Trial registration: NIH protocol no. NCT00767780

Keywords

Total knee replacement, Knee, Osteoarthritis, Pain, Healthcare resource, Biomechanical device

Abbreviations

OA: Osteoarthritis; TKR: Total Knee Replacement

Introduction

Chronic knee pain is a leading cause of disability among older adults. Between 18.1% and 23.5% of Americans older than 60-years-old report having significant knee pain, which was also associated with difficulties in performing physical function activities [1,2]. Loss of function and persistent pain generate substantial social and economic burden, accumulating

Utilising a non-surgical intervention in the knee osteoarthritis care pathway: a 6-year retrospective audit on NHS patients

Robyn Benn , Lewis Rawson and Amanda Phillips

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Abstract

Background: Knee osteoarthritis (OA) is a chronic, debilitating, musculoskeletal condition that affects millions. The increase in prevalence and its economic impact on healthcare and society raise the need for additional non-surgical interventions.

Objective: To assess the referral rates to secondary care consultation and clinical outcomes in patients with severe knee OA treated with a home-based, non-surgical intervention.

Design: This was a retrospective audit on 571 patients with knee OA who met the clinical criteria for total knee replacement (TKR) and received the service between October 2015 and March 2020.

Methods: Patients were treated with a non-surgical, home-based, biomechanical intervention that aims to reduce pain and improve function, involving a foot-worn device for gait rehabilitation. The device is adjusted to the patient based on their gait patterns and clinical symptoms. Patients are advised to use the device at home or work and continue their routine. Patients are also advised to return to follow-up appointments to readjust the device and treatment plan. The primary outcome measure was the referral rates to secondary care consultation. Secondary outcomes included patient-reported outcome measures to assess pain and function and a computerised gait test. Follow-up time was between 1 and 6 years post-treatment initiation with a mean follow-up time of 1308.1 (SD=473.4) days (i.e. 3.5years.).

Results: There were 65 (11.4%) referrals for secondary consultation with an average follow-up of 3.5years. The mean days to referral was 480.9 (SD=399.2) days. Of all referrals, 48% ($n=31$) occurred during the first year of treatment, and 32% ($n=21$) occurred during the second year. The rest were after more than 2 years of treatment.

Significant improvements were seen in all clinical outcomes, including a reduction in pain and an improvement in function and gait patterns ($p < 0.05$ for all).

Conclusion: Utilising this intervention as a non-surgical option for patients with knee OA who met the clinical criteria for TKR led to a significant reduction in pain and improvement in function after 3 months that was maintained for up to 3 years. Most patients (89%) did not proceed to secondary care consultation during their time in treatment for up to 6 years.

Plain language summary



Utilisation of a non-invasive biomechanical intervention improves pain and function and helps postpone total knee replacement

Knee osteoarthritis is a degenerative disease that causes pain and functional limitations. Currently, most of the treatments aim to address symptoms (reducing pain and improving function). Those include traditional physical therapy, exercise, body mass loss if appropriate. Other treatments include pain relief medications and intra-articular corticosteroid knee injections. Knee surgery is considered the end-stage solution if the patient has tried all

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INCIDENCE OF KNEE SURGERIES OVER 5 YEARS AMONG PATIENTS WITH KNEE OSTEOARTHRITIS TREATED WITH A NON-INVASIVE, HOME-BASED, BIOMECHANICAL INTERVENTION

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ABSTRACT

Background: The annual demand for total knee arthroplasty (TKA) will increase by 182%, from more than 700,000 in 2014 to 1.2M in the year 2030, placing an immense financial and social burden on healthcare systems to control medical costs and quality of care. This study aimed to examine the long-term effect of a home-based, non-surgical biomechanical intervention on surgery incidence amongst patients with moderate-severe knee osteoarthritis (OA).

Methods: This is a retrospective registry review done at the Department of Rehabilitation Medicine of Albert Einstein College of Medicine, Montefiore Medical Center. Between September 2015 and December 2018, 95 patients (81% females, mean age 62.6±8.3 years) diagnosed with primary knee OA were referred to receive a new non-invasive biomechanical foot-worn device after exhausting other non-surgical care. Patients were personally fitted with a non-invasive, biomechanical device, that alters the foot's pressure points to reduce loads, minimize symptoms, and promote neuromuscular control training using adjustable, convex pods under the sole. Patients used the device for short

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Other Conditions

Reduction in Healthcare Resource Utilization Following Treatment With a Home-Based Footworn Device in Patients With Knee Osteoarthritis: A Retrospective Claims Analysis

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ABSTRACT

Background: One in 7 US adults has knee osteoarthritis (OA) and almost two-thirds of them suffer from low back pain. OA is the third most rapidly rising condition associated with disability and leads to a significant burden on the healthcare system and society.

Objective: This study looked at the healthcare resource utilization (HCRU) in patients with knee OA and low back pain before and after the utilization of a new, home-based, noninvasive, biomechanical intervention.

Methods: This was a retrospective claims analysis of 585 patients treated with a personalized, noninvasive, home-based, biomechanical treatment that aims to alleviate knee pain and improve function (AposHealth®). The date of the first AposHealth claim was the index date. Data prior to the index date and post-index date were used to monitor changes in HCRU while in treatment. Descriptive statistics, including frequencies, means and standard deviations, were used to present patient characteristics. To standardize the results, an average monthly claims data rate was calculated and an expected annual rate was extrapolated. Annual HCRU rate per 1000 members was calculated.

Results: HCRU decreased after utilizing the new intervention including a decrease of 79% in diagnostic claims, a 70% decrease in outpatient services, a 22% decrease in non-operative treatments, a 61% decrease in pain medications including an 85% drop in opioids use, and a 44% decrease in intra-articular injections. The pre-index estimated rate for total knee replacement (TKR), which is based on existing literature, was 15.1%, whereas the post-index rate of TKR was 0.9%.

Conclusions: Patients with knee OA treated with a home-based, noninvasive, biomechanical intervention incurred fewer healthcare resources, leading to an overall reduction in the cost of care.

INTRODUCTION

Knee osteoarthritis (OA) is a prevalent degenerative joint disease characterized by the progressive breakdown of articular cartilage, leading to pain, stiffness, and impaired mobility.^{1,2} It is a leading cause of disability and a significant burden on healthcare systems worldwide.^{1,3} One in 7 US adults (32.5 million people) has knee OA,² and almost two-thirds of them suffer from low back pain.⁴ The prevalence of OA is the third most rapidly rising condition associated with disability, just behind diabetes and dementia,⁵ and the numbers are expected to grow with the aging of the population. It is estimated that by 2032, the number of people with knee OA will increase, and 1 in 6 people older than 45

years will seek physician consultation due to knee pain.⁶ In the United States, the estimated lifetime cost of a patient diagnosed with knee OA is \$140 300; over half of all patients will have a total knee replacement (TKR).⁷ The overall economic burden of knee OA is estimated at \$27 billion annually⁷ and is expected to rise with the increase in prevalence, highlighting the need for better disease management, new nonsurgical interventions, and technologies that will be effective and ideally demonstrate cost savings.

The management of knee OA involves a multidisciplinary approach, including nonpharmacological, pharmacological, and surgical interventions.⁸ Nonpharmacological interventions may include weight management, exercise programs, physical therapy, assistive



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Noninvasive biomechanical therapy improves objective and subjective measurements of pain and function in patients with knee osteoarthritis: a retrospective analysis

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ABSTRACT

Background:

Biomechanical interventions for the management of knee osteoarthritis (OA) are emerging. AposTherapy is one type of biomechanical therapy that has been shown to reduce knee adduction moment and improve gait patterns and clinical symptoms. The purpose of the current study was to further investigate the changes in gait patterns after this biomechanical therapy and to define its possible clinical benefits for patients with knee OA.

Methods:

Four hundred and twelve patients with knee OA were evaluated using a computerized gait test, as well as the Western Ontario and McMaster Osteoarthritis Index (WOMAC) and the SF-36 Health Survey self-evaluation questionnaires. After these measurements, the Apos system was individually calibrated to each patient according to his or her gait patterns and clinical evaluation. All patients received exercise guidelines and underwent 3 months of therapy. A second evaluation of gait and clinical symptoms was conducted after 3 months of therapy.

Results:

After 3 months of therapy, a significant improvement was found in all gait parameters (all $P < 0.01$), as well as in the level of pain, function, and quality of life (all $P < 0.01$). High correlations were found between the improvement in gait parameters and the improvement in self-evaluation questionnaires.

Conclusions:

The examined biomechanical therapy led to a significant reduction in pain and improvement in function, quality of life, and gait patterns. These findings support previous findings and deepen the understanding of this new noninvasive biomechanical therapy in patients with knee OA.

Key Words

knee, osteoarthritis, gait, pain, biomechanical therapy

INTRODUCTION

Osteoarthritis (OA) is the most prevalent form of arthritis.^{1,2} More than one third of elderly Americans over the age of 70 years have some degree of radiographic findings indicating knee OA,^{1,2} and approximately 10-12% of adults have symptomatic OA.³ Rates of knee OA are 1.7 times higher in women than in men⁴ and positively correlate with obesity.⁵ Common symptoms include pain, joint stiffness, tenderness, deformity, and muscle weakness. These symptoms may considerably alter a patients' function and quality of life.^{4,6} It is estimated that by the year 2020, the number of people with OA will have doubled because of the exploding prevalence of obesity and the aging of the baby boomer generation.⁷ One of the main goals of nonsurgical management of knee OA focuses on reducing knee pain and minimizing the accompanying functional limitation.

Patients with knee OA demonstrate pathologic gait patterns compared with healthy age-matched controls.^{8,9} Patients with knee OA tend to have a slower walking speed, shorter step length, and shorter single-limb support (SLS).^{8,10} In addition, patients with knee OA demonstrate elevated knee adduction moment (KAM) values compared with matched controls.^{11,12} The KAM is a primary biomechanical factor in knee OA. It tends to adduct the tibiofemoral joint, providing a major contribution to the elevated medial compartment loads. Subsequently, KAM was found to correlate with the progression of knee OA.¹³ One of the reasons for the altered gait patterns of these patients is impaired neuromuscular control.^{14,15} This impaired neuromuscular control affects the coordinated activity of the muscles surrounding the knee and its dynamic joint

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Effects of a customized biomechanical therapy on patients with medial compartment knee osteoarthritis

Effets d'une thérapie biomécanique sur des patients atteints de gonarthrose du compartiment fémorotibial interne

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Abstract

Objective. – Previous studies have shown that a customized biomechanical therapy can improve symptoms of knee osteoarthritis. These studies were small and did not compare the improvements across gender, age, BMI or initial severity of knee osteoarthritis. The purpose of this study was to evaluate the effect of new biomechanical therapy on the pain, function and quality of life of patients with medial compartment knee osteoarthritis. **Methods.** – Six hundred and fifty-four patients with medial compartment knee osteoarthritis were examined before and after 12 weeks of a personalized biomechanical therapy (AposTherapy). Patients were evaluated using the Western Ontario and McMaster Osteoarthritis (WOMAC) Index and SF-36 Health Survey.

Results. – After 12 weeks of treatment, the WOMAC-pain and WOMAC-function subscales were significantly lower compared to baseline (both $P \leq 0.001$). All eight categories of the SF-36 health survey significantly improved after treatment (all $P \leq 0.001$). Females and younger patients showed greater improvements with therapy.

Conclusions. – Twelve weeks of a customized biomechanical therapy (AposTherapy) improved symptoms of patients with medial compartment knee osteoarthritis. We recommend that this therapy will be integrated in the management of knee osteoarthritis.

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Keywords: Knee; Osteoarthritis; Gait; Pain; AposTherapy

Résumé

Objectifs. – Des études ont montré qu'une thérapie biomécanique adaptée pouvait améliorer les symptômes de gonarthrose. À ce jour, toutes les études publiées sur cette nouvelle thérapie concernaient des petits échantillons de patients et ne comparaient pas les améliorations en fonction de l'âge, sexe, IMC ou la sévérité initiale de la gonarthrose. Le but de cette étude était d'évaluer l'impact de cette nouvelle thérapie biomécanique sur la douleur, capacité fonctionnelle et qualité de vie des patients avec une gonarthrose du compartiment fémorotibial interne.

Méthodes. – Six cent cinquante-quatre patients avec une gonarthrose du compartiment fémorotibial interne étaient suivis avant et après 12 semaines d'un programme thérapeutique biomécanique spécifique (AposTherapy). Les patients étaient évalués avec l'index Western Ontario and McMaster Osteoarthritis (WOMAC) et le questionnaire généraliste de santé SF-36.

Résultats. – Après 12 semaines de traitement, les scores du WOMAC-douleur et du WOMAC-capacité avaient diminué de façon significative en comparaison avec les données initiales (les deux $p \leq 0,001$). Les huit catégories du SF-36 étaient considérablement améliorées après traitement (toutes $p \leq 0,001$). Les femmes et les patients jeunes ont montré un niveau d'amélioration plus important après le traitement.

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Research Article

Long-Term Effects of AposTherapy in Patients with Osteoarthritis of the Knee: A Two-Year Followup

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Several biomechanics treatments for knee osteoarthritis (OA) have emerged with the goal of reducing pain and improving function. Through this, researchers have hoped to achieve a transition from the pathological gait patterns to coordinated motor responses. The purpose of the study was to determine the long-term effects of a therapy using a biomechanical device in patients with knee OA. Patients with knee OA were enrolled to active and control groups. The biomechanical device used in therapy (AposTherapy) was individually calibrated to each patient in the active group. Patients in the control group received standard treatment. Outcomes were the Western Ontario and McMaster Osteoarthritis Index (WOMAC), Aggregated Locomotor Function (ALF), Short Form 36 (SF-36), and Knee Society Score assessments. The active and control groups were similar at the baseline (group difference in all scores $P > 0.05$). The active group showed a larger improvement over time between groups in all three WOMAC categories ($F = 16.8, 21.7$, and 18.1 for pain, stiffness, and function; all $P < 0.001$), SF-36 Physical Scale ($F = 5.8$; $P = 0.02$), Knee Society Knee Score ($F = 4.3$; $P = 0.044$), and Knee Society Function Score ($F = 6.5$; $P = 0.014$). At the two-year endpoint, the active group showed significantly better results (all $P \leq 0.001$). The groups showed a difference of 4.9, 5.6, and 4.7 for the WOMAC pain, stiffness, and function scores, respectively, 10.8 s in ALF score, 30.5 in SF-36 Physical Scale, 16.9 in SF-36 Mental Scale, 17.8 in Knee Society Knee Score, and 25.2 in Knee Society Function Score. The biomechanical therapy examined was shown to significantly reduce pain and improve function and quality of life of patients with knee OA over the long term.

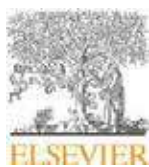
1. Introduction

Knee osteoarthritis (OA) is one of the leading causes of disability in the elderly [1]. Currently, there is no cure for knee OA, and therefore, the primary goal of treatment is to reduce pain and improve function [2]. In recent years, there has been growing evidence on the importance of biomechanical factors in knee OA. Several biomechanical treatments for knee OA have emerged with the goal of reducing pain and improving function. These treatments aim to unload the diseased articular surface by using wedged insoles, foot orthoses, or valgus braces [3–5]. Other treatments have instead aimed to modify neuromuscular patterns, with a specific goal of improving gait patterns.

The knee adduction moment (KAM) is an important parameter of gait that has been examined in recent years. A

varus alignment of the femur and tibia compresses the medial compartment of the knee [6]. KAM results from the medially directed vector of the ground reaction force (GRF) relative to the knee during the stance phase of gait, which creates greater compressive loads on the medial compartment relative to the lateral compartment [7, 8]. Patients with knee OA have a higher KAM relative to the normal population, which is believed to drive the rapid progression of the disease [9, 10].

By improving gait patterns, such as KAM, researchers have hoped to achieve a transition from the pathological gait patterns that characterize knee OA gait to coordinated motor responses [11]. This would require patients to undergo a process of motor learning. In order to meet the requirements for motor learning, these methods must incorporate challenges for the motor system in a graded and controlled fashion, with multiple repetitions within a functional context [12]. For



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Reduction in knee adduction moment via non-invasive biomechanical training: A longitudinal gait analysis study

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ABSTRACT

Biomechanical non-invasive interventions have been previously reported to reduce pain and facilitate superior levels of function in patients with medial knee osteoarthritis [OA]. One such treatment is the AposTherapy, a customized program utilizing a foot-worn biomechanical device allowing center of pressure modification and continuous perturbation during gait. The influence of this intervention on objective gait metrics has yet to be determined. The aim of the current study was to prospectively examine changes in kinetic and kinematic parameters in patients enrolled in this treatment program. Twenty-five females with symptomatic bilateral medial compartment knee OA were enrolled in the customized daily treatment program. All patients underwent barefoot gait analysis testing and completed subjective questionnaires prior to treatment initiation and on two follow-up visits. Significantly reduced knee adduction moment (KAM) magnitude was noted during barefoot walking after three and nine months of treatment. On average, the knee adduction impulse and the 1st and 2nd KAM peaks were reduced by 13%, 8.4%, and 12.7%, respectively. Furthermore, moment reduction was accompanied by elevated walking velocity, significant pain reduction, and increased functional activity. In addition to symptomatic improvement, our results suggest that this treatment program can alter kinetic gait parameters in this population. We speculate that these adaptations account for the symptomatic and functional improvement reported for this intervention.

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1. Introduction

Osteoarthritis (OA) is a complex disorder of the hyaline joints, characterized by wear, softening, and thinning of the articular cartilage and diminished compliance of the sub-chondral bone (Bijlsma et al., 2011; Felson and Zhang, 1998; Iannone and Lapadula, 2003). The knee is the most prevalent weight-bearing joint prone to the development of this destructive process, with the medial compartment affected nearly 10 times more often than the lateral compartment (Oliveria et al., 1995). Vast evidence supports the role of biomechanical factors in the pathophysiology of this disease (Radin et al., 1991). Abnormal joint loads have been related to the development and progression of the arthritic process (Radin et al., 1991; Roemhildt et al., 2010).

Abnormally high knee adduction moments (KAM) have been described in association with medial knee OA (Andriacchi, 1994; Sharma et al., 1998). Elevated KAM has been linked with the

progression of knee OA (Miyazaki et al., 2002), and has been recognized as a marker of disease severity (Hurwitz et al., 2002; Sharma et al., 1998).

Gait deviations have been reported in individuals suffering from knee OA (Baliunas et al., 2002; Debi et al., 2009; Elbaz et al., 2010; Gok et al., 2002; Hurwitz et al., 2000) and are thought to represent a compensatory protective mechanism intended to reduce stress and range of motion about the injured joint (Debi et al., 2009). With disease progression, altered morphological joint properties diminish the effectiveness of these mechanisms. Moreover, substantial evidence suggests that impairment of the neuromuscular control system and proprioceptive deficits are present in subjects suffering from knee OA and contribute to the load burden by altering joint biomechanics (Hortobagyi et al., 2005; Hurley, 2003; Johansson et al., 2000; Lewek et al., 2005). Several authors stressed the role of these contributions to the pathogenesis of the disease, suggesting that they convey elevated joint stress with higher impact loads and facilitate the development of cartilage degeneration (Sharma et al., 2003; Slemenda et al., 1998).

Biomechanical interventions focusing on foot center of pressure (COP) manipulation, agility, and perturbation training have been suggested for the treatment of knee OA (Bar-Ziv et al., 2010;

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RESEARCH ARTICLE

Open Access

A treatment applying a biomechanical device to the feet of patients with knee osteoarthritis results in reduced pain and improved function: a prospective controlled study

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Abstract

Background: This study examined the effect of treatment with a novel biomechanical device on the level of pain and function in patients with knee OA.

Methods: Patients with bilateral knee OA were enrolled to active and control groups. Patients were evaluated at baseline, at 4 weeks and at the 8-week endpoint. A novel biomechanical device was individually calibrated to patients from the active group. Patients from the control group received an identical foot-worn platform without the biomechanical elements. Primary outcomes were the WOMAC Index and ALF assessments.

Results: There were no baseline differences between the groups. At 8 weeks, the active group showed a mean improvement of 64.8% on the WOMAC pain scale, a mean improvement of 62.7% on the WOMAC function scale, and a mean improvement of 31.4% on the ALF scale. The control group demonstrated no improvement in the above parameters. Significant differences were found between the active and control groups in all the parameters of assessment.

Conclusions: The biomechanical device and treatment methodology is effective in significantly reducing pain and improving function in knee OA patients.

The study is registered at clinicaltrials.gov, identifier NCT00457132, <http://www.clinicaltrials.gov/ct/show/NCT00457132?order=1>

Background

Osteoarthritis (OA) is a major cause of disability in the older population [1], affecting nearly 21 million individuals in the United States alone [2]. Currently there is no cure for OA and treatment is focused on reducing pain and improving function [3].

There is a growing awareness of the importance of biomechanical factors in the pathogenesis and progression of knee osteoarthritis [4-6]. Studies have demonstrated a clinical association between loads, such as lifelong physical work [7], competitive sports [8,9], and obesity [10], and the formation and progression of

osteoarthritis [11]. These factors, together with the morphological changes in the musculoskeletal system that occur with age, affect the osteochondral structures [12-15] and neuromuscular control [16]. Neuromuscular control plays a significant part in determining the function and stability of the synovial joint [17] and in mediating the biomechanical structure of articular cartilage [18]. Impairment of the neuromuscular control system contributes to the pathogenesis of osteoarthritis by altering joint biomechanics and causing increased cartilage damage [19,20].

Two main types of non-surgical biomechanical interventions are available for reducing pain and improving function in patients with knee osteoarthritis. The logic behind the first type of intervention is unloading the diseased articular surface by means of wedge insoles,

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RESEARCH ARTICLE

Open Access

Patients with knee osteoarthritis demonstrate improved gait pattern and reduced pain following a non-invasive biomechanical therapy: a prospective multi-centre study on Singaporean population

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Abstract

Background: Previous studies have shown the effect of a unique therapy with a non-invasive biomechanical foot-worn device (AposTherapy) on Caucasian western population suffering from knee osteoarthritis. The purpose of the current study was to evaluate the effect of this therapy on the level of symptoms and gait patterns in a multi-ethnic Singaporean population suffering from knee osteoarthritis.

Methods: Fifty-eight patients with bilateral medial compartment knee osteoarthritis participated in the study. All patients underwent a computerized gait test and completed two self-assessment questionnaires (WOMAC and SF-36). The biomechanical device was calibrated to each patient, and therapy commenced. Changes in gait patterns and self-assessment questionnaires were reassessed after 3 and 6 months of therapy.

Results: A significant improvement was seen in all of the gait parameters following 6 months of therapy. Specifically, gait velocity increased by 15.9%, step length increased by 10.3%, stance phase decreased by 5.9% and single limb support phase increased by 2.7%. In addition, pain, stiffness and functional limitation significantly decreased by 68.3%, 66.7% and 75.6%, respectively. SF-36 physical score and mental score also increased significantly following 6 months of therapy (46.1% and 22.4%, respectively) ($P < 0.05$ for all parameters).

Conclusions: Singaporean population with medial compartment knee osteoarthritis demonstrated improved gait patterns, reported alleviation in symptoms and improved function and quality of life following 6 months of therapy with a unique biomechanical device.

Trial registration: Registration number NCT01562652.

Keywords: Knee, Osteoarthritis, Gait, Pain, Biomechanical device

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RESEARCH ARTICLE

Open Access



The effect of treatment with a non-invasive foot worn biomechanical device on subjective and objective measures in patients with knee osteoarthritis- a retrospective analysis on a UK population

Christopher Miles* and Andrew Greene

Abstract

Background: Osteoarthritis is a major cause of pain and disability worldwide, therefore ways of treating this condition are paramount to a successful health system. The purpose of the study was to investigate the changes in spatial-temporal gait parameters and clinical measurements following treatment with a non-invasive foot-worn biomechanical device on patients with knee osteoarthritis within the UK.

Methods: A retrospective analysis was carried out on 455 patients with knee osteoarthritis. All patients were evaluated using a computerized gait test and two self-assessment questionnaires (WOMAC and SF-36) at baseline and after 3 and 6 months of treatment. The biomechanical device is a shoe-like device with convex pods under the sole that have the capability of changing foot centre of pressure and training neuromuscular control. The device was individually calibrated for each patient to minimise symptoms whilst walking and train neuromuscular control. Patients used the device for short periods during activities of daily living. Repeated measures statistical analyses were performed to compare differences over time.

Results: After 6 months of treatment significant improvements were seen in all gait parameters ($p < 0.01$). Specifically, gait velocity, step length and single limb support of the more symptomatic knee improved by 13, 7.8 and 3%, respectively. These were supported by significant improvements in pain, function and quality of life (48.6, 45.7 and 22% respectively; $p < 0.001$). A sub-group analysis revealed no baseline differences between those who were recommended joint replacement and those who were not. Both groups improved significantly over time ($p < 0.05$ for all).

Conclusions: Our results suggest that the personalised biomechanical treatment can improve gait patterns, pain, function and quality of life. It may provide an additional solution to managing UK patients suffering from knee osteoarthritis but needs to be tested in a controlled setting first.

Keywords: Knee osteoarthritis, Gait, Pain, Function, Biomechanical treatment

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Alterations in Sagittal Plane Knee Kinetics in Knee Osteoarthritis Using a Biomechanical Therapy Device

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Associate Editor Amit Gefen oversaw the review of this article.

Abstract—Knee frontal (adduction/abduction) and sagittal (flexion/extension) moments have been implicated in the pathomechanics of knee osteoarthritis (OA). The aim of this study was to evaluate the change in the knee sagittal moment in a cohort of patients with knee OA undergoing a biomechanical training program. Twenty-five female patients with symptomatic medial compartment knee OA were enrolled in a customized biomechanical intervention program. All patients underwent consecutive gait analyses prior to treatment initiation, and after 3 months and 9 months of therapy. Self-evaluative questionnaires, spatio-temporal gait parameters, peak knee sagittal moments, knee sagittal impulses, and duration of knee moments were compared throughout the duration of therapy. Differences between baseline and follow-up values were examined using nonparametric tests. Peak knee flexion moment (KFM) at loading response decreased significantly with therapy ($p = 0.001$). Duration of KFM and impulse of knee flexion also decreased significantly ($p = 0.024$ and $p = 0.029$, respectively). These changes were accompanied by increased walking velocity, significant pain reduction, and increased functional activity. Post-training kinetic evaluation demonstrated profound alterations of knee sagittal moments at the loading response KFM. We speculate that knee sagittal moments can potentially be improved in patients with knee OA over time with a biomechanical training program.

Keywords—Kinetics, Moment, Flexion, Extension, Gait, Pain, Stiffness, Function.

INTRODUCTION

The role of biomechanics in the pathogenesis of knee osteoarthritis (OA) has been examined exten-

sively.^{1,19} Multiple studies have suggested that abnormal gait patterns may contribute to the disease progression.^{1,19} Knee OA patients walk with a slower velocity, greater double-limb support, reduced stride length, and decreased range of motion in all the lower limb joints.^{1,2,11} Bejek *et al.*⁴ analyzed the effect of gait speed on gait parameters in patients with OA and set a standard walking speed for gait analysis. They reported that 15 gait parameters (cadence, step length, walking base, time of swing phase and double support phase, motion of hip joint, motion of pelvis rotation, motion range of pelvis obliquity, maximal value and motion range of pelvis flexion) were significantly influenced by walking speed in patients with knee OA, and that the gait speed of 2.00 km/h was the highest gait speed suitable for all patients without pain and loss of coordination. In addition, they compared the gait patterns of patients with OA to healthy individuals. In comparison to healthy individuals, lower limb joint OA was compensated for in part by the pelvis and other joints in the lower limb.^{4,5}

With the advent of complex gait motion-analysis systems, researchers also examined the kinematic and kinetic gait changes in knee OA. Locomotion is generated through a balance of internal and external forces and moments acting on the lower limbs. Internal forces are comprised of both structural elements (bones, ligaments, cartilage, and more) and of muscles and tendons that are attached to the structural elements. The external forces result mostly from the ground reaction force (GRF). These internal and external forces create moments acting on the joint. Each magnitude of each moment is determined by the magnitude of the force and its sagittal distance from the center of rotation of the knee joint.³¹ The external moments are generated by the displacement of the

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Knee Osteoarthritis Functional Classification Scheme – Validation of Time Dependent Treatment Effect. One Year Follow-Up of 518 Patients

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Abstract

Objective: The purpose of the current study was to validate time dependent changes of a novel functional classification for patients with knee osteoarthritis (KOA), following a home-based biomechanical treatment (HBBT).

Methods: A retrospective analysis of 518 patients with KOA was conducted. All patients were classified using a novel knee osteoarthritis functional grade (KOFG) classification for KOA, based on spatio-temporal gait analysis. Patients were re-classified after 3 months and 1 year of HBBT to examine and validate this classification using time-dependant changes. The time dependent changes in the classification were compared to gold-standard self-assessment questionnaires, WOMAC and short form 36 (SF-36).

Results: The changes in KOFG were demonstrated over time, with most changes occurring after 3 months of treatment with consolidation of the effect at 12 months. For example, of 427 patients that were classified in KOFG 2-4 grade at baseline, 44.9% and 51.5% had lower (better) KOFG grades at 3 and 12 months of treatment, respectively. The changes in KOFG were validated with WOMAC and SF-36 questionnaires showing a significant correlation between KOFG changes and changes in WOMAC and SF-36. SF-36 pain sub-scale showed an improvement of 33.0% and 38.0% following 3 months and 12 months of treatment, respectively (p values <0.0001).

Conclusions: The results of the current study validate the knee osteoarthritis functional grade classification scheme as a tool to assess time dependant changes in KOA as well as its sensitivity to assess treatment effect. The KOFG can offer a more robust mode of reporting clinical results in describing the natural history and time-dependent treatment results of patients suffering from knee OA and should be considered as an additional outcome measure in future studies.

Keywords: Knee Osteoarthritis; Function; Classification; Gait

Introduction

Knee osteoarthritis (KOA) is among the most common degenerative diseases, affecting 15% of the world population, causing significant pain and functional limitation [1,2]. The risk of mobility impairments caused by KOA alone is greater than due to any other medical condition in people over 65 [3]. It leads to social, psychological and economical burdens, with substantial financial consequences [4]. It is estimated that by 2030 30% of the people over 60 and 50% of the people over 80 would suffer from KOA [5,6]. Along with the aging of the world population KOA is expected to be a great burden on the global health expense.

Several classification schemes for KOA have been proposed. The American College of Rheumatology has published clinical criteria and classification for KOA [7]. Kellgren and Lawrence have published their classification of OA based on x-ray films [8,9], which was shown to correlate with clinical function as represented in standard

questionnaires [10,11]. However, x-ray based classification is lacking since it represents the disease in the knee articular surface, rather than the function of the diseased joint. Functional assessment and classification of patients with KOA is lacking, even though previous gait analysis studies have shown that KOA alters gait patterns [12-19], and that gait changes are associated with KOA disease severity [20-25]. Only one study by Elbaz et al presented a functional classification for KOA severity based on spatio-temporal gait analysis. They have found that KOA functional severity can be classified according to stride length and cadence into four distinct severity groups.

Their data showed that knee osteoarthritis functional grade (KOFG) correlated with clinical questionnaires and Kellgren and Lawrence classification [26]. This functional classification is an objective, reproducible tool to assess the actual effect of the disease on patients' function. However, this classification has not yet been validated as a tool to report time-dependant clinical outcome of KOA treatment. It is important to determine the sensitivity of such a classification as a tool to assess time-dependant changes in functional severity as well as assessing treatment effect in terms of functional severity classification.



ORIGINAL ARTICLE

A novel self-care biomechanical treatment for obese patients with knee osteoarthritis

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Abstract

Aim: To examine the effect of a novel biomechanical, home-based, gait training device on gait patterns of obese individuals with knee OA.

Methods: This was a retrospective analysis of 105 (32 males, 73 females) obese (body mass index > 30 kg/m²) subjects with knee OA who completed a 12-month program using a biomechanical gait training device and performing specified exercises. They underwent a computerized gait test to characterize spatiotemporal parameters, and completed the Western Ontario and McMaster Osteoarthritis Index (WOMAC) questionnaire and Short Form-36 (SF-36) Health Survey. They were then fitted with biomechanical gait training devices and began a home-based exercise program. Gait patterns and clinical symptoms were assessed after 3 and 12 months of therapy.

Results: Each gait parameter improved significantly at 3 months and more so at 12 months ($P = 0.03$ overall). Gait velocity increased by 11.8% and by 16.1%, respectively. Single limb support of the more symptomatic knee increased by 2.5% and by 3.6%, respectively. There was a significant reduction in pain, stiffness and functional limitation at 3 months ($P < 0.001$ for each) that further improved at 12 months. Pain decreased by 34.7% and by 45.7%, respectively. Functional limitation decreased by 35.0% and by 44.7%, respectively. Both the Physical and Mental Scales of the SF-36 increased significantly ($P < 0.001$) at 3 months and more so following 12 months.

Conclusions: Obese subjects with knee OA who complied with a home-based exercise program using a biomechanical gait training device demonstrated a significant improvement in gait patterns and clinical symptoms after 3 months, followed by an additional improvement after 12 months.

Key words: biomechanical device, function, gait, knee osteoarthritis, pain.

INTRODUCTION

Knee osteoarthritis (OA) is a common disease caused by multiple factors. It is well established that obesity is strongly linked to knee OA and is considered a risk factor for both incidence and progression.^{1,2} Obese peo-

ple (body mass index [BMI] > 30 kg/m²) are at a 4.2–6.8 times higher risk of developing knee OA than matched normal weight controls.^{3,4} Ettinger *et al.* examined the effects of comorbid diseases on disability and found that knee OA and obesity were each significantly associated with poorer physical function, with odds ratios of 4.3 and 1.7, respectively. When obesity was combined with knee OA, the odds ratio increased to 9.8.⁴

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APOS therapy improves clinical measurements and gait in patients with knee osteoarthritis

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ABSTRACT

Background: The purpose of the study was to investigate the changes in gait patterns and clinical measurements following treatment with a novel biomechanical device on patients with knee osteoarthritis. **Methods:** Forty six patients with bilateral knee osteoarthritis were analyzed. Patients completed a gait test, Western Ontario and McMaster Osteoarthritis Index (WOMAC) questionnaire and SF-36 Health Survey at baseline and after 12 weeks. The biomechanical device was individually calibrated to each patient at baseline to allow training under reduced pain.

Findings: Gait velocity, step length and single limb support improved significantly and toe out angle decreased significantly (10%, 6%, 1% and 2%, respectively). WOMAC-Pain and WOMAC-Function significantly decreased (26% and 34%, respectively), and SF-36 score significantly increased following the 12 weeks of treatment.

Interpretation: Our results suggest an overall improvement in the gait patterns, level of pain and level of function of patients with knee osteoarthritis following 12 weeks of treatment with the novel biomechanical device.

The study is registered at clinicaltrials.gov, identifier NCT00767780, <http://www.clinicaltrials.gov/ct/show/NCT00767780>.

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1. Introduction

Osteoarthritis (OA) is the most prevalent form of arthritis in the elderly. It is estimated that 7% of men and 11% of women over the age of 65 have knee OA (Felson et al., 1987). Common symptoms include joint stiffness, tenderness, crepitus, joint enlargement, deformity, muscle weakness, limited motion, and impaired proprioception. The most significant symptoms of the disease are pain and functional disability (Katz, 2001; Felson and Zhang, 1998). Today, the management of knee OA focuses on reducing the levels of pain and functional limitation.

The main focus in the conservative, non-pharmacological management of these symptoms has been the lower limb musculature. Researchers believe that the muscles surrounding the knees may act as a potential protective mechanism of reducing loads and compressive forces on soft tissues and weight-bearing joints (Bennell et al., 2008). A common aspect of knee OA is poor muscle function with muscle weakness (Messier et al., 1992). Muscle weakness has been identified as a potential risk factor for the development and

progression of knee OA and is a widely accepted impairment in knee OA (Slemenda et al., 1997). The decrease in muscle strength causes the external load to be carried out by the knee joint (Slemenda et al., 1997). A specific aspect of muscle function that has been focused on in recent years is proprioception and neuromuscular control. Proprioceptive afferent information is essential to the coordinated activity of the muscles surrounding the knee and to the dynamic joint stability (Johansson et al., 2000). Studies have established that patients with knee OA demonstrate deficits in knee joint proprioception compared to healthy age-matched individuals (Koralewicz and Engh, 2000). This proprioceptive deficit contributes to functional instability that can ultimately lead to further microtrauma and re-injury (Lephart et al., 1997).

Studies have shown that specially designed functional knee braces can decrease pain and improve measures of function in patients with varus knee OA (Hewett et al., 1998; Lindenfild et al., 1997). They can also improve proprioception and postural control (Birmingham et al., 2001), however, there is no evidence of new motor learning post use. Haim et al. have recently investigated a novel therapy using a foot-worn biomechanical device (Haim et al., 2008). The therapy includes daily exercise with the device, according to an exercise program that is carried out in the patient's own environment (i.e. home/work). This device is a foot-worn platform with two adjustable convex rubber

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RESEARCH ARTICLE

Open Access



A non-invasive, home-based biomechanical therapy for patients with spontaneous osteonecrosis of the knee

Ehud Atoun¹, Amit Mor^{2*}, Ganit Segal², Ronen Debi¹, Dan Grinberg¹, Yeshaiau Benedict¹, Nimrod Rozen³, Yiftah Beer⁴ and Avi Elbaz²

Abstract

Background: The purpose of the current study was to examine the effect of a non-invasive, home-based biomechanical treatment program for patients with spontaneous osteonecrosis of the knee (SONK).

Methods: Seventeen patients with SONK, confirmed by MRI, participated in this retrospective analysis. Patients underwent a spatiotemporal gait analysis and completed the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) and the Short-Form-36 (SF-36). Following an initial assessment, patients commenced the biomechanical treatment (AposTherapy). All patients were reassessed after 3 and 6 months of treatment.

Results: A significant reduction in pain and improvement in function was seen after 3 months of therapy with additional improvement after 6 months of therapy. Pain was reduced by 53% and functional limitation reduced by 43%. Furthermore, a significant improvement was also found in the SF-36 subscales, including the summary of physical and mental scores. Significant improvements were found in most of the gait parameters including a 41% increase in gait velocity and a 22% increase in step length. Patients also demonstrated improvement in limb symmetry, especially by increasing the single limb support of the involved limb.

Conclusions: Applying this therapy allowed patients to be active, while walking more symmetrically and with less pain. With time, the natural course of the disease alongside the activity of the patients with the unique biomechanical device led to a significant reduction in pain and improved gait patterns. Therefore, we believe AposTherapy should be considered as a treatment option for patients with SONK.

Trial registration: Assaf Harofeh Medical Center Institutional Helsinki Committee Registry, 141/08; ClinicalTrials.gov NCT00767780.

Keywords: SONK, Biomechanical treatment, Pain, Function

Background

The knee, after the hip, is the second most common site for osteonecrosis (ON) [1]. Spontaneous osteonecrosis of the knee (SONK), first described by Ahlback et al. [2] in 1968, is considered to be the most common form of ON, with an incidence of 3.4 and 9.4% in persons older than 50 and 65 years of age, respectively [3]. However, the actual prevalence may be underestimated since many patients with end-stage osteoarthritis (OA) may have had an undiagnosed occult condition [4].

SONK is classically described as a focal, superficial subchondral lesion, affecting the medial femoral condyle in up to 94% of the time [5, 6]. The presenting symptom is usually an acute onset of pain over the medial side of the knee [7]. Focal tenderness over the medial femoral condyle is the most common finding on physical examination [8]. Patients often present deteriorated, asymmetrical gait patterns [9] and complain that the pain is worse during weight-bearing and at night [4]. The etiology of SONK remains unclear. Historically, it was thought to occur secondary to ischemia, which results in necrosis [2, 10]. However, recent evidence has demonstrated that it may be due to subchondral

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The outcome of a novel biomechanical therapy for patients suffering from anterior knee pain

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ABSTRACT

Background: This study was devised to examine the effect of a novel biomechanical therapy for patients suffering from anterior knee pain (AKP).

Methods: A retrospective analysis of 48 patients suffering from AKP was performed. Patients underwent a gait evaluation, using an electronic walkway mat, and completed the SF-36 health survey and the WOMAC questionnaire at baseline and after 3 and 6 months of therapy. A special biomechanical device was individually calibrated for each patient. AposTherapy is a functional, non-invasive rehabilitation therapy consisting of a biomechanical foot-worn device that is used during activities of daily living. Repeated measures analyses were performed to compare gait parameters and self-evaluation questionnaires between baseline, 3 months and 6 months.

Results: Walking velocity significantly increased by 5.7 cm/s, cadence increased by 1.6 steps/minute, and stride length increased by 3.4 cm in relation to pretreatment testing ($p < 0.001$ for all). End-point evaluation revealed additional improvement of these parameters; however these did not significantly differ from that of mid-treatment. Pain decreased by 36.6% and 49.2% following 13 and 26 weeks of treatment, respectively ($P < 0.01$) and function improved by 25.2% and 41.7% following 13 and 26 weeks of treatment, respectively ($P = 0.01$).

Conclusions: Based on the current study's results it may be concluded that this therapy might have a positive effect for patients with AKP.

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1. Introduction

Anterior knee pain (AKP) is a common musculoskeletal disorder affecting 25–36% of the general population with an impact on many aspects of daily life [1–3]. It has been reported to be the most common cause of knee pain in adolescents [4–6], to be more common in females than males [7,8], and to be the most common injury in runners [1]. AKP was reported as the cause of up to 40% of all visits to physiotherapy clinics as a result of knee pain [6,9] and often becomes chronic, with 94% of patients continuing to experience pain up to 4 years after initial presentation and 25% reporting significant symptoms up to 20 years later [10].

Presently, no consensus exists regarding classification and nomenclature of AKP [11,12]. Several clinical conditions have been described in association with AKP [13]. The terms “patello-femoral pain syndrome”

and “chondromalacia patella” which were historically utilized for subjects complaining of AKP in whom no other diagnosis could be made, have been disputed due to inconsistencies in diagnostic criteria [11,12]. The pathomechanics of AKP is multifactorial and partially unknown. Most investigators agree that the etiology of AKP in some patients arises from the retropatellar or peripatellar region and is partly related to faulty lower limb mechanics and poor neuromuscular control.

The study of gait in this population contributes to the understanding of the pathomechanics of this pathology and is important for developing new treatment strategies. In addition, defining variations in gait of these patients can offer objective clinical data for assessment of disease progression and outcomes of treatment modalities. Alterations in knee kinetics and kinematics were previously reported in association with AKP; subjects with AKP were found to display a reduced knee extensor moment during the loading response phase (LR) of the stance [14,15], and a reduced peak vertical ground reaction force (GRF) [16]. Reduced knee flexion during LR has been reported in some studies [16,17], but not in others [15,18,19]. Furthermore, changes were also noted in spatio-temporal parameters [20].

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A unique foot-worn device for patients with degenerative meniscal tear

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Abstract

Purpose The purpose of the current study was to assess the effects of a new foot-worn device on the gait, physical function and pain in patients suffering from knee osteoarthritis (OA) who had a low-impact injury to the medial meniscus causing a degenerative meniscal tear.

Methods A retrospective analysis of 34 patients with knee OA and a degenerative medial meniscal tear was performed. Patients underwent a gait evaluation, using an electronic walkway mat, and completed the SF-36 health survey and the WOMAC questionnaire at baseline and after 3 and 12 months of therapy. AposTherapy is a functional, biomechanical, non-invasive rehabilitation therapy consisting of a foot-worn device that is individually calibrated to each patient and is used during activities of daily living. Repeated-measures analyses were performed to compare gait parameters and self-evaluation questionnaires between baseline, and 3 and 12 months.

Results Significant improvements were found in gait velocity, step length and single-limb support of the involved knee following 12 weeks of therapy (all $p < 0.01$), alongside

an improvement in limb symmetry. These results were maintained at the 12-month follow-up examination. Significant improvements were also found in all three domains of the WOMAC index (pain, stiffness and physical function) and in the SF-36 Physical Health Scale and the SF-36 Mental Health Scale (all $p < 0.01$).

Conclusions Patients with knee OA and a degenerative medial meniscal tear using a biomechanical foot-worn device for a year showed improvement in gait, physical function and pain. Based on the findings of this study, it can be postulated that this biomechanical device might have a positive effect on this population.

Level of evidence Therapeutic study, Level IV.

Keywords Gait · Meniscal tear · Physical function · Pain · Osteoarthritis

Introduction

Meniscal tears are the leading cause of knee injury [34]. In the United States, 60 % of people over the age of 65 diagnosed with knee osteoarthritis (OA) suffer from chronic meniscal damage [13]. Meniscal tears have serious consequences as patients suffer from significant pain and a profound decline in their quality of life and physical function [34].

A variety of therapies exist to treat meniscal tears, ranging from pharmaceutical treatment [38] to physical therapy [15, 24] to surgery [2, 22, 30]. The most common invasive therapy has traditionally been meniscectomy [16], though the procedure has been reported to not halt the progression of cartilage destruction and premature OA [6, 29, 31], and it has even been suggested that the procedure may accelerate the development of OA [34–36]. Alongside this, Englund et al.

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A noninvasive biomechanical treatment as an additional tool in the rehabilitation of an acute anterior cruciate ligament tear: A case report

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Abstract

Objectives: Conservative treatments for anterior cruciate ligament (ACL) tears may have just as good an outcome as invasive treatments. These include muscle strengthening and neuromuscular proprioceptive exercises to improve joint stability and restore motion to the knee. The Purpose of the current work presents was to examine the feasibility of a novel non-invasive biomechanical treatment to improve the rehabilitation process following an ACL tear. This is a single case report that presents the effect of this therapy in a patient with a complete ACL rupture who chose not to undergo reconstructive surgery.

Methods: A 29-year old female athlete with an acute indirect injury to the knee who chose not to undergo surgery was monitored. Two days after injury the patient began AposTherapy. A unique biomechanical device was specially calibrated to the patient's feet. The therapy program was initiated, which included carrying out her daily routine while wearing the device. The subject underwent a gait analysis at baseline and follow-up gait analyses at weeks 1, 2, 4, 8, 12 and 26.

Results: A severe abnormal gait was seen immediately after injury, including a substantial decrease in gait velocity, step length and single limb support. In addition, limb symmetry was substantially compromised following the injury. After 4 weeks of treatment, patient had returned to normal gait values and limbs asymmetry reached the normal range.

Conclusions: The results of this case report suggest that this conservative biomechanical therapy may have helped this patient in her rehabilitation process. Further research is needed in order to determine the effect of this therapy for patients post ACL injuries.

Keywords

Anterior cruciate ligament tear, biomechanical therapy, proprioception

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Introduction

Presently, the most common treatment for anterior cruciate ligament (ACL) injuries in young patients is focused on surgical repair with rehabilitation. There is, however, growing evidence that conservative treatments may have just as good an outcome as invasive treatments. A recently published study by Frobell et al.¹ showed that patients treated immediately with reconstructive surgery did not fare better than those that had rehabilitation treatment with delayed reconstruction or no reconstruction.

Guidelines for the conservative treatments for patients with ACL tears focus on muscle-strengthening and neuromuscular proprioceptive exercises to improve joint stability and restore motion to the knee.² AposTherapy is a relatively

new noninvasive therapy currently used for a wide range of musculoskeletal disorders. This device allows for precise adjustment of the center of pressure (COP) of a patient's foot

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Original Article

New approach for the rehabilitation of patients following total knee arthroplasty



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ABSTRACT

Purpose: To investigate the effect of a biomechanical therapy on gait, function and clinical condition in patients following total knee arthroplasty (TKA).

Methods: Seventeen TKA patients participated in the study. Patients received a biomechanical therapy AposTherapy). Patients underwent a gait test, clinical examination and an assessment of pain, function and quality of life (QOL). Patients were examined again at one, three and six month follow-ups.

Results: A significant improvement over time was found in most gait measurements. Significant improvements were also found in pain, function and QOL.

Conclusions: The examined biomechanical therapy may help in the rehabilitation process following TKA.

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1. Introduction

Total knee arthroplasty (TKA) is the most common treatment for end-stage knee osteoarthritis (KOA). TKA has revolutionized the care of patients with KOA and the number of performed

surgeries has dramatically increased over the past decade. With the rise in life expectancy, projected increases in the incidence of KOA and TKA surgery will place an enormous burden on the healthcare system. A study based on the National Hospital Discharge Survey (1996–1999), predicts that in 2030 there will be over 474,000 TKA procedures performed in the U.S. alone.¹

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A Novel Non-Invasive Adjuvant Biomechanical Treatment for Patients with Altered Rehabilitation after Total Knee Arthroplasty: Results of a Pilot Investigation

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Background: Many factors contribute to suboptimal results after total knee arthroplasty (TKA) but little is known regarding the value of postsurgical rehabilitation after TKA. We examined the effects of an enhanced closed kinematic chain exercises program (AposTherapy) on gait patterns and clinical outcomes among patients with a lack of progress in their postsurgical rehabilitation.

Methods: Twenty-two patients were prospectively followed during the study. Gait spatiotemporal parameters were measured at the initial evaluation, after 15 minutes of therapy, and after 3 months of therapy. The Western Ontario and McMaster Osteoarthritis Index (WOMAC) and the short form (SF)-36 health survey were completed by patients before treatment and after 3 months of treatment.

Results: The WOMAC and SF-36 scores improved significantly after 3 months of treatment. Gait velocity, single limb support, and step length of the operated leg improved significantly even after a single 15 minutes treatment. Normal gait velocity was observed in 36% of patients after 3 months of treatment.

Conclusions: A physiotherapy program that included enhanced closed kinematic chain biomechanical therapy was beneficial for patients who experienced a suboptimal rehabilitation course after TKA.

Keywords: *Knee, Arthroplasty, Rehabilitation, Gait*

Total knee arthroplasty (TKA) reduces arthritic knee pain and provides most patients with adequate knee range of motion (ROM).^{1,2)} TKA also typically diminishes limitations in patient activities.³⁾ Improvements in these parameters is gradual and may take up to 1 year.⁴⁾ Patients exhibit marked impairments in voluntary activation of quadriceps

strength and in functional performance (e.g., walking and stair climbing) during the early postoperative period after TKA, most probably due to the surgical insult.^{5,6)} Most patients are expected to recover to their preoperative functional activity level within 1 year. However, impairments in strength and function may remain below a healthy age-matched population for years after TKA.⁶⁾

Bourne et al.⁷⁾ found that 19% of patients were dissatisfied after TKA. Many factors can contribute to a potentially suboptimal outcome after TKA, including patient characteristics, surgical technique, and postoperative factors. Patient-related factors include restricted preoperative ROM and underlying etiology, e.g., rheumatoid arthritis, morbid obesity, multitude of co-morbidities, sex,

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A Biomechanical Foot-Worn Device Improves Total Knee Arthroplasty Outcomes

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ABSTRACT

Background: Biomechanics after total knee arthroplasty (TKA) often remain abnormal and may lead to prolonged postoperative recovery. The purpose of this study is to assess a biomechanical therapy after TKA.

Methods: This is a randomized controlled trial of 50 patients after unilateral TKA. One group underwent a biomechanical therapy in which participants followed a walking protocol while wearing a foot-worn biomechanical device that modifies knee biomechanics and the control group followed a similar walking protocol while wearing a foot-worn sham device. All patients had standard physical therapy postoperatively as well. Patients were evaluated throughout the first postoperative year with clinical measures and gait analysis.

Results: Improved outcomes were seen in the biomechanical therapy group compared to the control group in pain scores (88% vs 38%, $P = .011$), function (86% vs 21%, $P = .001$), knee scores (83% vs 38%, $P = .001$), and walking distance (109% vs 47%, $P = .001$) at 1 year. The therapy group showed healthier biomechanical gait patterns in both the sagittal and coronal planes at 1 year.

Conclusion: A postoperative biomechanical therapy improves outcomes following TKA and should be considered as an additional therapy postoperatively.

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Total knee arthroplasty (TKA) is an excellent treatment for pain reduction and functional improvement in individuals with end-stage knee osteoarthritis (OA) [1]. Nevertheless, some patients continue to experience pain and decreased function postoperatively [2]. Several studies have shown that many patients after surgery still have abnormal gait patterns similar to gait patterns that developed over years of pain and degenerative joint disease preoperatively [1,3–8].

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Studies have shown that the adduction moment generated in the coronal plane and the flexion moment generated in the sagittal plane remain abnormal after TKA [2,5–8]. In recent years, a novel therapeutic approach to musculoskeletal pathologies has emerged that focuses on neuromuscular re-education [9]. One such treatment uses a specialized biomechanical device (BD) that is a shoe with 2 convex-shaped rubber elements attached to the sole. The BD has been validated in multiple studies showing that shifting the convex-shaped elements directly changes the center of pressure at the foot, moments acting on the lower extremity joints, and lower limb muscle activation patterns during gait in a predictable fashion [10–13]. Changing the convexity of the elements has also been shown to change perturbations on the lower limb [14]. Furthermore, when used as a therapy, the BD has been shown to improve biomechanics, reduce pain, and improve function in patients with knee and hip OA [15–17].



A Non-Surgical Foot-Worn Device for Patients with Hip Osteoarthritis who Meet Surgical Criteria for Joint Replacement: A Retrospective Audit on NHS Patients

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Abstract

Purpose: To investigate the effect of a personalised, home-based, biomechanical foot-worn device on the referral rates for secondary care amongst patients with Hip Osteoarthritis (OA) who meet the clinical criteria for joint replacement.

Methods: One hundred and fifty-seven patients with hip OA participated in a commercial programme by Circle Integrated Care (CIC) offering innovative musculoskeletal rehabilitation services and pathway management. Patients were calibrated with a foot-worn biomechanical device that re-distributes loads via centre of pressure manipulation and generates perturbation to train proprioception. Patients are personally calibrated based on their gait profile and symptoms, then receive a home-based treatment plan that typically includes daily wear for 30-60 minutes while going about daily activities. Patients were reassessed clinically after six months, 1, 2 and 3 years. A mixed linear model was used to examine clinical changes over time.

Results: There were thirty-one (19.7%) referrals for secondary consultation. The mean days to referral was 310.5 (SD=273.8) days. 67% of all referrals occurred during the first year of treatment. Significant improvements were calculated for all clinical outcomes.

Conclusion: The results of the study suggest a significant clinical improvement among patients who failed core therapies and meet the criteria for joint replacement, with over 80% of the patients avoiding it for at least three years. This intervention should be considered as an additional non-surgical option for patients with hip OA who meet surgical criteria for joint replacement.

Keywords: Hip osteoarthritis; Total hip replacement; Non-surgical interventions; Biomechanics; Pain; Function

Introduction

Hip Osteoarthritis (OA) is one of the leading causes of disability and chronic pain among adults, affecting millions worldwide. Around 10% of adults above 45 years old have radiographic and symptomatic hip OA [1] and according to recent statistics, the prevalence of hip OA is on the rise [2]. Some estimates conclude that one in four people will develop symptomatic hip OA by the age of 85, with older age and female sex being dominant risk factors [3]. While it is less prevalent than knee OA, evidence on the long-term prognosis of hip OA suggests that patients are at a significantly higher risk of progressing to total joint replacement and have a shorter window of opportunity for conservative treatment between diagnosis and surgery [4]. Current data from the National Joint Registry suggest that there are 85K primary total hip replacements (THRs) in the UK annually. With the aging population and the increase in hip OA prevalence, it is projected that by 2060 the number of THR surgeries in the UK will surge by almost 40% compared to 2018 [5]. Taken together, these trends highlight hip OA as a major healthcare concern and call for an effective management strategy to improve patients' quality of life and reduce the burden on healthcare systems.

Non-surgical treatments of hip OA focus on alleviating symptoms of pain and stiffness and maintaining function and generally include patient education, exercise, and use of pain medication such as non-steroidal anti-inflammatory drugs. Long-term prospective studies show that patients with symptomatic hip OA are likely to experience a rapid deterioration in pain and function, and a high proportion of them progress to surgery within three years since their initial consultation in the clinic [4,6-8]. This trend suggests that current conservative management of mild to moderate hip OA is not optimal

and highlights the need for treatment that provides pain relief and targeted mobility and functional rehabilitation whilst simultaneously addressing the underlying mechanisms of the disease. In the past Febade accumulating evidence has demonstrated the beneficial effect of a non-invasive biomechanical intervention for knee and hip osteoarthritis [9-14]. This intervention uses a customised, shoe-like device that shifts forces around the lower limb joints to alleviate pain while introducing controlled perturbation to train proprioception. The National Institute of Clinical Excellence (NICE) recently recommended the intervention as a safe, clinically effective and cost-saving non-invasive treatment for patients with severe knee OA who do not want surgery [15].

Circle Health Group is the UK's leading independent provider of hospital services. Part of this group, Circle Integrated Care (CIC), offers innovative musculoskeletal rehabilitation services and pathway management. Circle has been implementing this biomechanical intervention since 2015. Currently, the service is provided in clinical practices in Bedfordshire and Greenwich, covering a population of over 780,000. The current study aims to report our six-year experience utilising this intervention and monitor the rates of receiving referrals

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RESEARCH ARTICLE

Open Access

A non-invasive biomechanical device and treatment for patients following total hip arthroplasty: results of a 6-month pilot investigation

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Abstract

Background: The purpose of the study was to examine the effect of a foot-worn biomechanical device on the clinical measurements and gait patterns of patients with total hip arthroplasty (THA).

Methods: Nineteen patients, up to 3 months post-THA, were enrolled to the study. Patients underwent a computerized gait analysis to calculate spatiotemporal parameters and completed the Western Ontario and McMaster Universities osteoarthritis index and the SF-36 health survey. Patients then began therapy with a non-invasive foot-worn biomechanical device coupled with a treatment methodology (AposTherapy). Patients received exercise guidelines and used the device daily during their regular activities at their own environment. Follow-up examinations were conducted after 4, 12, and 26 weeks of therapy. Repeated measures ANOVA was used to evaluate changes over time. The clinical significance of the treatment effect was evaluated by computing the Cohen's effect sizes (ES statistic).

Results: After 26 weeks of therapy, a significant improvement was seen in gait velocity (50.3%), involved step length (22.9%), and involved single limb support (16.5%). Additionally, a significant reduction in pain (85.4%) and improvement in function (81.1%) and quality of life (52.1%) were noted.

Conclusions: Patients following THA demonstrated a significant improvement in gait parameters and in self-assessment evaluations of pain, function, and quality of life. We recommend further RCTs to examine the effect of this therapy compared to other rehabilitation modalities following THA and compared to healthy matched controls.

Trial registration: Clinical trial registration number NCT01266382

Keywords: Biomechanical therapy, Gait, Pain, Function

Background

Total hip arthroplasty (THA) is known to be a successful joint replacement procedure given that most patients experience significant pain alleviation, as well as an improvement in their health-related quality of life mostly during the first postoperative year and beyond [1,2]. The literature reveals, however, that despite these postoperative improvements, in some patients, the level of pain

and the quality of life following THA do not reach those of the general population [1-3], nor does their gait pattern return to normal [4-6].

Gait analysis is a useful tool in the evaluation of locomotor function after THA [7]. Several studies have shown that joint motion does not return to normal after 6 months and in some cases up to years postoperatively [4,5,8]. This atypical joint motion includes additional stress being placed on the unaffected leg that may eventually lead to the development of osteoarthritis (OA) in the contralateral limb [6,9-11] and other joint disorders, some of which may even require a second arthroplasty

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Positive Outcomes Following Gait Therapy Intervention for Hip Osteoarthritis: A Longitudinal Study

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ABSTRACT: Footwear-generated biomechanical manipulation of lower-limb joints was shown to beneficially impact gait and quality of life in knee osteoarthritis patients, but has not been tested in hip osteoarthritis patients. We examined a customized gait treatment program using a biomechanical device shown in previous investigations to be capable of manipulating hip biomechanics via foot center of pressure (COP) modulation. The objective of this study was to assess the treatment program for hip osteoarthritis patients, enrolled in a 1-year prospective investigation, by means of objective gait and spatiotemporal parameters, and subjective quality of life measures. Gait analysis and completion of questionnaires were performed at the start of the treatment (baseline), and after 3, 6, and 12 months. Outcome parameters were evaluated over time using linear mixed effects models, and association between improvement in quality of life measures and change in objective outcomes was tested using mixed effect linear regression models. Quality of life measures improved compared to baseline, accompanied by increased gait speed and cadence. Sagittal-plane hip joint kinetics, kinematics, and spatiotemporal parameters changed throughout the study compared to baseline, in a manner suggesting improvement of gait. The most substantial improvement occurred within 3 months after treatment initiation, after which improvement approximately plateaued, but was sustained at 12 months. Speed and cadence, as well as several sagittal-plane gait parameters, were significant predictors of improvement in quality of life. Clinical significance: Evidence suggests that a biomechanical gait therapy program improves subjective and objective outcomes measures and is a valid treatment option for hip osteoarthritis. © 2017 Orthopaedic Research Society. Published by Wiley Periodicals, Inc. *J Orthop Res*

Keywords: gait retraining; hip osteoarthritis; gait analysis; sagittal-plane hip parameters; footwear-generated biomechanical manipulations

Hip osteoarthritis (OA) is a debilitating disorder characterized by loss of articular cartilage and joint space, formation of osteophytes, pain, stiffness, and deterioration of physical function, neuromuscular pattern, and gait.¹ It is particularly disabling since it affects ambulation.^{2,3} It is one of the major causes of disability in the elderly,⁴ affecting an estimated 6.7–9.7 % of people over the age of 45 in the United States,^{5,6} with prevalence percentages increasing progressively with increasing age.^{7–9}

Hip OA is associated with antalgic gait which deviates significantly from healthy people.^{10–15} Patients may adopt abnormal gait patterns as compensatory mechanisms to avoid pain and joint loading, or due to joint laxity and joint deformity. The vast majority of hip OA gait analysis studies emphasize sagittal-plane gait parameters used as diagnostic indicators of hip OA, as well as indicators of efficacy of treatment interventions. Decreased hip flexion/extension range of motion (ROM),^{10,12,16–18} peak extension angle,^{10,14,15,17,19,20} external extension moment,^{12,21} stride and step length,^{14,15,17,22} cadence,^{15,17} single support duration,¹⁷ and gait speed,^{10,14,15,17,22} increased peak hip flexion angle,¹⁹ and overall gait asymmetry^{12,13,17,21} are consistent features of hip OA. Decreased extension moment is significantly correlated with increased level of pain,^{12,21} while loss of hip

extension may be a pain avoidance mechanism to decrease joint load.¹⁷ Efficacy studies using sagittal-plane gait parameters as clinical outcome measures report change in gait speed,^{23–27} stride length,^{23,25,27} single-support duration,^{26,28} gait symmetry,²⁶ sagittal-plane ROM,²³ peak extension angle,²⁷ peak flexion moment,²³ and peak extension moment.^{11,23} post total hip replacement or pharmacological treatment.

The current nonsurgical and nonpharmacological treatment recommendations for hip OA include appropriate footwear; however, according to Osteoarthritis Research Society International (OARSI) recommendations for the management of hip and knee OA, this recommendation is based on expert opinion alone and there have been no controlled trials of footwear in patients with hip OA.²⁹ Recent advances in this field from our research group have suggested clinical potential for footwear-generated manipulation of hip biomechanics to benefit hip OA patients by improving gait parameters associated with the hip^{30,31}; however, these studies investigated only immediate impact of a foot-worn device on gait. Therefore, the objective of the study was to assess the outcome of a 1-year long noninvasive footwear-based gait therapy program for hip OA patients. Based on a 12-week retrospective study, in which hip OA patients showed improvement in quality of life (QoL) measures and spatiotemporal parameters following the same gait treatment intervention as the present study,³² we hypothesized that self-reported QoL measures would improve throughout the 1-year treatment program. We further hypothesized that the improvement would be accompanied by

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Research Article

Open Access

A Non-Invasive Foot-Worn Biomechanical Device for Patients with Hip Osteoarthritis

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Abstract

Objective: The purpose of this study was to evaluate the effect of a biomechanical therapy on the pain, function, quality of life and spatio-temporal gait patterns of patients with hip osteoarthritis (OA).

Design: 60 patients with hip OA were examined before and after twelve weeks of a personalized biomechanical therapy (AposTherapy). Patients were evaluated using the WOMAC questionnaire for pain and function and the SF-36 Health Survey for quality of life, and underwent a computerized gait test.

Results: After twelve weeks of treatment, a significant improvement was found in the patients' velocity, step length and cadence ($P \leq 0.001$). WOMAC-pain, stiffness and function subscales were significantly improved compared to baseline ($P \leq 0.001$). SF-36 physical score subscale improved significantly ($P=0.007$).

Conclusions: Patients with bilateral hip OA treated with AposTherapy for twelve weeks showed statistically and clinically significant improvements in pain, function and gait patterns.

Keywords: Osteoarthritis; Hip; Gait; Biomechanics; Pain; Quality of life

Introduction

Osteoarthritis (OA) is a major health concern in modern society, affecting 10% of men and 21% of women over age 65. The hip joint is the second most common lower limb site after the knee [1], with an estimated prevalence of 1% - 11% [2].

Several articles have described locomotor deviations typical of individuals suffering from hip OA. The spatio-temporal gait of this population is characterized by a lower walking speed, lower cadence, shorter step length and shorter single limb support phase of the involved leg [3-5]. It is likely that patients continuously adapt their gait in response to pain, deformity or laxity in the joints of the lower extremities as their disease progresses [6]. These gait adaptations may influence the motion of the lower back and other joints of the lower extremities [7]. A recent study by Shakoor et al. explained that unilateral end-stage hip (OA) can lead to degenerative changes and eventually end-stage knee OA in the contralateral limb. Moreover, the loading and structural asymmetries appear early in the disease course, while the knees are still asymptomatic [8].

Treatments for OA are typically directed at the management of symptoms, with a goal of pain relief and improved function. Several studies emphasize the importance of physical therapy and biomechanical intervention for patients with hip OA, claiming that such therapies should aim to restore or maintain gait patterns close to normal, as well as improve walking efficiency and quality of life (QoL) [9,10]. However, a recent meta-analysis from 2009, which reviewed more than 4,000 articles, concluded that there was insufficient evidence to suggest that exercise therapy was an effective short-term management approach for reducing pain levels, improving joint function and QoL [11]. A novel biomechanical device (Apos System, APOS—Medical and Sports Technologies Ltd.) was recently introduced as a non-invasive therapy for different musculoskeletal problems [12-15]. Haim et al. showed that by using this biomechanical intervention for symptomatic bilateral knee OA, walking velocity and functional activity were increased while knee adduction moment and pain were reduced [16]. The effect of this therapy has not been

assessed in patients with hip OA, although it may be assumed that the same biomechanical principles apply.

The purpose of this current study was to examine the efficiency of this biomechanical therapy on the gait patterns and clinical symptoms in patients with hip OA. We hypothesize that patients who undergo this therapy will show improvement in gait patterns and function, as well as a relief in pain.

Methods

Participants

This was a retrospective study. The protocol was approved by the Institutional Helsinki Committee Registry (Registration number NCT00767780). A search for eligible data was performed through the research database of AposTherapy Center. Eligibility for the study was defined as follows: 1. Patients suffering from symptomatic hip OA for at least six months and who fulfilled the American College of Rheumatology clinical criteria for OA of the hip [17]; 2. Patients who completed a gait test, the Western Ontario and McMaster Osteoarthritis Index WOMAC [18] questionnaire and the Short Form SF-36 Health Survey [19] at the start of therapy (study baseline) and after twelve weeks of therapy. Exclusion criteria were: 1. Neurological and rheumatic inflammatory diseases; 2. Corticosteroid injection within 3 months of the study; 3. Earlier hip surgery excluding arthroscopy; 4. Joint replacement of the hip or knee; 5. Instability of the hip due to traumatic ligament injury; 6. OA in other lower extremity joints other

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Clinical Outcomes of a New Foot-Worn Non-Invasive Biomechanical Intervention Compared to Traditional Physical Therapy in Patients With Chronic Low Back Pain. A Randomized Clinical Trial

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Abstract

Study Design: Randomized Controlled Trial.

Objective: Chronic low back pain (CLBP) is a major public health concern that will continue to grow with the expected aging of the population. The purpose of this study was to examine the clinical effect of a personalized, home-based biomechanical intervention compared to traditional physical therapy in patients with CLBP.

Methods: This was a randomized controlled trial. One-hundred and sixty-two patients were randomized in a 2:1 ratio to a home-based biomechanical intervention (HBBI, AposHealth) or traditional physical therapy (TPT), respectively. Patients were assessed at baseline and after 12 weeks and 52 weeks. The primary outcome measure was pain at 52 weeks, using a standard Numeric Rating Scale (NRS). Secondary outcomes included pain and function metrics, quality of life and objective spatio-temporal gait test. A Linear Mixed Model assessed changes over time across all study visits.

Results: A significant reduction in NRS was found after 52 weeks with a superiority effect of the HBBI arm compared to TPT ($F = 13.82$, $P < 0.001$). Patients in the HBBI arm demonstrated a marginal mean reduction of 3.5 points, from 6.2 to 2.7 (a 56% reduction), while patients in the TPT arm reported a mean decrease of 1.8 points from 6.9 to 5.1 (a 26% reduction).

Conclusions: A new foot-worn, home-based, biomechanical intervention for patients with chronic non-specific back pain was found to be clinically effective. Given the lack of non-surgical, non-pharmacological interventions for this populations, this treatment might serve as an adjunct to the current standard of care.

Keywords

non-specific low back pain, chronic pain, function, traditional physical therapy, biomechanical intervention, value-based medicine

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Original Research

Footwear-Generated Dynamic Biomechanical Manipulation and Perturbation Training for Chronic Nonspecific Low Back Pain

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Abstract

Background: Home-based therapy optimizing biomechanics and neuromuscular control is increasingly recognized as a treatment option for chronic nonspecific low back pain (CNSLBP). However, its impact on pain, function, and gait is limited among patients in a metropolitan area.

Objective: To evaluate the change of pain, function, and gait parameters with home-based therapy with the use of footwear-generated biomechanical manipulation and perturbation training in a population with CNSLBP in a metropolitan area.

Design: Prospective observational study.

Setting: Outpatient rehabilitation clinic at an academic teaching hospital.

Participants: One hundred sixteen patients with CNSLBP for more than 6 months.

Intervention: Six months of home-based therapy with a biomechanical device using 4 modular elements attached to a foot-worn platform.

Main Outcome Measures: Instrumental gait analysis (gait velocity, step length, single limb support phase % of gait cycle), Numeric Rating Scale for pain, and Oswestry Disability Questionnaire Index for pain and function.

Results: Only 43 patients (37.1%) completed the study. Among 43 patients, mean gait velocity increased from 86.6 ± 20.7 to 99.7 ± 22.1 cm/s ($P < .0001$) in 6 months. Mean left step length increased from 51.1 ± 8.4 to 54.8 ± 9.8 cm ($P < .0001$). Mean right step length increased from 51.0 ± 7.9 to 55.4 ± 9.0 cm ($P < .0001$). Mean single limb support increased from 36.4 ± 2.8 to $37.2 \pm 2.5\%$, ($P = .208$) in the right side and from 36.6 ± 3.0 to $37.8 \pm 4.4\%$, ($P = .019$) in the left side. Median Oswestry Disability Questionnaire Index score improved from 28 (18-44; interquartile range) to 17 (10-35) ($P = .045$). Mean Numeric Rating Scale for back pain improved from 7.7 ± 1.8 to 3.3 ± 3.1 ($P < .0001$).

Conclusion: At 6 months, patients with CNSLBP undergoing home-based therapy with footwear-generated biomechanical manipulation and perturbation training demonstrated significant improvement of objective gait parameters, pain, and function.

Level of Evidence: IV

Introduction

Chronic low back pain (LBP) is very common, with lifetime prevalence estimates as high as 84% [1,2]. It is the leading cause of mobility disability and a major public health burden with a great cost to individuals and society [3,4]. Chronic nonspecific low back pain (CNSLBP) is the most common pattern, representing approximately 80% of chronic LBP [5]. CNSLBP, a heterogeneous condition, is known to be associated with

several lumbosacral structures, including the facet joint, intervertebral disc, ligament, muscle/muscle fascia, and sacroiliac joint; however, clinical tests do not reliably attribute the pain to those structures [6,7]. Abnormal lower extremity biomechanics affecting these lumbopelvic structures [8,9] and suboptimal neuromuscular control [10,11] have been recognized increasingly as contributors for CNSLBP.

An individualized therapeutic exercise program focusing on strengthening and trunk stabilization under

A Novel Biomechanical Device Improves Gait Pattern in Patient With Chronic Nonspecific Low Back Pain

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Eytan Debbi, BA,* Ganit Segal, BEd,* Yair Barzilay, MD,‡ and Ronen Debi, MD†

Study Design. A retrospective study on patients with chronic nonspecific low back pain (NSLBP).

Objective. To describe the gait stride characteristics of patients with chronic NSLBP, and to examine the effect of a novel biomechanical device on the gait stride characteristics of these patients.

Summary of Background Data. Patient with NSLBP alters their gait patterns. This is considered a protective mechanism as patients try to avoid extensive hip and spine ranges of motion and minimize forces and moments acting on the body. In addition, there are changes in the neuromuscular control system in patients with LBP that could possibly be attributed to the effects of pain on motor control.

Methods. Nineteen patients underwent a gait test, using an electronic walkway, at baseline and after 12 weeks of treatment. Spatiotemporal parameters were used to identify changes in gait pattern. A novel biomechanical device comprised of 4 modular elements attached to foot-worn platforms was used in the study. The modules are 2 convex shaped biomechanical elements attached to each foot, one is located under the hindfoot region and the other is located under the forefoot region. The device was individually calibrated to each patient. The patients were instructed to walk with the calibrated biomechanical device on a daily basis for a period of 12 weeks.

Results. Significant differences were found at baseline and after 12 weeks in normalized velocity ($P = 0.03$), cadence ($P < 0.01$), left normalized step length ($P = 0.02$), right normalized step length ($P = 0.02$), right swing ($P < 0.01$), right stance ($P < 0.01$), left single limb support ($P = 0.01$), left double limb support ($P = 0.02$), and right double limb support ($P = 0.02$).

Conclusion. Patients with NSLBP treated with the novel biomechanical device for 3 months increased walking speed through longer step length and eliminated asymmetrical differences.

Key words: gait, nonspecific low back pain, core stability. **Spine** 2009;34:E507–E512

Low back pain (LBP) is one of the leading causes of disability in the adult population. It has an estimated

lifetime incidence of 60% to 80%. Nonspecific low back pain (NSLBP) represents approximately 80% of these patients in which 7% to 10% of them have chronic NSLBP and account for 90% of the huge medical and related expenses.^{1–4}

In recent years, the subject of core stability therapy has received considerable attention. Researchers have found that the activation of the transversus abdominis muscle, which normally precedes movement, is delayed in LBP, probably as a result of back pain.^{5–9} Some researchers currently believe that core stability rehabilitation training, through improvement of transversus abdominis contraction and timing, will help resolve the back pain of patients with NSLBP.^{5,7}

The research paradigm in most core stability studies is to examine muscular activity whereas subjects perform rapid arm movements in various directions.^{5,6,10} These movements, however, do not reflect the daily functional activities of patients. Furthermore, Hodges *et al* reported that experimentally induced back pain not only causes a delay in the activation of the transversus abdominis muscle but also changes the activity of many other muscles acting on the spine.¹⁰ In fact, patients suffering from NSLBP have been shown to have decreased activity in their biceps brachii before and after an anticipated load,¹¹ and have decreased balancing ability.^{12–13} In addition, studies have shown that patients with NSLBP differ from healthy subjects in their motor control of anticipated perturbation,¹⁴ in response to perturbations¹⁵ and in reaching tasks.¹⁶ These changes in neuromuscular control could possibly be attributed to the effects of pain on motor control^{10,12,17} or to changes in the central nervous system.^{11,18,19} Several studies have also shown that patients with low back pain (LBP) suffer from higher lumbar posteroanterior stiffness.^{20,21} Stiffness might, therefore, also explain the differences in motor control behavior between healthy individuals and patients with LBP. We, therefore, conclude from the above that rehabilitation of chronic NSLBP must address the wider perspectives of generalized neuromuscular control and not relate to a specific muscle or function. It is reasonable to assume that the changes in neuromuscular control in patients with NSLBP are manifested in other motor tasks, such as walking. Indeed, studies examining gait patterns of patients with NSLBP have shown that they increase the activity of their lumbar erector spinae and decrease the counter rotation between their pelvis, lumbar, and thoracic spine.^{22–24} Although there is extensive information on the kinematics and kinetics of pa-

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The study was registered in the NIH clinical trial registration, protocol No. NCT00767780.

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Patients with chronic non-specific low back pain who reported reduction in pain and improvement in function also demonstrated an improvement in gait pattern

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Abstract

Purpose To assess the changes in gait pattern and clinical symptoms of patients with chronic non-specific low back pain (CNSLBP) following a home-based biomechanical treatment (HBBT).

Methods This was a retrospective analysis of 60 CNSLBP patients. All patients underwent a gait evaluation and completed self-assessment questionnaires at pre-treatment and after 3 and 6 months of a HBBT (AposTherapy). Twenty-four healthy, aged-matched individuals served as a reference group.

Results Significant differences were found in all gait parameters and clinical symptoms between patients with CNSLBP and healthy people before treatment. Significant improvements were found in all gait parameters and clinical measures following 6 months of therapy including an increase in gait velocity (10.6 %), step length (5.6 %), cadence (5 %), and quality of life and a decrease in pain

(13.3 %). There were no significant differences between groups in the gait parameters following 6 months of treatment.

Conclusions Significant differences exist between patients with CNSLBP and healthy controls in terms of gait pattern and self-assessed health status. The examined HBBT led to significant improvements in gait pattern, reduction in pain, improved function and increased quality of life. However, future studies should validate these results while comparing this treatment to other treatment modalities.

Keywords Gait · Non-specific low back pain · Biomechanical treatment · Physical function · Pain

Introduction

Low back pain (LBP) is a leading cause of office visits to physicians and accounts for a significant percentage of disability claims [1]. It has an estimated lifetime incidence of 60–80 %. Of LBP patients, 80 % were categorized as suffering from non-specific LBP (NSLBP), defined as pain not attributable to any recognizable pathology. Within this category, 7–10 % of patients proceeded to develop chronic NSLBP with profound effects on their quality of life and work productivity [2, 3].

Patients with NSLBP have a different gait pattern compared to matched controls. They demonstrate slower walking speed, shorter step length and asymmetrical step length [4]. These changes are considered a protective strategy, as patients try to avoid extensive hip and spine ranges of motion and minimize forces acting on the body [5–7] which may cause pain. In addition, earlier studies examining gait found that NSLBP patients with diminished

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Original Article

Gait abnormalities in patients with chronic ankle instability can improve following a non-invasive biomechanical therapy: a retrospective analysis

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Abstract. [Purpose] The purpose of this study was to evaluate the changes in gait patterns and clinical outcomes of patients with chronic ankle instability (CAI) following treatment with a home-based non-invasive biomechanical device. [Subjects and Methods] Thirty-three patients with CAI were compared with 43 healthy controls. Patients underwent a spatiotemporal gait assessment before and three months following treatment. Clinical evaluation was recorded with SF-36 Health Survey and the Foot and Ankle Outcome Score (FAOS). [Results] Significant baseline differences were found between groups. Patients with CAI showed a statistically significant improvement in velocity, cadence, symptomatic limb step length and single limb support over time. Significant improvements in SF-36 PCS and FAOS outcome scores were found in patients with CAI. [Conclusion] Patients with CAI have baseline spatiotemporal gait abnormalities as compared with healthy controls. However, clinical and gait metrics improvement can be expected after 12 weeks of perturbation training using a non-invasive biomechanical device.

Key words: Neuromuscular control, Walking patterns, Biomechanical device

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INTRODUCTION

The pathophysiology of progression from acute lateral ankle sprain to chronic ankle instability (CAI) is not well understood. It is estimated that CAI can develop in up to 40% of ankle sprains^{1–3)}. The prevalence of CAI in young adult population is estimated to be 1.1% in males and 0.7% in females⁴⁾. Chronic ankle instability is regarded to have multifactorial pathology, and can be caused by several co-existing etiologies. Mechanical instability^{5, 6)}, proprioception deficits^{7–10)}, neuromuscular control deficits^{11–13)}, postural control deficits^{14–16)}, and muscle weakness^{9, 17, 18)} have all been studied and demonstrated to contribute to CAI.

A debate exists regarding gender-based differences and ankle instability. Some authors found that males had a higher incidence of ankle sprains compared to age-matched females^{4, 19)}. Conversely, other authors found that ankle instability was more common in females²⁰⁾. Several publications have shown that female athletes are more prone to lower extremity

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2 Biomechanical alignment and perturbation





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Control of knee coronal plane moment via modulation of center of pressure: A prospective gait analysis study

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ABSTRACT

Objectives: Footwear-generated biomechanical manipulations (e.g., wedge insoles) have been shown to reduce the magnitude of adduction moment about the knee. The theory behind wedged insoles is that a more laterally shifted location of the center of pressure reduces the distance between the ground reaction force and the center of the knee joint, thereby reducing adduction moment during gait. However, the relationship between the center of pressure and the knee adduction moment has not been studied previously. The aim of this study was to examine the association between the location of the center of pressure and the relative magnitude of the knee adduction moment during gait in healthy men. **Methods:** A novel foot-worn biomechanical device which allows controlled manipulation of the center of pressure location was utilized. Twelve healthy men underwent successive gait analysis testing in a controlled setting and with the device set to convey three different para-sagittal locations of the center of pressure: neutral, medial offset and lateral offset.

Results: The knee adduction moment during the stance phase significantly correlated with the shift of the center of pressure from the functional neutral sagittal axis in the coronal plane (i.e., from medial to lateral). The moment was reduced with the lateral sagittal axis configuration and augmented with the medial sagittal axis configuration.

Conclusions: The study results confirm the hypothesis of a direct correlation between the coronal location of the center of pressure and the magnitude of the knee adduction moment.

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1. Introduction

Approximately 60–80% of the load across the knee is transmitted to the medial compartment (Andriacchi, 1994; Prodromos et al., 1985). The relatively high-medial compartment load is due to the fact that the line of force acting at the foot passes medial to the knee joint center during gait (Johnson et al., 1980), generating an adduction moment which is proportional to the combination of the ground reaction force (GRF) and the perpendicular distance of this force from the center of the joint (Schipplein and Andriacchi, 1991). This moment tends to adduct the tibiofemoral joint, providing a major contribution to the elevated medial compartment load. It has been proposed that the adduction moment plays a key role in the pathogenesis of

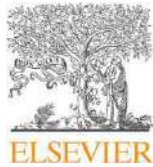
osteoarthritis (OA) of the knee through greater compression of the medial side of the joint and through induction of lateral joint laxity via chronic stretching (Goh et al., 1993). An abnormally high-knee adduction moment has been reported to be characteristic of the gait patterns in people with knee OA (Andriacchi, 1994). Likewise, knee adduction moment was found to be an important factor regulating bone size and mineral content in healthy and arthritic subjects (Hurwitz et al., 1998; Jackson et al., 2004; Wada et al., 2001).

Footwear-generated biomechanical manipulations (e.g., wedge insoles, foot orthoses) are commonly used in clinical practice to counter the effect of elevated adduction moments. These interventions utilize the principle that parts of the body act as a system of chained links (joint and motors), whereby the whole limb is regarded as one kinetic functioning unit, starting from the foot proximally through the body segments (Zajac et al., 2002). The application of a laterally wedged shoe insole was first introduced in the 1980s (Yasuda and Sasaki, 1987). Gait analysis studies in healthy subjects showed that, under dynamic conditions, wearing laterally wedged insoles reduced the magnitude of adduction

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The influence of sagittal center of pressure offset on gait kinematics and kinetics

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Knee flexion torque

ABSTRACT

Objectives: Kinetic patterns of the lower extremity joints have been shown to be influenced by modification of the location of the center of pressure (CoP) of the foot. The accepted theory is that a shifted location of the CoP alters the distance between the ground reaction force and the center of the joint, thereby modifying torques during gait. Various footwear designs have been reported to significantly alter the magnitude of sagittal joint torques during gait. However, the relationship between the CoP and the kinetic patterns in the sagittal plane has not been examined. The aim of this study was to evaluate the association between the sagittal location of the CoP and gait patterns during gait in healthy men.

Methods: A foot-worn biomechanical device which allows controlled manipulation of the CoP location was utilized. Fourteen healthy men underwent successive gait analysis with the device set to convey three different sagittal locations of the CoP: neutral, anterior offset and posterior offset.

Results: CoP translation in the sagittal plane (i.e., from posterior to anterior) significantly related with an ankle dorsiflexion torque and a knee extension torque shift throughout the stance phase. Likewise, an anterior translation of the CoP significantly reduced the extension torque at the hip during pre-swing.

Conclusions: The study results confirm a direct correlation between sagittal offset of the CoP and the magnitude of joint torques throughout the lower extremity.

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1. Introduction

During the stance phase of the gait cycle, a force is applied to the ground which is coupled with a ground reaction force (GRF). The magnitude of the GRF is equal and its direction is opposite to the force the body exerts (Winter, 1984). Consequently, joint torques develop which are equivalent to the magnitude of the GRF and the perpendicular distance from the joint center to the force (Gronley and Perry, 1984; Winter, 1984). Theoretically, altering the instantaneous center of pressure (CoP) of the foot would influence the orientation of this force and the resulting joint torques and angles through the body segments.

This principle has been the focus of previous research which examined the utilization of footwear-derived biomechanical manipulation. Application of wedge insoles were found to shift the location of the CoP in the coronal plane, thereby altering joint

torques from the foot proximally (Kakihana et al., 2005; Maly et al., 2002; Xu et al., 1999) and decreasing the load at the medial compartment of the knee joint in healthy and arthritic subjects (Crenshaw et al., 2000; Kakihana et al., 2005; Ogata et al., 1997; Yasuda and Sasaki, 1987). In a previous study (Haim et al., 2008), we examined the effect of controlled coronal plane CoP modulation at the foot. The magnitude of the knee adduction torque was found to significantly correlate with the coronal orientation of the CoP.

Several studies have investigated the effect of sagittal plane footwear modifications on kinematic and kinetic parameters of the lower extremities. Walking with different heel-height shoes has been reported to decrease stride length (de Lateur et al., 1991), to alter joint torques in the lower extremity (Snow and Williams, 1994), and to prolong midstance knee flexor torques during gait (Kerrigan et al., 2005). Missing-heel shoes were found to reduce walking speed and stride length, to increase cadence, and to considerably alter normal ankle joint function (Attinger-Benz et al., 1998). Gait analysis of negative heel rocker sole shoes showed an increase in cadence and a significant alteration of proximal joint metrics (Myers et al., 2006). Similarly, changes in CoP locus were reported with relation to rocker sole

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Effect of Center of Pressure Modulation on Knee Adduction Moment in Medial Compartment Knee Osteoarthritis

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ABSTRACT: The knee adduction moment (KAM) provides a major contribution to the elevated load in the medial compartment of the knee. An abnormally high KAM has been linked with the progression of knee osteoarthritis (OA). Footwear-generated biomechanical manipulations reduce the magnitude of this moment by conveying a more laterally shifted trajectory of the foot's center of pressure (COP), reducing the distance between the ground reaction force and the center of the knee joint, thus lowering the magnitude of the torque. We sought to examine the outcome of a COP shift in a cohort of female patients suffering from medial knee OA. Twenty-two female patients suffering from medial compartment knee OA underwent successive gait analysis testing and direct pedobarographic examination of the COP trajectory with a foot-worn biomechanical device allowing controlled manipulation of the COP. Modulation of the COP coronal trajectory from medial to lateral offset resulted in a significant reduction of the KAM. This trend was demonstrated in subjects with mild-to-moderate OA and in patients suffering from severe stages of the disease. Our results indicate that controlled manipulation of knee coronal kinetics in individuals suffering from medial knee OA can be facilitated by customized COP modification. © 2011 Orthopaedic Research Society. Published by Wiley Periodicals, Inc. *J Orthop Res* 29:1668–1674, 2011

Keywords: center of pressure; footwear-generated biomechanical manipulations; gait analysis; knee adduction moment; knee medial compartment osteoarthritis

The knee is the most prevalent weight-bearing joint prone to the development of osteoarthritis (OA).¹ The medial compartment of the tibiofemoral joint is affected more often than the lateral compartment.^{2,3} Various biomechanical factors have been implicated to account for this unequal distribution. Vast evidence suggests that repetitive articular cartilage overloading plays a key role in the development and progression of OA.⁴ Loads transferred through the medial compartment are ~2.5 times greater than those transferred through the lateral compartment.^{5,6} The relatively high medial loads are due to the line of force during gait acting under the foot's center of pressure (COP) passing medial to the knee joint center.⁷ This force generates an adduction moment about the knee proportional to the product of the magnitude of the ground reaction force (GRF) and the orthogonal distance between this force's line of action and the joint center.⁸ The knee adduction moment (KAM) tends to adduct the tibiofemoral joint, providing a major contribution to the elevated medial compartment load. An abnormally high KAM is characteristic of gait in subjects with knee OA,^{5,9} has been linked with progression of knee OA,¹⁰ and is recognized as a marker of disease severity.⁹

Mundermann et al.¹¹ examined KAM in patients with knee OA and matched healthy controls. In patients with severe OA, both the first peak (during midstance; MS) and the second peak (during terminal stance; TS) of the KAM were elevated, while in

patients early in the course of the disease, the second peak was lower. Thorp et al.¹² reported that in Kellgren–Lawrence (KL) grade II patients, the KAM and the knee adduction angular impulse were both significantly higher in symptomatic than in asymptomatic subjects. Several studies investigated the effect of footwear-generated biomechanical manipulations (e.g., wedge insoles and foot orthoses) to counter the effect of elevated KAM. These interventions are intended to convey a shift of the COP on the foot, thereby altering the orientation of the GRF vector and reducing the distance between the force and the center of the knee, hence reducing KAM.¹³ Using computer modeling simulation, Shelburne et al.¹⁴ reported that a 1 mm displacement of the COP can decrease KAM by 2%. In a recent study, an instrumented knee replacement was utilized to examine medial knee joint loading while walking with variable-stiffness shoes.¹⁵ This intervention reduced loading on the medial compartment. Moreover, the reduction in medial compressive force correlated with the external KAM. A beneficial effect of wearing a laterally wedged insole was reported in knee OA patients; medial- and lateral-wedged insoles increased and decreased lateral thrust at the knee during walking, respectively.¹⁶ Kakihana et al.¹⁷ reported a reduction in the KAM with the application of lateral wedged insoles. Similarly, Kerrigan et al.¹⁸ reported that the use of lateral wedged insoles reduced the KAM in patients with KL grades III and IV. On the other hand, Shimada et al.¹⁹ reported that wearing a laterally wedged insole significantly reduced the KAM during gait in patients with KL grades I and II, but not III and IV. However, a methodical examination of the association between the

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Foot Center of Pressure Trajectory Alteration by Biomechanical Manipulation of Shoe Design

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Abstract

Background: Footwear-generated biomechanical manipulations have been shown to alter lower limb kinetics. It has been suggested that this is due to altered trajectory of the foot's center of pressure (COP), conveying a shift in location of the ground reaction force and modifying moments and forces acting on proximal body segments. However, past studies have focused on qualitative association between footwear design and the COP locus. Moreover, this association was calculated via indirect analysis. The purpose of the present study was to directly examine and quantify the correlation between measured footwear biomechanical manipulation and the location of the COP trajectory during gait.

Methods: A novel biomechanical device allowing flexible positioning of 2 convex-shaped elements attached to its sole was utilized. A total of 20 healthy male adults underwent direct in-shoe pressure measurements while walking with the device set at 7 mediolateral configurations. COP data were collected during gait and analyzed with respect to different stance subphases.

Results: COP location significantly correlated with a shift of the elements medially or laterally. The linear model describing this correlation was found to be statistically significant.

Conclusion: There was significant correlation between the plantar orientation of the shoe device configuration and the COP.

Clinical Relevance: Changes in COP trajectory may be valuable in patients suffering from multiple foot disorders elevating pressure on the foot. Accurate COP control could aid in the manipulation of the forces acting on the proximal joints during gait. In addition, these findings may have implications in the field of biomechanical apparatus design and practice.

Keywords: foot center of pressure, gait, plantar pressures, wedge position

The foot center of pressure (COP) is a theoretical locus about the foot, which is the average location of all the forces acting between the plantar surface of the foot and the ground at any given time during the stance phase.^{3,15} Typically, the COP trajectory propagates from the medial aspect of the hindfoot, curving laterally at midstance and progressing medially at terminal stance.^{4,8,15} This reflects both the anatomical properties of the foot and the relationship of the location of the body's center of mass to the location of the foot.^{1,2,6,8,11,18} By definition, the projection on the ground plane of the ground reaction force (GRF), which is the average vector exerted by the ground on the body, and the trajectory of the COP during single limb support overlap.^{3,19}

Footwear-generated biomechanical manipulations have been proposed to alter the trajectory of the COP, thereby altering the location of the GRF and modifying moments and forces acting on proximal body segments.¹² This principle has been the focus of past studies and has been widely implemented in clinical practice.^{10,12} The application of a laterally wedged shoe insole was first introduced in the

1980s.²¹ Maly et al hypothesized that the mechanism of reduction of knee adduction moment (KAM) with the use of insoles is a lateral shift in the COP.¹³ Xu et al confirmed that insole conditions caused a change in the location of the COP during gait.²⁰ Using computer modeling simulation, Shelburne et al reported that a 1 mm displacement of the COP can decrease the KAM by 2%.¹⁶

The association between the COP and the footwear design is not trivial. On one hand, if the interface between the ground and the plantar surface of the footwear were

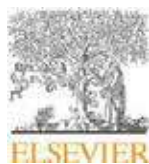
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Detecting and quantifying global instability during a dynamic task using kinetic and kinematic gait parameters

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ABSTRACT

Objectives: Instability during gait can be identified in many different ways. Recent studies have suggested utilizing spatiotemporal parameters to detect instability during gait. Detecting instability using kinetic and kinematic gait parameters has not yet been examined fully. In addition, these studies have not yet identified measures that are capable of assessing the magnitude of instability. The objective of the present study was to identify kinetic and kinematic gait parameters that can best identify instability and quantify its magnitude.

Methods: Ten healthy men underwent successive gait analysis testing under three controlled settings: (1) Stage 0 instability (control setting), (2) Stage 1 instability and (3) Stage 2 instability. The levels of instability were precisely applied with the use of a controlled perturbation device (AposTherapy System). Differences between all stages and between stages were identified using Friedman and Wilcoxon tests.

Results: Stride-to-stride variability (STSV) in kinetic and kinematic measures increased significantly between stages 0 and 1 or between stages 0 and 2 for almost all parameters (all $P < 0.05$). A significant increase between stage 0 and both stages 1 and 2 was found for knee flexion moment, knee varus moment, knee flexion angle and hip adduction angle. The increase between stages 1 and 2 was variable. Only the knee varus moment parameter showed a significant increase in STSV between stages 1 and 2 ($P = 0.026$).

Conclusions: Almost all kinetic and kinematic gait parameters are sensitive to changes in global instability in a dynamic task. The most sensitive are parameters measured at the knee. Of these, STSV in knee varus moment can be used to quantify the magnitude of dynamic instability.

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1. Introduction

Instability during gait has received considerable focus over the last several years due to its association with falling. Falling is a common and dangerous problem in society. In the elderly, falling is particularly prevalent and can be incapacitating when it occurs (Voermans et al., 2007). Falling is only predicted to increase in frequency as life expectancy continues to rise (Brauer et al., 2000). Instability and falling is also prevalent in patients with osteoarthritis (Arnold and Faulkner, 2007), Parkinson's disease (Bloem et al., 2001; Factor et al., 2011; Plotnik et al., 2011), Huntington's disease (Grimbergen et al., 2008), cerebral palsy (Tsirikos et al., 2003) and other neurological disorders.

Instability is classically defined according to the relationship between a person's center of mass (COM) and base of support

(BOS) (Winter, 1995). The further the COM is from the BOS, the more "unstable" the person (Winter, 1995). During gait, however, the situation becomes much more complex. During each gait cycle the location of the COM of the body follows a sinusoidal curve between both feet. The curve usually fits within the dynamic BOS created by footsteps during gait (Winter, 1995). In subjects who are unstable in gait, the COM curve creeps beyond the BOS defined by the feet until it reaches a maximum at which the patient is at risk for falling (Winter, 1995). Due to its complex manifestation in gait, stability in gait is often separated into local and global classifications (Dingwell et al., 2000). Local dynamic stability refers to the body's ability to recover from small perturbations. It can be quantified using Lyapunov exponents (LyE) (Arellano et al., 2009). On the other hand, global dynamic stability refers to the body's ability to recover from large-scale perturbations, such as slip or trip (Dingwell and Cavanagh, 2001).

Several techniques have been developed in order to identify global instability before a fall occurs. Many of these include static tests such as quiet standing and retropulsion tests (Bloem et al., 1998). Over the

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Reduction of Frontal-Plane Hip Joint Reaction Force Via Medio-Lateral Foot Center of Pressure Manipulation: A Pilot Study

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ABSTRACT: Footwear-generated biomechanical manipulation of lower-limb joints has been shown to influence lower-limb biomechanics. Numerous studies report the influence of such interventions on the knee, however little is known about the influence of these interventions on the hip. The present study analyzed kinetic and kinematic changes about the hip of 12 healthy young males who underwent biomechanical manipulation utilizing the APOS biomechanical device (APOS—Medical and Sports Technologies Ltd., Herzliya, Israel) allowing controlled foot center of pressure manipulation. Subjects underwent gait testing in four para-sagittal device configurations: Medial, lateral, neutral, and regular shoes. In the medial configuration, subjects demonstrated no change in step width (i.e., distance between right and left foot center of pressure), however inter-malleolar distance significantly increased. Likewise with the medial setting, greater hip abduction was recorded, while hip adduction moment and joint reaction force decreased significantly. We speculate that subjects adopt a modified gait pattern aimed to maintain constant base of support. As a result, hip abductor muscle moment arm increases and adduction moment and joint reaction force decreases. To the best of our knowledge this is the first study to show this relationship. These results contribute to the understanding of lower-limb biomechanics and warrant further investigation. © 2014 Orthopaedic Research Society. Published by Wiley Periodicals, Inc. *J Orthop Res*

Keywords: center of pressure; footwear-generated biomechanical manipulations; gait analysis; hip adduction and abduction; frontal-plane kinetics and kinematics of the hip

Footwear-generated biomechanical manipulation (e.g., wedge insoles and foot orthotics), commonly used in clinical practice, has been the focus of vast biomechanical research and has been shown to alter lower-limb biomechanics and reduce joint loads in both healthy and pathological subjects.^{1–8} These devices have been reported to shift the foot's center of pressure (COP) thus changing the locus and orientation of the resultant ground reaction force (GRF). They work on the principle that the lower limbs act as a system of chained links forming a functional kinetic unit.⁹ Thus the effect of changing the COP is carried up the chain starting from the most proximal joint (i.e., ankle, knee, hip). By changing the locus and orientation of the GRF, and hence the perpendicular distance from the GRF to the center of the joint being investigated, the kinematics, kinetics, and neuromuscular activity about the joint are also affected.^{1,7,8,10–12} This in turn may alter the loading conditions of the joint. Footwear-generated COP manipulation which displaces the COP in such a way to reduce joint loads via this mechanism has been the focus of vast research since recommendations for degenerative joint diseases include reducing load on the pathological joint.¹³ However, in-depth studies of influence of such interventions on the hip joint, specifically with an eye toward clinical implications, are scarce and, in general, there is a void of biomechanical analyses, with specific respect to the hip joint, of footwear capable of manipulating lower-limb biomechanics.

Loads in the hip joint during gait have been measured to be 2 to over 5 times body weight.^{14–17} These extreme loads may be detrimental to the joint, causing further damage, pain, and disease progression in the case of degenerative diseases.¹⁸ The abductor muscles' force acting across the hip joint contributes a major component of the load on the hip joint.^{19,20} In fact, it has been shown that the gluteus medius, a major hip abductor muscle, contributes the most to the vertical and medio-lateral components of the hip joint contact force out of all of the key muscles that span the hip joint, including abductors, adductors, flexors, extensors, and rotators, and also more than gravitational and centrifugal forces, as well as all other muscles of the ipsilateral limb.²¹ In addition, it was shown that the gluteus medius and minimus, also a hip abductor, were among the muscles that contributed the most to the first peak of the total GRF and were nearly solely responsible for the midstance GRF.²² It is also suggested that abductor muscles contribute more to the joint force than body weight.²³ According to the standard frontal-plane model of the hip-pelvis complex, in single limb stance, the hip acts as a fulcrum to keep the pelvis parallel to the ground (Fig. 1a). The moment about the hip produced by the body weight minus the weight of the ipsilateral leg (K^*a) is counteracted by the moment produced by contraction of the abductor muscles (M^*b). The effective body weight (K) plus the abductor muscles' force (M) produces a resultant joint reaction force (JRF).

Gait in the frontal, sagittal, and transverse planes occurs due to a balance or specific imbalance of internal and external forces acting about joints of the lower limbs. External forces about the joint result from the GRF, while internal forces result from active and passive anatomical structures including muscles, bones,

Conflict of interest: None.

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RESEARCH

Open Access



Alteration of the foot center of pressure trajectory by an unstable shoe design

Mona Khoury^{1*}, Amir Haim^{1,2}, Amir Herman³, Nimrod Rozen⁴ and Alon Wolf¹

Abstract

Background: Unstable sole designs have been used as functional or therapeutic tools for improving body stability during locomotion. It has been suggested that the narrow base of support under the feet generate perturbations that challenge the instability of different joints during motion, thereby forcing the body to modify its movement in order to maintain a stable gait. The purpose of the present study was to explore the correlation between the stability of the footwear-device and the magnitude of perturbation conveyed during gait.

Methods: Various levels of dynamic instability were achieved using a novel foot-worn platform with two adjustable convex rubber elements attached to its sole. A total of 20 healthy male adults underwent direct in-shoe pressure measurements while walking with the footwear device. Foot center of pressure (COP) and stride to stride variability measures were extracted to examine the correlation between the magnitude of the instability and the imposed perturbations during gait.

Results: A counterintuitive but significant correlation was found between stride to stride variability and the instability of the biomechanical elements. Moreover, there was significant correlation between the instability of the elements and the perturbations found in the COP trajectory. The linear model describing this correlation was found to be statistically significant.

Conclusion: There was significantly negative correlation between the level of instability induced by the shoe design and the amount of perturbations conveyed during gait. This suggests that the external perturbation must remain within a certain range limit. Exceeding this limit can negatively affect the treatment and probably lead to opposite results.

Keywords: Gait, Foot center of pressure, Plantar pressures, Unstable shoe design

Background

In recent years, a novel therapeutic approach to musculoskeletal pathologies, centered on neuromuscular reeducation, has emerged and has been the focus of a vast amount of research [1–3]. The principal behind these therapeutic interventions is that the neurological system controlling locomotion is plastic and, given accurate stimuli, can generate enhanced motor activation patterns that can compensate for anatomical pathologies which compromise gait [4].

It has been suggested that perturbation can generate the appropriate stimuli to improve proprioception and to adopt altered motor control strategies during gait.

Footwear-generated biomechanical manipulations have been commonly utilized for this objective [5]. Acting as an interface between the feet and the ground, footwear can manipulate sensory feedback information originating from the plantar surface of the foot and generate these stimuli. The idea behind these designs is to introduce controlled diminished support, thereby challenging joint stability and balance control, a strategy that may allow users to develop motor skills adequate to protect their joints from potentially harmful loads during functional activities [6].

Several unsteady shoe designs have been developed and have been reported to produce favorable outcomes of functional activity and pain reduction [6–10]. Findings related to the effect of the MBT unstable shoe sole showed that wearing these shoes in a standing position

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Reduction of Hip Joint Reaction Force via Medio-Lateral Foot Center of Pressure Manipulation in Bilateral Hip Osteoarthritis Patients

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ABSTRACT: Loading/excessive loading of the hip joint has been linked to onset and progression of hip osteoarthritis. Footwear-generated biomechanical manipulation in the frontal plane has been previously shown in a cohort of healthy subjects to cause a specific gait adaption when the foot center of pressure trajectory was shifted medially, which thereby significantly reduced hip joint reaction force. The objective of the present study was to validate these results in a cohort of female bilateral hip osteoarthritis patients. Sixteen patients underwent gait analysis while using a footworn biomechanical device, allowing controlled foot center of pressure manipulation, in three para-sagittal configurations: medial, lateral, and neutral. Hip osteoarthritis patients exhibited similar results to those observed in healthy subjects in that a medial center of pressure led to an increase in inter-maleolar distance while step width (i.e., distance between right and left foot center of pressure) remained constant. This adaptation, which we speculate subjects adopt to maintain base of support, was associated with significantly greater hip abduction, significantly decreased hip adduction moment, and significantly reduced joint reaction force compared to the neutral and lateral configurations. Recommendations for treatment of hip osteoarthritis emphasize reduction of loads on the pathological joint(s) during daily activities and especially in gait. Our results show that a medially deviated center of pressure causes a reduction in hip joint reaction force. The present study does not prove, but rather suggests, clinical significance, and further investigation is required to assess clinical implications. © 2016 Orthopaedic Research Society. Published by Wiley Periodicals, Inc. *J Orthop Res*

Keywords: center of pressure; footwear-generated biomechanical manipulations; gait analysis; hip osteoarthritis; frontal-plane kinetics and kinematics of the hip

Hip osteoarthritis (OA) is one of the most common pathologies affecting the elderly with an immense social, economic, and personal burden. It is a chronic debilitating progressive disease characterized by pain, stiffness, loss of articular cartilage and joint space narrowing, formation of osteophytes, and significant gait and physical function abnormalities. It has been estimated by several epidemiologic studies to affect 6.7–9.7% of people over the age of 45 in the United States.^{1,2} As a result of increasing life expectancy and the obesity crisis, the need for total hip arthroplasty (THA) is expected to grow 174%, to 572,000 per year by 2030 in the United States alone, with actual numbers to date suggesting that this is an underestimation.³

Although the precise pathogenesis of OA is unknown, based on significant research, biomechanical factors play a critical role in its onset and progression.^{4,5,6–10} Specifically, excessive loading of the osteoarthritic joint may be detrimental.⁷ Mechanical failure of cartilage is caused by compressive and shear stresses on the joint.^{11,12} Thus, among the recommended non-pharmacologic and non-surgical treatments for hip OA, reduction of joint load in gait and daily activities is emphasized.¹³

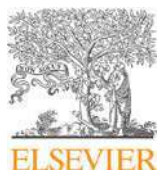
Footwear-generated biomechanical manipulation of lower limbs has been the focus of significant research. This manipulation shifts the foot's center of pressure trajectory, thus, changing the locus and orientation of the ground reaction force (GRF). This affects bio-

mechanics of all joints in the lower limbs starting with the ankle and progressing to the knee and hip.^{14–18} Our previous research has shown that external knee adduction moment and medial-compartment joint loads are reduced in the knee in both healthy¹⁴ and medial compartment knee OA patients.¹⁹ Recently, in a pilot study conducted on a cohort of healthy males, we used a novel biomechanical device capable of controlled foot center of pressure (COP) manipulation to examine the effects of medio-lateral COP displacement on kinematics and kinetics of the hip joint.¹⁶ We showed that hip joint reaction force is significantly reduced with a medial displacement of COP in this cohort. Subjects maintained a constant step width (distance between right and left foot COP) during medio-lateral COP manipulation, while increasing or decreasing intermaleolar distance (distance between lateral maleoli), in order to maintain a constant base of support (Fig. 1c). With a medially displaced COP, subjects increased inter-malleolar distance (IMD) via increasing hip abduction. Also observed was a concurrent decrease in external hip adduction moment, as well as an 8% decrease in frontal-plane hip joint reaction force (JRF) at the peak load-bearing portion of stance phase. We speculated that the mechanism for the decrease in frontal-plane JRF was as follows (Fig. 1a and b):

- medial shift in COP,
- increase in IMD/hip abduction in order to maintain base of support,
- suggested increase in abductor muscle moment arm²⁰ and hence decrease in abductor muscle force required to maintain level pelvis,

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Mechanism of reducing knee adduction moment by shortening of the knee lever arm via medio-lateral manipulation of foot center of pressure: A pilot study

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Foot center of pressure

ABSTRACT

Prominent conservative treatment options for medial-compartment knee osteoarthritis include footwear that reduces knee adduction moment (KAM) correlated with detrimental loads in the medial compartment of the knee, thus providing clinical benefit. The proposed mechanism by which they reduce KAM is a lateral shift in foot center of pressure (COP) and a consequent shortening of the knee lever arm (KLA), thereby reducing KAM, which can be simply calculated as KLA multiplied by the frontal plane ground reaction force (FP-GRF). The present study investigated this mechanism for a unique biomechanical device capable of shifting COP by means of moveable convex elements attached to the shoe. Fourteen healthy young male subjects underwent gait analysis in two COP configurations of the device for comparison: (1) laterally and (2) medially deviated. Average midstance KLA and KAM were decreased by 8.2% and 8.7%, respectively, in the lateral COP compared to medial. Ground reaction force parameters, frontal plane knee angle (FP-KA), and spine lateral flexion angle (SLF) did not differ between COP configurations. No study parameters differed for terminal stance. Linear mixed effects models showed that COP and FP-GRF components, but not FP-KA and SLF, were significant predictors of KLA. In addition, KLA and FP-GRF were significant predictors of KAM; although, FP-GRF did not change significantly with medio-lateral COP shift, while KLA did. This suggests that the mechanism by which the study device reduces KAM is primarily through shortening of KLA brought on by a lateral shift in COP.

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1. Introduction

Knee osteoarthritis (OA) is a debilitating progressive degenerative disease characterized by loss of articular cartilage, or joint space narrowing, bony enlargement, osteophytosis, crepitus, joint stiffness, joint laxity, and pain, among others (Altman et al., 1986; Felson et al., 2000). It is one of the leading causes of global disability with estimated global prevalence of 3.8% of radiographically confirmed knee OA in 2010 (Cross et al., 2014). Mechanical stress is suggested to be the primary factor contributing to knee OA (Visser et al., 2015). Therefore, current nonsurgical nonpharmacological treatment recommendations include load reduction on the diseased joint (Zhang et al., 2008), which may slow or stop disease progression (Lafeber et al., 2006; Marijnissen et al., 2002; Pollo and Jackson, 2006; van Valburg et al., 1995; 1999), provide

relief of symptoms, and increase quality of life (Erhart-Hledik et al., 2012; Erhart et al., 2010b; Haim et al., 2012).

The knee adduction moment (KAM) has been shown to be significantly correlated with medial-compartment knee loads, and is commonly enhanced in knee OA patients (Erhart et al., 2010a; Zhao et al., 2007). Likewise, it has been shown that frontal plane knee lever arm (KLA), or the perpendicular distance from the knee joint center (KJC) to the frontal plane ground reaction force (FP-GRF), is enhanced in knees with OA (Hunt et al., 2006; Weidenhielm et al., 1995, 1994). Manipulation of KAM by means of foot orthoses is a widely accepted conservative treatment option for medial-compartment knee OA (Erhart et al., 2008; Haim et al., 2012; Hinman et al., 2009; McAlindon et al., 2014). Specifically, foot orthoses that shift the foot center of pressure (COP) work on the principle that a lateral shift in COP, along the medio-lateral foot axis, shifts the point at which the FP-GRF vector acts to a location closer to the KJC. This consequently shortens KLA, and hence reduces KAM, since KAM is the product of KLA and FP-GRF magnitude.

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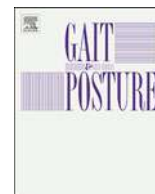
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Full length article

The effect of unstable shoe designs on the variability of gait measures

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ABSTRACT

Background: Unstable footwear designs are popular as training devices to strengthen human neuromuscular control, and many studies have evaluated their effect on gait parameters in comparison to conventional footwear designs. However, there is minimal research on variability of gait measures during walking with unstable shoes. Therefore, the study objective was to compare variability of gait measures between stable and unstable shoe configurations, in conjunction with kinematic and kinetic changes.

Methods: Fifteen healthy male subjects walked in both a stable and unstable footwear device configuration while full-body gait kinematic and kinetic data was collected. Averages and standard deviations of gait trials were compared between the two configurations at different stages of each step.

Results: Comparison of gait variability between both footwear configurations revealed that variability of frontal-plane foot center of pressure offset, transverse-plane ankle moment, and frontal-plane shoulder angle decreased significantly while walking in the unstable configuration, while transverse-plane spine angle variability increased. No changes in variability of gait measures at the knee, hip, or pelvis were observed. Kinematic and kinetic changes were observed throughout the whole body with the unstable shoe.

Conclusion: Our findings suggest that the unstable device used in the study may reduce gait variability at the two extremes of the kinematic chain (i.e., foot, ankle, and shoulders), but increase variability of spine rotation angle. This may suggest a compensatory mechanism to maintain both stability and adaptability, and may have potential clinical implications for gait retraining and enhancing dynamic gait stability and joint stability, pending further investigation.

1. Introduction

Natural gait is a repeatable consistent function in healthy populations [1], yet complex stride-to-stride variability exists [2]. Although "variability" and "stability" are not interchangeable terms, unstable walkers (i.e., young children, the elderly, Parkinson's disease patients) may have greater stride-to-stride variability [2], and increased variability may be a risk factor for falls in certain populations [3]. However, when discussing association between variability and stability, one must differentiate between global and local stability. In general, increased movement variability on the global (macroscopic) level may have negative impact on gait performance and should be minimized [4]. On the other hand, increased variability on an individual joint (microscopic) level may be a favorable indication of increased adaptability and flexibility, in allowing exploration of different movement patterns to find the optimal strategy, or the ability to overcome external perturbations [2,5]. However, the relationship between joint-level variability and

dynamic stability may be specific to an individual's circumstances and health status. For example, reduced joint-level variability may be an indication of pathology, but may reduce risk of falling [2,6]. Yet, excessive joint variability may provide evidence for development of degenerative joint diseases [7]. Given the complex relationship between variability and dynamic stability, investigation of variability while walking with unstable shoes is of great interest.

Unstable footwear designs have been widely studied and implemented over the last decade as devices to strengthen muscles and train neuromuscular control [8–11], including in treatment protocols for pathologies including degenerative diseases of lower-limb joints [8–10]. It is well known that unstable footwear alters gait pattern and neuromuscular activity [12–19], with several of these alterations identified as contributors, or potential contributors, to its clinical benefit [9,10,20,21]. As such, studies have largely focused on differences in these parameters between unstable and stable (control) shoes, but there is minimal literature regarding gait variability in unstable shoes.

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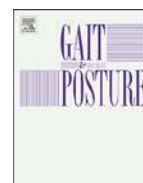
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The effect of center of pressure alteration on the ground reaction force during gait: A statistical model

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ABSTRACT

Background: Foot problems and lower-limb diseases (e.g., foot ulcers, osteoarthritis, etc.), are presented with a ground reaction force (GRF) that may deviate substantially from the normal. Thus, GRF manipulation is a key parameter when treating symptoms of these diseases. In the current study, we examined the impact of footwear-generated center of pressure (COP) manipulations on the GRF components, and the ability to predict this impact using statistical models.

Methods: A foot-worn biomechanical device which allows manual manipulation of the COP location was utilized. Twelve healthy young men underwent gait analysis with the device set to convey seven COP conditions: (1) a neutral condition, (2) lateral and (3) medial offset along the medio-lateral foot axis, (4) anterior and (5) posterior offset along the antero-posterior foot axis, and (6) a dorsi-flexion and (7) plantar-flexion condition. Changes in the magnitude and the early stance-phase impulse of the GRF components across COP conditions were observed. Linear models were used to describe relationships between COP conditions and GRF magnitude and impulse.

Results: With respect to ANOVA, the vertical and antero-posterior components of the GRF were significantly influenced by the COP configuration throughout the different stages of the stance-phase, whereas the medio-lateral components were not. The models of vertical, antero-posterior and medio-lateral GRF components were statistically significant.

Significance: The study results are valuable for the development of a method and means for efficient treatment of foot and lower-limb pathologies. The ability to predict and control the GRF components along three orthogonal axes, for a given COP location, provides a strong tool for efficient treatment of foot and lower-limb diseases and may also have relevant implications in sports shoe design. This study is a preliminary investigation for our ultimate goal to develop an effective treatment method by developing an autonomous GRF manipulations device based on closed-loop feedback.

1. Introduction

During gait, the foot is the point of physical contact between the environment and the body. As a result, the force acting on the foot, namely the three-dimensional ground reaction force (GRF), can simultaneously impact and be impacted by pathological disorders. Disorders such as degenerative diseases of the joints (e.g., osteoarthritis), injury, or foot problems (e.g., foot ulcers secondary to diabetes mellitus, plantar fasciitis) are presented with a GRF that may deviate substantially from the normal [1,2]. Thus, examination of the impact of

external perturbations on the GRF may be of great interest in areas such as shoe design and footwear orthotics designed to treat symptoms of lower-limb joint and foot diseases.

The three-dimensional GRF is a reflection of the total mass-times-acceleration product of all body segments [3]. The origin of the GRF vector is the foot center of pressure (COP) which is a locus defined as the average location of all external forces acting between the foot and the ground [4]. Numerous studies have shown the correlation between external perturbations applied to the foot during gait and alteration of lower-limb biomechanics, including kinematics, kinetics, and neuro-

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Trunk kinematic, kinetic, and neuro-muscular response to foot center of pressure translation along the medio-lateral foot axis during gait

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ABSTRACT

Footwear devices that shift foot center of pressure (COP), thereby impacting lower-limb biomechanics to produce clinical benefit, have been studied regarding degenerative diseases of knee and hip joints, exhibiting evidence of clinical success. Ability to purposefully affect trunk biomechanics has not been investigated for this type of footwear. Fifteen healthy young male subjects underwent gait and electromyography analysis using a biomechanical device that shifts COP via moveable convex elements attached to the shoe sole. Analyses were performed in three COP configurations for pairwise comparison: (1) neutral (control) (2) laterally deviated, and (3) medially deviated. Sagittal and frontal-plane pelvis and spine kinematics, external oblique activity, and frontal and transverse-plane lumbar moments were affected by medio-lateral COP shift. Transverse-plane trunk kinematics, activity of the lumbar longissimus, latissimus dorsi, rectus abdominus, and quadratus lumborum, and sagittal-plane lumbar moment, were not significantly impacted. Two linear mixed effects models assessed predictive impact of (I) COP location, and (II) trunk kinematics and neuromuscular activity, on the significant lumbar moment parameters. The COP was a significant predictor of all modeled frontal and transverse-plane lumbar moment parameters, while pelvic and spine rotation, and lumbar longissimus activity were significant predictors of one frontal-plane lumbar moment parameter. Model results suggest that, although trunk biomechanics and muscle activity were altered by COP shift, COP offset influences lumbar kinetics directly, or via lower-limb changes not assessed in this study, but not by means of alteration of trunk kinematics or muscle activity. Further study may reveal implications in treatment of low back pain.

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1. Introduction

Low back pain (LBP) is the leading cause of disability globally (Hoy et al., 2014), with a lifetime prevalence of up to 84% (Walker, 2000). It severely disrupts daily activities and work and, outside of the tremendous personal burden, has enormous economic detriment, costing tens of billions of dollars a year in productivity loss in the US alone (Rizzo et al., 1998).

Various causes of LBP have been proposed, including high impact forces during gait and abnormal foot biomechanics, with the latter associated with lumbopelvic muscular dysfunction (Papuga and Cambron, 2016). A connection has been observed between foot biomechanics and lumbopelvic function, as well as

lumbopelvic biomechanics and back pathologies (Barwick et al., 2012). It is thus not surprising that footwear-based treatment options are popular for LBP, and aim to minimize biomechanical contributors to LBP, particularly those associated with abnormal foot posture (Barwick et al., 2012; Papuga and Cambron, 2016). Significant improvement in LBP has been reported with shoe insoles and foot orthotics (Cambron et al., 2017; Shabat et al., 2005). However, several systematic reviews concluded that, although they might be effective, there was insufficient evidence to support them as a treatment for LBP (Chuter et al., 2014; Sahar and Cohen, 2009).

A specialized subcategory of therapeutic footwear composed of foot-worn devices which shift foot center of pressure (COP), such as wedge insoles (Leitch et al., 2011; Van Gheluwe and Dananberg, 2004), variable stiffness shoes (Boyer et al., 2012; Jenkyn et al., 2011), and a unique device with movable convex

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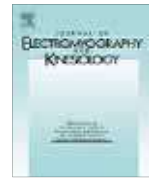
3 Specific muscle activation





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The effect of manipulation of the center of pressure of the foot during gait on the activation patterns of the lower limb musculature

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ABSTRACT

Background: Therapeutic devices that manipulate the center of pressure (COP) of the foot can induce kinetic and kinematic changes in gait. Appropriate changes in joint moments and muscle activation during gait have been proven to be beneficial for patients with neuromuscular and orthopedic disorders. The purpose of this study was to investigate the effect of different COP positions during gait on the activity of the lower limb musculature of healthy subjects.

Methods: A novel foot-worn biomechanical device that allows controlled manipulation of the COP during gait was used. Twelve healthy males underwent EMG analyses of the key muscles of the leg while wearing the device. The trials were carried out at six COP positions relative to neutral configuration: anterior, posterior, medial, lateral, dorsi flexion and plantar flexion.

Results: The EMG activity of the lateral gastrocnemius varied significantly with COP during terminal stance ($p = 0.023$) and preswing ($p = 0.020$), the tibialis anterior during load response ($p = 0.019$) and mid-stance ($p = 0.004$), the biceps femoris during terminal stance ($p = 0.009$) and the vastus lateralis during initial contact ($p = 0.010$).

Conclusion: There are significant changes in the muscle activity of the lower limb in response to manipulation of the COP of the foot during gait.

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1. Introduction

Pathologies such as patellofemoral pain syndrome (PFPS) and osteoarthritis (OA) are common musculoskeletal conditions (Dixit et al., 2007; Hogenmiller and Lozada, 2006). Therapists have turned to new devices that can manipulate a patient's foot center of pressure (COP) in order to decrease pain and improve function. The most prominent of these have been footwear-derived biomechanical devices. Investigators have defined the effects of some of these COP manipulations on kinetic patterns. Wedged insoles, for example, have been suggested to shift the location of the COP in the coronal plane, thereby altering resulting torques from the foot proximally (Kakihana et al., 2005; Maly et al., 2002; Xu et al., 1999). Application of wedge insoles has been reported to decrease the load and the magnitude of the adduction moment at the medial compartment of the knee joint in healthy and arthritic subjects (Kakihana et al., 2005; Crenshaw et al., 2000; Ogata et al., 1997; Yasuda and Sasaki, 1987). In two previous studies we analyzed the kinetic outcomes of a novel biomechanical apparatus that allows for controlled manipulation of the COP during gait. Adjusting the COP in the coronal plane (i.e., from medial to lateral)

correlated with significant changes in the knee adduction moment during stance (Haim et al., 2008). Likewise, manipulation of the COP in the sagittal plane (i.e., from posterior to anterior) significantly related with ankle dorsiflexion torque and knee extension torque during stance (Haim et al., 2010).

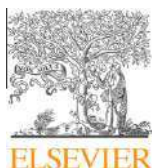
The current study is an extension of the studies reported in (Haim et al., 2008, 2010). In the current study we analyze the electromyography (EMG) data that was collected during the study described above (Haim et al., 2008, 2010), that is the kinematic, kinetic and electromyography data were collected simultaneously. Moreover, for consistency with the results reported in our previous works, we used the same methods at the same timeframes during the gait cycle so that the kinematic, kinetic and EMG phenomena could be correlated.

There have been several studies on the effects of COP changes on lower limb musculature activation. In a study by Mulavara et al. (1994), patients leaning forward moved their COP anteriorly and increased activation of their gastrocnemius (GC) muscle. Patients leaning backward moved their COP posteriorly and increased activation of their tibialis anterior (TA) muscle. In a study by Krishnamoorthy et al. (2004), patients who were asked to release a load from extended arms showed a forward shift in the COP.

To date, investigators have not examined the activation of the lower limb muscles in response to precisely controlled manipulation of the COP in multiple planes. This can be done using the novel

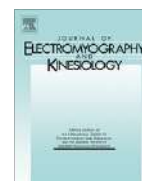
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Foot center of pressure manipulation and gait therapy influence lower limb muscle activation in patients with osteoarthritis of the knee

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ABSTRACT

Background: Foot center of pressure (COP) manipulation has been associated with improved gait patterns. The purpose of this study was to determine lower limb muscle activation changes in knee osteoarthritis patients, both immediately after COP manipulation and when COP manipulation was combined with continuous gait therapy (AposTherapy).

Methods: Fourteen females with medial compartment knee osteoarthritis underwent EMG analyzes of key muscles of the leg. In the initial stage, trials were carried out at four COP positions. Following this, gait therapy was initiated for 3 months. The barefoot EMG was compared before and after therapy.

Results: The average EMG varied significantly with COP in at least one phase of stance in all examined muscles of the less symptomatic leg and in three muscles of the more symptomatic leg. After training, a significant increase in average EMG was observed in most muscles. Most muscles of the less symptomatic leg showed significantly increased peak EMG. Activity duration was shorter for all muscles of the less symptomatic leg (significant in the lateral gastrocnemius) and three muscles of the more symptomatic leg (significant in the biceps femoris). These results were associated with reduced pain, increased function and improved spatiotemporal parameters.

Conclusions: COP manipulation influences the muscle activation patterns of the leg in patients with knee osteoarthritis. When combined with a therapy program, muscle activity increases and activity duration decreases.

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1. Introduction

Osteoarthritis (OA) is the most prevalent form of arthritis and occurs most commonly in the knee joint (Hogenmiller and Lozada, 2006). OA of the knee is one of the most common causes of disability in the elderly, affecting over 21 million people in the United States alone (Dillon et al., 2006; Felson et al., 1997). Patients with OA of the knee usually complain of pain, stiffness, poor function and muscle weakness (Hogenmiller and Lozada, 2006). Indeed, studies have shown that the muscle activity in the lower limb of patients with knee OA is below normal (Childs et al., 2004; Mc Alindon et al., 1993). Additionally, researchers have found that patients with knee OA have a longer duration of muscle contraction in comparison to healthy controls (Childs et al., 2004; von Tscharnier and Valderrabano, 2010).

Several studies have shown that muscle activity in knee OA can be improved through strength training, neuromuscular stimulation and standard rehabilitation exercises (Suettia et al., 2004; Graham and Fisher, 2003; Tal-Akabi et al., 2007). Other studies have shown that agility and perturbation training can improve the gait patterns of patients with knee OA (Elbaz et al., 2010; Fitzgerald et al., 2002; Hurley, 2003). Laterally wedged foot orthoses have been used for many years to treat medial compartment knee OA, which is the most common type of knee OA (Graham and Fisher, 2003). These orthoses have been shown to improve the pathological kinetics and kinematics in knee OA (Kerrigan et al., 2002). Previous studies have suggested that these orthoses act by shifting the center of pressure (COP) in the foot, leading to a reduction in the moment arm of the knee adduction moment (KAM) and thus the KAM itself (Maly et al., 2002).

In two previous studies, Haim et al. (2008, 2010) introduced a unique biomechanical device that is thought to combine COP shifts with agility and perturbation training. This device is a foot-worn platform with two adjustable convex rubber elements attached to its base. Through adjustment of the elements, the device is

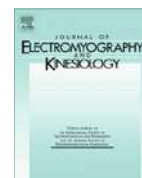
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Neuromuscular response of hip-spanning and low back muscles to medio-lateral foot center of pressure manipulation during gait



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ABSTRACT

Background: Footwear-generated medio-lateral foot center of pressure manipulation has been shown to have potential positive effects on gait parameters of hip osteoarthritis patients, ultimately reducing maximum joint reaction forces. The objective of this study was to investigate effects of medio-lateral foot center of pressure manipulation on muscle activity of hip-spanning and back muscles during gait in bilateral hip osteoarthritis patients. **Methods:** Foot center of pressure was shifted along the medio-lateral foot axis using a foot-worn biomechanical device allowing controlled center of pressure manipulation. Sixteen female bilateral hip osteoarthritis patients underwent electromyography analysis while walking in the device set to three parasagittal configurations: neutral (control), medial, and lateral. Seven hip-spanning muscles (Gluteus Medius, Gluteus Maximus, Tensor Fascia Latae, Rectus Femoris, Semitendinosus, Biceps Femoris, Adductor Magnus) and one back muscle (Erector Spinae) were analyzed. Magnitude and temporal parameters were calculated. **Results:** The amplitude and temporal parameter varied significantly between foot center of pressure positions for 5 out of 8 muscles each for either the more or less symptomatic leg in at least one subphase of the gait cycle. **Conclusion:** Medio-lateral foot center of pressure manipulation significantly affects neuromuscular pattern of hip and back musculature during gait in female hip bilateral osteoarthritis patients.

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1. Introduction

Hip osteoarthritis (OA) is a chronic, debilitating, painful, and progressive disorder affecting a large amount of the population and having a great economic burden. Symptomatic hip OA is estimated to have a prevalence of 9.2% (9.3 female, 8.7 male) for those over 45 years of age (Helmick et al., 2003). Radiological evidence can be detected in most people over the age of 55 (Kellgren and Lawrence, 1958). Cost of hospital expenditures for total hip replacements in 2009 was estimated at \$13.7 billion (Murphy and Helmick, 2012).

Hip OA is associated with radiographic evidence of pathology in the joint and gait that significantly deviates from normal. The abnormal gait is accompanied by neuromuscular patterns that also deviate from those of healthy people (Sims et al., 2002). Specific descriptions of muscle activation patterns in bilateral hip OA are

lacking in the literature. General neuromuscular abnormalities, however, are observed with hip OA, including muscle weakness and atrophy, due to disuse, pain, and joint dysfunction, causing potential joint instability, lack of support of the joint, and progression of OA (Garstang and Stitik, 2006; French et al., 2008). These gait changes may not only affect the pathological joint(s). Pathologically altered lumbar kinematics may lead to low back pain or lumbar dysfunction (Bejek et al., 2006; Watelain et al., 2001). Current clinical recommendations for the treatment of hip OA include reduction of load on the pathological joint(s) as well as muscle strengthening exercises (Zhang et al., 2008).

In our previous studies on the knee in both healthy and knee OA patients, it was shown that medio-lateral foot center of pressure (COP) manipulation decreases knee adduction moment and joint loads, known to play a major role in onset/progression of knee OA (Haim et al., 2008, 2011). This was associated with significant simultaneous effects on the neuromuscular pattern of lower-limb musculature (Goryachev et al., 2011a, 2011b). Recently, in a pilot study on healthy subjects, medio-lateral foot COP manipulation

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4 Knee osteoarthritis functional severity classification & gait analysis



Osteoarthritis and Cartilage



Novel classification of knee osteoarthritis severity based on spatiotemporal gait analysis



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SUMMARY

Objective: To describe a novel classification method for knee osteoarthritis (OA) based on spatiotemporal gait analysis.

Methods: Gait analysis was initially performed on 2911 knee OA patients. Females and males were analyzed separately because of the influence of body height on spatiotemporal parameters. The analysis included the three stages of clustering, classification and clinical validation. Clustering of gait analysis to four groups was applied using the kmeans method. Two-thirds of the patients were used to create a simplified classification tree algorithm, and the model's accuracy was validated by the remaining one-third. Clinical validation of the classification method was done by the short form 36 Health Survey (SF-36) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaires. **Results:** The clustering algorithm divided the data into four groups according to severity of gait difficulties. The classification tree algorithm used stride length and cadence as predicting variables for classification. The correct classification accuracy was 89.5%, and 90.8% for females and males, respectively. Clinical data and number of total joint replacements correlated well with severity group assignment. For example, the percentages of total knee replacement (TKR) within 1 year after gait analysis for females were 1.4%, 2.8%, 4.1% and 8.2% for knee OA gait grades 1–4, respectively. Radiographic grading by Kellgren and Lawrence was found to be associated with the gait analysis grading system.

Conclusions: Spatiotemporal gait analysis objectively classifies patients with knee OA according to disease severity. That method correlates with radiographic evaluation, the level of pain, function, number of TKR.

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Introduction

Knee osteoarthritis (OA) is the most common joint disease, with an estimated prevalence of 30% in individuals over 60 years of age¹. Due to the effect of a continually graying population, it is expected that nearly one-half of the US adult population will develop symptomatic knee OA by the age of 85 years². Populations in both developed and undeveloped countries share the effects of aging, making the problem a global one.

The diagnosis of knee OA and subsequent treatment decision-making are currently based on the clinical presentation together with the findings on standard knee radiography^{3–6}. The American Society of Rheumatology has established diagnostic criteria based on those findings⁷. They report that the sum of the sensitivity (91%) and specificity (86%) is highest when using combined clinical and radiological criteria. The classification criteria and arthroscopically defined cartilage damage were also found to be correlated⁸. A grading system for knee OA based solely on radiography has also been suggested in order to determine the relative severity of the condition⁶.

Gait analysis has become an important methodology in the study of knee OA^{9–16}. Several studies have characterized the differences in gait patterns between patients with knee OA compared to healthy subjects, including differences in spatiotemporal parameters (specifically, slower walking velocity, shortened step length and lower cadence) and in kinetics and kinematics

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RESEARCH PAPER

Correlation between single limb support phase and self-evaluation questionnaires in knee osteoarthritis populationsRONEN DEBI¹, AMIT MOR², GANIT SEGAL², OFER SEGAL², GABRIEL AGAR¹, EYTAN DEBBI², NAHUM HALPERIN¹, AMIR HAIM³, & AVI ELBAZ²¹Department of Orthopedic Surgery, Assaf Harofeh Medical Center, Zerifin, Israel, ²AposTherapy Research Group, Herzliya, Israel, and ³Sourasky Medical Center, Tel Aviv, Israel

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Abstract**Purpose.** To investigate the correlation between single limb support (SLS) phase (% of gait cycle) and the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) questionnaire and Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36 Health Survey) in patients with knee osteoarthritis (OA).**Method.** A prospective observational study was employed with 125 adults with bilateral medial compartment symptomatic knee OA who underwent a physical and radiographic evaluation. Velocity, step length and SLS were assessed by a computerised mat (GAITRite). Patients completed the WOMAC and SF-36 Health Survey questionnaires.**Results.** Statistical analysis examined the correlations between SLS and both questionnaires, between Kellgren & Lawrence (K&L) scores and both questionnaires and between SLS correlations and K&L correlations. We found significantly stronger correlations between SLS and WOMAC-pain, WOMAC-function, the SF-36 pain sub-category, velocity and step length than between K&L scores and these parameters (Pearson's $r = 0.50$ vs. 0.26 , 0.53 vs. 0.34 , 0.50 vs. 0.23 , 0.81 vs. 0.33 , 0.77 vs. 0.37 , respectively; all $p < 0.05$). Significant differences in SLS were found over WOMAC-pain, WOMAC-function and SF-36 overall score quartiles ($p < 0.05$ for all).**Conclusion.** We recommend integrating SLS as an objective parameter in the comprehensive evaluation of patients with knee OA.**Keywords:** Single limb support, osteoarthritis, gait, WOMAC, SF-36**Introduction**

In order to understand and assess the symptoms and functional severity of patients suffering from knee osteoarthritis (OA), clinicians and researchers use validated self-evaluation questionnaires such as the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36 Health Survey) [1,2]. Nevertheless, there is a lack in accurate, objective, non-invasive and simple clinical tools for assessing knee OA in terms of functional independence and performance.

In recent years, researchers have gained an increased understanding of important biomechanical gait pattern changes that occur during the pathogenesis and progression of knee OA [3–5]. Studies

comparing the gait spatio-temporal parameters of patients with knee OA with those of healthy individuals have shown that patients with knee OA tend to have a slower walking speed, shorter step length and shorter single limb support (SLS) [4,6,7].

The SLS value is a percent of the gait cycle that corresponds to the time spent on one limb while the contralateral limb swings forward. In healthy populations, this phase accounts for 38–40% of the gait cycle [8]. While a relationship has yet to be clearly established between decreased loads due to pain and decreased SLS values, studies have shown that patients with knee OA attempt to avoid pain by decreasing loads from the affected joint [9]. A patient can achieve this by decreasing the SLS phase and increasing the double limb support (DLS) phase. A valid assumption is, therefore, that patients with knee

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The Knee



Can single limb support objectively assess the functional severity of knee osteoarthritis? ☆

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ABSTRACT

There is a lack in objective measurements that can assess the symptoms of knee osteoarthritis (KOA). In a previous study it was shown that pain and function are in higher correlation with the single-limb support gait parameter than with radiographic KOA stage. Single limb support represents a phase in the gait cycle when the body weight is entirely supported by one limb, while the contra-lateral limb swings forward. The purpose of this study was to further examine the relationship between single-limb support and the level of pain and function in patients with KOA. 125 adults with bilateral KOA underwent a physical and radiographic evaluation, and completed the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the SF-36 health survey. Patients walked barefoot at a self-selected speed on a computerized mat. Statistical analysis was used to divide the patients into quintiles based on single-limb support phase value and determine the differences in WOMAC and SF-36 scores between quintiles. Significant differences were found in WOMAC and SF-36 sub-category scores between the single-limb support quintiles. The means of the WOMAC-pain and WOMAC-function sub-categories decreased gradually over single-limb support quintiles ($P < 0.001$), and the means of the SF-36 sub-categories increased gradually over the quintiles ($P < 0.001$). Results show that single-limb support quintiles can help determine the level of pain, function and quality of life in patients with KOA. These results suggest that single-limb support quintiles may be added as an additional scale for generally assessing the symptomatic stage of KOA.

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1. Introduction

Patients suffering from knee osteoarthritis (KOA) experience knee pain, stiffness and decreased range of motion, all of which affect their body locomotion. These symptoms can significantly limit daily activities and lead to a loss of functional independence [1]. Patients express these limitations in terms of pain, function and quality of life. The clinical assessment of KOA therefore includes self-evaluation questionnaires to help qualify the symptoms of pain, function and quality of life. These include the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the SF-36 health survey and others [2,3]. These questionnaires, however, subjectively measure the severity of KOA symptoms.

The American College of Rheumatology (ACR) has attempted to use radiographic findings to objectively measure the severity of symptomatic KOA. Their classification guidelines integrate the radiographic assessment with other clinical findings [4,5]. These guidelines, however, are limited because the interpretation of radiographic findings is by nature subjective and has intra and inter observer error [6].

Measurements of gait can objectively assess an individual's function. Studies have shown differences in gait patterns between patients with KOA and healthy individuals. Specifically, differences were found in the gait parameters of self-selected speed, step length and single limb support (SLS) (% of gait cycle) [7–9]. SLS represents a phase in the gait cycle when the body weight is entirely supported by one limb, while the contra-lateral limb swings forward. This phase usually accounts for 38–40% of the gait cycle [10,11]. In a previous study it was shown that pain and function are in higher correlation with SLS than with radiographic KOA stage. The purpose of this study was to further examine the relationship between single-limb support and the level of pain and function in patients with KOA. Specifically, the study was designed to test the hypothesis that SLS will decrease as pain and function worsen in patients with KOA.

☆ The study was approved by the Institutional Helsinki Committee Registry at Assaf Harofeh Medical Center, Zerifin, Israel (Helsinki registration number 185/07, NIH no. NCT00599729).

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RESEARCH ARTICLE

Open Access

Analysis of knee flexion characteristics and how they alter with the onset of knee osteoarthritis: a case control study

Ian McCarthy², Diana Hodgins¹, Amit Mor³, Avi Elbaz³ and Ganit Segal^{3*}

Abstract

Background: The purpose of this study was to examine the differences in gait profile between patients with knee osteoarthritis (OA) and healthy control and to create motion characteristics that will differentiate between them.

Methods: Twenty three patients diagnosed with knee OA and 21 healthy matched controls underwent a gait test using a sensor system (gaitWALK). Gait parameters evaluated were: stride duration, knee flexion range of motion (ROM) in swing and stance. T-Test was used to evaluate significant differences between groups ($P < 0.05$).

Results: Patients with knee OA had significant lower knee flexion ROM ($10.3^\circ \pm 4.0^\circ$) during stance than matched controls ($18.0^\circ \pm 4.0^\circ$) ($p < 0.001$). Patients with knee OA had significant lower knee flexion ROM ($54.8^\circ \pm 5.5^\circ$) during swing than matched controls ($61.2^\circ \pm 6.1^\circ$) ($p = 0.003$). Patients with knee OA also had longer stride duration ($1.12 \text{ s} \pm 0.09 \text{ s}$) than matched controls ($1.06 \text{ s} \pm 0.11 \text{ s}$), but this was not statistically significant ($p = 0.073$). Motion characteristics differentiate between a patient with knee OA and a healthy one with a sensitivity of 0.952 and a specificity of 0.783.

Conclusions: Significant differences were found in the gait profile of patients with knee OA compared to matched control and motion characteristics were identified. This test might help clinicians identify and evaluate a knee problem in a simple gait test.

Keywords: Osteoarthritis, Gait, Electronic measurement systems

Background

Osteoarthritis (OA) is by far the most common form of arthritis. Around 2.5% of the adult population suffer from OA of the hip or knee, most of whom are over 45 and this increases to 10% for women over 75 [1]. The main symptoms are pain and limitation in function, which normally leads to changes in gait patterns to accommodate the pain [2].

Because the prevalence of knee OA is high and increasing in the adult population, a means of early diagnosis is being sought. Current diagnosis in an orthopaedic clinic is done using a standard X-ray machine, and the level of degeneration is assessed. One common grading score for hip and knee OA is the Kellgren and Lawrence score [3]. However, it is very

difficult to quantify this, particularly at the early stages. Previous studies have reported that changes to the knee joint occur even before radiographic changes are detected [4-6]. Shakoor et al. reported in 2003 that knee loading at the contralateral limb increases following hip arthroplasty and increase the rate of developing knee OA [6]. Furthermore, previous studies have stressed the poor correlation between radiographic changes and symptoms of pain and function [7,8]. Researchers and clinicians are seeking a method of ascertaining the functional severity of the OA, which ideally can be used alongside X-ray data, to detect early stage OA [9].

Biomechanics plays an important role in the progression of knee OA and many studies have been carried out in gait laboratories to ascertain which parameters are affected for people suffering with knee OA compared to healthy subjects [2,10]. Many papers have concluded that reduction in gait velocity is a prominent change in

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5 Additional scientific evidence



Research article

Open Access

Differences in gait patterns, pain, function and quality of life between males and females with knee osteoarthritis: a clinical trial

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Abstract

Background: The aim of this study was to gain a deeper understanding of the gender differences in knee osteoarthritis (OA) by evaluating the differences in gait spatio-temporal parameters and the differences in pain, quality of life and function between males and females suffering from knee OA.

Methods: 49 males and 85 females suffering from bilateral medial compartment knee OA participated in this study. Each patient underwent a computerized gait test and completed the WOMAC questionnaire and the SF-36 health survey. Independent t-tests were performed to examine the differences between males and females in age, BMI, spatio-temporal parameters, the WOMAC questionnaire and the SF-36 health survey.

Results: Males and females had different gait patterns. Although males and females walked at the same walking speed, cadence and step length, they presented significant differences in the gait cycle phases. Males walked with a smaller stance and double limb support, and with a larger swing and single limb support compared to females. In addition, males walked with a greater toe out angle compared to females. While significant differences were not found in the WOMAC subscales, females consistently reported higher levels of pain and disability.

Conclusion: The spatio-temporal differences between genders may suggest underlying differences in the gait strategies adopted by males and females in order to reduce pain and cope with the loads acting on their affected joints, two key aspects of knee OA. These gender effects should therefore be taken into consideration when evaluating patients with knee OA.

Trial Registration: The study is registered in the NIH clinical trial registration, protocol No. NCT00599729.

ORIGINAL ARTICLE

Sex and Body Mass Index Correlate With Western Ontario and McMaster Universities Osteoarthritis Index and Quality of Life Scores in Knee Osteoarthritis

Avi Elbaz, MD, Eytan M. Debbi, BA, Ganit Segal, MA, Amir Haim, MD, Nahum Halperin, MD, Gabriel Agar, MD, Amit Mor, MD, Ronen Debi, MD

ABSTRACT. Elbaz A, Debbi EM, Segal G, Haim A, Halperin N, Agar G, Mor A, Debi R. Sex and body mass index correlate with Western Ontario and McMaster Universities Osteoarthritis Index and quality of life scores in knee osteoarthritis. *Arch Phys Med Rehabil* 2011;92:1618-23.

Objective: To examine the associations of sex, body mass index (BMI), and age with knee osteoarthritis (OA) symptomatology severity.

Design: A cross-sectional retrospective analysis.

Setting: Patients completed the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire and Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). Data were acquired from a stored database of a private therapy center.

Participants: Patients (N=1487) with symptomatic knee OA were evaluated.

Interventions: Not applicable.

Main Outcome Measures: WOMAC questionnaire and SF-36.

Results: BMI correlated significantly with worse knee OA symptoms for all WOMAC and SF-36 subcategories (all $P \leq .001$). Age correlated significantly with worse symptoms only for WOMAC function and SF-36 physical functioning ($P = .001$ and $P = .009$, respectively). A significant difference across BMI quintiles was found for all WOMAC and SF-36 subcategories (all $P \leq .01$). Women showed worse knee OA symptoms in all WOMAC and SF-36 subcategories (all $P \leq .001$). There was a significant interaction of sex by BMI in WOMAC pain and WOMAC function ($P = .01$ and $P = .02$, respectively).

Conclusions: Based on the results of this analysis, it can be concluded that women and patients with a higher BMI with knee OA are at a greater risk for worse symptoms.

Key Words: Body mass index; Gender identity; Osteoarthritis; Pain; Questionnaires; Rehabilitation.

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KNEE OSTEOARTHRITIS (OA) is the most common type of OA, with an estimated 12.1% of adults in the United States suffering from pain and functional limitations.¹ Many studies have attempted to identify factors that are associated with symptomatic knee OA. The most important of these include sex, body mass index (BMI), and age.¹⁻³

With regard to sex, several studies have shown that radiographic knee OA is more prevalent in women than in men. In the United States, the prevalence of radiographic knee OA in adults older than 60 is 42.1% in women and 31.2% in men.¹ In Japanese patients aged 60 to 69 years, the prevalence of radiographic knee OA is 57.1% in women and 35.2% in men.⁴ With regard to the prevalence of symptomatic knee OA, the Third National Health and Nutritional Examination Study in the United States (1991–1994) found that the prevalence of symptomatic knee OA did not differ by sex.¹ Other studies have examined whether sex differences exist in symptoms among patients already with knee OA.^{2,3,5} In a previous study,² we found no significant sex differences in symptomatic knee OA severity. This finding, however, may have been due to the small sample size relative to the national studies.² Two large national studies in Finland (1996) and France (2009) found that women were associated with greater knee OA pain and disability.^{3,5} As a whole, these studies suggest that there is a possible association between sex and knee OA severity and that, if a relationship indeed exists, the specific symptomatic parameters predicted by sex must be clearly defined.

In contrast to sex, research on the association between BMI and symptomatic knee OA is more consistent. The French⁵ and Finnish³ national studies and the Third National Health and Nutritional Examination Study¹ all found a strong link between BMI and knee OA disability. As early as 1992, Felson et al⁶ predicted that a 2 BMI unit reduction in women could reduce the risk for developing knee OA symptoms. This was confirmed by Coggon et al,⁷ who found that BMI is one of the greatest risk factors in knee OA development and that a 5kg loss could dramatically reduce a patient's need for surgery. Although the association between BMI and symptomatic knee OA is strong, the association may not be linear across all BMI levels. In addition, few studies have examined the strength of this association within different sexes. In 1 study in 1988, Felson et al⁸ suggested that the correlation between BMI and knee OA disability is stronger in women.

With regard to age, most knee OA epidemiologic studies have shown that radiographic and symptomatic knee OA is

List of Abbreviations

BMI	body mass index
OA	osteoarthritis
SF-36	Short Form 36 Health Survey Questionnaire
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index



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Clinical Biomechanics

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Differences in gait pattern parameters between medial and anterior knee pain in patients with osteoarthritis of the knee[☆]

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ABSTRACT

Background: Patients with osteoarthritis of the knee have unique spatiotemporal gait alterations. These gait changes have not yet been differentiated according to the location of knee pain. The purpose of this study was to compare the gait patterns of patients with symptomatic knee osteoarthritis that exhibit either anterior or medial joint pain.

Methods: 240 Patients with knee osteoarthritis were evaluated at one therapy center. Patients were divided into two groups according to the location of greatest pain in their worse knee. Patients underwent a computerized spatiotemporal gait analysis. Differences in gait patterns between the two knee pain locations were also examined within each gender.

Findings: Compared with patients with pain in the anterior knee compartment, those with pain in the medial knee compartment exhibited a significantly slower walking speed ($P < 0.01$), shorter step length ($P < 0.01$), lower single-limb-support phase ($P < 0.01$). These differences are witnessed mainly between the females in each group, whereas males differed only in single-limb-support.

Interpretation: The results of this study suggested underlying gait differences in the nature of medial and anterior knee pain. Furthermore, gender differences in gait may exist between patients with medial knee pain compared to patients with anterior knee pain.

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1. Introduction

Diagnosing and gauging the severity of knee osteoarthritis (OA) is a highly debated topic. Historically, knee OA has been evaluated by a combination of radiographic imaging techniques, physical examination and self-evaluation questionnaires (Altman et al., 1986). Recent studies have also shown that gait measurements may be a valuable functional measure of knee OA (Kaufman et al., 2001).

Studies have shown differences in spatiotemporal gait patterns between knee OA patients and healthy individuals. Patients with knee OA demonstrate a slower walking velocity, shorter step length and decreased single-limb-support (SLS) (Brandes et al., 2008; McKean et al., 2007; Mundermann et al., 2005). SLS represents the phase in the gait cycle when the body weight is entirely supported by one limb, while the

contra-lateral limb swings forward. Previous studies have shown a poor–moderate correlation between SLS and self-reported knee OA symptoms (Debi et al., 2011; Elbaz et al., 2011). Debi et al. (2011) reported a correlation of -0.5 and -0.53 between SLS and WOMAC pain and WOMAC function, respectively. Elbaz et al. (2011) reported a correlation of -0.5 and -0.49 between SLS and SF-36 pain and SF-36 physical function, respectively. Another study also showed correlations between walking velocity and step length and self-reported knee OA symptoms (Nebel et al., 2009). A correlation of -0.16 was found between pain and velocity and correlations of -0.24 and -0.20 were found between WOMAC function and velocity and step length, respectively (Nebel et al., 2009).

Patients with OA of the knee often complain of pain in specific locations of the knee. The three classic locations of pain are in the medial, anterior and lateral compartments (Altman et al., 1986). Medial compartment pain is by far the most prevalent location, with an estimated 75% of patients complaining of pain in this location (Altman et al., 1986; Koshino and Machida, 1993; McAlindon et al., 1992; Saito et al., 2002). This is explained by the fact that the medial compartment of the tibiofemoral joint carries a 2.5 times greater load than other

[☆] The study is registered at clinicaltrials.gov, identifier NCT00767780, <http://www.clinicaltrials.gov/ct/show/NCT00457132?order=1>.

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Gait metric profile of 157 patients suffering from anterior knee pain. A controlled study

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ABSTRACT

Purpose: Gait metric alterations have been previously reported in patients suffering from anterior knee pain (AKP). Characterization of simple and measureable gait parameters in these patients may be valuable for assessing disease severity as well as for follow-up. Previous gait studies in this population have been comprised of relatively small cohorts and the findings of these studies are not uniform. The objective of the present study was to examine spatio-temporal gait parameters in patients with AKP in comparison to symptom-free controls. Furthermore, the study aimed to examine the relationship between self-reported disease severity and the magnitude of gait abnormalities.

Methods: 157 patients with AKP were identified and compared to 31 healthy controls. Patients were evaluated with a spatiotemporal gait analysis via a computerized mat, the Western Ontario and McMaster Osteoarthritis Index (WOMAC) questionnaire and the Short Form (SF)-36 health surveys.

Results: AKP patients walked with significantly lower velocity (15.9%) and cadence (5.9%), shorter step length (9.5%), stride length (9.6%), and showed significant differences in all gait cycle phases ($P < 0.05$ for all). Study group reported higher levels of pain (96%), functional limitation (94%), and poorer perception of mental quality of life (30%) ($P < 0.05$ for all).

Conclusion: Significant differences were found between the spatiotemporal gait profile of AKP patients and symptom-free matched controls. In addition, an association was found between subjective disease severity and gait abnormalities. These findings suggest the usefulness of gait parameters, alongside with the use of self-evaluation questionnaires, in identifying deviations of these patients from healthy population.

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1. Introduction

Anterior knee pain (AKP) is a common complaint, affecting 25–36% of the general population [1–3]. AKP was reported as the cause of up to 40% of all visits to physiotherapy clinics for knee pain [4–6]. Symptoms often become chronic, with 94% of patients continuing to experience pain up to four years after initial presentation and 25% reporting significant symptoms up to 20 years later [7].

Currently there are no consensuses for classification and nomenclature of AKP [8,9]. Multiple clinical conditions have been described in association with AKP [10]. Likewise, numerous physical signs and findings have been described by different authors [10]. Historically the term “patello-femoral pain syndrome” was utilized for subjects complaining of anterior knee pain in whom no other diagnosis could be made. This term, however, has been disputed and has gone out of

favor due to inconsistencies in diagnostic criteria [8,9]. Nonetheless most investigators agree that the etiology of AKP in some patients arises from the retropatellar or peripatellar region and is related to faulty lower limb mechanics and poor neuromuscular control. These include, patellar mal tracking and imbalance between the vastus medialis and vastus lateralis [11], increased femoral internal rotation [12], increased hip adduction [13], weakness of hip external rotators and abductors and increased foot pronation. These have all been implicated with the pathomechanics of this syndrome [14].

Alterations in knee kinetics and kinematics were previously reported in association with AKP; subjects with AKP were found to display a reduced knee extensor moment during the loading response phase (LR) of the stance [15,16], and a reduced peak vertical ground reaction force (GRF) [17]. Reduced knee flexion during LR has been reported in some studies [17,18], but not in others [11,16,19]. The above-mentioned studies, however, were comprised of relatively small cohorts. Moreover, the results reported in these studies are not uniform. The study of gait in this population contributes to the understanding of the pathomechanics of this pathology and is important for developing new treatment strategies. In addition, defining variations in gait of these patients can offer objective clinical data

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The Reliability of a Gait Analysis Mat in Assessing Patients with Knee Osteoarthritis

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ORIGINAL ARTICLE

Gait metric profile and gender differences in hip osteoarthritis patients. A case-controlled study

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Purpose: Hip osteoarthritis (OA) is a slowly progressive destructive disease that results in alterations in joint loads and biomechanics to which patients adapt compensatory alterations and abnormal gait patterns. This prospective cross-sectional, case-controlled study examined these alterations in gait metrics and evaluated gender differences in gait spatiotemporal parameters. Correlations between function and gait metrics were also investigated.

Basic Procedures: Hip OA patients (138 females and 122 males) and healthy controls (14 females and 26 males) matched for age and gender underwent the same investigative protocol consisting of a spatiotemporal gait analysis followed by functional evaluations using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the SF-36 Health Survey (SF-36).

Main Findings: Differences between the patient and the control groups were significant in all the spatiotemporal parameters. There were significant gender differences within the hip OA group in all parameters except for cadence and single limb support percentage. WOMAC and SF-36 scores revealed significant differences between the study and control groups in most components. Significantly higher scores in the three components of the WOMAC as well as in six SF-36 score components were found among males compared to females in the patient group.

Principal Conclusions: Gait, WOMAC and SF-36 were effective objective and subjective tools for evaluating a large cohort of patients with hip OA, and can be highly useful for supplementing the assessment of hip OA severity and enhancing treatment efficacy during the course of the disease.

Keywords: Hip, Osteoarthritis, Gait, Pain, Quality of life

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INTRODUCTION

Hip osteoarthritis (OA) is one of the most prevalent disabling disorders of the elderly. The reported prevalence of the symptomatic disease is up to 10% in the USA (1) and it is the most common indication for total hip replacement (2). Osteoarthritis is a slowly progressive destructive disease, characterised by pain and functional limitations that mainly

affect the articular cartilage but also the periarticular bone. The diagnosis is made clinically by characteristic features, such as pain and stiffness, and confirmed by radiography (3). The aetiology of OA is multifactorial and involves local factors within the joints as well as systemic predisposing factors (4). Local factors include trauma, physical and occupational activity and neuromuscular function (4), while age, gender and obesity are other prominent risk factors (4-6).



RESEARCH

Open Access

Clinical outcomes following ankle fracture: a cross-sectional observational study

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Abstract

Background: The purpose of the current study was to examine objective and subjective differences between three severity groups of ankle fractures patients compared to healthy controls.

Methods: This was a case-controlled study. 92 patients with an ankle fracture injury of which 41 patients were eligible to participate in the study. 72 healthy people served as controls. All patients underwent a computerized gait test, completed self-assessment questionnaires (The Foot and Ankle Outcome Score (FAOS) and the SF-36), evaluated with the American Foot and Ankle Score (AOFAS) form and completed the 6-min walk test. The control group performed a computerized gait test and completed the SF-36 health survey.

Results: All ankle fracture patients presented compromised gait patterns and limb symmetry compared to controls ($p < 0.05$). Ankle fracture patients also had lower SF-36 scores compared to controls ($p < 0.05$). Significant differences were found between the unimalleolar group compared to the bimalleolar and trimalleolar groups in most parameters, except for the FAOS scores. There were no significant differences between the bimalleolar fracture group and the trimalleolar fracture groups.

Conclusions: Although all fracture severity classification groups presented a compromised gait pattern and worse clinical symptoms compared to controls, it seems that patients with a unimalleolar fracture is a different group compared to bimalleolar and trimalleolar fracture. Furthermore, it seems that bimalleolar fracture and trimalleolar fracture affect the gait pattern and clinical symptoms to an equal extent, at least in the short-term.

Trial registration: NCT01127776.

Keywords: Ankle fracture severity, Gait, Clinical outcomes

Background

Ankle fractures are one of the most common injuries of the lower limb [1]. There has been a constant increase in ankle fracture rates amongst young, active patients as well as in the elderly population over the last several decades [2,3]. Operative treatment of ankle fracture includes open reduction and internal fixation [4], followed by immobilization and rehabilitation [5-7].

Ankle fractures severity can be defined and classified to three sub-groups including unimalleolar, bimalleolar and trimalleolar fractures. Several studies have examined the differences between severity groups in regard to functional outcomes and showed conflicting results.

Some concluded that a fracture severity classification is a consistent predictor of functional outcome following surgery [8-10]. However, recent work by Egol et al. concluded that the type of fracture had no influence on functional recovery [11]. Most studies used self-assessment questionnaires and functional scores to evaluate the functional status of the patient post an ankle fracture surgery. Although questionnaires are considered a valid method of assessment, they are subjective, and objective methods of evaluation are warranted.

Gait analysis is widely used to characterize functional performance of different populations [12-15]. It is also used as an outcome measure for decision making and for evaluating different treatments [16-19]. Recently, functional severity classification for patients with knee osteoarthritis, which is based on gait analysis, was presented

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The correlation between radiographic knee OA and clinical symptoms—do we know everything?

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Abstract This study aims to evaluate the correlations between common clinical osteoarthritis (OA) diagnostic tools in order to determine the value of each. A secondary goal was to investigate the influence of gender differences on the findings. Five hundred and eighteen patients with knee OA were evaluated using the Western Ontario and McMaster Osteoarthritis Index (WOMAC) questionnaire, short form 36 (SF-36) Health Survey, and plain radiographs. Analysis of variance (ANOVA) was used to compare the different domains of the WOMAC and SF-36 questionnaires between genders and the radiographic scale. Higher knee OA x-ray grade were associated with worse clinical outcome: for women, higher scores for the WOMAC pain, function and final scores and lower scores in the SF-36 final score; in men, lower SF-36 overall and physical domains scores. Gender differences were found in all clinical scores that were tested, with women having worse clinical scores for similar radiographic

grading (p values <0.001). Knee radiographs for OA have an important role in the clinical evaluation of the patient. Patients with higher levels of knee OA in x-ray have a higher probability of having a worse clinical score in the WOMAC and SF-36 scores. The gender differences suggest that for similar knee OA x-ray grade, women's clinical scores are lower.

Trial registration: NCT00767780

Keywords Function · Knee osteoarthritis · Pain · Quality of life · X-ray

Background

Knee osteoarthritis (OA) affects about 10 % of the population over the age of 60, with increased prevalence among women and elderly patients [1–3]. Reliable grading of the severity of knee OA is important for monitoring the patients during their follow-up period and evaluation of various treatment modalities. Several clinical tools are currently in practice for objective and subjective assessment of symptoms and disease severity in knee OA [1]. At present, however, there is no consensus as for the “gold standard” for the evaluation of disease severity and progression [4]. Thus, it is difficult to assess the validity of the present clinical tools. Furthermore, several epidemiologic studies suggest a profound gender difference in the manifestations of symptoms and functional performance. Thus, while some clinical parameters could be valuable for pathology evaluation in females, others may be more suitable for males [5, 6]. Debi et al. concluded that males and females with knee OA adopt different gait strategies in response to knee OA symptoms. Furthermore, although there were no gender differences in radiographic grading of knee OA degeneration, some differences in self-assessment questionnaires

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RESEARCH

Open Access

Deviations in gait metrics in patients with chronic ankle instability: a case control study

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Abstract

Background: Gait metric alterations have been previously reported in patients suffering from chronic ankle instability (CAI). Previous studies of gait in this population have been comprised of relatively small cohorts, and the findings of these studies are not uniform. The objective of the present study was to examine spatiotemporal gait metrics in patients with CAI and examine the relationship between self-reported disease severity and the magnitude of gait abnormalities.

Methods: Forty-four patients with CAI were identified and compared to 53 healthy controls. Patients were evaluated with spatiotemporal gait analysis via a computerized mat and with the Short Form (SF) - 36 health survey.

Results: Patients with CAI were found to walk with approximately 16% slower walking velocity, 9% lower cadence and approximately 7% lower step length. Furthermore, the base of support, during walking, in the CAI group was approximately 43% wider, and the single limb support phase was 3.5% shorter compared to the control group. All of the SF-36 8-sub scales, as well as the SF-36 physical component summary and SF-36 mental component summary, were significantly lower in patients with CAI compared to the control group. Finally, significant correlations were found between most of the objective gait measures and the SF-36 mental component summary and SF-36 physical component summary.

Conclusions: The results outline a gait profile for patients suffering from CAI. Significant differences were found in most spatiotemporal gait metrics. An important finding was a significantly wider base of support. It may be speculated that these gait alterations may reflect a strategy to deal with imbalance and pain. These findings suggest the usefulness of gait metrics, alongside with the use of self-evaluation questionnaires, in assessing disease severity of patients with CAI.

Keywords: Chronic ankle instability, Gait, Quality of life

Background

The definition and classification of chronic ankle instability (CAI) are problematic. Clinically, it is defined as recurrent subjective complaint of the ankle joint “giving way” [1,2] and as “repetitive bouts of lateral ankle instability resulting in numerous ankle sprains” [3]. CAI is usually the sequelae of acute ankle sprain [4], and up to 34% of the patients suffer from a residual problem within the 3 years following their first incident [4]. Some individuals

with CAI are limited in participating in sports and even in activities of daily living for years after the initial injury [5,6]. The first insult usually involves hyper-supination (a combination of inversion, plantar flexion, and internal rotation) of the hind foot in relation to the tibia, resulting in injury to the lateral ankle ligaments. The most commonly injured ligaments are the anterior talofibular and the calcaneofibular [7].

The term “mechanical instability” (MI) has been used to describe patients with objective physical examination and radiologic findings (e.g., stress radiographs) suggestive of ligamentous incompetence about the ankle-joint complex. However, there is a low correlation between these findings and long-term prognosis. Freeman et al.

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Gait characteristics and quality of life perception of patients following tibial plateau fracture

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Abstract

Introduction The purpose of the current study was to evaluate the long-term functional outcome as measured by gait patterns and quality of life assessment of patients with high-energy tibial plateau fracture compared to matched controls.

Materials and methods Thirty-eight patients were evaluated in a case-controlled comparison. Twenty-two patients with tibial plateau fracture were evaluated after 3.1 (1.63) years (sd) from injury. Patients underwent a computerized spatiotemporal gait test and completed the SF-12 health survey. 16 healthy subjects, matched for age and gender served as a control group. The main outcome measures for this study were spatiotemporal gait characteristics, physical quality of life and mental quality of life.

Results Significant differences were found in all gait parameters between patients with tibial plateau fracture and healthy controls. Patients with tibial plateau fracture walked slower by 18 % compared to the control group ($p < 0.001$), had slower cadence by 8 % compared ($p = 0.002$) to the control group and had shorter step length in the involved leg by 11 % and in the uninvolved leg by 12 % compared to the control group ($p = 0.006$ and

$p = 0.003$, respectively). Patients with tibial plateau fracture also showed shorter single limb support (SLS) in the involved leg by 12 % compared to the uninvolved leg and 5 % in the uninvolved leg compared to the control group ($p < 0.001$ and $p = 0.017$, respectively). Significant differences were found in the Short Form (SF)-12 scores. Physical Health Score of patients with tibial plateau fracture was 65 % lower compared to healthy controls ($p < 0.001$), and Mental Health Score of the patients was 40 % lower compared to healthy controls ($p < 0.001$). Finally, significant correlations were found between SF-12 and gait patterns.

Conclusion Long-term deviations in gait and quality of life exist in patients following tibial plateau fracture. Patients following tibial plateau fracture present altered spatiotemporal gait patterns compared to healthy controls, as well as self-reported quality of life.

Keywords Tibial plateau fracture · Gait · Quality of life

Introduction

Tibial plateau fractures represent a complex injury to the knee. These fractures are usually classified using the Schatzker classification system [1]. This classification helps to separate the fractures into groups with similar mechanisms and patterns and has 6 grades. Schatzker 5 & 6 are caused by high-energy trauma and are considered to be more severe. Schatzker 5 is characterized with bicondylar injury whereas Schatzker 6 is characterized with split extends of the metadiaphysis [1]. Usually, they include a combination of axial loading and varus/valgus applied forces [1]. Tibial plateau fractures are associated with significant osseous [2], soft tissue injuries [2–4] and

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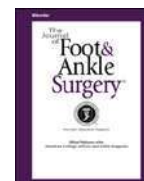
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Original Research

Lower Extremity Kinematic Profile of Gait of Patients After Ankle Fracture: A Case-Control Study

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ARTICLE INFO

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trauma

ABSTRACT

The present study examined the differences in the lower extremity gait kinematic profile of patients recovering from ankle fracture compared with healthy controls. In addition, we inquired whether the profile would differ among fracture severity groups. A total of 48 patients participated in the present prospective, case-control study. The gait of 24 patients recovering from an ankle fracture injury and 24 healthy matched controls was examined using an inertial measurement unit sensor system. The following gait parameters were evaluated: knee range of motion (ROM) during the swing phase, maximum knee flexion angle during stance, thigh and calf ROM, and stride duration. Statistically significant differences were found between the ankle fracture group and the control group for all parameters. The patients with ankle fracture had a lower knee ROM during swing phase compared with the control group (mean \pm standard deviation $43.0^\circ \pm 15.5^\circ$ compared with $66.7^\circ \pm 5.1^\circ$, respectively; $p < .001$). The maximum knee flexion angle during stance was lower in the patients with ankle fracture than in the control group (mean \pm standard deviation $10.5^\circ \pm 6.1^\circ$ compared with $21.2^\circ \pm 4.5^\circ$, respectively; $p < .001$). Patients with ankle fracture also had lower gait cycle thigh and calf ROM angles ($p < .001$) and a longer stride duration ($p < .001$) compared with the control group. No statistically significant differences were found among the severity groups. These results suggest that the gait kinematic characteristics vary between healthy people and patients recovering from an ankle fracture injury during the short-term period after injury.

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The ankle joint complex is of great importance in normal ambulation, daily activities, and sports. Ankle fracture is one of the most common injuries of the lower limb (1) and the incidence of ankle fracture injuries has increased in the recent decades (2–4). Thus, research to further understand how an ankle fracture affects the gait is becoming more relevant.

People with an ankle fracture injury often experience pain, stiffness, weakness, swelling, and limitations in activities such as stair climbing and walking (5). This can last for ≤ 2 years after injury (1). Comprehensive research of gait analysis has been performed in patients who have undergone procedures such as ankle fusion and total ankle replacement, patients with ankle and tibial stress fractures, and patients with ankle sprains. This is not the case for ankle fractures,

and lower limb motion abnormalities expressed in ankle or knee range of motion (ROM) during gait have not been commonly investigated (6–9).

The portable walkway is a simplified method to study spatio-temporal parameters. It saves the high costs and logistic efforts inflicted by the usually used dedicated gait laboratory. A recent case-control study used a portable walkway to provide information on the spatiotemporal characteristics of gait and found compromised gait patterns and limb symmetry in patients after an ankle fracture injury compared with the controls (10). Nevertheless, portable walkway systems cannot be used to measure joint motion or kinetics, which can add information and reflect the patient's condition. Recent studies have shown that inertial measurement units are accurate and reproducible in the measurement of joint and limb segment ROM in the assessment of gait in aging patients (11) and in knee osteoarthritis (12). Inertial measurement units are comparatively easy to use, requiring no specialist facilities, and have the potential to be used within a busy clinic or rehabilitation unit (13).

Several studies have examined the feasibility of using a severity fracture classification system as a consistent predictor of the surgery

Financial Disclosure: None reported.**Conflict of Interest:** Amit Mor and Avi Elbaz hold shares in the AposTherapy Research Group.

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Gait Assessment of Patients with Spontaneous Osteonecrosis of the Knee: A Retrospective Case Controlled Study

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Abstract

Background: The purpose of this study was to characterize the gait patterns of patients with spontaneous osteonecrosis of the knee (SONK).

Methods: Twenty-eight patients (16 females and 12 males) diagnosed with SONK with a mean \pm SD age of 67.3 \pm 8.3 years participated in this study. 27 age-matched healthy controls, mean \pm SD age 64.6 \pm 10.7 years, were also evaluated. All patients underwent computerized spatiotemporal gait assessment during level walking at a self-selected speed. Primary outcome measures were gait velocity, cadence, step length and single limb support.

Results: Significant differences were found between patients with SONK and healthy controls in all spatiotemporal gait parameters. Patients with SONK had a significant lower walking speed (66.4 cm/s compared to 107.0 cm/s, a 38% decrease), lower cadence (59.9 steps/min compared to 110.3 steps/min, a 46% decrease), shorter step length (43.5 cm compared to 58.0 cm, a 25% decrease) and lower single limb support values (31.1% of gait cycle compared to 39.6% of gait cycle). Furthermore, patients with SONK presented significant asymmetry between the involved limb and uninvolved limb in SLS (31.1% of gait cycle compared to 38.8% of gait cycle for the involved and uninvolved limbs, respectively).

Conclusions: Patients with SONK present alterations in spatiotemporal gait parameters compared to normal control, suggesting that gait is significantly compromised by the disease. Furthermore, significant asymmetry was found in several gait parameters between the involved limb and uninvolved limb of patients with SONK.

Keywords: Osteonecrosis; Knee; Gait

List of abbreviations

SONK: Spontaneous Osteonecrosis of the Knee; NSAIDs: Non-Steroidal Anti-Inflammatory Drugs; UKA: Uni-compartmental Knee Arthroplasty; TKA: Total Knee Arthroplasty; OA: Osteoarthritis; BMI: Body Mass Index; GC: Gait Cycle; SLS: Single Limb Support (%GC); DLS: Double Limb Support (% GC)

Background

Spontaneous osteonecrosis of the knee (SONK) is considered to be the most common form of osteonecrosis of the knee [1]. The incidence of SONK has been reported as 3.4% and 9.4% in persons older than 50 and 65 years of age, respectively [1]. However, the actual prevalence may be underestimated since many patients who present with end-stage osteoarthritis (OA) may have had occult undiagnosed SONK [2]. Historically, SONK was thought to occur secondary to ischemia, which would result in necrosis. However, recent evidence has demonstrated that it may be due to subchondral insufficiency fractures in osteopenic bone, with no evidence of necrosis [3].

Non-operative management of early stages of SONK includes treatment with non-steroidal anti-inflammatory drugs (NSAIDs), protected weight bearing, analgesics and bisphosphonate [4]. Surgical management includes joint-preserving techniques such as arthroscopic debridement [5] microfracture [6] and core decompression [7]. In end stage SONK, uni-compartmental knee arthroplasty (UKA) or total knee arthroplasty (TKA) are the most common treatment options [8,9].

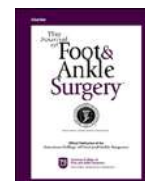
The use of gait analysis as a clinical tool is well recognized [10]. It is used to assess the effect of various pathological conditions on biomechanical properties of the lower limbs [11-13], evaluate severity of disease [14] and determine the effect of different treatment modalities [13,15-17]. Furthermore, gait analysis has been shown to be an objective measurement tool to assess pain, function and quality of life [18-20].

However, to the best of our knowledge, there is no data on the effect of SONK on the gait patterns of the patients. Assessing gait pattern of patients with SONK may add more knowledge on the pathomechanics of the disease. Therefore, the purpose of this study was to characterize the gait patterns of patients with SONK. The hypothesis tested was that the spatiotemporal gait parameters will be significantly lower than normal in this population.



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Association Between Knee Osteoarthritis and Functional Changes in Ankle Joint and Achilles Tendon



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ARTICLE INFO

Level of Clinical Evidence: 3

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osteoarthritis index

ABSTRACT

Increasing evidence has shown that biomechanical forces often drive the progression of knee osteoarthritis (OA). Attention should be given to the changes in adjacent joints and their relation to knee OA. The purpose of the present study was to examine the changes in Achilles tendon thickness of individuals with knee OA and to evaluate the correlation between Achilles tendon thickness and knee OA severity in a case-control prospective observational study. A total of 93 participants with no previous ankle injuries were recruited. Of the 93 participants, 63 had knee OA of the medial compartment and 30 served as controls. The subjects underwent a clinical examination that included measurements of weight, height, Achilles tendon thickness, and 1-leg heel rise. The subjects also underwent a computerized gait test and completed the Hebrew version of the Western Ontario and McMaster Osteoarthritis Index and 36-item short-form (SF-36) health survey. Significant difference was found in Achilles tendon thickness between the subjects with knee OA and the healthy controls (17.1 ± 3.4 versus 15.1 ± 3.1 ; $p = .009$). Significant differences were also found between the 2 groups in the 1-leg heel rise test, Western Ontario and McMaster Osteoarthritis Index scores, SF-36 scores, and all gait measures. Significant correlations were found between the Achilles tendon thickness and the following measures: weight ($r = 0.46$), body mass index ($r = 0.55$), Kellgren and Lawrence OA severity grade ($r = 0.25$), 1-leg heel rises ($r = -0.50$), and SF-36 score ($r = -0.25$). Subjects with knee OA presented with a thicker Achilles tendon compared with the healthy controls. Furthermore, a significant correlation between Achilles tendon thickness and knee OA severity was found. A comprehensive assessment of the Achilles tendon and ankle joint should be a part of the knee OA evaluation process.

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Many factors have been reported to be associated with knee osteoarthritis (OA) prevalence and progression, including muscle weakness, proprioception deficits, age, excessive weight, and knee alignment that decreases joint stability (1,2).

Increasing evidence has shown that biomechanical forces often drive the progression of knee OA and that the pathologic response of tissues to such forces leads to further joint deterioration, symptoms, and reduced functioning (3). Studies have found increased muscle

activity in subjects with knee OA (4,5). This increase in muscular activity is considered to be the bracing of the muscles around the knee (4,5) in an attempt to increase the stability of the joint and could lead to altered forces around the ankle joint.

It is known that subjects with knee OA demonstrate different gait patterns compared with their matched controls (6–9). This could potentially be damaging to the Achilles tendon because an improper gait is one of the risk factors for developing Achilles tendinopathy (4,10,11). Studies have also shown that the ankle joint movement strategy was more prominent in those with symptomatic knee OA, which might explain the compensatory action to achieve gait patterns similar to those of healthy controls (12).

Few studies have examined the relationship between knee OA and ankle joint parameters (13–16). To the best of our knowledge, no data

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Original article

Knee osteoarthritis, degenerative meniscal lesion and osteonecrosis of the knee: Can a simple gait test direct us to a better clinical diagnosis



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ABSTRACT

Introduction: The purpose of the current study was to compare the gait patterns in patients with three differing knee pathologies – knee osteoarthritis (OA), degenerative meniscal lesion (DML) and spontaneous osteonecrosis of the knee (SONK) and a group of healthy controls.

Hypothesis: A simple gait test will detect differences between different knee pathologies.

Material and methods: Forty-seven patients with bilateral knee OA, 47 patients with DML, 28 patients with SONK and 27 healthy controls were included in this analysis. Patients underwent a spatiotemporal gait assessment and were asked to complete the Western Ontario and McMaster University (WOMAC) Index and the Short-Form (SF)-36 Health Survey. ANOVA tests, followed by Bonferroni multiple comparison tests and the Chi² tests were performed for continuous and categorical variables, respectively.

Results: Significant differences were found for all gait measures and clinical questionnaires between healthy controls and all knee conditions. Patients with SONK differed from patients with bilateral knee OA and DML in all gait measures and clinical questionnaires, except for WOMAC subscales. There were no significant differences between patients with bilateral knee OA and patients with DML. Symmetry was also examined and revealed asymmetry in some gait parameters in patients with SONK and DML.

Discussion: Based on the differences in gait parameters that were found in the current study, adding an objective functional spatiotemporal gait test may assist in the diagnostic process of knee pathologies.

Type of study: Case Control study Level III.

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1. Introduction

The knee is a weight-bearing joint which copes with massive loads during standing and walking and therefore is prone to injuries and degenerative changes. Woolf et al. examined the burden of major musculoskeletal pathologies and found knee osteoarthritis (OA) to be one of four conditions with a high burden on individuals, health systems and social care systems. Furthermore, they suggested that the increase in life expectancy and ageing will make OA the fourth leading cause of disability by the year 2020 [1].

Gait analysis is commonly used to assess lower extremity pathologies. Amongst others are pathologies at the knee joint,

including chronic and acute conditions. The aims of gait analysis can be divided into three different categories: to characterize the gait pattern of a certain population, to classify and categorize the functional severity of a certain population and to evaluate the effect of a given intervention.

Regarding chronic knee conditions, the most investigated condition is knee OA. Numerous studies have characterized the gait patterns of patients with knee OA compared to healthy controls [2–5] or comparison of different degrees of knee OA severity [6–8]. Others have presented a functional classification system based on gait properties [9,10] and evaluated the effect of various interventions [11–16]. Another evaluated knee condition is a degenerative meniscal lesion (DML). Studies have characterized the gait deviation of this population compared to healthy controls [17,18], evaluated the effect of various interventions [19] and questioned the necessity of surgical intervention [20–22] in this population. A less common condition at the knee joint is spontaneous

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Correlation between gait analysis and clinical questionnaires in patients with spontaneous osteonecrosis of the knee

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ABSTRACT

Background: Spontaneous osteonecrosis of the knee is usually verified by magnetic resonance imaging accompanied by clinical questionnaires to assess the level of pain and functional limitation. There is a lack however, in an objective functional test that will reflect the functional severity of spontaneous osteonecrosis of the knee. The purpose of the current study was to examine the correlation between spatiotemporal gait parameters and clinical questionnaires in patients with spontaneous osteonecrosis of the knee.

Methods: 28 patients (16 females and 12 males) were included in the analysis. Patients had unilateral spontaneous osteonecrosis of the knee of the medial femoral condyle confirmed by magnetic resonance imaging. All patients performed a computerized spatiotemporal gait analysis and completed the Western Ontario and McMaster University Osteoarthritis Index and the Short-Form 36. Relationships between selected spatiotemporal gait measures and self-assessment questionnaires were assessed by Spearman non-parametric correlations.

Findings: Significant correlations were found between selected spatiotemporal gait parameters and clinical questionnaires (r ranged between 0.28 and 0.79). Single limb support was the gait measure with the strongest correlation to pain ($r = 0.58$), function ($r = 0.56$) and quality of life.

Interpretation: Spatiotemporal gait assessment for patients with spontaneous osteonecrosis of the knee correlates with the patient's level of pain and functional limitation there by adding objective information regarding the functional condition of these patients.

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1. Introduction

Spontaneous osteonecrosis of the knee (SONK) is a pathology with a prevalence of almost 10% in persons older than 65 years of age who report meniscal complaints (Pape et al., 2002). However, the actual prevalence may be underestimated since many patients with end-stage osteoarthritis (OA) may have had undiagnosed occult SONK (Mont et al., 2011).

At initial evaluation, plain radiographs should be obtained, although in the early course of the disease they are often negative and in some cases remain negative for the duration of clinical symptoms (Haupt et al., 1983). Bone scintigraphy may show increased uptake in the affected condyle. However, this method has poor sensitivity and specificity (Mont et al., 2008; Pivec et al., 2013). Magnetic resonance imaging

(MRI) is recommended for detection of early stages of the disease due to its high sensitivity in detecting bone edema (Fotiadou and Karantanis, 2009). Furthermore, MRI is often used as an outcome measures to assess the effect of treatment alongside self-reported questionnaires to assess pain and function (Breer et al., 2013; Heyse et al., 2011). Nevertheless, MRI is an expensive test and usually requires a relatively long appointment time.

To understand and assess the symptoms and functional severity of patients suffering from various knee pathologies, clinicians and researchers use validated self-evaluation questionnaires such as the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36 Health Survey) (Bellamy et al., 1988; Ware and Sherbourne, 1992). There is, however, a lack of accurate, objective, non-invasive and straightforward clinical tools for assessing SONK in terms of functional independence and performance.

Gait analysis has been used to assess the effect of various pathological conditions on the biomechanical properties of the lower limbs (Allet et al., 2008; Andriacchi and Hurwitz, 1997; Simon, 2004), evaluates the

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Using gold standard patient - reported outcome measures in clinical practice – A new approach to facilitate their use



Abstract

Introduction: To analyze two gold-standard Patient-Reported Outcome Measures (PROMs) in knee OA (WOMAC and SF-36) and determine which questions are the most reflective of the overall score.

Methods: This was a retrospective study on 4,983 patients with primary knee pain. Patients had WOMAC and SF-36 at two-time points, pre-treatment and after three months of treatment. A decision tree classifier supported with a linear mix model regression was applied to determine, identify, and categorize the most influential questions that determine the overall score in each of the questionnaires.

Result: For SF-36, the most influential items were Q22 (39%), Q32 (24%), Q11 (19%), Q25 (19%). For WOMAC, the most influential predictors were Q14 (39%), Q10 (24%) and Q15 (21%). A significant improvement in WOMAC and SF-36 was seen after three months of treatment ($p < 0.01$). For SF-36, the main predictor items were Q11, Q22 and Q32, Regression model $R^2 = 0.841$, $p < 0.01$, $t[55.62] = 0.001$, Beta for Q22 = 0.409, Q32 = 0.352, Q11 = 0.278. For WOMAC, the main predictor items were Q10 and Q15, Regression model $R^2 = 0.930$, $p < 0.01$, $t[35.4] = 0.001$, Beta for Q15 = 0.548, Q10 = 0.4639.

Conclusion: Two questions from the WOMAC questionnaire predicts 93% of the overall score and four questions from the SF-36 predict 84%. The creation of a clinically meaningful assessment tool based on larger scientifically validated PROMs will help to facilitate its use by clinicians and acceptance by patients in clinical practice.

Keywords: patient reported outcome measures, clinical practice, knee

Abbreviations: PROMs: Patient-Reported Outcome Measures; MSK: Musculoskeletal; VAS: Visual Analogue Scale; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; EQ-5D: EuroQol Five Dimensions Questionnaire; SF-12: Short Form-12; SF-36: Short Form-36

Introduction

Patient-Reported Outcome Measures (PROMs) are self-administered questionnaires that are used to assess a patient's health state, quality of life, and functional status associated with their health condition without the interpretation of the physician or anyone else [1,2]. There are growing efforts to shift from using PROMs in health research to implementing them in clinical practice [2-4]. Integrating PROMs in clinical practice can serve the entire health care system, including patients, care providers, insurers, and government regulators, and will enhance high-quality clinical care and improve shared decision-making processes [1,5,6]. From a patient's point of view, this will help to quantify health status, monitor changes over time, help to set up expectations, and increase patient engagement [5,7].

PROMs in Musculoskeletal (MSK) conditions are essential to facilitate patient-clinician communication and improve the shared decision-making process. Adding assessments from the patient's perspective provides a patient centered approach that will help to assess disease severity as well as the effectiveness of treatments [2,8,9]. There are some commonly used disease-specific PROMs in MSK conditions, amongst them are the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Short Form-36 (SF-36) [10,11].

Implementing PROMs in clinical practice is still a challenge [10]. The current integration of PROMs in clinical practice is minimal as they are considered complex and resource-intensive [4,12,13]. In essence, there are several barriers to real-life implementation and the adoption of PROMs in clinical practice. Amongst these are skepticism about the validity and potential

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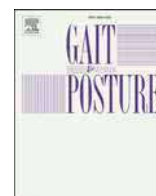
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Smartphone-based inertial sensors technology – Validation of a new application to measure spatiotemporal gait metrics

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Background: Smartphones are increasingly recognized as the future technology for clinical gait assessment.

Research

Question: To determine the concurrent validity of gait parameters obtained using the smartphone technology and application in a group of patients with musculoskeletal pathologies.

Methods: Patients with knee, lower back, hip, or ankle pain were included in the study (n = 72). Spatiotemporal outcomes were derived from the walkway and the smartphone simultaneously. Pearson's correlations and limits of agreement (LoA) determined the association between the two methods.

Results: Cadence and gait cycle time showed excellent correlation and agreement between the smartphone and the walkway (cadence: $r = 0.997$, $LoA = 1.4\%$, gait cycle time: $r = 0.996$, $LoA = 1.6\%$). Gait speed, double-limb support and left and right step length demonstrated strong correlations and moderate agreement between methods (gait speed: $r = 0.914$, $LoA = 15.4\%$, left step length: $r = 0.842$, $LoA = 17.0\%$, right step length: $r = 0.800$, $LoA = 16.4\%$). The left and right measures of single-limb support and stance percent showed a consistent 4% bias across instruments, yielding moderate correlation and very good agreement between the smartphone and the walkway ($r = 0.532$, $LoA = 9\%$ and $r = 0.460$, $LoA = 9.8\%$ for left and right single-limb support; $r = 0.463$, $LoA = 5.1\%$ and $r = 0.533$, $LoA = 4.4\%$ for left and right stance).

Significance: The examined application appears to be a valid tool for gait analysis, providing clinically significant metrics for the assessment of patients with musculoskeletal pathologies. However, additional studies should examine the technology amongst patients with severe gait abnormalities.

1. Introduction

Quantitative gait assessment adds unique value for clinicians who treat patients with musculoskeletal conditions. Gait analysis may help health professionals to estimate severity of the pathology [1], track disease progression [2] or capture functional changes in response to therapy [3,4]. Instruments for gait analysis range from the high-end motion capture laboratory, through pressure-sensor gait mats or insoles, to the simple step counter. While the motion-lab analyzes gait kinetics and kinematics both accurately and comprehensively, it is an expensive tool that requires designated space and trained personnel, thus making it irrelevant in clinical practice. To address this issue, researchers adopt different tools that better integrate in their work stream. Amongst them are wearable inertial measurement units (IMUs), a low-cost and accessible technology that deliver valid and reliable gait

metrics [5] and reflect multiple aspects of mobility [6]. More specifically, some studies found that IMUs have good to excellent reliability and validity in measuring mean spatiotemporal gait parameters among healthy adults [5] and in patients with osteoarthritis [7], with sensors placed across variable locations. Thus, these adaptive technologies allow clinicians to better implement gait analysis as part of the clinical and functional assessment of a patient and monitor changes over time.

Accumulating evidence suggest that smartphones may further bridge the gap between the laboratory and the clinic when examining gait. Smartphones have inherent inertial sensors and a processing core that can capture and analyze the walking signal for immediate results. The validity of smartphones as gait assessment tools was tested among healthy young [8–10] and older adults [11], patients with Parkinson's disease [12–14], chronic stroke survivors [15] and just recently in a large group of older adults with diverse health conditions [16]. In a

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