

# DISEASE SEVERITY INFLUENCES PATIENT RESPONSE TO VARIABLE-STIFFNESS WALKING SHOE AFTER ONE YEAR OF WEAR

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## INTRODUCTION

Many studies have reported the effectiveness of footwear modifications using laterally-wedged insoles (Kerrigan et al. 2002, Toda et al. 2004) and, more recently, variable-stiffness soles (Erhart et al. 2007) in patients with medial compartment knee osteoarthritis (OA) in reducing the adduction moment at the knee. The adduction moment is known to be associated with the progression (Miyazaki et al. 2002) and treatment outcome (Andriacchi et al. 1994) of medial compartment knee OA. Studies of clinical effects with lateral wedges, however, have shown mixed reports on improvement (Baker et al. 2007, Tohyama et al. 1991) and it is possible that OA severity may affect clinical outcome (Sasaki and Yasuda 1987, Shimada et al. 2006).

The purpose of this study was to test the hypothesis that the severity of OA in patients with medial compartment knee osteoarthritis will influence the reduction in the knee adduction moment and the reduction in pain and improvement in function after 12 months of wearing a variable-stiffness shoe, while no differences will be related to severity for patients wearing a control shoe for 12 months.

## METHODS AND PROCEDURES

The data was obtained from 49 patients with radiographically diagnosed (Kellgren-Lawrence grade  $\geq 1$ ) medial compartment knee OA. At an initial visit, subjects were randomly assigned to either a uniform stiffness control shoe (n=23) or a variable-stiffness intervention shoe (n=26) to wear as

their main walking shoe for 1 year. Subjects were blinded as to their shoe type. The intervention shoe had a lateral heel sole stiffness 2.3 times greater than the medial heel, and lateral forefoot sole stiffness 3 times greater than the medial forefoot, with the medial sole stiffness comparable to the stiffness of the control shoe. Both intervention and control subjects were divided into 2 groups based on OA severity: less severe (KL  $\leq 2$ ) and more severe (KL  $> 2$ ). Demographic data is provided in Table 1. If patients were affected bilaterally, their more severely affected side was used for analysis. Subjects participated in the study after giving written consent in accordance with the Institutional Review Board.

Table 1: Demographic data of patients

Group	Severity	Male	Female	Age (yrs)	Height (m)	Mass (kg)
Intervention	KL $\leq 2$	7	6	60.0 (7.4)	1.67 (0.07)	73.2 (14.9)
	KL $> 2$	7	6	66.8 (3.7)	1.70 (0.09)	87.1 (13.8)
Control	KL $\leq 2$	4	9	57.8 (9.9)	1.68 (0.10)	73.0 (10.0)
	KL $> 2$	6	4	64.0 (9.3)	1.71 (0.07)	82.7 (12.9)

Subjects completed WOMAC functional improvement-based ratings specific to OA to assess pain and function (Bellamy et al. 1988) at the baseline and 12 month time points. At the 12 month time point, subjects performed 3 walking trials at a self-selected normal speed in their personal walking shoe (comfortable walking shoe used by patient) and their study shoe (control or intervention). Kinematic and kinetic data were collected using an 8-camera optoelectronic motion capture system. External inter-segmental forces and moments were calculated for the lower limb using previously described methods (Andriacchi et

al. 2004). The first peak knee adduction moment was calculated for each trial. Average values for each shoe and subject were determined for each subject's more affected leg. Paired two-tailed Student's T-tests ( $\alpha = 0.05$ ) were used to compare the different shoes and to compare the WOMAC ratings between the baseline and 12 month time points.

## RESULTS

The knee adduction moment of the less severe intervention group ( $KL \leq 2$ ) was significantly reduced with the variable-stiffness shoes versus the subjects' own personal walking shoes after 12 months of wear (7.6%,  $p=0.001$ ). These subjects also had a significant reduction in total WOMAC score, with an average absolute reduction of 40 points, translating to a 56% reduction from baseline ( $p=0.01$ ). There was no statistically significant reduction in WOMAC score in the intervention shoe subjects with more severe OA ( $KL > 2$ ), and no significant reduction in knee adduction moment. For both the less severe ( $p=0.03$ ) and more severe ( $p=0.01$ ) control shoe groups, there were increases in knee adduction moment, 3.8% and 7.9%, respectively, with the control shoe versus the subjects' own personal shoes after 12 months of wear. There was no change in total WOMAC score in patients with the control shoe regardless of Kellgren-Lawrence grade.

## DISCUSSION

The use of a variable-stiffness intervention shoe successfully reduced the knee adduction moment in less severe patients after 12 months of wear, supporting our hypothesis. This reduction in knee adduction moment was accompanied by a reduction in pain and improvement in function in this group. These results were not seen in the more severe intervention patients or in the control groups. These results demonstrate the usefulness of the intervention shoe in early osteoarthritis,

both in reducing pain and improving function and in possibly slowing the rate of progression of the disease by lowering the adduction moment at the knee.

## SUMMARY

The results of this study help to clarify which subjects may benefit the greatest from a footwear intervention. The data supports the recommendation for use of the variable-stiffness sole intervention shoe in subjects with early medial compartment osteoarthritis ( $KL \leq 2$ ).

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