CHAPTER 32

EFFECT OF A MEDIAL-WEDGE INSOLE ON THE KNEE JOINT

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INTRODUCTION

The clinical efficacy of foot orthoses (FO) in the management of a variety of foot and ankle disorders have been widely demonstrated in literature (1-5). However, the validity of FO in the treatment of proximal joint diseases in the lower extremity, especially the knee, has remained controversial. For example, in regard to the treatment of the medial compartment knee osteoarthritis (OA), Sasaki and Yasuda first showed in 1987 that a 5 degree laterally wedged insole might prove effective in treating medial compartment knee OA (6). Since then, various authors have documented the effectiveness of a full length lateral wedge of 5 degrees or higher to be efficacious in reducing the knee adduction moment (7-11). Conflicting reports by other authors, however, reported no effect on knee loading when testing insoles that loaded only the medial rearfoot (12-15).

Lateral wedges have been tested for their efficacy in treating knee osteoarthritis, whereas FO posted with a medial rear foot or medial sole post have been widely utilized by foot and ankle specialists in controlling excessive pronation of the foot. If the biomechanical rationale that a lateral wedge would reduce knee adduction moment were held true, conversely, a medial wedge would increase the knee adduction moment, with a potentially detrimental effect in a patient with medial compartment knee OA. Baliunas et al suggested that subjects with knee OA walk with a greater than normal peak external knee adduction moment (16). Knee OA typically causes a loss of joint space in the medial compartment, leading to knee varus angulation (8). Due to the elevation in varus torque (or adduction moment), the medial joint space loss potentiates progressive joint space loss and angulation, leading to a vicious cycle (8).

All the previously-cited studies relating to knee forces involved either in vitro measurements or estimates using mathematical models, which could have contributed to the conflicting results. To better understand the full effect of the wide spread practice of medial rear foot posting on the knee joint, a more sensitive and consistent way of assessing the knee joint force distribution is necessary. D'Lima et al from the Shiley Center for Orthopaedic Research and Education at Scripps Clinic (SCORE) previously reported the first direct measurement of knee forces in vivo after total knee arthroplasty (TKA) (17,18). The tibial component used in the studies was instrumented with 4 load cells that measured the axial components of load on the 4 quadrants of the tibial tray. These instrumented implants measured the total axial force (Fz) and the location of the center of pressure. However, shear and moments, which are also important components of knee forces, could not be directly measured in this particular design. For this reason, Kirking et al from the same research laboratory developed a second-generation, force-sensing device that measured all components of tibial forces, in collaboration with Zimmer (Warsaw, IN) (19). The stem of this design was instrumented with strain gauges that measured all 6 components of forces, namely the total force along the 3 axes of the orthogonal coordinate system (Fx, Fy, Fz), and the moment around each axis (Mx, My, Mz) (Figure 1).

Given the common practice of medial heel posting to control the subtalar joint pronation, it would be beneficial to determine the full effect of medial wedges on the knee joint, especially ones with medial compartment OA. In this preliminary prospective study, we aim to test the hypothesis that a medial rear foot wedge of increasing increment would show an increase in the knee adduction moment, by means of measurements derived from the tibial components (E-Knee) developed at SCORE. We will report on the in vivo measurements of the axial forces (Fx, Fy, Fz) and moments (Mx, My, Mz) in the knee while walking on varying degrees of medial rear foot wedge insoles.

PATIENTS AND METHODS

A total of 4 patients underwent TKA with the E-Knee implants by a single surgeon from 2004 to 2006. Three of the 4 patients were located in San Diego, and invited to SCORE for data collection (Table 1). One patient (JW) had the first generation implant. The other two (DM, PS) were given the second-generation design.

The first generation E-Knee consisted of a titanium alloy tray instrumented with 4 uniaxial load cells, a microtransmitter, and an antenna (17, 18). The uniaxial load cells were located 20.4 mm medial and lateral, and 9.8 mm anterior and posterior of the center of the tibial tray, respectively. The instrumented knee transmitted tibial force data from the 4 sensors at 70 Hz. Custom PC-based software was developed to read, display, and store data. Medial (lateral) compartment loading was calculated as the sum of the medial (lateral) anterior and medial (lateral) posterior compressive loads (20). Due to the limitations in the design, only the total compressive joint force (Fz) could be directly measured by summing of the medial and lateral compressive loads. The torque around the y axis (My), which represents the adduction/abduction moment, could be indirectly derived according to the formula t=rxF, where t is the magnitude of torque, r is the length of the lever arm, and F is the magnitude of the net vertical force. For the one patient in our study with the first generation Electronic Knee, r represented the distance between the center of the implant and the mediolateral tibiofemoral contact points, which remained constant during gait at 0.8 inches. The net vertical force was calculated as the difference between medial and lateral compartment forces. The rest of the parameters – Fx, Fy, Mx, Mz – could not be measured from the first generation E-Knee.

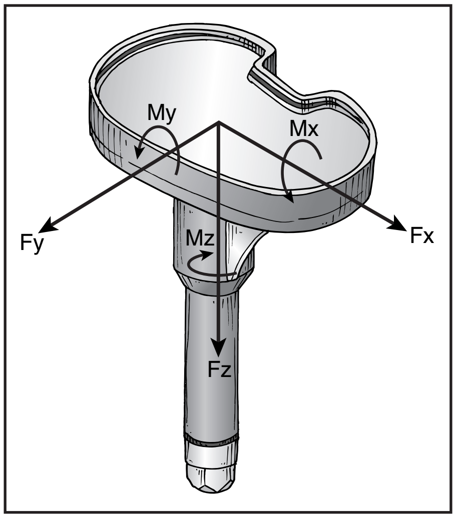

Figure 1. Electronic Knee coordination system.

The second generation E-Knee was manufactured by Zimmer, based on the Natural Knee II (NK-II) tibial tray design (Figure 1). The tray and locking mechanism were identical to the standard design for implantation with a standard insert. The stem was instrumented with strain gauges to measure 3 orthogonal forces (Fx, Fy, Fz) and 3 moments (Mx, My, Mz). The stem also housed a microtransmitter that performed analog-to-digital conversion, filtering, and multiplexing before transmitting data via a hermetic glass-feed-through tantalum antenna. External coil induction was used to power the implant. Details of the implant design, strain gauges, micro-transmitter, telemetry system, and accuracy have been previously reported (19).

The pre-fabricated insoles utilized in the study were manufactured by Powerstep, with a snap-on 0-, 2-, and 4-degree medial wedge rear foot post options, where the 0-degree post served as the nonwedged, even thickness control insole. The insole featured a full length Poron cushioning and a heel cup with intrinsic Poron cushion and EVA enhancement. These insoles were ordered according to the foot size of the each subject prior to the day of data collection.

The protocol to assess the effect of the medial rear foot wedge insoles on the knee joint was approved by the Institutional Review Board and written informed consent was obtained from each subject. The 3 subjects were asked to walk at their comfortable walking speed across a 10-meter gait laboratory walkway. A total of 50 steps per walking condition were collected for each subject. The conditions were 1) regular tennis shoe with neutral or 0 degree post insole, 2) regular tennis shoe with 2 degree

Table 1

PATIENT DEMOGRAPHICS.

Subject	DOS	Age, years	Height (in)	Weight (lbs)	Side
JW	02/27/2004	86	66	144	R
PS	01/24/2006	87	70	168	L
DM	06/20/2006	82	68.5	153	R

medial wedge insole, 3) regular tennis shoe with 4 degree medial wedge insole. All posts were applied in the rearfoot only. Knee force distribution and torque were measured and recorded using a wireless RF receiver. Knee flexion angle was recorded using an electro-goniometer. Knee flexion angle was used to analyze, extract, and average individual gait cycles.

Data

The first peak in the vertical force through the longitudinal axis of the E-Knee (Fz) after heel strike was determined the most relevant point of the gait cycle for this analysis for 2 reasons: it represents the point of a weight shift of the greatest magnitude to the rearfoot; and the medial wedges are used only under the heel, therefore, they would affect the knee to the greatest degree while weight shift is occurring through the heel (first peak) while causing a negligent effect on the rest of the gait cycle. Force and torque measurements along the 3 axes of the orthogonal coordinate system of the E-Knee were taken under all 3 walking conditions, throughout all 50 gait cycles (50 measurements).

Fz at its first peak and the rest of the axial forces and torques at the corresponding point in gait cycle (50 measurements per parameter) were singled out from the rest of the gait cycle for each subject (except for the 1 subject with the first generation E-Knee, for whom only Fz and My could be generated) (Figure 2). The axial forces are reported as multiples of body weight (xBW), and moments as forces multiplied by the lever arm in inches (xBW*in). Two-way ANOVA tests were performed to compare the 3 walking conditions and the 3 subjects, and the Scheffé Post-Hoc test was used where significant differences were found (*P* < 0.05).

RESULTS

Fx (mediolateral shear force)

Positive Fx indicates lateral shear force. Data were derived only from the second generation E-Knee in PS and DM. DM showed less medial shear force than PS, with statistical significance (F [1,244] = 124.010, *P* < 0.001). The E-Knee recorded significantly higher medial shear force with the neutral post for PS only (F [5,244] = 31.408, *P* < 0.001). On average, both 2- and 4-degree wedges demonstrated lower medial shear force than the neutral post; however, no significant difference was appreciated between the two (*P* = 0.731) (Table 2, Figure 3).

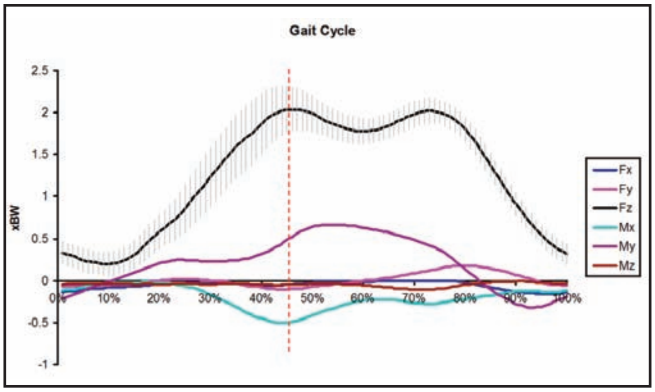

Figure 2. First peak.

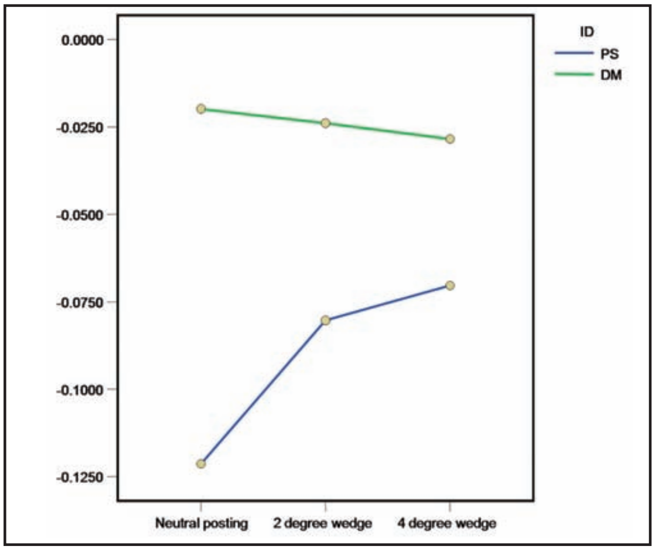

Figure 3. Fx (mediolateral shear force).

Fy (anteroposterior shear force)

Positive Fy indicates anterior shear force. Data were derived only from the second generation E-Knee in PS and DM. The 2 patients demonstrated contrary types of sheer force, PS with posterior sheer force and DM with anterior sheer force. The difference between subjects was statistically significant (F [5,244] = 94.635, *P* < 0.001). The E-Knee recorded the least amount of anteroposterior shear force with the 4 degree wedge, but among the wedges there was no statistically significant difference (*P* = 0.170) (Table 2, Figure 4).

Fz (vertical compression force)

Positive Fz indicates downward vertical compressive force. Data were derived from all 3 patients. Subject JW with the first generation E-Knee showed the least compressive force when compared to PS and DM. PS experienced significantly

Table 2

AVERAGE OF 50 MEASUREMENTS OF AXIAL FORCE AND TORQUE AT FIRST PEAK

Force Measured	Orthosis	PS	DM	JW
Fx	Neutral	-0.121	-0.020	
	2 degree	-0.080	-0.024	
	4 degree	-0.070	-0.024	
Fy	Neutral	-0.095	0.047	
	2 degree	-0.074	0.051	
	4 degree	-0.070	0.046	
Fz	Neutral	2.355	2.295	1.791
	2 degree	2.365	2.149	1.685
	4 degree	2.406	2.367	1.704
Mx	Neutral	-0.505	-0.954	
	2 degree	-0.479	-0.905	
	4 degree	-0.493	-0.989	
My	Neutral	0.696	0.372	0.911
	2 degree	0.744	0.400	0.855
	4 degree	0.795	0.405	0.878
Mz	Neutral	-0.057	-0.055	
	2 degree	-0.055	-0.056	
	4 degree	-0.041	-0.083	

more compressive force than both DM and JW (F [8,382] = 152.538, $P < 0.001$). The combined first and second generation E-Knee showed the least amount of downward vertical compressive force with the 2-degree wedge, statistically different from both neutral and 4 degree wedges (F [2,382] = 11.261, $P < 0.001$). There was no difference between the neutral and 4 degree posts ($P = 0.766$) (Table 2, Figure 5).

Mx (flexion/extension moment)

Negative Mx indicates knee flexion moment. Data were derived only from subjects PS and DM with the second generation E-Knee. PS displayed less knee flexion moment than DM with statistical significance (F [5,244] = 230.375, $P < 0.001$). The least amount of flexion moment in the knee was seen with the 2-degree wedge. There was no difference between the neutral and 4-degree posts; however, significant differences were seen between the 2-degree and 4-degree posts (F [2,244] = 4.708, $P = 0.01$) (Table 2, Figure 6).

My (adduction/abduction moment)

Positive My indicates knee adduction moment. Attributes of the knee adduction moment include higher medial compartment loading, tibia being pushed away from the sagittal plane (abduction), and varus knee. Data were derived from all 3 subjects. Statistically significant differences were appreciated among all 3 patients with DM displaying the least adduction moment and JW with the highest adduction moment (F [8,382] = 156.597, $P < 0.001$). The least amount of adduction moment in the knee was seen with the neutral post. There was no difference between the neutral and 2 degree posts ($P = 0.476$) and between 2-degree and 4-degree posts ($P = 0.461$), however, statistically significant differences were seen between the neutral and 4-degree posts (F [2,382] = 3.142, $P < 0.05$) (Table 2, Figure 7).

Mz (internal/external rotation moment)

Negative Mz indicates tibial internal rotation moment. Data were derived again only from PS and DM, subjects with the second generation E-Knee. Although the 2 patients displayed near identical pattern in tibial internal rotation moment with neutral and 2 degree posts, PS showed less tibial internal rotation moment than DM on the 4-degree wedge, with statistical significance (F [5, 244] = 3.510, $P < 0.01$). When averaged together, however, there was no statistically significant difference among the wedges ($P = 6.23$) (Table 2, Figure 8).

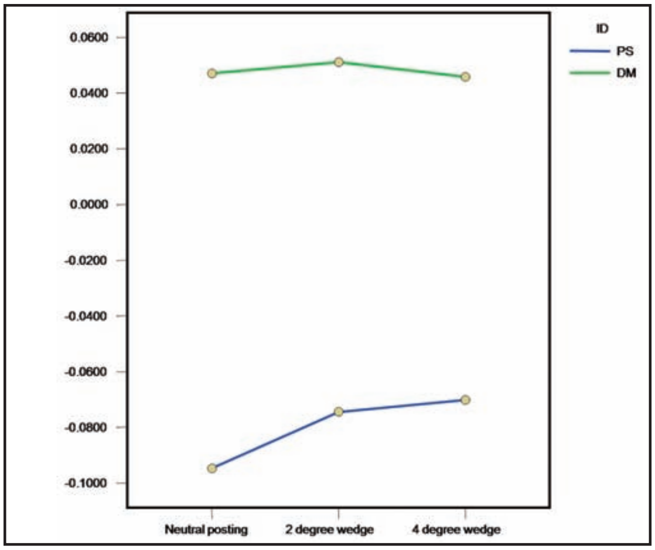

Figure 4. Fy (anteroposterior shear force).

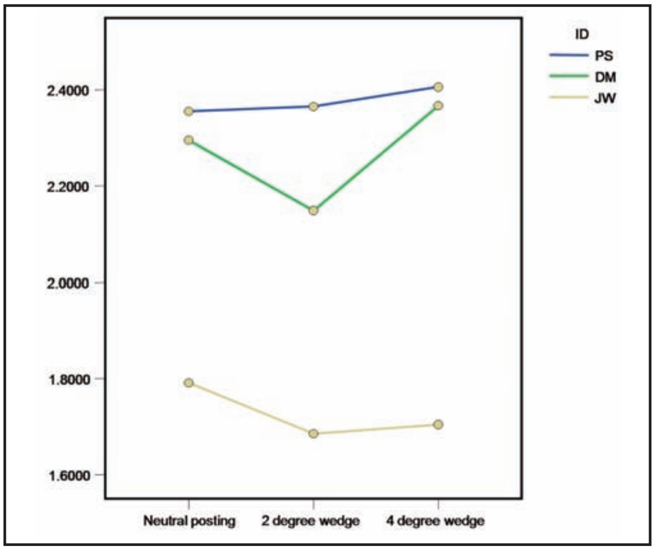

Figure 5. Fz (vertical compression force).

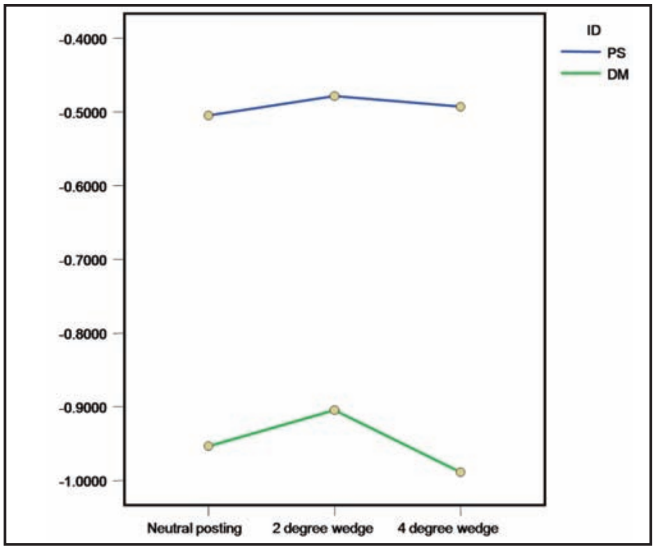

Figure 6. Mx (flexion/extension moment).

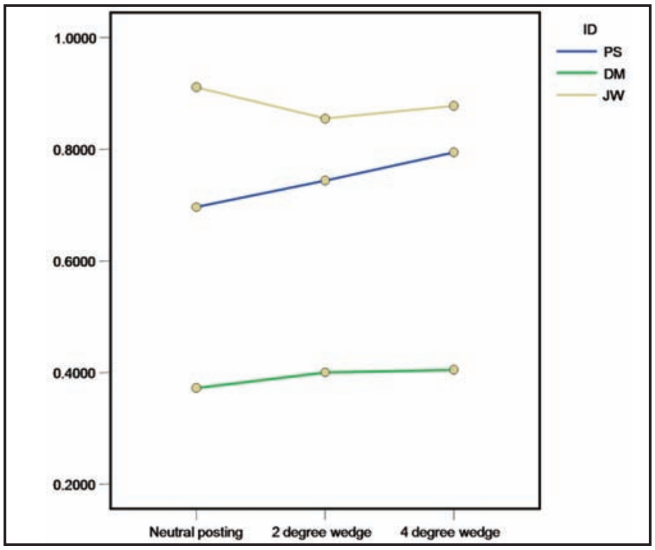

Figure 7. My (adduction/abduction moment).

DISCUSSION

It has been shown that during walking, healthy individuals have an almost continuous large, external, adduction moment about their knees throughout stance, with the resultant findings of pronounced varus knee and higher medial compartment loading (9). Even individuals with valgus deformities in the knee will have a varus moment throughout stance (9). During gait, approximately 60-80% of the loads across the knee are transmitted to the medial compartment (21). An FO with a lateral wedge would therefore transmit greater loads across the lateral compartment, while one with a medial wedge would transmit greater loads across the medial compartment. In particular, a rearfoot medial post may prove effective in controlling rear foot pronation, however, it may be potentially detrimental if used in a patient with medial compartment knee OA.

Given the wide spread practice of a medial rear foot posting to limit rear foot pronation, we investigated the full in vivo effect of a medial rear foot wedge on the knee joint by utilizing the E-Knee. In this study, we tested the hypothesis that a medial rear foot wedge of increasing increment would show an increase in the knee adduction moment. Our study has demonstrated this hypothesis to be correct: the 4 degree post showed higher adduction moment (My) with statistically significant difference from the neutral post. Apart from My, however, we could not find any

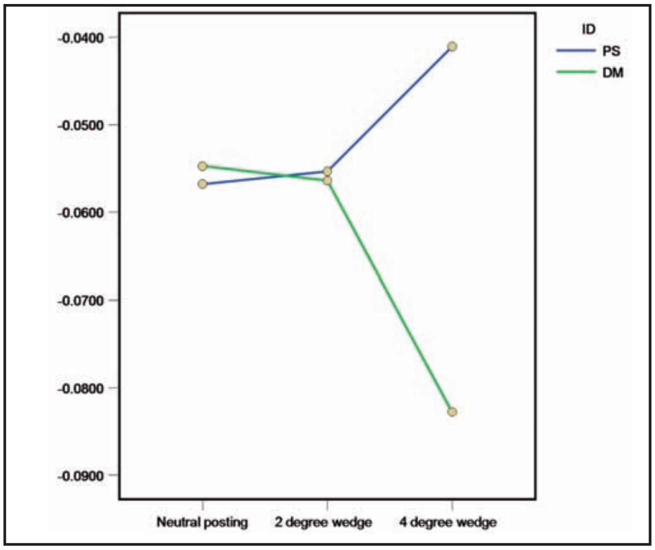

Figure 8. Mz (internal/external rotation moment).

consistent effect on the knee joint (where a higher degree post causes a more pronounced effect) in the rest of the parameters tested. Other than Fz, where the subject with the lightest weight (JW) demonstrated the least vertical compressive force and the heaviest subject (PS) showed the most with statistical significance, the rest of the parameters displayed unique variations in each patient and failed to display any definite pattern. The primary limitation of this study being the use of only 3 subjects with an E-Knee, further investigation with a larger sample size with the E-Knee implants would be required to draw conclusions about the full effects of FO in the knee joint.

The demonstrated efficacy of a medial wedge raises questions about the popular practice of medial heel posting to control excessive subtalar joint pronation, especially in patients with a known history of medial compartment knee OA. In prescribing a medial wedge, are we saving the foot to the detriment of the knee? Can a neutral orthotic device that is posted with a lateral rear foot or lateral sole post still control the pronation of the foot? In patients with a forefoot valgus foot type, we may support the foot with a forefoot valgus post rather than a rearfoot medial wedge, which will aggravate the medial knee compartment pain. However, in patients with medial knee OA who present with a forefoot varus foot type, which causes the subtalar joint pronation, would not an everting lateral wedge cause or allow more pronatory force? Do we protect the knee or the foot?

The demonstrated efficacy of a medial rear foot only wedge in increasing the adduction moment in the knee also indirectly lends support to the validity of a lateral wedge, both full length or rearfoot only, in the treatment of knee osteoarthritis. Although a few authors reported no effect on knee loading when tested lateral wedges that loaded only the rearfoot (12-15), we have shown a statistically significant difference in knee adduction moment with medial wedge insoles in the rear foot only. Our success most likely stems from the E-Knee affording us a more sensitive in vivo measurement that can detect the less pronounced effect of a rearfoot post versus a full length post. Whereas a full length post would impact the knee throughout the stance phase of gait cycle, a rearfoot post would exercise its effect only through the heel strike and midstance phases while the weight shift is occurring through the heel.

In summary, this study directly demonstrated that a rearfoot medial wedge insole of increasing degrees can increase the in vivo knee adduction moment. This finding indirectly supports the previous investigations that showed the success of lateral wedge insoles in decreasing the adduction moment as well as the medial compartment load in the knee (7-11). This result suggests that FO may possibly be able to slow the rate of progression of cartilage breakdown, and serve as a therapeutic intervention to delay the need for invasive surgery for medial compartment knee osteoarthritis.

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