THE UNIVERSITY OF CALGARY

Are the Kinematic Changes to Gait Caused by Foot Orthotic Use in a Pronated Population Permanent, or Mitigated during a One-Month Period of Adaptation?

by

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Abstract

The purpose of this research was three-fold: to determine whether the kinematic changes to gait of highly pronated subjects ($\geq 12^{\circ}$ eversion) caused by foot orthotic use were consistent over time; to develop a new method of measuring in-shoe calcaneal motion without bone pins; and to develop a method of repeatably setting static neutral position.

In the primary study (consistency of effects) only one measured variable was significantly affected. Time of maximal tibial internal rotation during the first 20% of stance occurred significantly earlier when compared to timing at initial orthotic use.

Most kinematic variables showed throughout the study an oscillation in effects and never had a stable consistent pattern during gait. Only a few variables, those that were initially unchanged by the orthotic intervention in a very few subjects were stable throughout the study.

This research shows that foot orthotic effects may not be permanent or even consistent over time and results indicate it may not be realistic to interpret orthotic effects with only initial use data. It also supports earlier research, which determined foot orthotics primarily affected tibial rather than calcaneal motion [48]. Finally, since kinematic changes to gait were not consistent, results may indicate that changes to gait kinematics may not be the mechanism by which foot orthotics contribute to injury recovery.

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To all the other students at the Human Performance Lab that introduced me to soccer, squash and never once to my face (behind my back only) made snide remarks about Americans. Huh!

Dedication

To my daughter Rebecca Maree, in front of whom failure was not an option.

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1.0 Introduction

Among clinicians it is generally held that a link between abnormal biomechanics (of which excessive pronation is a cited example) and injury exists [25;45;68]. Excessive pronation of the foot has been defined as a condition in which the foot which does not return or returns too late to subtalar joint neutral position during the final stages of stance [17]. In a study to determine if a link between excessive pronation and injury exists, Messier and Pittala [45] found runners in a shin splint group (n=17) had more pronation than runners from the control group (n=19). Subotnick [68] states "The foot must be neutral just prior to the time that the heel leaves the ground. When this situation does not exist, the muscles of the lower extremity work overtime, a stable propulsion is impossible, and there is an increased torque upon the leg, which results in overuse injury of the lower extremity." Halbach [25] states "In an athlete, there is one possible structural and biomechanical problem that can cause low back pain, hip pain, knee pain and foot pain: excess pronation of the foot."

Functional custom foot orthotics are a generally accepted treatment for overuse injuries related to excessive pronation and are prescribed with the belief that foot orthotics affect gait biomechanics [30;41;73]. Further, Milgrom [46] has determined that when prescribed prophylactically, foot orthotics reduced the incidence of stress fractures in soldiers.

Researchers have not reached consensus whether foot orthotics affect foot kinematics or what those effects may be. However, it is clear that a generally held belief is: whatever the effects may be, they are consistent over time and long lasting [20;31;53;66]. This can be inferred from the fact that although researchers have measured kinematic effects and have hypothesized how the effects result in injury improvement, there has been little if any discussion concerning the constancy or consistency of effects. An orthotist whom provides custom foot orthotics for over-use injuries was consulted [11]. He explained that even if the treated injury was running related, his expectation and advice to patients was that the prescribed foot orthotics should be continuously worn, not for running only, but for everyday use. His goal was for the devices to be worn at least 80% of the patients waking hours. Follow-up visits were considered necessary only if pain persisted. Otherwise, the assumption was the orthotics were functioning as intended, by consistently and permanently altering gait kinematics.

It is clear that investigations into the permanence and consistency of foot orthotic effects have been minimal. Only one study could be found specifically investigating orthotic effects over time [64]. Unfortunately, since the subjects were Down Syndrome children exclusively, the results may not be applicable to a general population. Therefore, little if anything currently is known concerning orthotic long-term effects.

Specific kinematic variables of the lower foot, ankle and shank have been measured for immediate effects only. For example, shoe inserts were found by some researchers to decrease maximal calcaneal angle or maximal eversion during stance phase [22;34;36;38;74]. However, others found no affect on stance phase calcaneal angle or eversion [5-7]. Eng and Pierrynowski [22] found subjects with shoe inserts had decreased transverse plane rotations of the shank during walking but increased rotations during running. A 1990 study determined that shoe inserts increased knee transverse range-of-motion (ROM) by 10% during walking [34]. In 1986, Smith et al. [66] determined that shoe inserts decrease the rate of eversion, while later studies found no velocity effect [6;38].

Reasons for these dichotomies are many. Neutral trial stance position of the subjects was not standardized between experimenters [3;22;38;69]. Some researchers analyzed two-dimensional (2D) [6;31;37] data while others analyzed three-dimensional data (3D) [34;38;53]. Marker configuration for collecting calcaneal or foot motion data was varied. Techniques to view calcaneal skin markers through shoe holes and slots [6;7] were used in addition to shoe counter mounted markers [53] and a calcaneal mold [37]. Foot orthotic posting technique or material of manufacture were varied [22], or possibly not mentioned [6;6;59;74]. Subject inclusion criteria differed between studies [53;66]. One publication was based on one case study only [42]. All of these are obvious methodological differences, which may typically exist between any conducted experiments.

However, factors other than methodological differences should be considered. From a research standpoint, the most interesting and least understood factor is the hypothesis that human adaptation may play a role in the variability of results. Examples of human adaptation and its possible effects may be seen in the following research results: it has been determined that denser midsole running-shoe material does not necessarily lead to appreciably greater ground reaction forces [14;50]; nor do ten-degree wedges alternately placed medially and laterally under the calcaneus appreciably alter a subject's knee position [7]. The second finding led Cavanagh to hypothesize that human adaptation may affect research results. This hypothesis is important, as a logical conclusion is; human kinematic reaction to orthotic interventions in the laboratory may not be indicative of real world reactions, if subjects are given time to adapt to the same intervention.

For this thesis, it was felt the best way to study human adaptation and its affects on kinematic changes caused by foot orthotic use, was to repeatably measure subjects' gait during a period of adaptation to foot orthotics. However, research has indicated there may be a problem with currently used methods. Firstly, Reinschmidt et al. [56] determined that shoe markers did not accurately reflect in-shoe calcaneal motion. Secondly, when kinematics are measured in 3D, the absolute position of one body segment with respect to another around the common joint is determined by comparison of the new position with a static neutral position. Unfortunately, neither a standard definition of ankle neutral position nor a method of repeatably setting it has been accepted by researchers. To proceed with this research both problems had to be addressed. It was necessary to develop a method a measuring in-shoe calcaneal motion that did not, as most past research has, rely on shoe markers. Further, it was necessary to define an ankle neutral position and a method of repeatably setting it that was anatomically based.

Therefore, the purpose of this research is to examine if human adaptation influences the kinematics of highly pronated subjects during one-month of adaptation to custom functional foot orthotics. Also, to develop and test a technique of directly measuring in-shoe calcaneal motion and to develop a standard ankle joint neutral position with a method of repeatably setting it.

Chapter 2 of this thesis is a literature review of human anatomy specific to the ankle and foot, a review of human gait and lastly a review of foot orthotic design. Chapter 3 is the pilot study on neutral position definition and repeatability of position setting. Chapter 4 is the pilot of a new method of obtaining in-shoe calcaneal motion, while Chapter 5 contains all sections related to the primary study on consistency and permanence of foot orthotic effects. Each chapter contains related literature reviews.

2.0 Review of Anatomic and Gait Literature

This literature review is intended to provide background necessary to understand issues fundamental to the purpose and design of this study. Literature concerning foot orthotic effects on ankle and lower extremity angular motion during gait and effects of human adaptation will be reviewed. Sections on ankle anatomy, planes of motion, definitions of normal and abnormal gait and foot orthotic development are included as background.

This review is divided into three sections. The first section examines the ankle joint, normal and abnormal gait and foot orthotic development. As such, it will not review research, so much as it will provide basic information. Section 2 is used to examine foot orthotics and their measured affects on gait, while Section 3 is used to review work related to human gait adaptation. Literature related to the specific methodology problems of measuring in-shoe calcaneal motion and repeatable setting of lower extremity and ankle joint/foot neutral position will be examined separately in pilot study chapters three and four.

It should be noted that pronation and eversion are used interchangeably in the scientific literature. However, pronation is a 3D motion and cannot be directly measured. Therefore, eversion is typically measured and since it is the largest component of pronation, it is substituted. In this thesis when describing previous literature, the terms from that literature will be used. When used originally, the term eversion will be substituted for pronation where permissible.

2.1 Joint Anatomy and Motion

2.1.1 Ankle Joint

The ankle joint is described typically as a simple hinge joint, with rotation of the talus within the ankle joint mortise being around a single axis [29]. The ankle joint axis in general passes from medial to lateral, but is not parallel directly to any anatomic plane. It is inclined so that it passes from lateral, plantar and posterior to medial, dorsal and anterior [9;60]. It is located physically by the medial and lateral malleoli, which are the distal most ends of the tibia and fibula respectively. These ends serve to reduce medial and lateral translation of the talus within the ankle joint mortise. However, the talus does in fact rotate in the mortise [29;63].

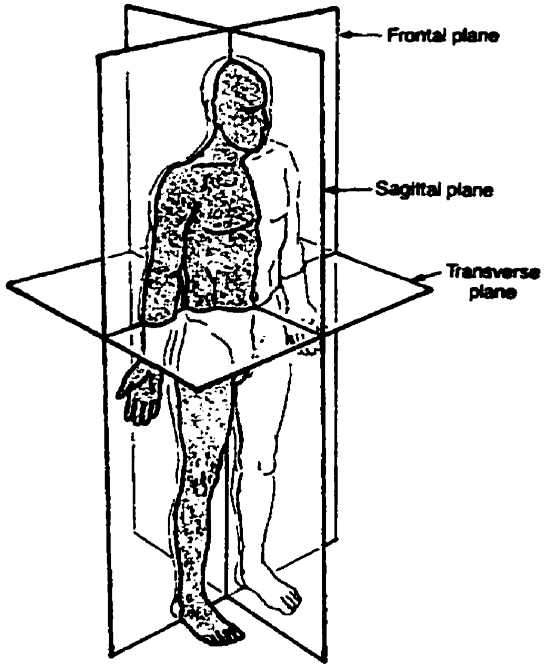

Fig. 2.1: Anatomic body planes. From Seibel 1988.

The primary motion of the ankle joint is plantar-dorsiflexion, which is a movement in the sagittal plane (Fig. 2.1). However, the axis inclination imparts additional out of plane motion to the foot as it moves through the ankle joint range-of-motion (ROM). The foot moves from a slightly adducted position at full plantarflexion to abducted at dorsiflexion [60].

2.1.2 Subtalar joint

The subtalar joint (STJ) consists of the three articulations of the calcaneus and talus [58;60]. Functionally these three articulations act as a single unit and move about a single axis [58]. Like the ankle joint, the subtalar joint is not parallel to any of the three primary anatomical planes. Instead it is inclined and runs along an axis that runs from distal, medial and dorsal to proximal, lateral and plantar [29;58;62;72]. The specific degree of inclination varies between individuals. Seibel [62] reports the axis is angulated 16° from the sagittal plane and 42° from the

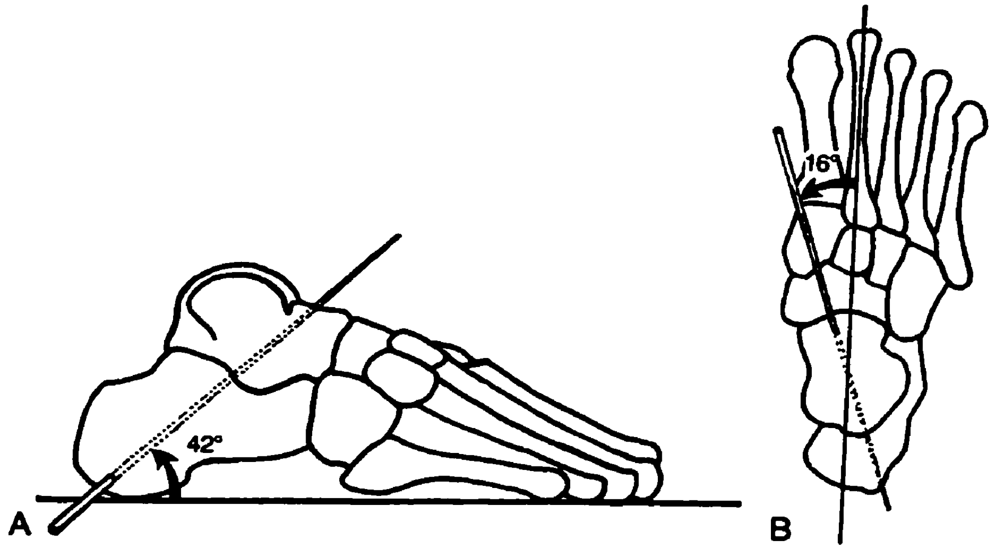

Fig. 2.2: Views of subtalar joint axis. From Seibel, 1988.
A. lateral view. B. transverse view.

transverse plane (Fig. 2.2). However, Manter further reports the angle of inclination as ranging between 8-24° from the sagittal plane and ranging between 29-47° from the horizontal plane [28;58]. In this case, the sagittal plane is defined as being parallel to a line through the heel and the space between the first and second toes.

The STJ axis of rotation is not parallel to any of the anatomic planes, which therefore imparts a triplane motion to movements around the STJ axis [29;62]. Therefore, although individual components of subtalar joint motion are parallel anatomic planes, actual STJ rotations are not. The motions of abduction, dorsiflexion and eversion are considered to be parallel to the transverse, sagittal and frontal planes respectively and comprise pronation movement around the STJ. Motions of adduction, plantarflexion and inversion comprise supination movements around the STJ.

Root [60] considers the normal foot to have twice the available supination range as pronatory range. It should be noted that due to its triplane nature there is no direct way to measure degrees of pronation and supination. Often in/eversion movement of the calcaneus is presented in literature as supination and pronation.

2.2 Gait

2.2.1 Components

The gait cycle as defined for walking is standardized as the time between two successive heel strikes of the same foot [17;60]. Each cycle is divided into two primary events; stance and swing phases, which are then further subdivided.

The subdivisions of stance phase (contact, midstance, and propulsion) are reported more often in research than is swing phase, because stance is the only weight acceptance or closed kinetic chain portion of gait. The events of heel contact, weight acceptance, foot flat, beginning swing phase of the opposite limb, heel off, and toe off are all parts of stance phase (Fig. 2.3).

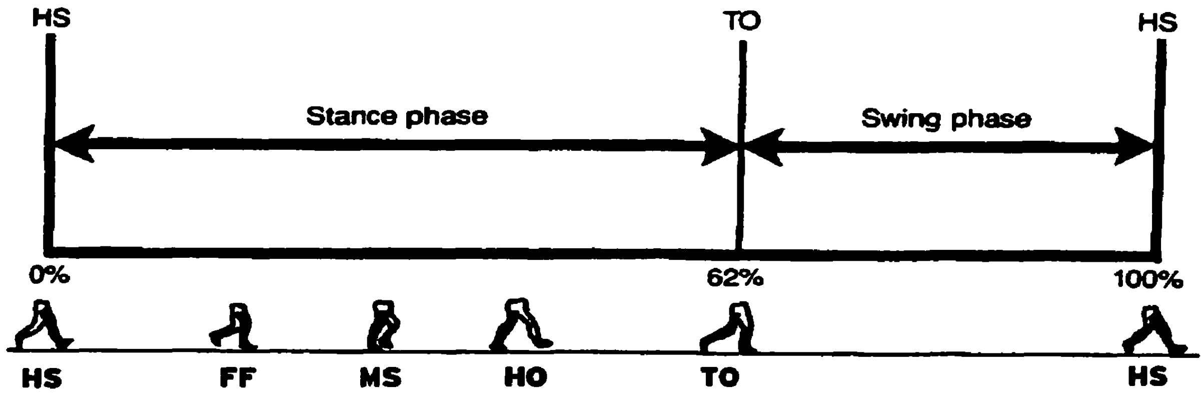

Fig. 2.3: Phases of walking gait. From Seibel, 1988.
HS-heel-strike, FF-foot-flat, MS-midstance, HO-Heel-off, TO-toe-off..

2.2.2 Timing of gait

Stance is approximately 60% of a complete walking gait cycle, while swing is approximately 40%, although these percentages vary with walking speed [60;62;75]. As speed increases swing becomes proportionately longer while stance shortens [47;75]. At heel strike, which begins stance, the body is in double limb support. Double support continues until the beginning of swing phase of the opposite limb. This first portion from heel strike to toe-off of the opposite foot is approximately 30% of stance. Midstance is the longest period of stance phase, at approximately 40% duration. It begins with toe-off of the opposite limb and ends at heel-off of the stance limb. The propulsive phase constitutes the final 30% of stance and ends with toe-off of the stance limb.

2.2.3 Kinematics and Kinetics

Two primary motions of the foot during gait are pronation and supination. Both are triplane motions that occur around the subtalar joint axis. Supination is considered the more stable of the two. In a supinated position, the foot functions as a rigid lever for efficient toe-off [62]. In a pronated position, the foot lacks stability and rigidity [60]. Early in stance, pronation is used to enable the foot to adapt to the angle and inconsistencies of terrain, to absorb the shock of heel strike and store energy for propulsion [17].

During normal gait, the foot is in a slightly supinated or neutral position at heel strike [17;60;62] and immediately begins pronating as weight acceptance continues through contact phase. Pronation continues as the foot plantarflexes to foot flat and swing phase of the opposite leg begins. Vertical ground reaction force (VGRF) rises from initial heel contact through the end of contact phase, when the foot also stops pronating [60].

During midstance VGRF decreases and the foot begins resupinating for propulsion phase [60]. The beginning of heel off marks the end of midstance and beginning of propulsion phase.

During propulsion, the foot functions as a rigid lever to propel the body forward. According to Holzreiter [17;26] 80-85% of propulsive energy comes from that stored in the plantarflexors during contact phase. VGRF rises during propulsion, to as much as 125% of body weight. The foot slowly supinates through midstance and propulsion, then repronates during early swing, to effectively shorten the limb and increase ground clearance [60;62]. At the end of swing the foot again supinates to begin the process again.

2.2.4 Abnormal gait

Although some variability is present in normal gait, the previously discussed pattern is considered normal. Abnormal gait is a regular deviation from that pattern [75]. It has been reported the most common cause of abnormal gait is excessive subtalar and oblique midtarsal joint pronation [27].

Excessive pronation can be characterized in one of three ways: 1) failure to resupinate during midstance, 2) late pronation during propulsion, 3) early excessive pronation [17]. A foot that may normally pronate during contact phase but does not move towards supination during midstance and into propulsion phase characterizes a failure to supinate. A foot that does not fully pronate during contact phase characterizes late pronation. Instead, late pronation is delayed pronatory movement, until heel-off when supination is rapid. Early excessive pronation characterizes a foot that is fully pronated at heel strike and has no pronatory ROM left for the rest of contact [17].

Each of the preceding abnormalities may lead to similar symptoms. Since the rigid lever function of the pronating foot is lost at propulsion, efficiency of the propulsive muscles is lost. Therefore, chronic fatigue and strain of the propulsive foot and tibial muscles are possible [60;62]. Another symptom of excessive pronation is plantar fasciitis, due to strain on the aponeurosis [33]. The plantar aponeurosis maintains the foot longitudinal arch. During pronation the foot lengthens by flattening of the arch, this is resisted by the aponeurosis. The entire list of symptoms related to excessive pronation is quite extensive and helps us understand why custom foot orthotic devices which are designed to limit pronation are so often used to treat injuries related to excessive pronation [39;60].

2.3 Foot Orthotics

2.3.1 Definitions

Root [61] classified three static abnormal foot types or deformities that could cause abnormal function. They are forefoot varus, forefoot valgus and rearfoot varus. All three alter foot alignment at the subtalar joint. Definitions for foot orthotics have also been formulated. Typically they have focused on the biomechanical imperatives of orthotic design. "A device that aligns an improperly balanced foot by controlling subtalar motion", was the definition of foot orthoses posed by D'Ambrosia [13]. Alternatively, "the function of a biomechanical orthotic is to control excessive and potentially harmful subtalar and midtarsal joint movement" [17]. However, others have mentioned the necessity of using foot orthotics to position the foot near subtalar joint neutral [30]. Hunter [28] called foot orthoses "a device placed in a person's shoe to reduce or eliminate pathological stresses to the foot or other portion of the lower kinetic chain". Regardless of definition specifics, it is evident that orthotics are used to control motion for reduction or elimination of injury symptoms.

Doxey [18] proposed that the goals of functional orthotic design were to reduce mechanical stress and allow normal foot function to occur. This can be accomplished by studying the patient's anatomic structure, alignment, diagnosis, age and activity level. The specific orthotic design protocol suggested by McPoil [41] is: 1) determine deformity; 2) measure amount of deformity; 3) cast foot to capture deformity; 4) construct functional orthoses to prevent abnormal or excessive foot motion. To accomplish these goals three types of foot orthotics may be used.

2.3.2 Types

Foot orthotics may be rigid, semi-rigid or soft. Rigid foot orthotics are manufactured from non-flexible acrylics or graphite and are used when the greatest control of excessive motion is required. Semi-rigid orthotics may be manufactured from materials such as: low temperature thermoplastics, foams, corks and leather. Semi-rigid materials are used when control of motion with shock absorbing capabilities are required. Finally, soft orthotics are used mostly to control or redistribute pressure and are not as often used to control motion.

2.3.3 Design and Manufacture

Regardless of material, foot orthotics are generally formed around a foot mold, molded to the foot directly or carved using foot geometry data from a CAD/CAM measuring system. Posts, which are the portion of the orthotic used to control motion, are either added separately after molding or built into the shell during the molding process.

Rearfoot posts are added to control abnormal movement of the rearfoot at heel strike while forefoot posts support the forefoot and potentially decrease the need for compensatory and abnormal subtalar and midtarsal joint movement [17]. Rigid orthotics are often posted intrinsically, which means the posting is built into the shell during the molding procedure. Semi-rigid and soft orthotics are extrinsically posted usually. Extrinsic posts are added after molding. Unfortunately, prescriptions for posting of orthotics are not based on proven principles, and methods vary [32].

Some orthotic prescriptions may call for posting to subtalar joint neutral (STJN) [71] but the principle of underposting has also found support [39]. Underposted orthotics more easily fit into shoes and are often more comfortable to wear. In a study to evaluate soft foot orthotics in the treatment of patellofemoral pain syndrome, the following formula for post development was used: if subjects had calcaneal valgus during relaxed stance of 4-6°, a 2° rearfoot medial post was used. With forefoot varus of 6-10°, a 2° forefoot medial post was used. If forefoot varus was greater than 10°, 4-6° forefoot and 2-4° rearfoot posts were used. Maximal posting was 6° forefoot and 4° rearfoot because larger posts were not comfortable for the subjects [21]. Regardless of the method, the determination of posting requires understanding of foot biomechanic principles and determination of STJN and amount of foot deformity.

2.4 Conclusion

This literature review was meant to provide necessary background in ankle anatomy, gait and foot orthotic manufacture. A definition of foot orthotics derived from their perceived kinematic or anatomic function was provided [13]. To determine if the definition is based on real rather than assumed facts is the purpose of this thesis. Do foot orthotics continuously and systematically affect the kinematics of gait over time? Remaining chapters of this thesis examine new research methods necessary to answer this question. Lastly the actual long-term kinematic effects of foot orthotics on the gait of non-symptomatic over-pronators will be quantified.

Standard terminology used in this section will be used throughout the thesis. Additional subject specific literature concerning neutral position, collection of in-shoe calcaneal motion data, foot orthotic effects and human adaptation will be reviewed in each additional chapter.

3.0 Neutral Repeatability

3.1 Introduction

Kinematic studies are regularly conducted to gain normative data or to determine the effects of a specific intervention. Examples are studies to 1) quantify gait changes caused by shoe design [49;51;52], 2) quantify kinematic effects of foot orthotics on human gait [6;31], 3) assemble normative gait data for clinical diagnosis. Maximum research value can be derived if data from various experiments are directly comparable. However, especially for three-dimensional studies (3D), methodological differences make comparability difficult. Acceptance and use of a standard lower limb neutral alignment and joint coordinate system are essential. However, a standardized system has yet to be embraced by the research community.

Two-dimensional (2D) motion analysis techniques were regularly used as recently as ten years ago. Accuracy of 2D data depends on parallelism of the studied motion to the camera focal plane. Therefore, during research setup the camera focal plane is aligned as closely as possible with the studied motion. Angles between markers or lines drawn on the segments can then be directly measured with respect to each other or in space. However, distorted measurements are a problem, as typically human motion is not so precise or simple as to occur in one plane only.

The problem of motion/camera parallelism and distortion was resolved with the advent of 3D data collection. A minimum of three markers is used to define a plane of each segment. Three-dimensional coordinates from each marker permit the calculation of the planar positions in space. Continuous angular relationships, velocities and accelerations can be calculated from rotations about axes of an anatomically relevant coordinate system.

The angular relationships are expressed in terms of negative and positive rotations with respect to a given neutral position. The purpose of the neutral trial is to set the reference or 0° position of the segments and is generally established with a static data trial (neutral trial) prior to dynamic data collection. The degree of movement, such as in/eversion is then determined relative the neutral alignment.

Therefore, while 3D data collection has resolved one problem (out-of-plane movement) it has created another. Neutral position absolutely affects data results. A neutral position shift results in a data shift of equal magnitude. A lack of standardized neutral position prevents direct comparability of research data.

Several proposals which recommend a standardized procedure have been published [2;10;24;75]. The recommendations of Allard et al. [2] have been conceptualized as a standardization proposal to the International Society of Biomechanics (ISB). It is the only standardization proposal that includes positional relationship of the foot with respect to the tibia in addition to joint coordinate system (JCS) recommendations.

However, the non-orthogonal JCS is created by calculating the vector cross-product of the long axes of the foot and tibia to create the floating axis. The segmental neutral alignment is achieved by using calculations in the analysis software to align the two joint coordinate systems parallel. This method ignores the actual position of the subtalar joint. Therefore, the position of the joint around which one of the most commonly studied foot motions (in/eversion) takes place is not controlled. Additionally, not all current biomechanics software packages are capable of the recommended segmental manipulations or of the computations to form the JCS (Kintrak, Motion Analysis Corp., Santa Rosa, CA; Vicon, Oxford Metrics, Oxford, U.K.). Therefore, use of the ISB recommendations would require custom programs. While custom software creation may be possible at the research level, it is not often practical clinically. These are primary reasons why the ISB protocol, though conceptually sound, should be modified.

The purpose of this research is, therefore, fourfold: 1) to develop a standardized neutral position, which includes the STJ, with the ISB recommendation as a guideline; 2) to develop a repeatable, mechanically based neutral alignment method; 3) to determine repeatability of the system; 4) to determine if the repeatability of mechanical alignment is enhanced by placing smaller permanent marks (permanent black felt pen) on the bony prominences (lateral malleolus, lateral knee center, tibial tubercle, navicular) selected to set neutral position alignment.

3.2 Literature Review

A Joint Coordinate System for the Ankle Joint Complex has already been put forward as the International Society of Biomechanics (ISB) standardization proposal for ankle joint studies [2]. The fundamentals regarding lower limb alignment and joint coordinate system (JCS) from that proposal will be used, with modifications, for this research. However, the proposal does not stipulate a standard subtalar joint position.

Calcaneal in/eversion occurs around the subtalar joint and is often used as the frontal plane approximation of pronation. Excessive pronation is often perceived to have a causal relationship with overuse injuries of the lower extremities [22;30;35;48]. This relationship has led many researchers to analyze in/eversion motion around the subtalar joint. Therefore, a standard subtalar position should be included in the ISB proposal.

The purpose of this literature review is to research the two primary issues (subtalar joint neutral position (STJN) and techniques for resolving movements in 3D space) involved in setting a usable neutral standard for lower extremity research and clinical use. Finally, it will recommend specific changes in the ISB standardization proposal. Each topic will be examined in separate sections of this review.

3.2.1 Subtalar Joint Neutral

The neutral joint position sets the 0° point for describing joint position. In terms of calcaneal motion, neutral is the point when the subtalar joint is neither pronated nor supinated. Neutral joint positions are reference points that make it possible to describe joint positions and motions. It has been stated, "when the criteria used to establish a neutral position are well defined and are easily visualized, the concept of neutral position has profound clinical application as well" [60].

Three methods are commonly used to determine STJN: 2:1 ratio of calcaneal inversion to eversion, parallel bisection method, and finally the palpation method. An explanation of each method follows.

3.2.1.1 2:1 Ratio Method

From patient examinations, Root and colleagues determined the 2:1 ratio of inversion to eversion for normalcy [61]. According to Root, the foot everts following heel strike in order to adapt to the terrain and absorb shock [28;60;62]. Therefore, eversion is a necessary part of normal foot function and the 2:1 ratio represents the ratio found in normal individuals.

Other researchers examined the 2:1 relationship in 15 subjects using tomograms and the palpation method to set STJN [4]. Mean STJN was found to be 36.2% of total calcaneal ROM, which is acceptably close to the 2:1 ratio. However the standard deviation was 19.2% and the maximal STJN position was 71.4% of ROM.

Therefore, for the following reasons the 2:1 method is not acceptable as a standard system for repeatably setting neutral:

1) No normal definition had previously been established, therefore, Root had no method by which to determine normalcy in subjects.
2) The 2:1 ratio may not exist for many people, as demonstrated by the standard deviation and range of the Bailey et al. [4] data.
3) The 2:1 ratio does not account for common injuries such as sprains, this may act to unequally reduce available ROM.
4) The 2:1 ratio does not directly measure subtalar joint position, instead an approximation is used.

3.2.1.2 Parallel Bisection Method

The parallel bisection method is another portion of the normal foot description by Root [61]. It states when the subtalar joint of a normal person is in neutral position, the calcaneal and tibial bisections are parallel [60;70]. The converse is not necessarily true, but, parallel alignment has been used to determine neutral and joint motion in previous research [6;54;59].

There are several problems with this definition of neutral:

1) The parallel bisection is based on unsubstantiated ideas of the normal foot [43].
2) The method does not account for common calcaneal deformities such as varus, of which 2° – 3° is said to exist in most subjects [70]. McPoil et al. [44] found subtalar varus in 83.6% of 116 female feet from 58 healthy female subjects.
3) The parallel bisection method does not directly measure joint position, but instead approximates position based on indirect measurement.

Due to the listed deficiencies, the parallel bisection method also is considered unsuitable for a standardization proposal.

3.2.1.3 Palpation Method

The palpation method directly determines the talar position (Fig. 3.1). It can be used when the subject is either non-weight or weight bearing. In non-weight bearing measurement, the subject is positioned prone on their stomach, with feet extended beyond the end of the examination table. One hand of the examiner is used to firmly dorsiflex and evert the forefoot at the fifth metatarsal head. The remaining hand is used to palpate the medial and lateral talar domes at the talonavicular joint. The foot is rotated between inversion and eversion by pressure at the fourth and fifth metatarsal heads. Subtalar joint neutral is considered the point where the talus is felt equally on the medial and lateral talonavicular sides [19;28;65]. Elveru et al. [19] recommended this method as the standard, although both intertester [65] and intratester data have been reported to have poor reliability. This method benefits from directly assessing the joint. Therefore, despite low inter and intratester reliability, the palpation method will be used to determine STJN in this research.

Fig. 3.1: Palpation technique. From Hunter, 1995.

3.2.2 Motion Analysis Techniques

Human motion studies are often conducted to determine motion or segment relationships in more than one plane simultaneously. For 2D studies, individual cameras for each studied plane are required since only motion that parallels the camera focal plane is recorded without distortion. Camera setup is therefore difficult, as a minimum of two body segments are usually involved and movements of each segment in each anatomic plane must be recorded by a parallel camera.

This situation was resolved with the advent of 3D measurement capabilities and the development of the Direct Linear Transformation (DLT) algorithm. With use of a calibrated frame and the DLT, it is possible to determine the position of any number of cameras in the lab space from an infinite number of locations. Once camera position is established, it is possible to derive the 3D spatial coordinates of any marker within the calibrated frame volume.

In practical application, three markers are used to establish a plane for each segment studied. From the 3D coordinates of each marker, the segment location and orientation in space is always known. By rotating one segment about the other with an established coordinate system, it is possible to calculate segmental angular relationships.

Three different methods have been used: Cardan/Euler angles, JCS and finite helical axis. With finite helical axis it is possible to determine one axis of rotation with a translation and rotation that describes the movement of one body segment in 3D space with respect to another. Cardan/Euler angles and JCS can be used to determine motion around three separate axes. The axes are defined by markers placed strategically on the segments of interest or by the axes of the calibrated frame used during camera calibration. Segmental position is defined relative a quasistatic neutral position. This section of the literature review will examine the development of each 3D method. Merits and deficiencies of each will be discussed.

3.2.2.1 Euler Angles

Euler angles are a commonly used method of resolving angles of rotation in 3D space. They are based on the concept that three independent angles that correspond to three rotational degrees of freedom can be used to determine the position of a body in space [77]. Once a starting position is established, Euler angles can be used to determine required rotations about three independent axes as a segment sequentially moves with respect to another. Resolution of rotation angles involves decomposition of three predetermined rotation or cosine matrices.

Cosine matrices are assigned according to axis rotational order. In other words, three distinct matrices are used, one each for the 1st, 2nd and 3rd rotations. The formula for solving rotation matrices is in the form of:

$$\begin{bmatrix} x' \\ y' \\ z' \end{bmatrix} = \begin{bmatrix} \\ R \\ \\ \end{bmatrix} \begin{bmatrix} x \\ y \\ z \end{bmatrix}$$

where x', y' and z' represent unit vectors of the new location of the coordinate system and x, y and z represent the original location. [R] is the rotation matrix selected to determine angle of rotation for either the first, second or third rotation. Matrices are shown in Fig. 3.2.

Although several rotational orders may be used, they generally fall into two categories: 1) the first and last rotations are about identical rotational axes from the global and body (segment) coordinate system [X y x], or 2) three distinct ordered axes [X y z]. The two rotational orders are respectively called Euler and Cardan angles (Fig. 3.3).

$$\mathbf{R} = \underbrace{\begin{bmatrix} \cos\alpha & -\sin\alpha & 0 \\ \sin\alpha & \cos\alpha & 0 \\ 0 & 0 & 1 \end{bmatrix}}_{\textbf{Matrix A}} \underbrace{\begin{bmatrix} \cos\beta & 0 & \sin\beta \\ 0 & 1 & 0 \\ -\sin\beta & 0 & \cos\beta \end{bmatrix}}_{\textbf{Matrix B}} \underbrace{\begin{bmatrix} 1 & 0 & 0 \\ 0 & \cos\gamma & -\sin\gamma \\ 0 & \sin\gamma & \cos\gamma \end{bmatrix}}_{\textbf{Matrix C}}$$

Fig. 3.2: Cosine matrices. From Zatsiorsky, 1998.
Matrices A-C: rotation matrices used to solve for 1st, 2nd and 3rd rotations, respectively.

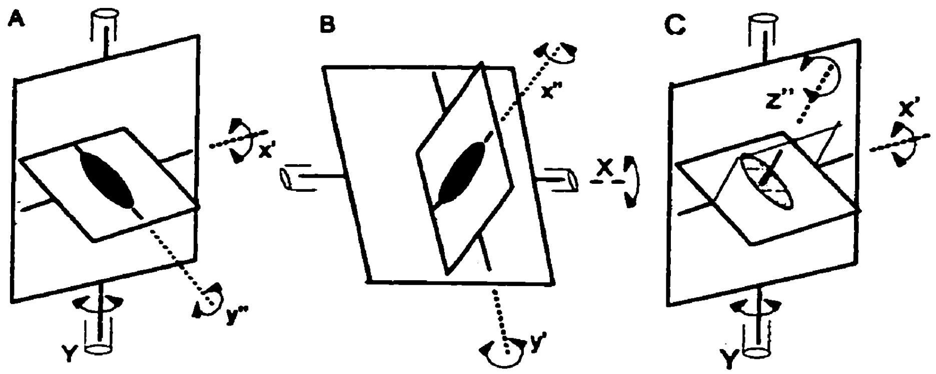

Fig. 3.3: Representation of Euler's and Cardan's angles as the angles of a gimbal suspension. From Zatsiorsky, 1998.
In part A, Euler's suspension, Yx'y" convention is shown. The outer gimbal rotates about the vertical Y axis of the global reference system; the internal gimbal rotates about the local y" axis fixed with the gimbal; and the intermediate gimbal rotates about the x' axis, which is not fixed firmly with either the global or with the local system. In part B, Euler's suspension, Xy'x" convention is shown. The conventions differ in the order in which the three coordinate angles are measured. In part C, Cardan's suspension, Yx'z" convention is shown.

A problem with the Euler system of angular resolution is that the coordinate system is not necessarily aligned with anatomic axes as typically clinically defined. Therefore, association of given angles of rotation with clinical descriptions such as in/eversion may be difficult. A second system of resolving angular rotation was designed to reduce this problem.

3.2.2.2 Joint Coordinate Systems

Joint coordinate systems rely on two segment coordinate systems one each in a distal and adjacent proximal body segment, such as foot and shank. These segment systems are stated in terms of the global system, but are typically developed in the segment. In other words, markers typically placed on anatomic landmarks are used to define the coordinate systems. For instance, the vector between markers placed on the medial and lateral malleoli marker can be used to establish the shank longitudinal axis, about which in/external rotation of the shank may be determined (Fig. 3.4).

The actual axes of rotation are assembled similarly to Euler angles, except the first rotational axis is taken from the proximal segment coordinate system rather than the global system. The third rotational axis is from the distal segment and second (floating) is the cross product of the first and third. Rotational order is therefore, proximal, floating and distal.

Currently, problems with use of the JCS method to resolve rotations of segments have to due with prepackaged software. As previously mentioned, some are not written to calculate the floating axis. Instead, they rotate segments about the three orthogonal axes of the LCS as defined by the calibration frame.

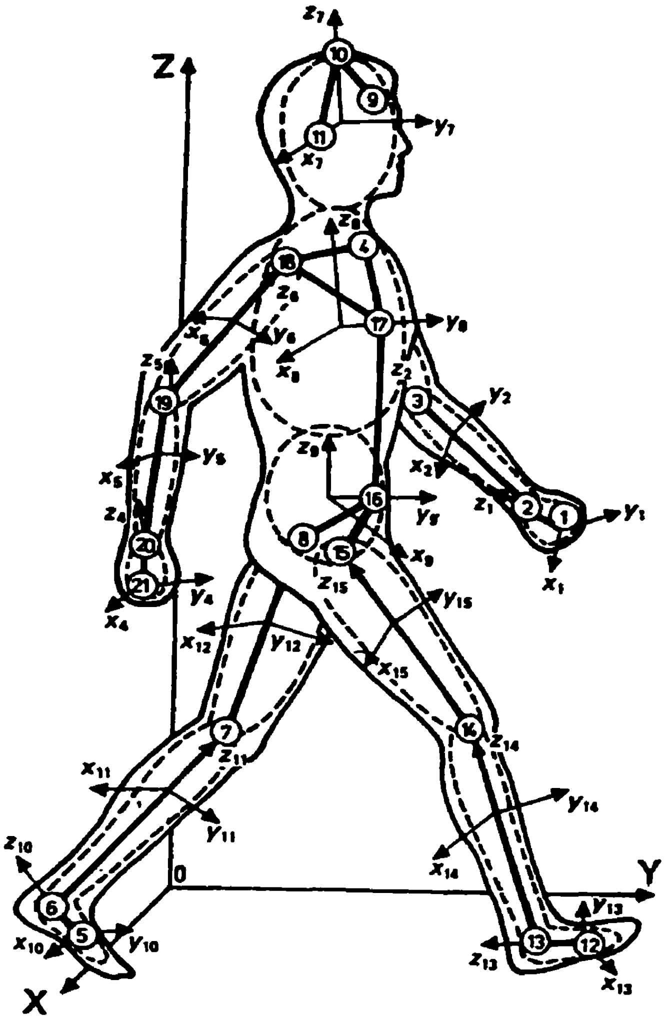

Fig. 3.4: Reference systems used to study gait. From Zatsiorsky, 1998.
Numbered markers establish joint centers and segment longitudinal axis.

3.2.2.3 Helical Axis System

The final system typically used is the helical axis system. It determines one singular axis of rotation coupled with a translation that accounts for the sequential realignment of segment coordinate systems. It is often referred to as a screw axis as its function is similar to a screw aligned along the axis of rotation, with the rotation of the screw in degrees and screw pitch used to determine translation.

As mentioned the screw axis system reduces rotations around all three anatomic axes to an equal rotation and translation around only one, which may not be anatomically aligned. Therefore, conceptually it is difficult to understand the rotations when applied to complex human movement.

3.2.3 ISB Standardization Proposal

The ISB standardization proposal is an attempt to standardize ankle complex research to ensure comparability of methods. It relies on JCS methods to calculate segment positional data and stipulates marker placement, JCS development and alignment of the tibia with the foot for neutral trials.

3.2.3.1 Marker Placement (Definitions in this section are taken directly from the ISB Proposal) [2]

Designated markers are used for establishing joint centers, forming the JCS and aligning the foot with the shank. They are located on the medial and lateral

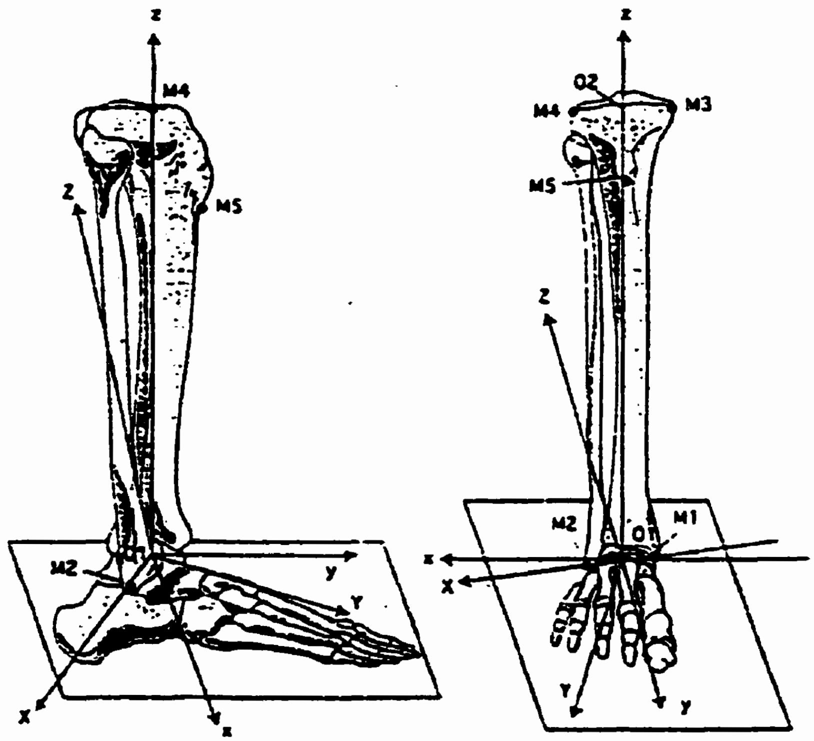

Fig. 3.5: Definition of the body fixed reference frames for the tibia/fibula and calcaneus. From Liu et al., 1997.

malleoli, medial and lateral tibial condyles and the tibial tubercle. Ankle and knee joint centers are calculated to be 50% of the distance and on the line established between the respective joint center markers (Fig. 3.5). Calculated joint centers are O1 (ankle) and O2 (knee).

3.2.3.2 Definition of Segmental, Body Fixed Orthogonal Reference Frames

- Frontal plane of the tibia/fibula – The plane containing point O1, M3 and M4.
- Sagittal plane of the tibia/fibula – Plane perpendicular to the frontal plane and containing the long axis of the tibia/fibula.
- The long axis of the tibia/fibula being defined as the line connecting points O1 and O2.
- Transverse plane of the tibia/fibula – The mutual perpendicular to the frontal and sagittal planes.

3.2.3.3 Definition of Body Fixed Anatomical Frame of the Tibia/Fibula (right leg) - XYZ

- O1 – The origin is located midway between the medial and lateral malleoli.
- X – The line connecting the medial and lateral malleoli (M1 and M2). Positive X is in the direction from the medial malleolus to the lateral malleolus. (Note: for the left leg, the positive X – axis is in the direction from lateral to medial).
- Y- Line perpendicular to the frontal plane of the tibia at the origin – O1. Positive Y is in the direction from posterior to anterior.
- Z – The common perpendicular which forms a right handed Cartesian frame.

3.2.3.4 Definition of Body Fixed Anatomical Frame for the Calcaneus - xyz

- O2 - The origin coincides with that of the tibia/fibula frame (O1) in the neutral configuration (neutral definition follows).
- z – With the ankle complex in the neutral configuration, this axis coincides with the long axis of the tibia/fibula (i.e. – the line connecting points O1 and O2). Positive z is from O1 to O2.
- y – With the ankle complex in its neutral configuration this axis is perpendicular to the frontal plane of the tibia/fibula. Positive y is from posterior to anterior.
- x – The common perpendicular to y and z and forming a right – handed Cartesian frame. (Note: the definition is the same for a left leg. However, the x-axis will be pointing from lateral to medial).

3.2.3.5 Definition of Joint Coordinate System Axes (Fig. 3.6)

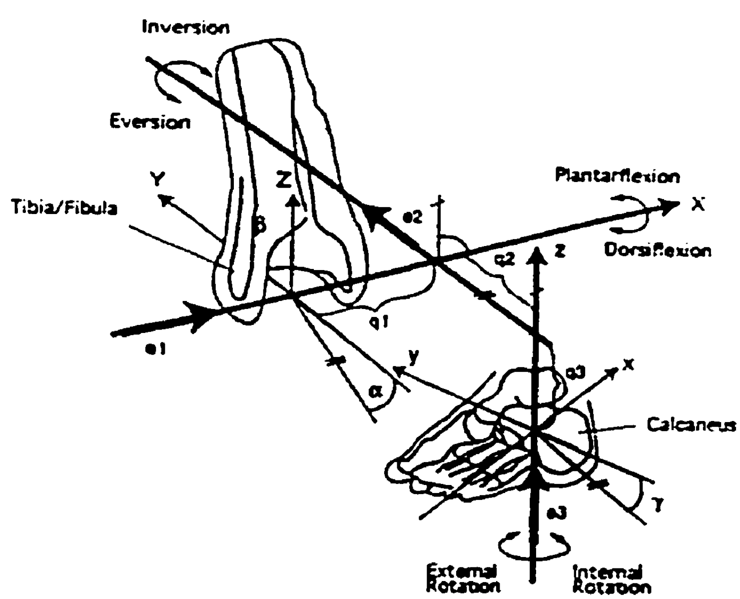

Fig. 3.6: Rotations about JCS. From Allard et al., 1995.

- e1 – The axis fixed to the tibia/fibula and coincides with the X-axis of the tibia/fibula frame. Rotation about it – α, corresponds to dorsi/plantar flexion.
- e2 – The floating axis. The common perpendicular to e1 and e3. Rotation about it – ß, is defined as in/eversion.
- e3 – The axis fixed to the calcaneus and coincides with the z axis of the calcaneal frame. Rotation about it -γ, corresponds to internal/external rotation.

3.2.3.6 Definition of Neutral Configuration of the Ankle Joint Complex

- Neutral dorsiflexion/plantarflexion - Defined as zero degrees between the projections in the sagittal plane of the tibia of a line connecting the lateral malleolus – M1 with the lateral tibial condyle M4 and the line perpendicular to the plantar aspect of the foot.
- Neutral inversion/eversion – Defined as zero degrees between the projections in the frontal plane of the long axis of the tibia/fibula and the line perpendicular to the plantar aspect of the foot.
- Neutral in/external rotation – Defined as zero degrees between the projections onto the transverse plane of a line going through the second metatarsal and the line connecting the tibial tuberosity M5 with the midpoint between M1 and M2 – O1.

3.2.4 Recommended Modifications to ISB Proposal

The ISB proposal defines a standardized neutral and JCS in order that data from various studies be directly comparable. However, it is several years old and has not gained acceptance, perhaps due to a few inherent weaknesses:

1) The mathematics computations necessary to create the segment and JCS are not written into some popularly used data analysis software.
2) The alignment of the foot with the tibia does not standardize the subtalar joint.
3) The alignment of the foot with the tibia relies on software manipulation.

As presently defined the ISB method can be used only in laboratories capable of writing software. However, minor modification will simplify use, solve usability issues and still adhere to general ISB guidelines, with the exception of tibial rotation.

The proposed definition is:

1) One axis of the laboratory coordinate system (LCS) will be aligned parallel the subject walking direction (parallel the sagittal plane). The LCS will be orthogonal.
2) The subject lower limb will be aligned parallel the LCS, by aligning the line through the second metatarsal head and the posterior calcaneal bisection with the subject walking direction.
3) The foot will be placed in STJN through use of the palpation method.
4) The tibia will be aligned with the anterior surface of the patella parallel the frontal plane formed by the LCS.
5) The line between the lateral malleolus and lateral tibial condyle will be perpendicular the foot plantar surface sagitally.
6) The line between the tibial tubercle and second metatarsal head will be perpendicular the foot plantar surface frontally.

Specific directions on techniques for alignment are included in the Methods Section. It should be noted, a current shortcoming of this technique is reliance on visual methods to control tibial rotation in neutral position.

3.2.5 Literature Review Conclusion

The methods presented (Euler/Cardan rotations, JCS and helical axis) to resolve rotations of one segment with respect to another in space each have important problems. The Euler/Cardan system is sensitive to rotational order and prescribes an orthogonal axis system that may not be anatomically aligned. The JCS method resolves the problem of axes system alignment by using markers, anatomically positioned to locate joint axes. However, currently not all software has been written to develop a coordinate system using this method. Since the ISB standard [2] relies on JCS methods, this problem also relates to current use of the ISB standard. In addition, since the JCS method relies on Euler/Cardan segmental rotations, it also has sensitivities to rotational order. Finally, helical angles resolve movement of one segment with respect to another into a single rotational axis and a translation. This method however, is difficult to conceptually relate to human movement, as human movement is three-dimensional and definitions of the axes of movement are already widely used.

The ISB has attempted to solve these problems by standardizing marker placement, the reference and joint coordinate systems, and finally rotational order. However, the proposal does not include the subtalar joint, which is considered essential in this study. In addition, the chosen software for this study (Kintrak, Motion Analysis Corp., Santa Rosa, CA) cannot develop the coordinate systems as defined.

Therefore, the decision was made to use the ISB proposal as a guideline for development of a new standard. The new standard was designed to meet the requirements of functionality in a clinical environment by using manual segmental alignment methods and coordinate system procedures adaptable to current software systems.

3.3 Methods

3.3.1 General

Five subjects volunteered for this pilot study and were divided into two groups (N_1=2, N_2=3). One member of group N_1 was tested twice, one time on each of two successive days. This resulted in three data sets for each group.

Groups were tested in one of two ways. Group N_2 was tested with permanent marks from a felt tip pen added to each bony landmark (tibial tubercle, lateral knee joint center and navicular) to aid in neutral alignment. Group N_1 was tested without marks applied. Therefore, the larger natural skin surfaces of the bony prominences were used for neutral setting. The purpose was to determine if missing permanent anatomic alignment landmarks affected repeatability.

Subject 1 from N_2, was identically tested twice as stated. During each test session the lateral knee and tibial tubercle were left unmarked. Subject 2 from this group was tested with only the navicular mark missing. In this manner, it was possible to determine if any mark was more essential for correct alignment. Data collection sessions for each group consisted of eight trials during which subjects were repeatedly realigned in neutral position. The first trial from each subject was used as the reference to which all others were compared.

3.3.2 Kinematic Measurements

3.3.2.1 Markers, Bony Prominences and Their Function

For all subjects, bony prominences were used to establish neutral alignment or to calculate either the ankle or the knee joint center. The medial and lateral malleolus were used to establish the ankle joint center 50% of the distance between the two markers. The knee joint center was established 50% of the distance between the medial and lateral knee joint markers.

Collectively the tibial tubercle, lateral malleolus and lateral knee were used to set the relationship of the foot and tibia in the frontal and sagittal planes. The height from the ground of the navicular was used to repeatably reset STJN. Prior to actual data collection, the palpation method was used to set STJN and the navicular height was recorded. For all data trials, resetting navicular height set STJN.

3.3.2.2 Tools and Tool Setup

Graph paper with a 1 cm orthogonal grid was attached to the force platform surface, parallel the platform sides. It established the sagittal and frontal planes. The calibration frame, stands with anthropometers and the subject's foot were all aligned on the grid system to ensure parallelism (Figs. 3.7 & 3.8, 4.4).

Fig. 3.7: Anthropometers.

Eighty-centimeter anthropometers aligned vertically were used to accurately establish tibial and foot alignment in the frontal and sagittal planes. The anthropometers were vertically fastened to stands that had adjustable feet at each corner. The units were placed on the force platform and a digital level (SMARTTOOL, Macklanburg-Duncan, Oklahoma City, OK) was used to set orthogonality with the floor to within ±0.1° in the sagittal and frontal planes.

The feet of the anthropometer stand were locked in position. Anthropometer alignment was maintained in the transverse plane by visually aligning the sliding arms with the force platform grid. The anthropometer and stand units were periodically checked to maintain calibration. Four Falcon high-speed cam

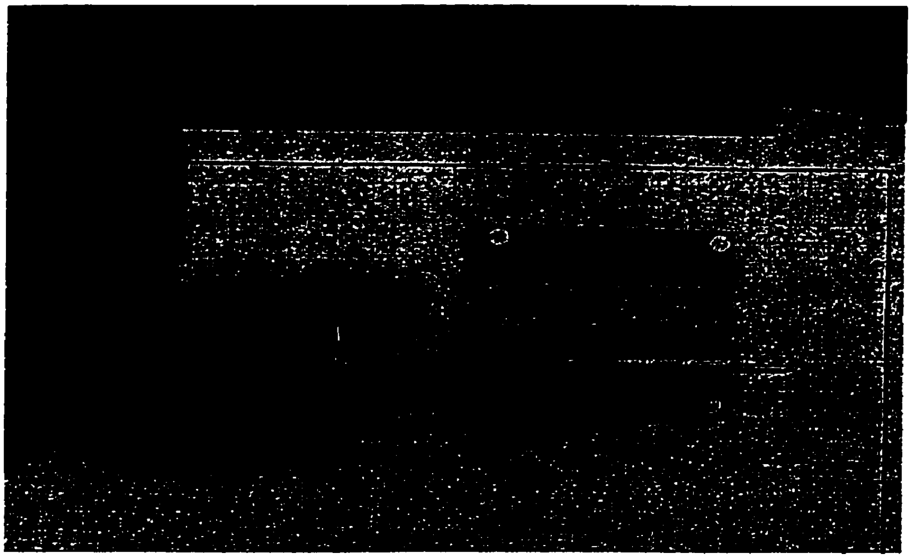

Fig. 3.8: Foot and anthropometer alignment on force platform grid.

eras were arrayed around the force platform (refer to fig. 4.3). The space above the force platform was calibrated with a 75 x 50 x 79 cm. calibration cube using a DLT approach. The cube had eight retroreflective markers, one at each corner. The cube X and Y axes were aligned parallel the direction of progression by visually aligning the cube with the orthogonal grid system attached to the force platform surface (refer to fig. 4. 4). Subject data was collected for one second at 120Hz with 480 lines of resolution (EVA, Motion Analysis, Santa Rosa, CA).

3.3.3 Neutral Position

3.3.3.1 Definition

Neutral positions of the foot and tibial segments were defined as follows:

1) The foot bisection line (imaginary line, from the center of the posterior calcaneus through the center of the 2nd metatarsal head) was aligned parallel the direction of progression, by alignment with the force platform grid.
2) The subtalar joint was placed in neutral (STJN) position by setting navicular height.

3) The tibia was positioned with the lateral knee joint marker above the lateral malleoli marker in the sagittal plane. The tibia was positioned with the tibial tubercle mark above the 2nd metatarsal head in the frontal plane.

3.3.3.2 Neutral Alignment Process

All subjects were aligned with the identical alignment procedure, but the method for determining anatomic mark location was different depending on whether subject was missing permanent marks. The following is the general alignment procedure. See Section 3.3.1 for specific differences.

1) Permanent marks were placed on the subjects' tibial tubercle, medial and lateral malleoli and knee joint centers, and navicular.
2) Small retroreflective markers (6.35 mm) were glued in place at all locations with the exception of the navicular.
3) The posterior calcaneal bisection was marked with a permanent felt tip pen.
4) The subject was aligned barefoot on the force platform. The right foot calcaneal bisection and second metatarsal head were aligned with the grid system, parallel the direction of progression (Fig. 3.8).
5) The subject rotated the tibia until the patella appeared parallel the frontal plane. Subjects were permitted to position their left foot wherever comfortable to achieve this position.
6) The palpation method was used to align the STJ in STJN. The height of the navicular permanent mark from the force platform surface was measured and recorded to the nearest millimeter. For subsequent trials, STJN was set by in/everting the calcaneus until the navicular height was identical the recorded measure.
7) Each anthropometer was placed on the force platform. One was aligned

with the moveable arms parallel the X-axis. The other was aligned parallel the Y-axis.

8) The tibia was aligned in the frontal plane with respect to the second metatarsal head with the following method:
   a) Positioning the arms of the anthropometer (parallel the LCS X-axis) over the second metatarsal head.
   b) Raising the moveable arm to the height of the tibial tubercle marker.
   c) While maintaining the patella alignment the tibia was ab/adducted until the tibial tubercle mark was aligned with the moveable arm. This aligned the lower extremity with the foot plantar surface in the frontal plane. In conjunction with STJN, this position represented 0° neutral for in/eversion of the foot with respect to the tibia.
9) Sagitally the tibia was aligned by:
   a) Positioning the arms of the anthropometer (parallel the LCS Y-axis) against the lateral malleolus marker. The distance from the arm tip to the center of the anthropometer was recorded.
   b) The moveable anthropometer arm was moved to the height of the lateral knee joint center marker.
   c) The tibia was moved through flexion/extension until the knee joint center marker was aligned with the moveable arm.
   d) The moveable arm was extended until it contacted the knee center marker, the distance from the arm tip to the center of the anthropometer was recorded.
   e) For repeatable positioning, the recorded dimensional difference between the amount of extension of the moveable and fixed arm

was preset for each subject anytime they were positioned in neutral.

3.3.4 Coordinate Systems and Markers

3.3.4.1 Coordinate Systems

The LCS, formed from the coordinates of the calibration frame, was set parallel to human anatomic planes by aligning it with the force platform grid system used for subject alignment (Fig. 3.4). The right-handed LCS was created with X positive anteriorly, Y positive medially (right foot) and Z positive vertically upward.

Two segment coordinate systems (SCS, ankle and shank) were created at the ankle and knee joint centers (50% of the distance between the medial and lateral knee joint center and malleoli markers) parallel the LCS.

A single axis from each segment SCS was used to create the JCS, around which all motions were calculated. Rotations in Kintrak (Motion Analysis, Santa Rosa, CA) were taken by revolving the second segment (segment of interest) around the first segment in the order of hinge, cross and finally long. Therefore, the joint coordinate system was formed with the hinge axis of the first segment as e1, the long axis of the second segment as e3 and the cross as e2. Rotations were around the hinge axis of the first, the cross axis, and finally thirdly, around the long axis of the second.

3.3.4.2 Segment Markers

In addition to alignment markers, three markers defined segments. The shank segment had markers placed on the fibular head and both the superior and inferior tibial crests. The marker triad attached to the calcaneal mold defined the calcaneus.

3.3.5 Data Collection Procedures

Subjects were aligned according to the neutral guidelines. Anthropometers were removed and data collection was started when the researcher moved through an infrared beam in front of the force platform. Each trial was collected at a sampling rate of 60Hz for one second. Between trials, markers were removed and subjects were asked to leave the immediate data collection area and return for realignment.

3.3.6 Data Analysis

Markers were automatically tracked with EVA software (Motion Analysis). Data was imported to Kintrak software (Motion Analysis), where it was filtered at 6Hz with a Butterworth lowpass 2^{nd} order filter. Each data set's first trial was selected as the reference trial for the remaining seven. Calculations were performed to determine calcaneal position around the foot long axis (in/eversion) and shank position around its long axis (in/external rotation).

3.4 Results

Values of the two dependent variables from each data session are listed in Table 3.1. Variables are: calcaneal position (CP), tibial position (TP) around their respective longitudinal axes. Subjects 1 and 2 are from group N_1 (missing alignment marks) and subjects 3-5 are from group N_2.

Calcaneal position was more repeatable than tibial position. Mean CP range was 2.7°, while mean TP range was 4.3°. Group N_1 (missing alignment marks) had a mean CP range of 3.0°, while group N_2 had a mean range of 2.5°. Group N_1 had a mean TP range of 4.0°, while group N_2 had a TP mean range of 4.5°. Group N_1 had greater variability for CP position, but equally reduced variability for TP position. There is no clear pattern demonstrating a loss of neutral positioning accuracy due to missing subject marks. In group N_1, subject 1 (missing tibial marks) had greatest range of both TP and CP. This finding may indicate the tibial marks are more important than navicular marks for accurately setting neutral.

	Subject 1A		**Subject 1B**		**Subject 2**		**Subject 3**		**Subject 4**		**Subject 5**	
Trial	**CP**	**TP**	**CP**	**TP**	**CP**	**TP**	**CP**	**TP**	**CP**	**TP**	**CP**	**TP**
1	**0.7**	-0.5	-1.4	**0.9**	**-0.4**	**1.9**	-1.2	**-0.7**	**0.4**	**-1.8**	**0.4**	**0.6**
2	-0.4	**1.9**	**-1.5**	0.7	1.4	0.1	1.1	**-4.3**	0.0	-0.2	0.4	-0.1
3	-0.1	-1.2	**4.0**	0.2	1.6	-1.0	**1.3**	-0.9	-0.1	-1.0	0.8	-1.1
4	**-0.6**	**-2.9**	-0.5	0.3	1.4	**-2.7**	0.6	-1.8	**-1.9**	-1.0	1.2	-0.4
5	0.3	-2.5	-0.7	-0.7	**1.9**	0.2	-1.4	-1.5	-1.7	-0.4	**2.1**	-1.8
6	0.1	-0.7	-0.8	**-1.7**	1.5	-0.1	**-2.2**	2.5	-1.1	-0.3	0.8	-0.1
7	0.5	0.6	3.2	-1.0	1.5	-0.2	0.1	-1.9	-1.4	**1.8**	1.9	**-2.6**
Range	1.3	***4.8***	**5.5**	2.7	2.2	4.5	**3.5**	***6.7***	2.2	3.6	1.7	3.2
SD	0.5	*1.7*	***2.3***	1.0	0.8	1.4	**1.4**	**2.0**	0.9	1.1	0.7	1.1

Table 3.1: Values of independent variables, in degrees.
Two sessions of subject 1 are listed as 1A and 1B. Variable values of independent trials are the mean value of the 1 s. trial. **CP** is calcaneal position, with positive values representing inversion. **TP** is tibial position with positive values representing internal rotation. **Bolded** numbers in the trial section represent minimums and maximums of CP and TP from each test session. **Bolded** numbers in Range or SD row, represent greatest range or SD from groups N_1 or N_2. ***Italicized bold*** number represents greatest overall CP or TP range or SD. Range is expressed as the difference between the minimum and maximum values of each variable from a single session.

3.5 Discussion

Of twelve published research articles on 3D kinematic analysis of the ankle and shank, only three researchers described neutral position [20;22;37]. Of those, only one controlled the relative positions of the shank [66]. Control of the calcaneal position was never discussed. Without standardized neutral positions, results of independent studies are not directly comparable.

To resolve the problem, A Joint Coordinate System for the Ankle Complex was introduced by the ISB for the stated purpose of proposing "a joint coordinate system for the ankle complex which can be used by the Biomechanics community and other associated professional communities, as a standard for reporting on the kinematics of the human ankle complex" [2]. Unfortunately the definitions do not include the STJ position and software manipulation is required to achieve the defined alignment. Many biomechanics software packages currently available are not capable of the required computations. It was therefore, necessary to determine a more inclusive neutral position set with use of readily available mechanical methods.

Methods used, whenever possible were taken directly from the ISB standard. Anatomic marks for alignment and retro-reflective marker locations were directly from the standard. Like the ISB standard, the neutral alignments chosen for this study set the tibia position perpendicular the foot plantar surface in all planes possible. The line between markers M4 and M1 is set perpendicular the foot plantar surface sagitally (Fig. 3.5). Frontally, a slight departure from ISB recommendations was needed and the tibial tubercle was set over the second metatarsal. Since the tibial tubercle and second metatarsal are used to define tibial/foot centers and alignment in the transverse plane, it is assumed that using each to also set frontal plane alignment is in keeping with ISB intentions.

Inclusion of calcaneal position and lack of transverse plane neutral definitions are departures from ISB recommendations. However, use of calcaneal alignment around the STJ is considered to make the ISB standard more powerful, by effectively standardizing in/eversion through use of common tools and a currently accepted STJN position.

The same cannot be said for the lack of a manual method for controlling transverse position. It is possible to develop a manual transverse standard. A reasonable one may be to place the line between lateral and medial knee joint centers parallel the frontal plane as defined by the LCS, when the tibial tubercle is aligned with the second metatarsal frontally. However, practically it could not be accomplished in this study, with a subject position and equipment location that allowed two camera visibility of all markers.

It is hoped that newly designed alignment tools, additional cameras and further experiments with subject position during neutral trials (standing or seated) will permit the inclusion of a transverse plane neutral position standard. Until then, despite the lack of a transverse standard, the method does benefit from procedures that control intra-subject transverse position over time.

The developed alignment system also accomplished the goal of relying on mechanical methods only. With the exception of goniometers, all tools were inexpensive and readily available. If it is necessary to reduce costs, goniometric function can easily be duplicated with inexpensive tools and parts from any hardware store.

Repeatability testing determined that calcaneal position across all subjects was controlled within a mean range of only 2.7°. Greatest range was 5.5° from subject 1B. It should be noted this subject had the two trials with greatest variation from neutral of all subjects, 4.0 and 3.2°. Other subjects had only one trial with greater than 2° variation and these were only 2.2 and 2.1°.

Extreme subject sway was hypothesized as a cause of greater variation since trials were one second long. However, the 4.0 and 3.2° trials were shown by data graphs to have less sway than others from the same session. Currently the reason for this high variability from only one data set is unknown.

Tibial alignment was shown to have greater overall variability. This was expected, as motions further up the kinetic chain are larger and more difficult to control. Still mean range across subjects was only 4.3° and greatest variability was

6.7°.

There is no available data to indicate whether these ranges are reduced from uncontrolled neutral trials. Nevertheless, it is unlikely that subjects aligned without any anatomic constraints would have less variation.

It was hypothesized that missing alignment marks would greatly increase variability. In the case of CP, variability improved with marks, but in the case of TP lack of marks improved variability. In either case, the difference was only 0.5°, which should not be of concern, since variability of these parameters during normal gait is considerably higher. Therefore, the data did not support the hypothesis. However, it should be noted that the numbers of subjects for either the marker or markerless conditions were insufficient to statistically support the hypothesis.

Equipment design complicated data collection. Data collection could not be automatically started with the researcher in position at the lower extremity to help subjects maintain neutral alignment. Although sway was eliminated as a cause of variability, subjects may have shifted and then firmly maintained a new position when released by the researcher. This may have especially been true for subjects with a normal position considerably everted or inverted from the standardized neutral position. The anthropometers used for alignment, in combination with marker size may also have contributed to this problem. Small markers (6.35 mm) were used on the lateral knee joint center and malleoli alignment marks to improve both placement accuracy and related joint center calculations. The ends of the anthropometer used for vertical alignment were large enough to obscure the small markers from camera view. This necessitated stand removal prior to remote triggering of data collection. This increased the previously mentioned time during which subjects maintained unassisted neutral alignment. The situation could be remedied by tapering the ends to a point, so that markers were not obscured, and by equipment modification to permit commencement of data collection while still assisting with subject position.

3.6 Conclusion

The four purposes of this pilot were to, 1) to develop a standardized position, which includes the STJ, with the ISB recommendation as a guideline, 2) to develop a repeatable mechanical alignment method, 3) to determine repeatability of the system, 4) to determine if missing marks undermine repeatability.

The standardized position developed in this pilot for use in the remainder of this thesis research was based on the ISB proposal. However, the ISB definition was broadened to include and define a standard STJ position. This position was based on a commonly used and medically accepted technique known as the palpation method. Mechanical methods, which relied on commonly available anthropometric tools, were developed to repeatably set neutral alignment. The method relied on anthropometers fixed perpendicular the force platform in movable and adjustable stands. Marks on lower extremity anatomic prominences were positioned adjacent the stands to set neutral alignment.

Quantifying the range (over seven independent neutral trials) of each subject's calcaneal and tibial positions around each segment's respective long axis tested repeatability. It was found that calcaneal position was more repeatable than tibial position as mean CP range was 2.7°, while mean tibial range was 4.3°.

Dividing the subjects into two groups tested the effect of missing anatomic alignment markers. One group had all alignment marks permanently applied while the other had marks which were removed and reapplied for each of their seven neutral trials. It was determined that the quantified data did not show a difference in repeatability between the two groups.

It is felt this study demonstrated the efficacy of the newly designed alignment method. Readily available mechanical tools were used and the ISB proposal for standardization was made for functional by inclusion of the STJ position. Repeatability was quantified and it was determined that missing alignment marks, which are an anticipated problem in the primary one-month portion of this thesis study were determined to not affect repeatability. Therefore, this method is recommended for use in the remainder of this research.

4.0 Mold Validation

4.1 Introduction

Studies of foot orthotic kinematic effects often focus on changes in calcaneal movement or position around the subtalar joint. Two methods are primarily used to determine calcaneal motion when footwear or foot orthotic testing is involved: 1) either windows are cut into the shoe heel counter to view markers placed directly on the skin, or 2) reflective markers are placed on the outer surface of the shoe heel. Both methods have advantages and disadvantages.

It is understood that shoe holes or slots used to view markers placed on the skin directly may alter shoe function. In addition, during gait the foot moves inside the shoe. The attendant repositioning of the markers with respect to the viewing slots makes marker viewing unreliable and camera setup difficult. Placement of markers on the external shoe surface is a commonly used solution. This solution is not without problems.

The goal of a substantial amount of gait research is generally to determine foot rather than shoe movements. However, external shoe markers actually measure shoe movement, which researchers must assume represents the foot. The use of external shoe markers requires acceptance of the hypothesis that the shoe mimics foot movement. This hypothesis means that the shoe and foot function as a rigid body. Research has demonstrated this assumption to be false [56].

Reinschmidt et al. [56] conducted research to compare calcaneal position measured with a bone pin to position measured with external shoe markers. It was determined that shoe markers tended to overestimate inversion and eversion data when compared to bone pins.

Bone pins yield the most reliable data due to their fixation directly in the bone of the segment being studied and their inherent rigidity. However, the use of bone pins seriously complicates research, since it is considered unethical for human subjects in North America. Bone pin use requires a doctor be present during testing, as a local anesthetic must be administered, an incision through the skin to bone depth must be made and a hole in the bone must be drilled. As with any surgery, there is also the risk of infection.

Currently, methods of obtaining 3D foot or calcaneal kinematic data have accuracy, reliability and ethical problems. Therefore, a new method of marker placement and fixation should be developed. The goal should be to as closely as possible duplicate benefits of bone pins without the ethical and procedural problems.

Polinsky [54] developed a method that permitted external visibility of calcaneal markers when a shoe was worn. The device consisted of thin thermoplastic formed directly around and then attached firmly to the subject's calcaneus. A vertical extension on the device was visible above the calcaneus. When external markers were attached to a vertical extension, the in-shoe calcaneal motion was externally visible. This technique has been used to collect 2D calcaneal motion data, but has not been tried or appropriately refined for 3D.

Therefore, the purpose of this study was four-fold: 1) to refine Polinsky's design for 3D data analysis; 2) to determine how kinematic data collected during walking differs between conventional skin markers and the calcaneal mold system; 3) to determine whether differences in segment rigidity exist between calcaneal mold and skin marker defined calcaneal segments; 4) to decide suitability for in-shoe calcaneal motion data collection.

4.2 Literature Review

4.2.1 Overview

Human motion studies probably began with a basic interest and fascination with the human body and its workings. However, technological developments, especially in the last one hundred years have made it possible to scientifically study and quantify human motion and the involved forces. Within the last two decades, techniques have been further refined so that kinetic and kinematic tools are available for patient diagnostics.

Techniques commonly used to measure joint angular values in either two or three dimensions most recently have been based on photographic, goniometric or magnetic approaches. Two-dimensional techniques are capable of accurately measuring motion parallel to the plane of interest only. Photographic techniques will distort or lose out-of-plane motion, while the hinge joint on a 2D goniometer is incapable of recording motion not parallel to the hinge.

The subtalar joint has been shown to be tri-planar with a non-orthogonal axis system unique to individual subjects [17;29;60]. It can be seen that during gait, the shank moves through a large range-of-motion (ROM) sagitally. However, it also has transverse (internal and external rotation) and frontal (ab/adduction) plane movements as well. The use of 2D techniques to measure simultaneous movement of the tibia and calcaneus in several planes is extremely difficult and cannot be applied with acceptable accuracy.

4.2.2 Electrogoniometer

In 1985, Taunton et al. [69] authored a study of 3D running mechanics. An electrogoniometer (Canadian Arthritis and Rheumatoid Society, University of British Columbia) was used to measure 3D kinematics of the knee and foot in ten male runners. Calculated angular results were similar to reported results from other studies. The device was seemingly less complex and costly than 3D photographic systems. Despite this, only one additional orthotic study with goniometric data was found. Why it has not been used more regularly is unclear. However, it is understood the arms of the electrogoniometer may be difficult to rigidly attach to the segment of interest.

4.2.3 DLT Technique

Three-dimensional photographic techniques are now commonly used in research facilities [22;34;38;48;53]. Acceptance is probably related to the direct linear transformation (DLT) method of camera calibration reported on by Abdel-Aziz and Karara [1] in 1971. The technique allowed standard (non-metric) cameras to be used and provided an easier method of determining spatial coordinates. Three-dimensional techniques require a minimum of three markers per studied body segment. These markers must be non-colinear and continuously visible to a minimum of two cameras. At least 60°, but not more than 120° for greatest accuracy must separate cameras.

4.2.4 Marker Placement Techniques

For 3D optical techniques, markers are generally spherical and, in the case of non-barefoot studies, have been attached to the shoe surface. In 1989, Eng and Pierrynowski [20] studied the kinematics of the knee with thigh and shank mounted skin markers and external shoe markers. In 1994 they co-authored a study, this time of kinematic effects of soft foot orthotics, also with shoe marker derived data [22]. McCulloch et al. [38], Nigg and Morlock [52], as well as Novick and Kelley [53] among others have also used shoe mounted markers to measure foot motion. With the possible exception of a study by Nawoczenski et al. [48], which used skin markers viewed through sandal straps, externally mounted shoe markers have been used typically in recent 3D studies.

Reinschmidt et al. [56] examined differences in calcaneal motion of subjects with the simultaneous use of a calcaneal bone pin and external shoe markers. Differences between in/eversion angles measured with external shoe markers or the bone pin were on the order of 5°, with a maximum of 7.1° and minimum of 4.2°. In five of six subjects, the eversion indicated by external shoe markers was overestimated when compared to eversion measured with the bone pin triad. In three subjects eversion angle was overestimated by more than 100%, in another by approximately 30%. The sixth subject did not demonstrate an everted position when calculated with shoe markers, although bone pins measured approximately 3° eversion. Ab/adduction results were better while plantar/dorsiflexion differences were similar to those of in/eversion. However, it must be remembered that plantar/dorsiflexion ROM was significantly larger, therefore the percentage of error was not as great.

Reinschmidt et al. [56] rated agreement between curve shapes as good for in/eversion curves, good for ab/adduction and excellent in plantar/dorsiflexion. However, no method for determining agreement was given. They concluded that reasons for differences in kinematic variables between shoe marker and bone pin triad could be either that: 1) the movement of the shoe is different from the movement of the foot, or 2) movement between foot/shoe and shank may occur in the talonavicular joint rather than in the joints (talocalcaneal and talocrural) located between calcaneus and tibia. This study demonstrated that data derived from shoe markers could be unreliable. Unfortunately, the alternative (bone pins) has major ethical and practical drawbacks that cannot be readily overcome.

Polinsky [54] conducted an experiment that tested a polyform mold technique for measuring in-shoe calcaneal motion. The mold of heat formable plastic was formed and attached around subject's calcaneus and tested both barefoot and in shoes. An extension of the mold, externally visible with two linear markers, was used to measure calcaneal motion in two dimensions. Polinsky determined first that 2D calcaneal data measured with the mold was not significantly different from data collected with calcaneal skin markers. Results for in-shoe motion of the calcaneus measured with the mold were also not significantly different from those measured with external shoe markers. Polinsky stated the results indicated validity of the polyform mold in-shoe provided one accepts validity of the mold barefoot and accepts that the shoe does not influence mold movement.

4.2.5 Literature Review Conclusion

From the review of literature, it was evident that 3D techniques were the most reliable for measurement of calcaneal motion, but that marker placement methods should be improved. It appeared that the mold developed by Polinsky was a noteworthy attempt to imitate bone pins without the ethical problems. In-shoe data were similar to data externally measured, which is unlike Reinschmidt's findings with bone pins. However, it is possible that differences between the mold and external skin markers were obscured by the 2D technique used in Polinsky's research.

Therefore, the purpose of this pilot study is to determine if the calcaneal mold is adaptable to 3D methodology. Also to report differences and similarities between subject kinematic data collected with calcaneal skin markers and the calcaneal mold with 3D modifications. Finally, from analysis of the results to assess the mold's validity as the method for obtaining in-shoe calcaneal motion for other aspects of this total research.

4.3 Methods

Four subjects, two female and two males volunteered for this study. All were in good health with no discernible gait abnormalities. Subject walking data was collected for ten trials in each of two conditions: 1) walking with calcaneal skin markers; 2) walking with the calcaneal mold. Video data (Motion Analysis, Santa Rosa, CA) at 120 Hz as well as force data (Kistler Instrumente AG, Winterhur, Switzerland) at 1200 Hz was collected.

During walking with either skin or calcaneal mold markers, all markers were glued securely to the subject with Medical Adhesive™ (Hollister, Libertyville, IL). The tibia of each subject was identically defined with three markers: two on the tibial crest, one located approximately 3 cm below the tibial tubercle and one approximately 15 - 20 cm distal, depending on length of subject's tibia; the third tibial segment marker was located on the fibular head.

During collection of skin marker data the right calcaneus only was defined with three skin markers (12.7 mm dia.): two were located horizontally, separated by approximately 3 cm on the lateral calcaneus and the third was on the medial calcaneus. When walking with the calcaneal mold, all calcaneal skin markers were removed and replaced with the calcaneal mold and triad combination.

Markers (6.35 mm dia.) on the medial and lateral malleoli and knee joint centers as well as on the tibial tubercle were used for neutral reference position setting and to calculate joint centers. Ankle and knee joint centers were calculated to be fifty percent of the distance between the lateral and medial markers.

Subjects walked at a controlled self-selected pace, calculated as the mean elapsed time of five practice walking trials. Time was measured between two photocell systems parallel the subject direction of progression and separated by 1.9 m. Photocells were activated by the subject passing through one of two separate beams, immediately before and after contact with the force platform. Individual trials outside ± 10% of the self-selected pace were immediately discarded.

4.3.1 Mold Manufacture

Custom calcaneal molds with attached marker triads were made for each subject (Fig.4.1). Molds were manufactured of 2 mm heat formable plastic (Sans-splint™). The plastic form was heated in 90°C water until soft, then draped around the subject's calcaneus and wrapped with an elastic bandage until cool. The bandage was used to maintain correct position and pressure to form a mold that closely followed the contours of the calcaneus. A 180° bend for attachment of the marker triad to the mold most proximal external portion was also formed by the tester during the cooling period.

4.3.2 Marker Triad

The calcaneal marker triad was formed by welding three short (approximately 5 cm) pieces of 1.59 mm stainless steel welding wire together at a central union (Fig. 4.2). A standoff (approximately 5 cm) with mount, perpendicular to the plane of the three pieces was also welded to the union. A screw through the mount and matching hole drilled in the mold was used to firmly secure the triad to the mold. The triad was made as small as possible to maximize stiffness without introducing optical tracking problems related to closely spaced markers.

Fig. 4.1: Calcaneal mold with marker triad.

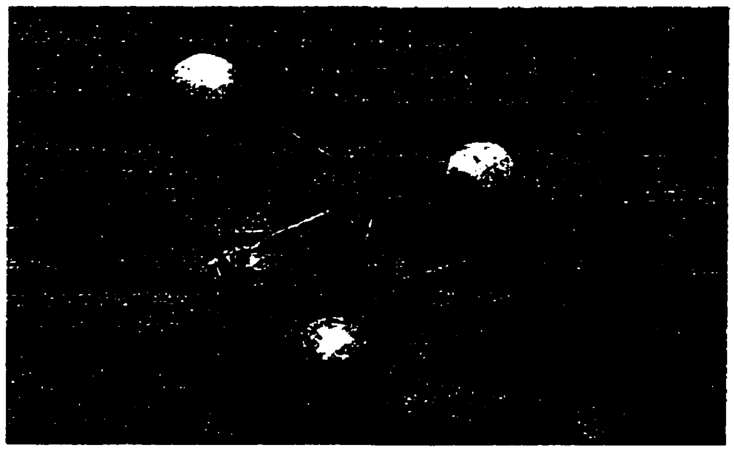

Fig. 4.2: Marker triad.

Each marker was mounted at a 5 cm radius from the triad center. Two markers formed an angle of approximately 75° and the third marker bisected the 75° angle (Fig. 4.2). On the triad ends, 12.7 mm diameter polystyrene balls covered with retroreflective tape (3M Corporation, St. Paul, MN.) were mounted. Mounting holes (1.46 mm) were drilled in each ball for wire insertion.

4.3.3 Instrumentation

Four Falcon high-speed digital cameras (Motion Analysis, Santa Clara, CA) were arrayed around the force platform (Fig. 4.3). Two cameras, focused primarily on the posterior foot during walking, were mounted low to the ground (lens height approximately 30–75 cm from ground) to enhance visibility for improved calcaneal marker tracking. Video data was collected at 120 Hz. Camera resolution was 648 x 480 pixels. Field-of-view was approximately 1.3 m for camera 1 and 1.8 m

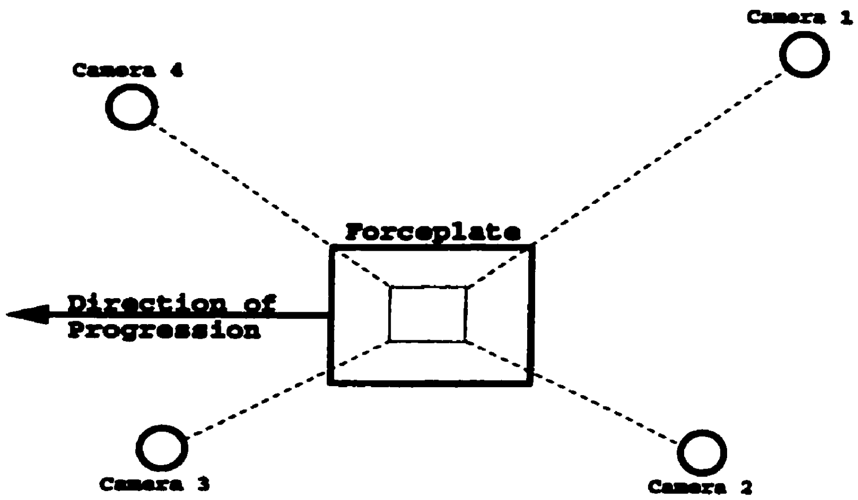

Fig. 4.3: Camera positions.

for cameras 2 – 4, measured at the force platform.

The 3D volume above the force platform was calibrated using a DLT approach with a 75 X 50 X 79 cm calibration cube with eight markers, one at each corner. An orthogonal grid system attached to the force platform surface was used to align the cube X and Y axes parallel the direction of progression and subject frontal plane respectively (Fig. 4.4). When aligned this way, the anatomical coordinate system as defined by Kintrak (Motion Analysis, Santa Rosa, CA) for calculation of segment positional data was parallel the lab coordinate system (Chapter 3).

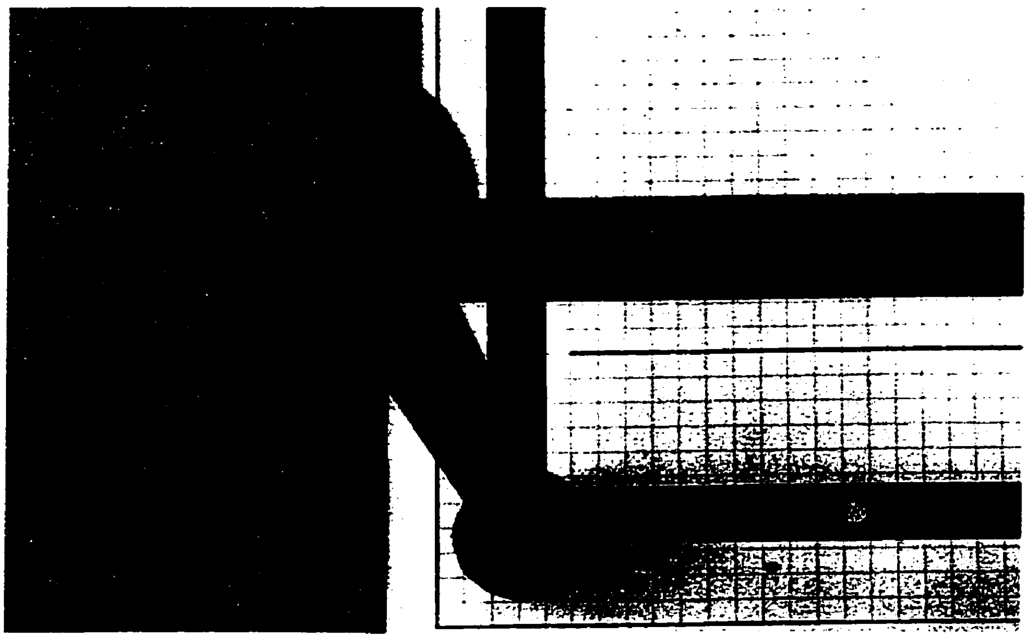

Fig. 4.4: Calibration cube on force platform.

4.3.4 Data Collection

Skin markers to define the subjects' tibia and calcaneus were attached, as were neutral reference markers. The subject was aligned in neutral reference position on the force platform (Neutral Repeatability, Chapter 3) and a one-second neutral trial was collected.

Immediately following collection of neutral data, all neutral markers were removed. Walking data was collected for ten trials and the calcaneal skin markers were then also removed. Neutral trial markers and the calcaneal mold (Fig. 4.5) were added and the neutral trial for the calcaneal mold walking condition was recorded. Immediately following neutral recording, the neutral markers were again removed and ten trials of walking with the calcaneal mold were recorded. Finally, a second camera calibration trial was taken, to be used if the cameras were somehow moved during data collection of walking.

Markers were tracked to determine 3D spatial coordinates with EVA software (Motion Analysis, Santa Clara, CA). All data prior to ten video frames before heel-strike (HS) and after toe-off (TO) were removed. The ten frames before HS and after TO were necessary to avoid endpoint errors caused by the data filtering algorithms. Time of HS and TO were determined with analog force data (Kistler Instrumente AG, Winterhur, Switzerland), synchronized to the kinematic data.

Fig. 4.5: Calcaneal mold on foot.

4.3.5 Data Analysis

Data analysis was completed between HS and 80% of stance normalized between heel-strike and toe-off. Previous literature was studied to learn which filter frequency had been found effective for kinematic data filtering. Stacoff [67] and Masse [37] filtered with a Butterworth lowpass 10 Hz filter, while Nawoczenski [48] filtered at 7.14 Hz and Novick [53] filtered at a frequency that contained 95% of the power in the Fx (medio/lateral) direction. In each case the method or rationale for frequency selection was not discussed.

The goal of filtering is to separate real data from noise. Noise could be in the form of electronic noise in the circuits themselves or vibration of the markers on the skin. For kinematic data of a low frequency movement such as gait (approximately 1 Hz), existing noise may be seen on the actual kinematic data curves. Therefore, the correct filter frequency may be determined by progressively (from high to low) filtering the data until the curve is smoothed, without having affected the distance between minimum and maximum points on smooth portions of the original curve. For studies in this thesis, the correct frequency was determined to be 6 Hz.

Analysis of only 80% of stance was necessitated by camera setup. Only two cameras were available to view the calcaneal mold from the rear during stance. It was therefore, impossible to optimize marker visibility during midstance and optimize visibility at heel-off and toe-off. The decision was made to study from heel-strike to shortly after heel-off since foot orthotic effects are considered most pronounced during early stance [22;48].

Foot orthotics have been proposed to reposition the foot and tibia during gait, by limiting maximal eversion and maximal tibial internal rotation. Therefore, both maximal position and total range-of-motion of each segment were dependent variables in this study. Further, it was hypothesized that heel fat pad damping action may slow the skin markers' response more so than the calcaneal mold response to calcaneal movement. Movement timing could therefore be mismeasured. For this reason times of maximal eversion and tibial internal rotation were also analyzed.

The following variables were investigated: skin marker maximal eversion (SME), calcaneal mold maximal eversion (CME), time of skin marker maximal eversion (TSME), time of calcaneal mold maximal eversion (TCME), skin marker maximal tibial internal rotation (SMIR), calcaneal mold maximal tibial internal rotation (CMIR), time of skin marker maximal tibial internal rotation (TSMIR) and time of calcaneal mold maximal tibial internal rotation (TCMIR), and finally segmental ROM.

In/eversion variables were calculated as rotation of the calcaneus about its long axis (reference coordinate system y-axis, Chapter 3-Neutral Repeatability). The y-axis was the anterior/posterior axis, set parallel to the lab coordinate system by alignment of the subject and calibration frame with the force platform grid.

Tibial internal rotation was calculated as rotation of the tibia about its long axis (reference coordinate system z-axis, Chapter 3-Neutral Repeatability). Refer to Chapter 3 for a complete alignment procedure description. Calcaneal ROM was calculated as the difference between calcaneal position around its long axis at HS and maximal eversion. Tibial ROM was calculated as the difference between maximal internal and external rotation.

The ROM of tibial motion necessitated differences in the two calculation techniques when compared to calcaneal motion. For all subjects, calcaneal position at HS was the most inverted position during stance. Therefore, the formula (calcaneal position at HS – maximal everted position) was representative of total calcaneal motion around its long axis. However, for the tibia this was not the case.

Tibial external rotation was regularly greater after HS, than at HS. Therefore, the formula (maximal tibial internal position – maximal tibial external position) was necessary to describe total tibial motion around its long axis.

Additionally the hypothesis Reinschmidt et al. proposed concerning skin marker movement was tested, by analyzing data to determine if differences in rigidity of the calcaneal segment when defined by either skin or mold marker systems could be responsible for any segment kinematic data differences. X, Y and Z coordinates from EVA tracked data were used to calculate vector lengths between the markers of the calcaneal mold triad and vector lengths between markers of the calcaneal skin marker system.

$$l=((x1 - x2)^2 + (y1 - y2)^2 + (z1 - z2)^2)^{1/2}$$

Lengths were calculated for each vector between the three markers used on the skin marker or calcaneal mold defined calcaneal segment. It was felt the largest change in vector length, if any, would occur during or slightly following HS. Therefore, vector lengths were calculated for video data at one and fifteen frames post HS. Vectors from walking data were then compared to lengths calculated from static neutral trial data to determine percentage of change.

4.4 Results

Four subjects participated, but neutral trials of one subject were unusable. Therefore, only three subjects will be discussed. Maximal calcaneal and tibial angular positions around their respective long axes for both skin marker and calcaneal mold data are listed in Table 4.1. Calcaneal and tibial ROM are listed in Table 4.2. Calculations of between marker, vector length changes are contained in Table 4.3. Graphs of calcaneal and tibial rotations about their respective long axes are in Appendix A.

Subj.	SME	CME	TSME	TCME	SMIR	CMIR	TSMIR	TCMIR
2	-5.8 *1.1*	-4.9 *0.5*	45.0 *16.6*	51.1 *11.8*	9.7 *1.0*	9.3 *0.8*	23.0 *17.7*	16.0 *5.5*
3	-13.3 *0.5*	-12.2 *0.9*	34.4 *10.1*	50.7 *11.5*	12.7 *1.6*	11.6 *1.0*	24.0 *14.0*	31.0 *15.9*
4	-12.0 *0.5*	-7.9 *0.6*	60.3 *7.4*	58.4 *2.3*	16.1 *1.4*	13.2 *0.9*	65.0 *4.7*	59.0 *9.0*

Table 4.1: Comparisons of Calcaneal Mold and Calcaneal Skin Marker Derived Data.
Means of study variables for in each condition (skin marker and calcaneal mold) for subjects 2-4. Standard deviations are in *italics*. Variables are: skin marker maximal eversion (SME), calcaneal mold maximal eversion (CME), time of skin marker maximal eversion (TSME), time of calcaneal mold maximal eversion (TCME), skin marker maximal tibial internal rotation (SMIR), calcaneal mold maximal tibial internal rotation (CMIR), time of skin marker maximal tibial internal rotation (TSMIR) and time of calcaneal mold maximal tibial internal rotation (TCMIR). Maximal positions are expressed in degrees and time variables are expressed in per cent of stance, normalized from HS to TO. *Note*: calcaneal eversion is a negative rotation with respect to neutral position and is, therefore expressed in degrees of negative rotation.

Maximal calcaneal eversion was greater for all subjects when represented with skin markers. In one subject (Subject 3), mean time of maximal eversion was delayed by 16.3% of normalized stance for the calcaneal mold trials. For the remaining two subjects time of maximal eversion was delayed by 6.1% or advanced by 1.94%.

Subject	Condition	Inversion/ Eversion ROM	Internal/ External Rotation ROM
Two	Skin	9.4 *1.2*	4.8 *1.2*
	Mold	7.4 *0.7*	3.9 *0.6*
	Difference	**2.0**	**0.9**
Three	Skin	8.4 *1.6*	6.8 *1.9*
	Mold	6.7 *1.3*	6.9 *2.1*
	Difference	**1.7**	**0.1**
Four	Skin	12.6 *1.2*	8.4 *1.9*
	Mold	8.8 *0.8*	7.4 *1.1*
	Difference	**3.8**	**1.0**

Table 4.2: Segment range-of-motion.
Range-of-motion data is calculated as the difference between the minimal and maximal segmental angular positions from the calcaneal and tibial curves in degrees. Standard deviations are in *italics.*

Tibial internal rotation was also greater for all subjects when represented with skin markers. Time of maximal internal rotation was delayed in two subjects and advanced in one subject, when comparing skin marker to calcaneal mold data. The range of tibial timing difference was 6-7 percent for all subjects.

In all subjects calcaneal ROM was greater with calcaneal skin markers than with the calcaneal mold. Range of difference was between 1.7° and 3.8°. In two cases tibial rotation was greater with skin markers. Range of difference was between .9° and 1.0°. In one case the skin markers underestimated by only .1°.

Segment distortion was determined by calculating the change in 3D vector lengths between the three skin or mold markers used to establish the calcaneal segment. The mean marker vector length change across all subjects and times was three times greater with skin markers than with the calcaneal mold (2.4/0.8%). Maximal skin marker change was 5.4 times greater than with the calcaneal mold

(9.1/1.7%). Subjects 2,3 & 4 had 5.9, 11.8 and 2.7 times greater (5.3/0.9, 11.8/1.0, 10.2/3.8) respectively, maximal length change with skin than with calcaneal mold markers.

		Link 1	Link 2	Link 3
Subject 2	Skin+1	-3.8	-1.3	-1.1
	Skin+15	-3.5	-5.3	-0.2
Subject 3	Skin+1	-0.9	-0.4	-0.5
	Skin+15	-1.4	-11.8	-0.1
Subject 4	Skin+1	-1.3	0.0	0.2
	Skin+15	-0.4	-10.2	1.0
Subject 2	Triad+1	0.9	-0.1	-0.5
	Triad+15	0.0	-0.3	-0.8
Subject 3	Triad+1	-0.3	-0.8	0.6
	Triad+15	-0.7	-0.9	1.0
Subject 4	Triad+1	3.8	-0.3	-0.2
	Triad+15	2.5	-0.5	-0.5
Mean skin change	+1	2.0	0.6	0.6
	+15	1.8	9.1	0.4
Mean triad change	+1	1.7	0.4	0.4
	+15	1.1	0.6	0.8

Table 4.3: Percent change of marker vector lengths.
Calculations are from one randomly selected walking trial only for each subject at 1 and 15 frames post heel-strike and compared with the static neutral trial. Neutral lengths are average vector lengths from 60 frames data collection. Links 1,2 and 3 for skin markers respectively are: vector from medial calcaneal to lateral anterior calcaneal marker, from lateral anterior calcaneal to lateral posterior calcaneal marker and finally from lateral posterior calcaneal to medial calcaneal markers. Triad markers are circularly arranged at 0, 120 and 240°. Vectors are clockwise from 0-120° marker, from 120-240° marker and finally from 240-0° marker. Negative values denote shortening compared to neutral lengths. Means are listed quantitatively only, no reference to direction of change is given.

4.5 Discussion

The purpose of this study was four-fold: 1) to refine Polinsky's design for 3D data analysis; 2) to determine how kinematic data collected during walking differs between conventional skin markers and the calcaneal mold system; 3) to determine whether differences in segment rigidity exist between calcaneal mold and skin marker defined calcaneal segments; 4) to decide suitability for in-shoe calcaneal motion data collection.

To use the mold system for 3D data collection required the addition of a marker triad. A triad was designed as rigid, small and light as possible, but still large enough to eliminate marker tracking problems caused by crosstalk.

Two problems were discovered related to use of the calcaneal mold with marker triad system. The first was that the combined weight was more than athletic tape, as used in Polinsky's [54] study could reliably secure to the skin around the calcaneus. The second was that two cameras following heel-off could not reliably view the markers of the triad, when positioned to optimize visibility at heel-strike and foot-flat.

The first problem was resolved by using Medical Adhesive™ (Hollister, Libertyville, IL) instead of athletic tape. It was found that the adhesive provided a much stronger bond that was reliably maintained for the duration of the trials.

The second problem was not resolved for this study, as it was deemed not necessary to analyze data beyond 80% of stance. However, at least two solutions are available. The first is to add additional markers to the marker triad, in a configuration that forms a vertical plane during heel-off. The second is to use additional cameras in the rear to view the triad. The cameras can be optimized for to view the triad following heel-off by setting them high and aiming them downward.

It has been previously shown that external shoe markers overestimate in-shoe calcaneal motion [56]. The calcaneal mold with included marker triad was intended as a method to overcome shoe marker problems, without resorting to an invasive surgical procedure such as bone pins. Previous uses of the mold have been exclusively for 2D data collection. The first documented use of a calcaneal mold appears to be the original study by Polinsky [54]. In that study, the mold was determined to be a suitable replacement for skin markers, although there were differences in data. For example, time of reinversion in the latter portion of stance phase occurred later when measured with the calcaneal mold than when measured with skin markers.

In the present study, of six possible observations, mold data for time of maximal eversion and time of maximal tibial internal rotation was equally divided between occurring earlier and occurring later when compared to skin marker data. Therefore, it was not possible to determine if timing differences should be expected when a calcaneal mold with attached 3D-marker triad instead of skin markers is used.

Polinsky [54] determined differences in maximal eversion for mold and skin markers were minor (13.24°±4.77° and 12.38°±3.41°, respectively). In contrast, the present study found maximal eversion and internal tibial rotation mean differences were as high as 4.0° for in/eversion and 3.1° for tibial in/external rotation. Additionally, it was determined that skin markers always overestimated maximal position when compared with the calcaneal mold. Results of Reinschmidt et al. [56] were similar in that in/eversion was overestimated with skin markers by as much as 7.1° in one subject, but typically by 5.7° across all subjects. Foot ab/adduction was overestimated by as much as 5.7° in one subject and 4.2° across all subjects when compared to bone pin data. It should be noted that foot ab/adduction from the study of Reinschmidt et al. and internal tibial rotation from this study are equal rotations about the tibial long axis (z). Foot ab/adduction is simply the position of the foot with respect to the tibia, while tibial in/external rotation is position of the tibia with respect to the foot.

When compared with Polinsky's study it is felt differences in results could be due to 2D versus 3D data collection methods. Two-dimensional methods generally place two markers over the posterior calcaneus, vertically aligned. These markers would be only minimally distorted by vertical repositioning of the medial or lateral calcaneal fat pads during midstance.

However, since separate neutral trials were required for each test condition (skin vs. calcaneal mold) it is possible in this study that maximal positions were overestimated due to offsets in neutral positions. However, random error is as likely to have caused overestimation of mold maximal position as skin marker maximal position. Therefore, since the overestimation is systematic (skin marker maximal kinematic data is always greater than mold maximal kinematic data) it is felt that skin markers do result in overestimation of maximal positions when compared with the calcaneal mold.

This study also found that calcaneal ROM was always overestimated by skin markers. Overestimation ranged between 1.7° and 3.8°, which in one subject was as much as 40% of the total mold determined ROM. Tibial ROM was overestimated in two of three subjects by as much as 23% of mold determined ROM or as high as 1.0°.

Reinschmidt et al. [56] similarly found that skin markers overestimated ROM. However, the range was as much as 5° and 11° for calcaneal position. It was felt that tibial position was well reflected by skin markers when compared with bone pins. However, tibial ROM of two of five subjects were still overestimated by skin markers when compared to bone pin data. They hypothesized that lack of segment rigidity was responsible for errors with external shoe markers.

Findings from this current study lend credence to the statement, as it was shown that vector lengths between skin markers that define the calcaneal segment can change by an order of magnitude of 11 times greater than the vector length change of the same subject with the calcaneal mold. However, as the triad and skin markers were differently oriented, it is not possible to relate differences in rigid body function to a specific error in segment position. It is interesting to note that the skin marker vector with the greatest length change is aligned along the lateral calcaneus in the direction of progression. Heel strike is posterior and lateral and more likely to affect the posterior of the two lateral calcaneal markers. Movement in the +Z (upward) direction of the posterior marker due to fat pad displacement would result in overestimation of calcaneal position in the eversion direction. This movement may also have accounted for overestimation of skin and shoe markers from Reinschmidt et al. [56].

One landmark in curve shape is sometimes apparent in this pilot and final thesis data. Immediately following heel-strike, at approximately 10-15% of stance there is a noticeable step in the in/eversion curve. This step is evident as a momentary stop in eversion movement or even a slight move back toward inversion. The movement is more pronounced with the calcaneal mold/triad than with skin marker data. Interestingly, this step is also sometimes visible in the bone pin data presented by Reinschmidt et al., but the significance is unknown.

4.6 Conclusion

The purpose of this study was four-fold: 1) to refine Polinsky's design for 3D data analysis; 2) to determine how kinematic data collected during walking differs between conventional skin markers and the calcaneal mold system; 3) to determine whether differences in segment rigidity exist between calcaneal mold and skin marker defined calcaneal segments; 4) to decide suitability for in-shoe calcaneal motion data collection.

The calcaneal mold by application of retro-reflective triad marker system was modified to provide 3D data. Reliability was improved from the original design by using Medical Adhesive® to attach the calcaneal mold system to the skin. Analysis of the quantified data showed that differences between calcaneal mold and skin marker determined kinematics existed and skin markers regularly overstated segment movement and position when compared with the calcaneal mold system. Differences in segment rigidity were found to exist and the substantially greater distortion of the calcaneal segment when represented with skin markers was hypothesized to be the reason for overestimation of data. Lastly, the mold was deemed suitable for measurement of calcaneal 3D position.

4.7 Recommendations for Future Work

This study sample is small, therefore it is desirable to verify its results with more subjects. Further, it is not understood which is the correct eversion data curve; that with the minor step or the skin marker curves without the step. A larger study with skin marker placement specifically selected to determine plane of marker stretch and faster capture rates to measure triad/mold vibration could prove beneficial.

Bone pin data is considered the most accurate due to direct bone attachment. Therefore, it would also be interesting to conduct a study to compare bone pin and calcaneal mold data.

5.0 Adaptation and Consistency of Foot Orthotic Kinematic Effects

5.1 Introduction

Foot orthotics are regularly used as a treatment for overuse and other injuries (e.g. plantar fasciitis, ankle instability, patellofemoral pain syndrome, shin splints) of the foot and lower extremity. Among clinicians it is generally held that orthotics are an effective treatment, especially for overly pronated patients. Anecdotal evidence from orthotic users that attribute symptom elimination and performance enhancement to orthotic use also exists. It is presumed that the permanent elimination of abnormal gait kinematics is the curative mechanism by which foot orthotics function.

Unfortunately, despite continuous research during the last 30 years, researchers have not reached conclusive agreement as to which kinematic variables of gait are affected by orthotic use. Additionally the permanence of effects has not been investigated beyond one study of Down Syndrome children that is not applicable to a standard patient population [64]. Rather it has been assumed that any measured effects must be permanent and consistent over time.

It has been hypothesized that human adaptation may affect research results. The principal investigator of this current research further speculates that human adaptation may even affect the permanence or consistency of the changes to gait that may be caused by foot orthotic use.

The purpose of this study is to determine if the kinematic effects of foot orthotics are consistent during one month of adaptation by highly pronated (≥12°) subjects. As has been previously mentioned, one difficulty in comparing results of different research is the diversity of methods, the lack of a standard ankle neutral position and the lack of reliability in data collected with shoe markers. Therefore, to eliminate data shifts and data of questionable value due to non-standard neutral position and shoe markers respectively from this research, methods will include the recommended neutral standard position from Chapter 3 and the calcaneal mold from Chapter 4.

5.2 Literature Review

5.2.1 Orthotic effects

Research to quantitatively determine foot orthotics effects has been conducted [6;22;33;67]. These studies focused on the kinematic and kinetic changes to gait immediately after initial insertion in shoes. Typically subjects were screened for pronation during static stance and fitted with soft, semi-rigid or hard custom molded foot orthotics. Immediately during subject initial use, the kinetic and kinematics of gait were determined. However, results when directly compared between studies, were varied and inconclusive.

Masse [37] found that pronated subjects (standing, >10° rearfoot angle) walking on a treadmill did not significantly decrease their maximal angle of pronation when custom foot orthotics were used. Two-dimensional (2D) data were collected using a neutral position of feet separated by natural stance width while pointing forward and parallel. Shoe type and orthotic posting were not discussed, while orthotic length and firmness was varied. Ten subjects wore full-length semi-rigid orthoses, while two subjects wore full-length soft versions. This study is one of only a few that applied controls to neutral position. However, since most subjects walk with an abducted foot position, the neutral and walking position do not match. This mismatch does create a problem with data distortion since the camera is aligned for the neutral trial, rather than the abducted walking trial. As previously mentioned movement not parallel to the camera plane is distorted in 2D data collection. There was an additional problem in this study related to statistical interpretation. Final data reporting was based on a repeated measures ANOVA, performed across all subjects. However, different test conditions existed across subjects as foot orthotic type was varied. Therefore, it was not possible to reasonably compare data across subjects.

In a study of soft foot orthotic effects, it was reported that calcaneal ROM in the frontal and sagittal planes and maximal angle of pronation all decreased with foot orthotics [22]. However, it was also reported that inter-subject data in the frontal and transverse planes were highly variable. Ten women with patellofemoral pain syndrome and calcaneal valgus or forefoot varus greater than 6° participated. Custom orthotics were formed, beginning with an off-the-shelf shell from a Spenco™ insole (Spenco Sports Medicine Products, Toronto, ON, CDN). Medial posting was 2° hindfoot for subjects with between 4-6° calcaneal valgus. A 2° forefoot post was used with 6-10° forefoot varus, while greater than 10° forefoot varus was posted 4-6° forefoot and 2-4° hindfoot. Maximal posting was 6° and 4°, forefoot and rearfoot respectively. Three-dimensional (3D) video data was collected with external shoe markers used to determine calcaneal motion. Neutral position was reported as relaxed standing with feet pointing forward and parallel.

The study of Eng et al. (1994) benefited from the use of 3D-motion analysis. Accuracy of 3D analysis does depend on rigidity of the body segments. The bones that form the tibial segment of course are very rigid. Nevertheless, for data collection the segment is considered as the plane formed by segment markers fixed to the overlying skin. Therefore, actual segment rigidity is dependent on marker placement and skin movement. To improve segment stability markers should be placed on bony prominences. In this study, two of five tibial segment markers were placed directly on muscles. It appears either one marker is on the extensor digitorum longus or peroneus longus while another is on the gastrocnemius. This marker placement may contribute to data inaccuracies. This study used female subjects with prescribed orthotics for the treatment of patellofemoral pain syndrome. If the assumption that foot orthotics are an effective treatment for overuse leg injuries is accepted, then it is possible the study's results are due to pain alleviation rather than a true orthotic affect.

In Johanson et al.'s [31] study of orthotic post placement effectiveness, it was determined that during walking in running shoes, calcaneus-to-calf and calcaneus-to-vertical angles were reduced when orthotics posted in the fore and rearfoot were used. Subjects were measured for forefoot deformity and rearfoot motion, but no measure of natural stance pronation was made part of the inclusion criteria. Custom foot orthotics were used with a posting technique that took into account the forefoot varus deformity by setting forefoot posting at 30% of the sine of the forefoot varus angle multiplied by forefoot width. Rearfoot posts were 80% height of the forefoot post. Maximum allowable post height was 7mm fore and 6mm rearfoot. Two-dimensional techniques were used with the entire posterior portion of the shoe heel counter removed for marker visibility. Tibial and calcaneal bisections were used for angle determination. Johanson et al. cited accuracy problems related to 2D analysis as a possible confounder. Markers were also placed directly on the calcaneus and were visible through large slots cut in the shoe heel counter. In this case although the slots may have altered shoe and orthotic function, they may not have affected study results as all conditions would have been equally impacted.

In running trials, Nawoczenski [48] determined that foot orthotics decreased the ratio of lower leg abduction to lower leg internal rotation which occurred between heel contact and maximal abduction, and heel contact and maximal internal tibial rotation. This change was related to decreased tibial internal rotation. Three-dimensional techniques were used with markers attached directly to the foot and visible through sandal straps. Semi-rigid custom orthotics were used, but posting techniques were not described. Pronation was not an inclusion factor, instead subjects were chosen from a pool of volunteers that had reported to local practitioners for injury consultations. Therefore, this study also suffered from methodology weaknesses previously discussed for Eng et al. (1994) related to symptom elimination. Neutral position was with subjects in comfortable base of stance and their natural toe-out position.

In an experiment that studied foot orthotic effects during the loading response time of gait [53], orthotics were found to decrease the maximal calcaneal angle (relative the sagittal plane) as well as maximal calcaneal eversion angle (relative tibial bisection in the frontal plane) and total rearfoot movement. Weak statistically significant evidence ($p<0.0627$) was found to support a reduction of maximum calcaneal eversion angular acceleration. However, highly statistically significant results ($p<0.0036$) were found for maximum eversion moment about the ankle joint center due to ground reaction. It was determined foot orthotics significantly reduced maximum eversion moment at the ankle. This study by Novick and Kelley (1990) was conducted with 3D data collection and shoe markers. Markers were placed on the posterior shoe heel counter and the dorsal aspect of the toe-box. Therefore, the foot or shoe positions are measured rather than calcaneal position around the subtalar joint. It is not known how this change affects data. Foot abduction during walking gait was corrected during final data analysis. Rather than use a standard neutral position, abduction during static stance was measured and used as a correction factor applied to walking gait. However, this correction would not account for non-sagittal plane data such as in/eversion.

These previous results, which indicate the effectiveness of foot orthotics in changing kinetics and kinematics, are not universally supported. A study of the effect of wedges on rearfoot angle during quasi-static stance [8], found little change in rearfoot angle, when 5° and 10° wedges were placed under subjects' bare feet, in both varus and valgus positions. The results were similar when identical wedges were placed inside shoes. This study is interesting in that it shows it is possible to resist the changes, which should be caused by wedging. However, it is quasi-static only, so cannot be presumed to represent results during gait. In addition, although wedging or posting is part of orthotic design, it does not encompass all features typical to foot orthotics.

Brown et al. [6] studied the effects on maximum pronation, calcaneal eversion, maximum pronation velocity, time-to-maximum pronation, and total pronation of biomechanical orthoses in shoes during treadmill walking. Eversion was measured as the angle between the calcaneal bisection and a line perpendicular to the floor, while pronation was the angle between the calcaneal and tibial bisections. No statistically significant ($p \leq 0.05$) effect on maximum pronation, calcaneal eversion and total pronation could be determined. The data for maximum pronation velocity and time-to maximum pronation were unreliable due to excessive variability. This study was conducted with 2D data collection on a treadmill. It is important to note that subjects who previously used foot orthotics were included and this factor was stated to have heavily influenced the time-to-maximum pronation in foot orthotics. Why previous orthotic use affected time-to-maximum pronation was not understood, but it was hypothesized there may have been a learned response.

5.2.2 Adaptation

Due to results of the previously discussed study of 10° wedges, the authors hypothesized that subject compensation eliminated any consistent trends [8]. Researchers other than Cavanagh [8] have hypothesized adaptation has been responsible for surprising results in their studies. Research of the kinetic and kinematic adaptations of the body to shod and barefoot running determined the ground reaction forces to be similar in barefoot or shod running [15]. This test was performed in running shoes that normally would be expected to reduce VGRF due to dissipation through the soft midsole. In a similar study, Nigg et al. [50] found a slight but not significant ($\alpha=0.05$) decrease of less the 10% in impact force peaks as midsole Shore value increased. Nigg et al. [50] found that increased initial speed of pronation was responsible for the surprisingly small change in impact force peaks when midsole hardness was increased. However, he was unable to conclude whether this change in pronation speed was caused solely by mechanical changes to the midsole (Shore hardness), or by the combined effect of mechanical changes and internal adaptation of the neuromuscular control system. Alternatively, in another study it was determined that initial vertical impact force peak significantly ($p<0.05$) decreased when midsole Shore value was increased [16].

In a similar study, McNair and Marshal [40] found significant differences between barefoot and shoe conditions in accelerometer measured tibial accelerations during treadmill running. However, they reported knee joint activity throughout stride cycle was relatively invariant across shoe types and barefoot. They further determined that although the foot was maintained in a more plantarflexed position when barefoot, the net amount of plantar and dorsiflexion was similar between conditions. Therefore, since kinematic changes were small they could not determine how accelerations between barefoot and shoes were mediated. They speculated there might be numerous combinations of joint and muscle activity that may only require small alterations to produce considerable footstrike kinetic changes. A later study found slightly different, but similarly non-intuitive results [14]. Smaller impact peaks were correlated with harder shoe soles.

Runners' leg stiffness was recently tested for first steps on new surfaces [23]. Two force platforms were used to measure VGRF beneath two different stiffness rubber running surfaces as runners transitioned from one surface to the next. Results showed leg stiffness differences of 29% or more between the last step and first step during the transition between two different surfaces.

5.2.3 Summary

Studies of foot orthotics have focused on immediate affects and have not yet reached consensus. Certainly methodological differences account for variations in results. Orthotic materials and posting techniques have varied. Some research was over-ground while others used treadmills. Both 2D and 3D video methods have been used and it is known that 2D results can be affected by out of plane movements. Neutral positions have also varied. However, these effects are well understood. No research has been conducted to determine if adaptation plays a role in results or even to determine if orthotic effects are consistent over time.

It has been hypothesized that adaptation by human subjects may affect results. It has been further speculated that adaptation specifically may be responsible for surprising kinematic and kinetic results in some studies of lower extremities. Further, it is known that human subjects may alter segmental characteristics in response to surface hardness [23].

From reviewing the literature it has been determined that shoe and skin markers do not accurately reflect in-shoe calcaneal motion. Also, it has been seen that the lack of a standard and regularly used definition of calcaneal neutral position has made it difficult to compare kinematic results from different research. Finally it was seen that some have hypothesized that human adaptation may play a role in determining the changes to gait of individual subjects caused by foot orthotic use. However, adaptation's role in altering foot orthotic kinematic effects has not been exhaustively studied.

Therefore, in this proposed research, subject lower limb kinematics will be repeatedly measured during one-month of continuous foot orthotic use. Shoes, foot orthotics and minimum wear time will be identical for all subjects, and all subjects will be highly pronated ($\geq 12°$). A calcaneal mold to reduce shoe marker inaccuracies will be used to measure in-shoe calcaneal motion and differences between kinematic measurements taken with the mold or with skin markers will be reported on in Chapter 3. Further a definition for calcaneal neutral and a manual method for repeatedly and accurately resetting neutral will be developed and reported on in Chapter 4. By maintaining as closely as possible identical conditions for all subjects, and taking repeated measurements it will be possible to determine if subject kinematics are stable over time.

5.3 Methods

5.3.1 Subject Criteria and General Study Information

Posters were placed throughout the University of Calgary to advertise the study and request volunteers. Fifteen subjects, eight males and seven females were accepted from the larger pool of volunteers. Ages ranged from eighteen to fifty-four, with a mean of thirty-three. Inclusion criteria included, 12° total pronation on the right foot only, no orthotic use for the previous twelve months, and no history of or current injuries that affected gait. Study period was five weeks.

A sport medicine physician examined all volunteers to evaluate inclusion criteria and to obtain other anatomic measurements. Those that met inclusion criteria then signed an informed consent form (Appendix B) according to university guidelines and their information was recorded in the Subject Evaluation Form (Appendix C). Subjects were supplied identical test shoes (ECCO Shoes Canada, Inc., Markham, Ont.) and custom firm foot orthotics (Amfit Corp., Santa Clara, CA.).

Data collection sessions were held in the University of Calgary Human Performance Laboratory and were conducted by the principal researcher. During data collection sessions twelve trials were recorded for each condition scheduled.

5.3.2 Test Shoes

Two test shoe models (Life-men, Mobile-Lo-women) with leather uppers and polyurethane midsoles were supplied by ECCO Canada. Shoes were chosen for durability, comfort and last shape that easily accommodated foot orthotics. Both models featured a removable insole, which was replaced with the foot orthotics. Shoes were appropriately sized for each subject and checked for comfort prior to study commencement.

5.3.3 Foot Orthotics

All custom foot orthotics were manufactured by a local orthotist with firm foot orthotic blanks and CAD/CAM software and hardware supplied by Amfit, Inc. (Santa Clara, CA). Orthotics were identically posted 4° in the medial rearfoot and 6° in the medial forefoot (4+2 posting). During CAD digitization, subjects were positioned in relaxed calcaneal stance, with feet straight-ahead and equally weighted, and the foot midline separated by anterior superior iliac spine (ASIS) width.

5.3.4 Study Time Line and Wear Requirements

Subjects began test shoe wear for a one-week adaptation period, immediately prior to data collection commencement (Fig. 5.1). At Time 1, which was the end of the one-week shoe adaptation period, kinetic and kinematic data were first collected walking in shoes only. Immediately after collection of shoe only data, shoe insoles were removed and replaced with subjects' foot orthotics for a second data collection period. Foot orthotic data were again collected at Time 2 (one week later) and Time 3 (three weeks following Time 2). During the one-month orthotic use period, subjects were required to wear the test shoe with foot orthotic combination a minimum of 8 hrs./day, 6 days/week. Test shoes or orthotics could not be separately worn, and no maximum daily or weekly wear time was set. Wear time was verified with subject maintained daily wear logs.

1 wk shoe adaptation		1 wk orthotic adaptation		3 wk orthotic adaptation

Time 0	**Time 1**	**Time 2**	**Time 3**
Shoes distributed	Shoe data Orthotics added Shoe/orthotic data	Shoe/orthotic data	Shoe/orthotic data

Fig. 5.1: Study time line

5.3.5 Equipment Setup and Data Collection

Walking data (1.2m/s ±10%) was identically collected (12 trials per condition) for each subject and condition according to the study schedule. The elapsed time between the infra-red start and stop beams was 1.43 – 1.74s. Any trial outside the designated time was immediately discarded.

Cameras, camera calibration, marker placement and subject alignment were arranged and performed as outlined in Chapter 4. Subjects wore individual calcaneal molds with attached marker triad (Chapter 3).

Subjects were permitted practice trials to determine a natural take-off point, that permitted striking the force platform center with the right foot while walking at the correct speed. Take-off point was a minimum of five steps from the platform center.

5.3.6 Shoe Wear

Shoe wear was checked following each data session. An adjustable metal frame (Fig. 5.2) was set parallel the table surface and the alignment was verified with a digital level (SMARTTOOL™, Macklanburg-Duncan, Oklahoma City, OK). During the first data collection session, two marks were placed on the midsole inner surface under the shoe insole aligned medial to lateral across the heel. Mark spacing was identical to the adjustable frame arm width.

To test shoe wear, the shoe was placed on the table surface and the frame with digital level was aligned vertically over the marks and shoe angle was recorded. The frame was removed and reset for each of the ten individual measurements. Data were then averaged to obtain mean angular change.

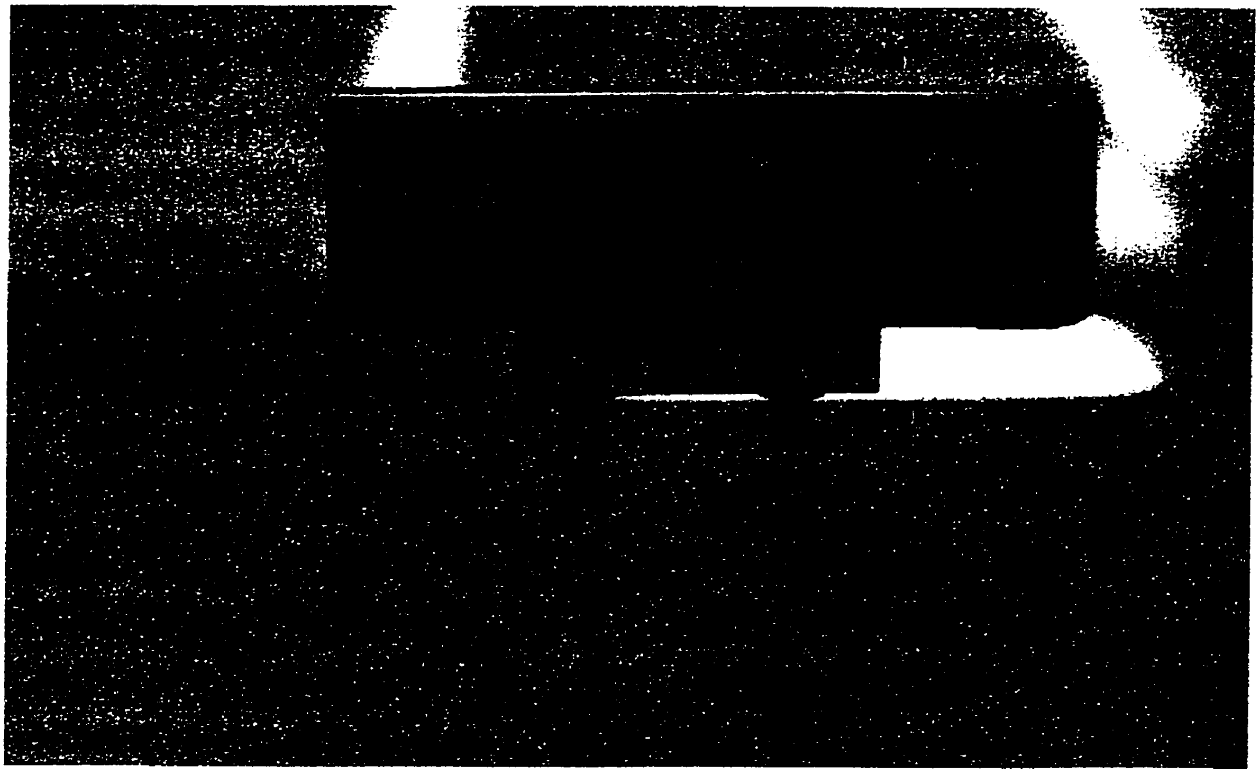

Fig. 5.2: SMARTTOOL on adjustable measuring frame.

5.3.7 Data Analysis

Trials were tracked with EVA software, while filtering and calculation of variables was completed with Kintrak (Motion Analysis, Santa Rosa, CA). Kinetic data were used to normalize trials with time from heel-strike (HS) to toe-off (TO) set to 100%. Fourteen dependent variables were calculated:

1) **CEMX20** – maximal calcaneal eversion during first 20% of stance.
2) **CEMX80** – maximal calcaneal eversion during first 80% of stance.
3) **CROM20** - range of calcaneal movement from heel-strike (HS) position to maximally everted position during first 20% of stance. Expressed in positive degrees.

4) **CROM80** – range of calcaneal movement from maximal inverted position to maximal everted position during first 80% of stance. Expressed in positive degrees.
5) **CEVMX20TM** – maximal velocity of calcaneal eversion during first 20% stance.
6) **CEMX20TM** – time in % of stance when calcaneus is maximally everted during first 20% of stance.
7) **CEMX80TM** – time in % of stance when calcaneus is maximally everted during first 80% of stance.
8) **TIRMX20** – maximal tibial internal rotation during first 20% of stance.
9) **TIRMX80** – maximal tibial internal rotation during first 80% of stance.
10) **TROM20** – range of tibial motion from minimal position to maximal position (internal rotation) during first 20% of stance.
11) **TROM80** – range of tibial motion from minimal to maximal position during first 80% of stance.
12) **TIRVMX20** – maximal velocity of tibial internal rotation during first 20% of stance.
13) **TIRMX20TM** – time in % of stance when tibia is maximally internally rotated during first 20% of stance.
14) **TIRMX80TM** – time in % of stance when tibia is maximally internally rotated during first 80% of stance.

All values were rounded to one significant figure. Friedman's non-parametric ranking test was used to determine significance of orthotic effects over time for each dependent variable. A Friedman number of greater than 7.82 was necessary for significance at $p \leq 0.05$. For any variable with a significant Friedman test, the Wilcoxon test was used to analyze which contrast/s (T1C1/T1C2, T1C2/T2C2, T1C2/T3C2, or T2C2/T3C2) were significantly affected.

5.4 Results

Fifteen subjects were accepted for participation in this study. Final presented data are from eleven subjects only, seven males and four females. One female resigned due to scheduling conflicts, three others (two females and one male) were dropped due to video problems that rendered their data unusable. The males ranged in age from 18-54, while female ages ranged from 21-35. Female's weight ranged between 57-74 kg and males between 66–86 kg. Heights were between 165-171 cm for women and 169-188 cm for men. Subjects wore test shoes an average of 6 days/wk. for 10.2 hrs/day (Appendix D). One subject daily wear form was not returned and another was incomplete (subjects 3 and 13 respectively). They were not included in calculations to determine average daily wear. However, as verbal verification of their compliance with study methods was obtained, their kinematic data was included for analysis. One subject left the study on day 3 of the fourth week. The results from the final week of this subject were not included for shoe wear calculations, but were included for orthotic adaptation analysis.

The angle of the shoe heel section in the frontal plane, due to abrasion of the heel or permanent material deformation changed an average of only 0.6° over the length of the study (Appendix E). The highest change was only 1.3°. All shoes changed to a more inverted position. The Smarttool (SMARTTOOL, Macklanburg-Duncan, Oklahoma City, OK) measuring device used to measure the shoe heel angle, when tested with machinist's blocks was found to repeatably measure the block angle within 0.1°.

Subject kinematic curves (Appendix H) showed that at heel-strike, each subject's calcaneus was generally close to neutral position. Subjects immediately began everting and most reached near maximal eversion within the first 25% of stance. However, for many there was a step during the first 25% of stance in the eversion curve, during which subjects inverted prior to smoothly continuing eversion. Eversion generally slowly continued until 70% of stance following which rapid and constant inversion began through to toe-off. Tibial position was not nearly so consistent, as it exhibited several oscillations during midstance. Subjects were generally internally rotated at heel-strike and continued slow internal rotation through approximately 40% of stance. At which time, position stayed relatively constant until at approximately 70% external rotation began through to toe-off.

Several interesting patterns were found to exist in the changes of the subject kinematic variables over time. Data to identify the patterns of adaptation are taken from the subject gait curves in Appendix H and the graphs of quantified results in Appendix I. The graphs in Appendix I show increases and decreases in subject kinematic positional variables of a minimum of 1° and changes in velocity or timing of gait of at least 10% of the initial value measured walking in test shoes only. Graphs are not to scale and a straight line represents changes of less than 1° or 10%. In most graphs 4 distinct points can be seen. They represent in order: 1) walking in test shoes only at T1; 2) walking in test shoes with foot orthotics at T1; 3) walking in test shoes with foot orthotics at T2; 4) walking in test shoes with foot orthotics at T3.

Generally, if there was an initial kinematic effect at T1, it was not consistently present at T2. However, one week of stability in initial effects can be seen in subject 5 and 13, for example. The most often occurring initial result that was consistent through at least T2, was a finding of no initial effect. However, additional patterns were clear.

One pattern was that calcaneal and tibial effects could be discreet in some subjects. This pattern can be clearly seen in subjects 1 and 13. In subject 1 there were only slight effects both initially and over time of the foot orthotics on the kinematics of the calcaneus. However, tibial kinematics were affected both initially and over time. Conversely, subject 13 experienced more stability of kinematics in the tibia than with the calcaneus.

These same subjects also demonstrated a pattern experienced with some variables in other subjects. The pattern was that both initially and following one week of orthotic wear there were no kinematic changes of some variables caused by foot orthotic use. However, following one month of use, there was change.

The third pattern was an oscillation around the initial conditions of walking without foot orthotics. This pattern can be seen in tibial kinematics of subject 4 and calcaneal kinematic of subject 11. This pattern showed that a movement which results in either an increase or decrease of some variable was often counteracted the following week with a movement in the opposite direction. It is not known whether this pattern indefinitely continues or eventually results in stable adaptation. Actual quantified values with standard deviation for each dependent variable and subject are in Appendix J.

Of the fourteen dependent variables analyzed in this study only TIRMX20TM (time in % of stance when tibia is maximally internally rotated during first 20% of stance) was found to have significant effects (Friedman number > 7.82 at $p \leq 0.05$, Table 5.1). Calculations of the Friedman Number for each dependent variable and subject are in Appendix F.

CEMX 20	CEMX 80	CROM 20	CROM 80	CEVMX 20	CEMX 20TM	CEMX 80TM
2.97	2.67	4.09	2.81	4.20	4.09	4.42
TIRMX 20	**TIRMX 80**	**TROM 20**	**TROM 80**	**TIRVMX 20**	**TIRMX20 TM**	**TIRMX80 TM**
3.33	2.26	6.19	3.22	2.67	**10.66**	4.53

Table 5.1: Study variables with Friedman numbers.
Bolded values > 7.82 show significant consistent effects.

Of the four possible significant contrasts, only T1C2 with T3C2 was found to be significant (Table 5.2). Wilcoxon critical number < 11 at $p \leq 0.05$. Since the negative rank sum was significant it was determined that time of maximal internal rotation occurred consistently significantly earlier at T3 than at T1. Wilcoxon calculations are in Appendix G.

	T1C1/T1C2	T1C2/T2C2	T1C2/T3C2	T2C2/T3C2
Wilcoxon rank sum, negative	20	13	**10**	25
Wilcoxon rank sum, positive	46	42	56	41
Wilcoxon critical number	11	8	11	11

Table 5.2: Results of Wilcoxon Test.
Values lower than the Wilcoxon critical number represent significant changes and are **bolded**.

5.5 Discussion

5.5.1 Relevance

The purpose of this research was to determine whether kinematic effects of foot orthotic use were stable over time. It was hypothesized that the continuous kinematic effects of foot orthotics would not be consistent with the effects initially measured.

Foot orthotics are used medically for treatment of overuse injuries, many of which have serious effects on patient lifestyles. Anecdotal evidence has shown foot orthotics often provide relief, but researchers have been unable to reach consensus as to the mechanism by which foot orthotics function. By researching if orthotic effects are consistent over time, it is believed that not only additional information would be obtained about orthotic function, but insight might possibly be gained into why consensus has been unattainable. It was felt that the adaptation hypothesis by Cavanagh and Edington [7] was an important concept that might explain the difficulties. This idea had not been investigated previously.

With only one exception, orthotic effects were typically not consistent over time in this investigation. For many conditions, subjects' kinematics exhibited an oscillation in effects, that centered around the values initially measured, walking without foot orthotics. For other subjects, it was observed that although no initial effects of orthotic use were evident, changes to gait were seen following extended use. Still other cases existed where orthotics had only very limited effects, following even prolonged continuous use.

It is proposed that human adaptation may be the reason for different effects over time and also the reason for different effects among similar individuals. It is felt possible, even likely that some individuals more readily permit their bodies to accommodate to a new environment (foot orthotics) and that the methods of accommodation may differ between individuals. Further, it is believed that the pattern of oscillations may indicate adaptation is a learned response to a new environment and many variations may be necessary before a final solution is determined.

The importance of these findings are: 1) they show that the initial and permanent effects of an orthotic intervention may not be the same; 2) they provide and explanation for why researchers have had difficulty reaching consensus; 3) they indicate that it may not be possible to explain orthotic function with data collected only during initial use.

Only one kinematic change related to foot orthotic use was consistent enough across subjects to achieve statistical significance ($p \leq 0.05$). The change was that TIRMX20TM (time of maximal tibial internal rotation during first 20% of stance) was found to occur significantly earlier when compared with initial kinematics. This supports earlier results of Nawoczenski et al. [48] and indicates that humans may not adapt to foot orthotic intervention as we would intuitively expect. In other words, it is reasonable to expect foot orthotics to alter foot function since they interface directly with the foot to change the topography immediately under the foot. However, it appears humans may most consistently adapt to this alteration with tibial changes rather than calcaneal changes. Perhaps, the consistency of tibial function is more important than consistency of foot function to the quality of our locomotion.

5.5.2 Limitations and Strengths

5.5.2.1 Neutral Position Control

To conduct a study on effects of adaptation it was necessary to obtain repeated measures of kinematic variables. To obtain repeatable measures it was necessary to repeatably set the neutral position. It was known that variability of neutral position would impact data accuracy. Neutral variability could negatively or positively shift data or cause crosstalk between different movements. A method to manually set neutral was developed with conceptual ideas from the ISB standardization proposal [2].

A pilot study was conducted to determine repeatability of position around the long axes of the calcaneus and tibia. It was determined the mean calcaneal variability was 2.7° with a maximum of 5.5°. Standard error was a maximum of 2.3°, but typically was below 1.0°. Mean tibial variability was 4.3°, with a maximum of 6.7°. Standard error was a maximum of 2.0° and averaged 1.4°. It was also determined that missing permanent alignment marks did not negatively impact results.

No previous studies were found that determined normal variability of uncontrolled neutral position, but it was felt that subjects' position would be at least as variable if no controls were used. However, even if variability was found to be equal, the devised system still benefited by making intra-subject data more meaningful and by minimizing crosstalk by anatomically aligning subjects parallel the lab coordinate system. Still, in order for orthotic effects to be significant, it was necessary they be greater than 2.0° at the calcaneus and 4.3° at the tibia due to random errors in neutral position setting.

5.5.2.2 Calcaneal mold

A previous study demonstrated that external shoe markers did not provide accurate data when compared to bone pins[55]. Polinsky[54] designed a method (calcaneal mold) to obtain in-shoe calcaneal motion without the use of shoe markers. It had been favorably tested, but for 2D studies only.

For this study it was modified for 3D use and tested against skin markers during barefoot walking. Results showed that in/eversion and tibial rotation curves were similar between conditions. Moreover, skin marker data showed greater maximal segmental position when compared with the calcaneal mold. Reinschmidt[56] similarly found external shoe markers over-represented motion when compared to bone pins. The mold, therefore, exhibited characteristics similar to those of bone pins and was deemed acceptable for this study. However, final study data curves exhibited a possible artifact in early stance that may actually be attributable to the calcaneal mold.

5.5.2.3 Curve Shape

Subjects' in/eversion curves were similar to typical descriptions in that the foot was inverted at HS and proceeded to evert during midstance. However, for some subjects there was a reinversion peak during the first 20% of stance, prior to smoothly everting into midstance (Appendix H). At times, this reinversion peak was greater in magnitude than HS inversion. Maximal eversion was typically attained during midstance between 40 and 60% of normalized stance. However, some subjects delayed to 70% or peaked as early as 20%. Calcaneal ROM was generally between 5-10%.

At heel-strike on the tibial internal/external rotation curve the tibia was typically externally rotated and internal rotation began immediately. However, in this study, especially for those subjects with an early reinversion peak there is a coincident out-of-phase tibial internal rotation peak. This indicates the tibia continued to internally rotate despite the fact that the calcaneus was inverting. At present this motion cannot be explained. Since this motion is evident in more than 50% of subjects it is possible the data is correct. Certainly although it was anticipated the use of a different neutral position would affect data magnitudes, no hypothesis is apparent to explain how neutral position could introduce new movements into the calcaneal curve. Therefore, if the data is incorrect in early stance the calcaneal mold may be a more likely cause of the problem.

In barefoot walking trials from the mold validation study the movement into eversion lacks the reinversion motion. It is possible there was interference between the shoes and the mold, although mold modifications were made if the subjects felt there was a fit or binding problem. However, the test shoes did snugly fit the Achilles tendon area where the mold cleared the shoe proximal posterior. During heel-strike and early stance when calcaneal velocity was greatest the shoe may have influenced mold movement. Interestingly, overall ROM, velocity and timing of maximal eversion appear to have been unaffected.

5.5.3 Comparisons with Other Research

Although there has not been strong consistent agreement among researchers as to the mechanism of orthotic function, some significant effects have been reported. It has been proposed that excessive pronation is detrimental to health: it reduces shock absorption; causes excessive internal tibial rotation or malalignment; overworks muscles required for ambulating. Some researchers discovered that foot orthotics decrease both maximal angle of eversion [5;31;53], while others found tibial internal rotation decreased [12;22].

Bates et al. [5] and others found that foot orthotics decreased maximal pronation [31;53]. However, a difference between the 1979 study of Bates et al. [5] and this current one is the use of injured subjects. Six runners with a history of injuries that caused them to be treated with foot orthotics were used as subjects. The use of injured subjects is thought to add a confounder to data interpretation. Since foot orthotics are often prescribed for injury treatment, it is possible the measured change in kinematics were caused by a reduction in pain rather than by the mechanical realignment effects of foot orthotics. It has been proposed and is currently being investigated in this lab, that foot orthotics may function by affecting sensory feedback or plantar pressure rather than by affecting anatomic alignment. Still there is an important outcome from Bates' et al. study. They discovered that in the case of their research, shoes affected kinematics more when compared to barefoot walking than the addition of foot orthotics to shoes. The implication is that to fairly assess foot orthotic effects, all subjects must use the same shoes. This finding was used to help set methods for this current study, in which all subjects were supplied identical test shoes as well as identically posted foot orthotics.

The other two mentioned studies both used injury free subjects, as did this study. However, Johanson et al. [31] collected only 2D data. Problems with 2D collection have already been described. Additionally the posterior heel counter was removed entirely with unknown effects on kinematics. Novick [53] collected 3D data, but placed markers to define the tibial segment on the malleoli and femoral condyles. However, the femoral condyles are not a part of the anatomic tibial segment and their movement is different from the tibia, therefore results that use tibial position as part of the calculation may not accurately reflect actual position.

A common thought among orthotic researchers is that reduction of tibial internal rotation by foot orthotics may be responsible for reduction of knee pain reported by some runners. This study found no significant magnitude effect either initially or over time. This differs with results of other recent studies [12;22]. In the case of Cornwall and McPoil [12] only two subjects were examined, however both did experience a reduction of tibial angle. In both subjects the effects of shoes were greater than the effects of orthotics in shoes and one subject complained of arch pain caused by the orthotics. Since tibial internal rotation is linked with eversion and eversion lowers the arch, it is possible the reduction of internal rotation was caused by the subject maintaining a higher arch to avoid pain during gait.

In the latter study tibial internal rotation was found to be significantly less with a reduction of only 0.8°. This finding highlights an important limitation of this current study, especially with regards maximal angular data over time.

In this study neutral position around the tibial long axis was found to vary as much as 6.7° with a mean of 4.3°. Therefore, over time a significant shift of only 0.8° would be completely hidden by the random data shift caused by variability of neutral position. This shift makes it impossible to find significant consistent effects of maximal angular positions over time unless they are very large. Typical reductions caused by foot orthotics have been measured at only a few degrees. Unless it is possible to refine the neutral positioning method to greatly improve repeatability it will never be possible to find significant effects of angular changes less than 4.3°.

When calcaneal and tibial ROM were studied several interesting results were reported. It had been noted that motions at the subtalar joint and tibial rotation are linked, reportedly at a 1:1 ratio. Yet Nawoczenski [48] reported the effects of orthotics may be related to changes in tibial axial rotation only. Further it was reported that effects were strongest in early gait. If the link between STJ position and tibial rotation is as strong as previously identified, it is reasonable to expect orthotics could not affect the tibia without equally affecting the STJ. The answer may lie in research that found the talus may rotate in the transverse plane inside the ankle mortise [63]. Therefore, it is possible for the tibia to rotate a limited amount without eliciting equal STJ motion. The implications are that although foot orthotics apply positioning forces to the foot it is possible for those forces to cause unequal or different effects at the tibia.

Eng et al. [22] reported decreases in tibial and calcaneal ROM, similarly the effects were early in gait but well prior to the 50% mentioned by Nawoczenski. Eng [22] and Nawoczenski [48] both used subjects with an injury history, so again it is possible the injury altered orthotic effects. Additionally it is possible the individual methods of this current study impacted data. Although within reason neutral position should not affect ROM, it is conceivable the calcaneal mold did. Although results in this current study were not significant, a similar pattern to Eng [22] and Nawoczenski's [48] is evident for many subjects. While ROM is reduced in early stance, by late stance it is equivalent or even greater when the non-orthotic and orthotic conditions are compared. From the current understanding of the function of pronation these results seem reasonable.

Pronation is thought to reduce forces transmitted through the body at heel-strike and to assist the foot with alignment on uneven terrain. Excessive pronators are thought to pronate rapidly to the end of STJ ROM and remain there. If orthotics function to decrease ROM in early stance, then pronation is slowed and there is more time to absorb impact forces. Finally if the overall effect is to increase ROM over total time of stance, joint functionality would also improve. However, although the pattern exists in this study it is to random to be significant.

In this study velocity around the respective long axes of each segment ranged between 27 and 157 deg./s for the calcaneus and between 51 and 254 deg./s for the tibia. Calcaneal velocity averaged around $80^{o}/s$ while the tibia was somewhat faster. Both are within the range of common reporting [6;12;53;67]. No velocity changes were significant.

Only Novick [53] reported a significant decrease in calcaneal angular velocity. Others reported either a non-significant decrease or random effect. Only Cornwall and McPoil[12] reported on the transverse tibial velocity. They found a decrease, but with only two subjects studied results cannot be conclusive.

Unlike other variables in this study a significant timing effect was determined for TIRMX20TM. No other timing variables were affected similarly. TIRMX20TM was found to occur significantly earlier ($p \leq 0.05$) when the T3 orthotic condition was compared to the T1 orthotic condition. When compared to the T2 orthotic condition the change was not significant. Therefore, a change occurred between T1 and T2 that acted to reduce effects later in the month. This change without accompanying calcaneal change is in agreement with Nawoczenski et al. [48] findings that foot orthotic effects seem to be limited to the tibia.

5.6 Conclusion

The purpose of this study was to determine if foot orthotic kinematic effects were consistent during one month of adaptation by highly pronated subjects. Analysis of the data showed that only one test condition (time of maximal tibial internal rotation during the first 20% of stance) had any significant change during the study period. It in fact occurred significantly earlier in stance following one month of adaptation. Other variables did not have significant changes and most typically were seen to oscillate around the values initially measured during gait without foot orthotics. Overall, foot orthotic effects were not consistent throughout the study.

6.0 Summary and Recommendations

In this thesis a new definition and method of setting neutral position for foot and lower extremity research was proposed. It was based on the ISB standardization proposal, but unlike the proposal a controlled and defined position of the subtalar joint was included. Further, this position could be manually set, rather than accomplished by software manipulation only. This method therefore, is functional in all clinical settings.

Also a new method of obtaining actual 3D in-shoe calcaneal motion was presented. It benefited from direct attachment to the calcaneus, unlike the regularly used method of attaching markers to the external shoe surface. It, therefore, directly measured calcaneal motion, rather than measuring shoe motion. Data from this study showed that during barefoot walking the calcaneal mold returned data similar to bone pins.

It was also determined that, unlike past assumptions, human gait kinematics were not stable over a one-month period of adaptation to foot orthotics. Rather, they typically showed repeated oscillations. This data was felt to be important as it showed human adaptation may affect research results and that current research methods may not be adequate to answer regularly researched questions.

Results of this study demonstrate: if the goal of an experiment is to explain the effects on human gait of foot orthotic intervention, analysis of only initial use data may not provide accurate or meaningful information. Further, it is felt reasonable that this conclusion is equally applicable to kinematics and interventions of any human or animal body segment. However, several important questions remain unanswered and unexamined:

1) What is the normal variability of human gait over time without foot orthotic intervention?
2) When orthotic interventions are used, will foot kinematics eventually stabilize, or rather do they regularly oscillate around a set point?
3) If stabilization takes place, how long does it take?
4) If stabilization is never reached, will the oscillation of kinematics take place around a set point of values from gait with or without orthotic intervention?
5) Do symptomatic and non-symptomatic subjects react identically?
6) How did the use of the calcaneal mold affect the results?

To answer these questions the following future studies are recommended:

1) A long term study to quantify the variability of human gait.
2) Longer-term study of human adaptation to foot orthotics. This study would consist of two test groups, symptomatic and non-symptomatic subjects. Both subjects would conform to the same orthotic wear schedule from this current study but for a longer time period.
3) A study to further test functionality of the calcaneal mold for in-shoe studies.

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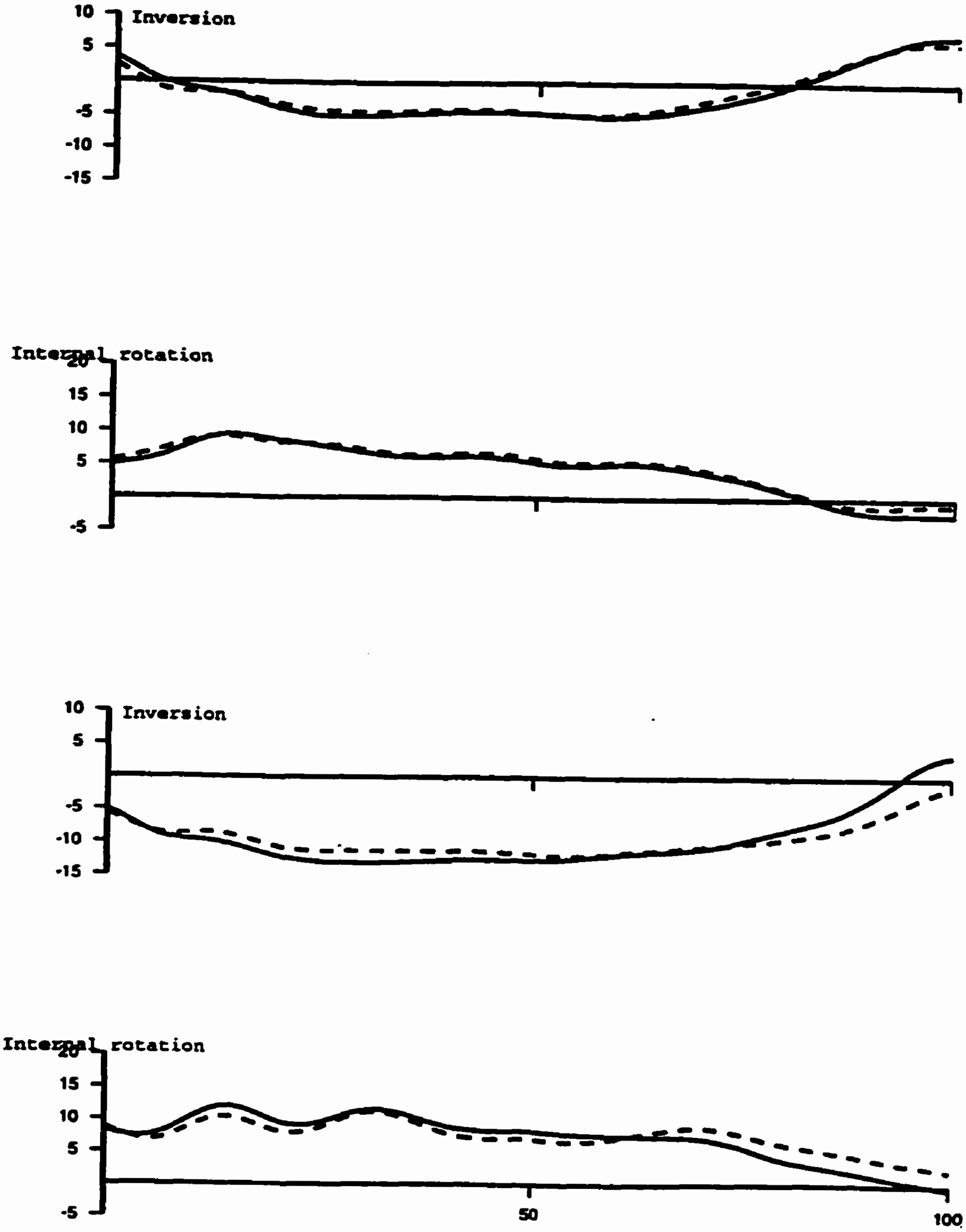
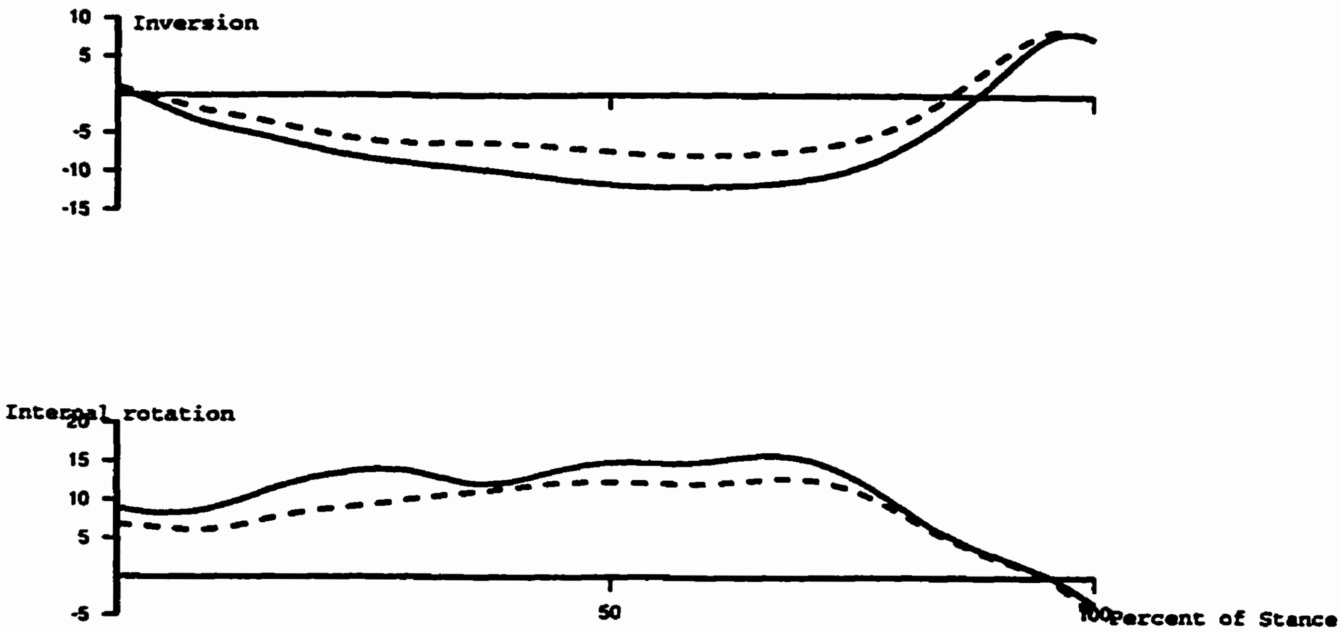
Appendix A



Subject gait curves comparing skin markers with the calcaneal mold.
Skin markers —— Calcaneal mold - - - -
Top two graphs are subject 2. Bottom two graphs are subject 3. Curves are normalized from HS to TO.

Appendix A



Subject gait curves comparing skin markers with the calcaneal mold.
Skin markers —— Calcaneal mold - - - -
Graphs are of subject 4. Curves are normalized from HS to TO.

Appendix B

Consent Form

Research Project Title: Are the kinetic and kinematic changes to gait caused by foot orthotic use in a pronated population permanent, or mitigated during a one-month period of adaptation.

Investigators: Louis B. Rosenfeld
Daryl Caswell, Ph.D
Janet Ronsky, Ph.D.
Preston Wiley, M.D.

This consent form, a copy of which has been given to you, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this form carefully and to understand any accompanying information.

Purpose of research: Some medical practitioners have stated that many overuse injuries of the lower extremities are caused by excessive foot pronation. One definition of a pronated foot position is one in which the calcaneus (heel bone) is not vertically aligned with the tibia (lower leg shaft bone) during normal stance. The calcaneus is instead rolled outward, which may give the appearance the subject is walking on the inside of their foot, or that they have a low arch. It should be noted there is no exact medical definition of excess pronation, so often the physician is simply noting individual distinctive tendencies in gait or foot position which are thought to contribute to injury. Excess pronation is considered to be present when a patient rolls inward, to a degree that the position of the calcaneus may be related to patient symptoms. Custom semi-rigid foot orthotics are used commonly to treat injuries thought to be caused by excess pronation.

Some researchers have indicated that foot orthotics may reduce the amount and speed of pronation. Based on these results it has been proposed that foot orthotics are effective treatments for injury due to their effect on pronation. Unfortunately, other researchers have not been able to repeat these findings. Also, no research has been conducted to prove the effects of orthotics on gait and pronation are permanent.

The purpose of the research in which you are volunteering is to determine if orthotic effects are permanent or reduced over time by your own adaptation during normal wear. The results will contribute to the body of knowledge about foot orthotic function and may also provide new information concerning adaptation.

In order for this research to have clinical significance it is necessary that all subjects have a naturally pronated foot position during walking, and not currently have any injuries or symptoms which could be related to excess pronation. You have been chosen because you volunteered for this research and met the previously mentioned criteria.

Experimental procedures

~~You will be examined~~ by a Sport Medicine Physician from the University of Calgary. The physician will take a basic medical and lower extremity injury history and examine your legs for range of motion and anatomic alignment of the knee and ankle joints. A copy of the form he will complete is included with this letter.

Ecco test shoes will be ordered in your size and foot orthotics, from a digital foot image will be manufactured by Colman Prosthetics and Orthotics. All orthotics will be identically posted 4° medial rearfoot + 2° medial forefoot. This posting was selected as it is not unusually large for someone with the required minimum angle of eversion of people in this study, but is anticipated to be large enough to force visible changes to gait.

The study's time line is included with this consent form. During the six weeks of study you are required to wear the shoes and orthotics as a unit, eight hrs/day, six days/week. Neither the foot orthotics or test shoes may be worn separately during the study period.

During data collection, video and force platform information of your gait will be obtained at your normal walking speed. You will be asked to wear shorts so that your lower leg is visible to the knee. Nine reflective foam markers, 1cm in diameter will be attached to your lower right leg and ankle with double-sided tape or medical adhesive. Their purpose is to enhance visible motion details in the camera system. Approximately ten walking trials in each study condition will be collected, during which you will walk between an array of digital cameras and over a force platform. The walking path is flat and free of obstacles.

At no time during research will you be asked or expected to perform any movement other than walking. Nor will you be asked to perform any movement that you may consider dangerous. The principal researchers name and telephone have been included with this consent form and he can be contacted at any time if you feel it necessary.

Your rights and confidentiality
Your participation is voluntary and you are under no obligation to complete this study. You may drop out at any time. Collected data will be identified with a number only and will not be linked to you in any way. The reference list to correlate subject with number will be maintained by the researcher, and will not be available to other researchers. At the study conclusion, all data will be stored with the principal researcher and graduate supervisor only and destroyed at the end of seven years. Standard ethical and legal requirements will be followed.

Cost and remuneration
Any costs related to this study will not be billed to participants, nor will you receive direct cash remuneration for your participation. However, the foot orthotics and test shoes will be yours to keep at the experiment's conclusion.

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation. If you have further questions concerning matter related to this research, please contact:

Louis B. Rosenfeld
(W) 220-8948
(H) 282-0008
e-mail lou@kin.ucalgary.ca

If you have any questions concerning the ethics review of this project, or the way you have been treated, you may also contact the Office of the Vice-President (Research) and ask for Karen McDermid, 220-3381. If you have concerns about the project itself, please contact the researcher.

Participant	Date

Investigator	Date

A copy of this consent form has been given to you to keep for your records and reference.

Appendix C

Subject Evaluation Form

Subject No.________ DOB________ Email________ Phone______________

Age________ Weight________ Height________ Sex________ Shoe size_____

1. Do you currently have any lower extremity pain, which affects your walking ability or gait? y n
2. Are you being treated currently for any injury that may affect your walking ability or gait? y n
3. Are you currently limiting <u>any</u> physical activity due to pain or injury? y n If yes, describe limitations:
4. Do you currently use foot orthotics? y n
5. Are you able to wear foot orthotics and the supplied test shoes for a minimum of five hours/day for 45 days during testing? y n

Examination

Supine Exam

Maximal inversion_______° Maximal eversion_______° ROM_______°

STJN palpation_______° STJN 1/3 ROM_______°

Forefoot varus/valgus_______°

Maximal ankle dorsiflexion (leg bent)_______° leg extended_______°

Maximal great toe dorsiflexion_______°

Standing Exam

Eversion relaxed calcaneal stance_______° Eversion relaxed calcaneal stance STJN_______°

Ev. relaxed calcaneus stance (ASIS)_____° Ev. relaxed calcaneal stance STJN (ASIS)_____°

Tibial varum/valgus (relaxed calcaneal stance)_______° Q angle_______°

ASIS width_______cm Cant_______°

Appendix D

Subj No.	Week 1							Week 2							Week 3							Week 4						
	1	2	3	4	5	6	7	1	2	3	4	5	6	7	1	2	3	4	5	6	7	1	2	3	4	5	6	7
1	8	10	11	10	9	12	10	12	10	11	13	11	13	11	10	8	13	9	12	9	13	23	8	8				
2	11	12	11	12	6	2	11	10	10	7	10	4	14	7	12	4		8	15	4			4		14	5	3	8
3	N	O	T		R	E	T	U	R	N	E	D																
4	8	8	13	5	8	8	10	9	9	8	10	5	6	9	6	9	9	9	9	9	13	9	9	8	11	9	6	6
5	14	6	10	12	12	17	12	11	6	8	12	13	15	12	14	14	12	2	16	16	16	16	16	10	2	2	16	14
6	9	12	9		9	14	17	14	8	9		17	10	10	13	5	7		11	12	9	16	13	9		12	9	13
7	7	9		9	11	10	9	10	10	3	11	8	9	13	12	13	13	13	12	12	7	7	9	5		9	9	11
9	8	14	14	14	14		10	10	10	11	10	16	9	10	11	11	8	8			8	8	16	15	15	14	8	8
11	10	10	16	14	11		13	10	10	10	10	9		9	11	10	10	10	7			9	10	10	9			
12	12	16	8	8	11	11	12	8		10	8	12	12	12	12	12		8	12	12	13	11	13		9	14	12	12
13	13	10		8	15	12	12	18	19	20	18	I	N	C	O	M	P	L	E	T	E							

Foot orthotic and test shoe daily use.
Values are rounded to nearest whole hour.

Appendix E

Subject	Mean T1	Mean T2	Mean T3	Range
1	1.37	1.39	0.69	0.7
2	4.84	4.26	4.35	0.6
3	2.05	1.57	1.32	0.7
4	0.85	1.45	1.43	0.6
5	1.68	1.74	1.02	0.7
6	0.3	0.56	0.53	0.5
7	3.57	3.2	2.27	1.3
9	0.21	0.32	0.08	0.24
11	2.39	2.01	2.26	0.38
12	1.02	1.23	1.54	0.52
13	1.75	1.61	1.77	0.16

Shoe angular change.

T1, 2 and 3 equal 1st, 2nd and 4th week of study. Values are the means of ten measurements to 0.01°. Shoe angle is measured as the slope from medial to lateral. A position of 0° represents a shoe with the inner medial/lateral heel surface parallel the floor. Positive values represent an inverted position and negative values represent an everted position. Range is the difference between the highest and lowest mean at T1, T2, or T3 for each subject.

Appendix F

CEMX20				
	T1C1	T1C2	T2C2	T3C2
Subject 1	1	2	3	4
2	1	2	4	3
3	3	4	2	1
4	3	4	2	1
5	3	4	1	2
6	1	2	3	4
7	1	2	4	3
9	2.5	2.5	1	4
11	3	4	1	2
12	1	2	3	4
13	3	4	2	1
	22.5	32.5	26	29
Friedman	Number	2.97		

CEMX80			
T1C1	T1C2	T2C2	T3C2
1	2	4	3
1	2	4	3
4	3	2	1
4	3	2	1
3	4	1	2
1	3	4	2
1	3	4	2
2	3	1	4
3	4	1	2
1	2	3	4
3	4	2	1
24	33	28	25
2.67			

CROM20				
	T1C1	T1C2	T2C2	T3C2
Subject 1	2.5	1	2.5	4
2	1	2	4	3
3	2.5	4	2.5	1
4	3	2	4	1
5	2	4	3	1
6	3	4	2	1
7	1	2	3	4
9	3	2	1	4
11	1	2	4	3
12	2	1	4	3
13	1	2	4	3
	22	26	34	28
Friedman	Number	4.09		

CROM80			
T1C1	T1C2	T2C2	T3C2
1	2.5	4	2.5
1	2	4	3
4	2	3	1
4	2	1	3
3	4	2	1
3	4	2	1
4	3	2	1
3.5	3.5	1	2
2	3	4	1
2	1	4	3
1.5	1.5	4	3
29	28.5	31	21.5
2.81			

CEVMX20				
	T1C1	T1C2	T2C2	T3C2
Subject 1	1	2	3	4
2	1	2	4	3
3	3	4	1	2
4	3	2	4	1
5	1	4	3	2
6	2	3	4	1
7	3	1	2	4
9	3	2	1	4
11	2	1	4	3
12	3	1	4	2
13	1	2	4	3
	23	24	34	29
Friedman	Number	4.20		

CEMX20TM			
T1C1	T1C2	T2C2	T3C2
1	2	4	3
1	2	3	4
3	4	2	1
1	3	4	2
3	4	2	1
3	4	2	1
1	2	4	3
3	2	1	4
2	3	4	1
2	1	4	3
2	1	4	3
22	28	34	26
4.09			

CEMX80 TM				
	T1C1	T1C2	T2C2	T3C2
Subject 1	4	2	1	3
2	4	3	2	1
3	3	1	4	2
4	2	3	1	4
5	3	2	4	1
6	4	3	2	1
7	2	3	4	1
9	3	2	1	4
11	3	4	2	1
12	2	4	3	1
13	4	2	1	3
	34	29	25	22
Friedman	Number	4.42		

TIRMX80				
	T1C1	T1C2	T2C2	T3C2
Subject 1	3	4	2	1
2	1	2	4	3
3	2	3	4	1
4	3	2	4	1
5	3	4	2	1
6	2	1	3	4
7	3	4	1.5	1.5
9	2	3	4	1
11	3	2	4	1
12	2	3	1	4
13	3	1.5	1.5	4
	27	29.5	31	22.5
Friedman	Number	2.26		

TROM80				
	T1C1	T1C2	T2C2	T3C2
Subject 1	2.5	2.5	4	1
2	1	2	4	3
3	3	4	2	1
4	3	1	4	2
5	1	3	2	4
6	2	1	4	3
7	4	3	2	1
9	3	1	2	4
11	2.5	2.5	1	4
12	2	1	4	3
13	2	1	3	4
	26	22	32	30
Friedman Number		3.22		

TIRMX20			
T1C1	T1C2	T2C2	T3C2
3	4	2	1
3	4	2	1
3	2	4	1
3	2	4	1
3	4	2	1
3	1	2	4
3	4	1	2
2	3	4	1
3	2	4	1
2	3	1	4
3	1	2	4
31	30	28	21
3.33			

TROM20			
T1C1	T1C2	T2C2	T3C2
2	1	3	4
1	2	4	3
4	3	2	1
3	1	4	2
1	3	2	4
2.5	1	4	2.5
4	3	2	1
3	2	1	4
2.5	1	2.5	4
2	1	4	3
2	1	3	4
27	19	31.5	32.5
6.19			

TIRVMX20			
T1C1	T1C2	T2C2	T3C2
2	1	3	4
1	2	4	3
3	4	2	1
2	1	4	3
1	3	2	4
4	1	3	2
3	4	2	1
4	1	2	3
4	3	2	1
4	1	3	2
2	1	4	3
30	22	31	27
2.67			

TIRMX20 TM				
	T1C1	T1C2	T2C2	T3C2
Subject	1	2	4	3
2	1	2	4	3
3	2	4	1	3
4	4	2	3	1
5	1	2.5	2.5	4
6	2	1	3	4
7	1	2	4	3
9	2.5	1	2.5	4
11	1	2	4	3
12	1	2	3	4
13	1	4	2	3
	17.5	24.5	33	35
Friedman Number		10.7		

TIRMX80TM			
T1C1	T1C2	T2C2	T3C2
4	3	1	2
1	2	3	4
2	4	1	3
4	1	3	2
2	1	3	4
2	3	1	4
2	3	4	1
2	1	3	4
2	3	1	4
1	2	3	4
1	4	2	3
23	27	25	35
4.53			

Friedman Number calculation for each dependent variable.

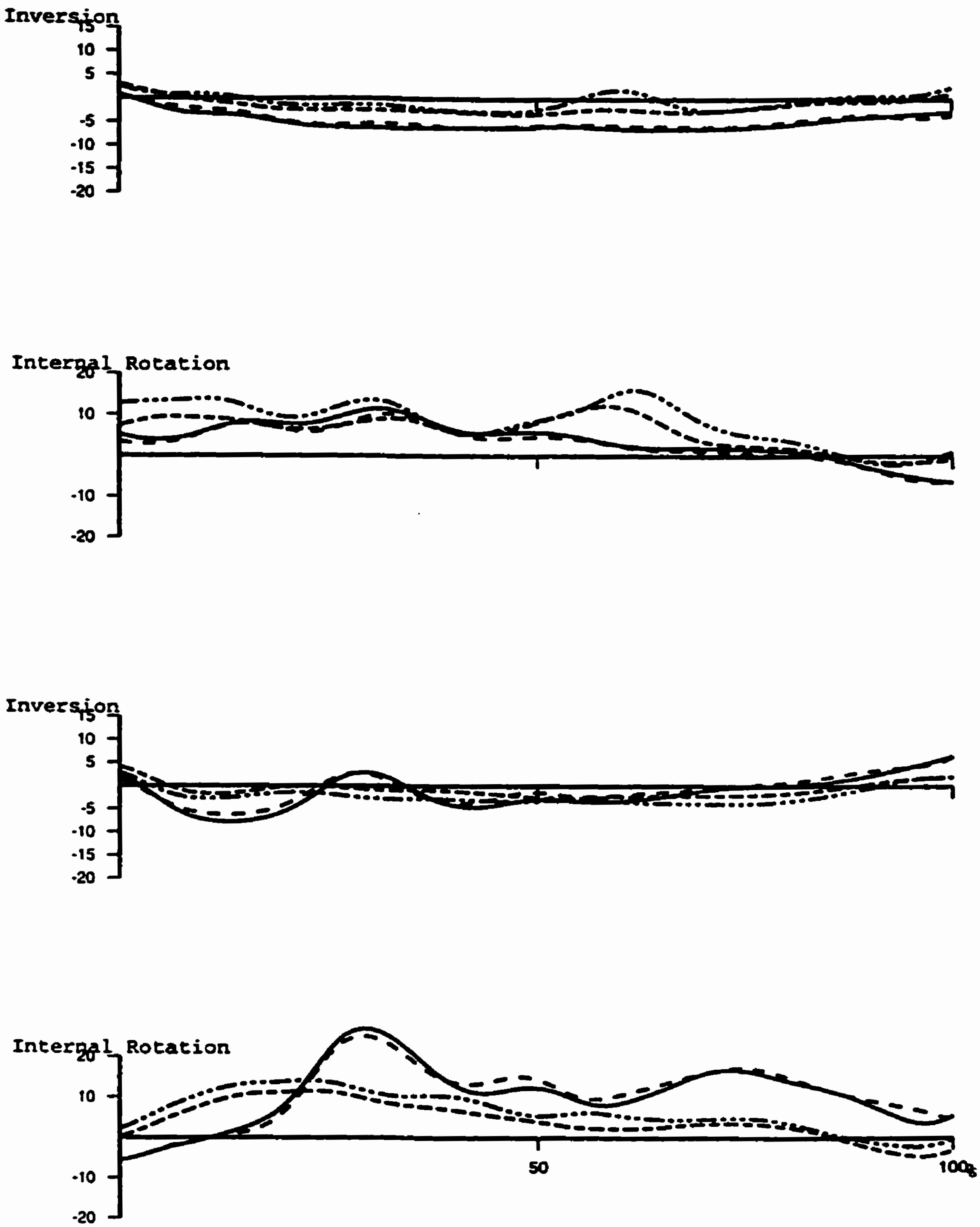
Appendix G

Subject No	T1C1	T1C2	T2C2	T3C2	T1C1/T1C2	T1C2/T2C2	T1C2/T3C2	T2C2/T3C2
1	16.6	15.6	7.0	8.5	1.0	8.6	7.1	-1.5
2	20.3	20.2	19.1	19.5	0.1	1.1	0.7	-0.4
3	17.0	14.9	18.7	16.5	2.1	-3.8	-1.6	2.2
4	17.1	20.3	19.9	20.4	-3.2	0.4	-0.1	-0.5
5	19.7	19.5	19.5	18.7	0.2	0.0	0.8	0.8
6	18.2	18.4	17.3	12.6	-0.2	1.1	5.8	4.7
7	19.1	19.0	14.3	17.4	0.1	4.7	1.6	-3.1
9	19.6	20.0	19.6	18.4	-0.4	0.4	1.6	1.2
11	16.9	14.4	10.5	11.3	2.5	3.9	3.1	-0.8
12	17.8	17.6	17.1	16.6	0.2	0.5	1.0	0.5
13	19.5	16.2	18.1	16.4	3.3	-1.9	-0.2	1.7

Rank of Differences	T1C1/T1C2	T1C2/T2C2	T1C2/T3C2	T2C2/T3C2
1	7	10	11	-7
2	1.5	4.5	3	-1
3	8	-7	-7	9
4	-10	1.5	-1	-2.5
5	4	0	4	4.5
6	-4	4.5	10	11
7	1.5	9	7	-10
9	-6	1.5	7	6
11	9	8	9	-4.5
12	4	3	5	2.5
13	11	-6	-2	8
	26	29	46	16
Rank sum negative	20	13	10	25
Rank sum positive	46	42	56	41
Wilcoxon critical no.	11	8	11	11

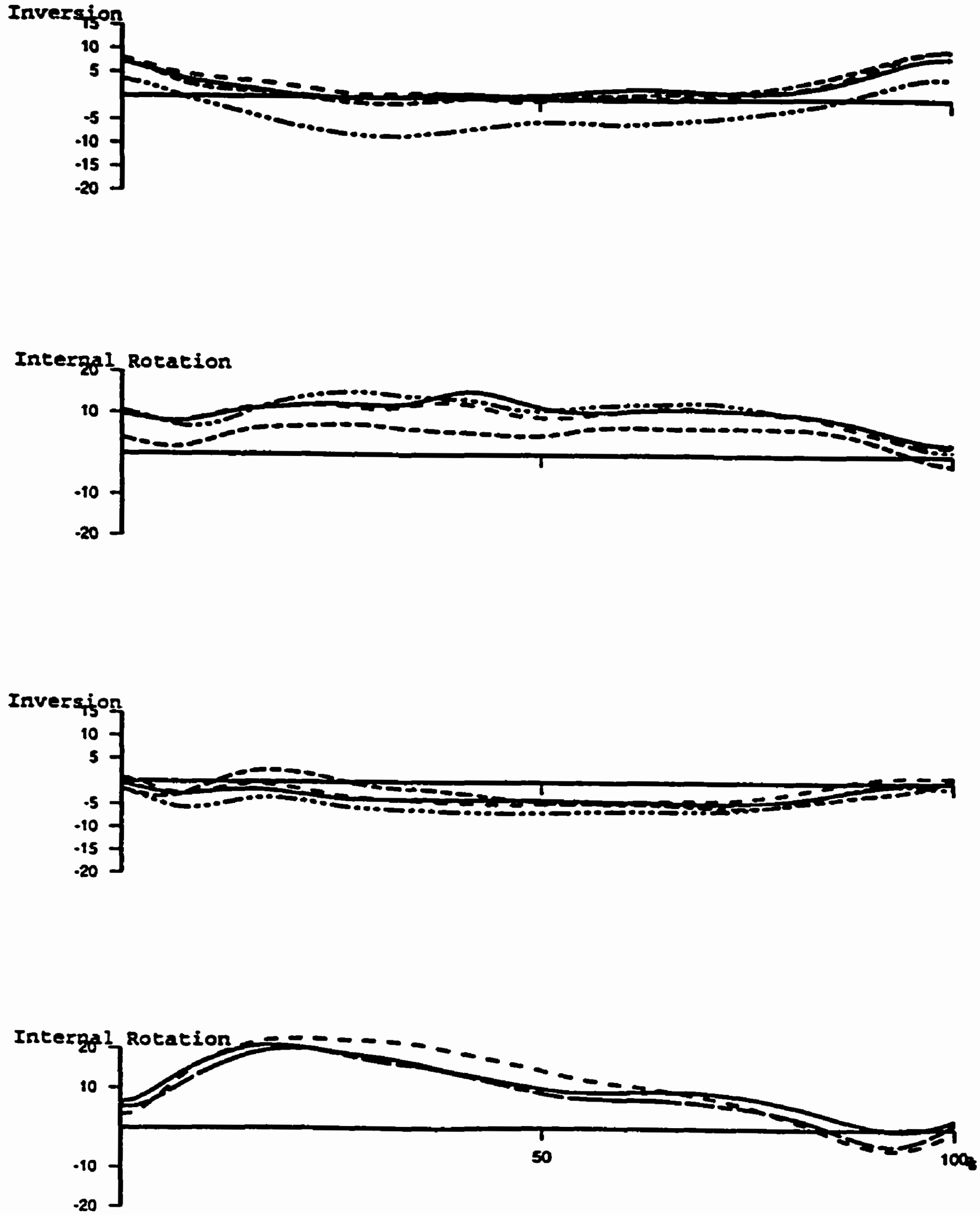
Calculation of Wilcoxon number.
Quantities in rank sum negative or positive, which are below the critical number indicate significant differences.

Appendix H



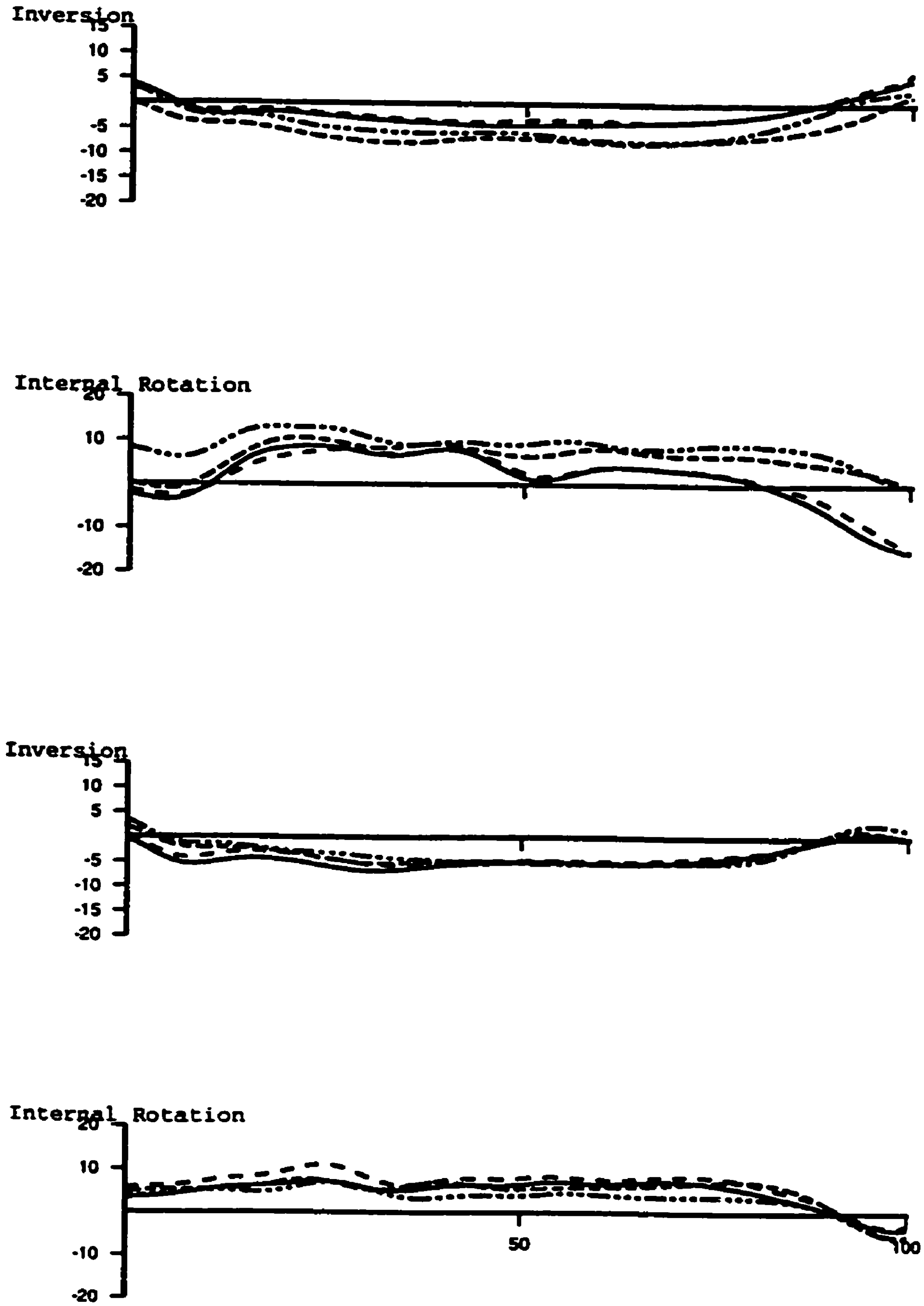
Subject gait curves from adaptation study, normalized from HS to TO.
Top 2 graphs are Subject 1. Bottom 2 graphs are subject 2.
—— Time 0 shoes, ----- Time 0 orthotics, ---- Time 1 orthotics
---- Time 2 orthotics

Appendix H



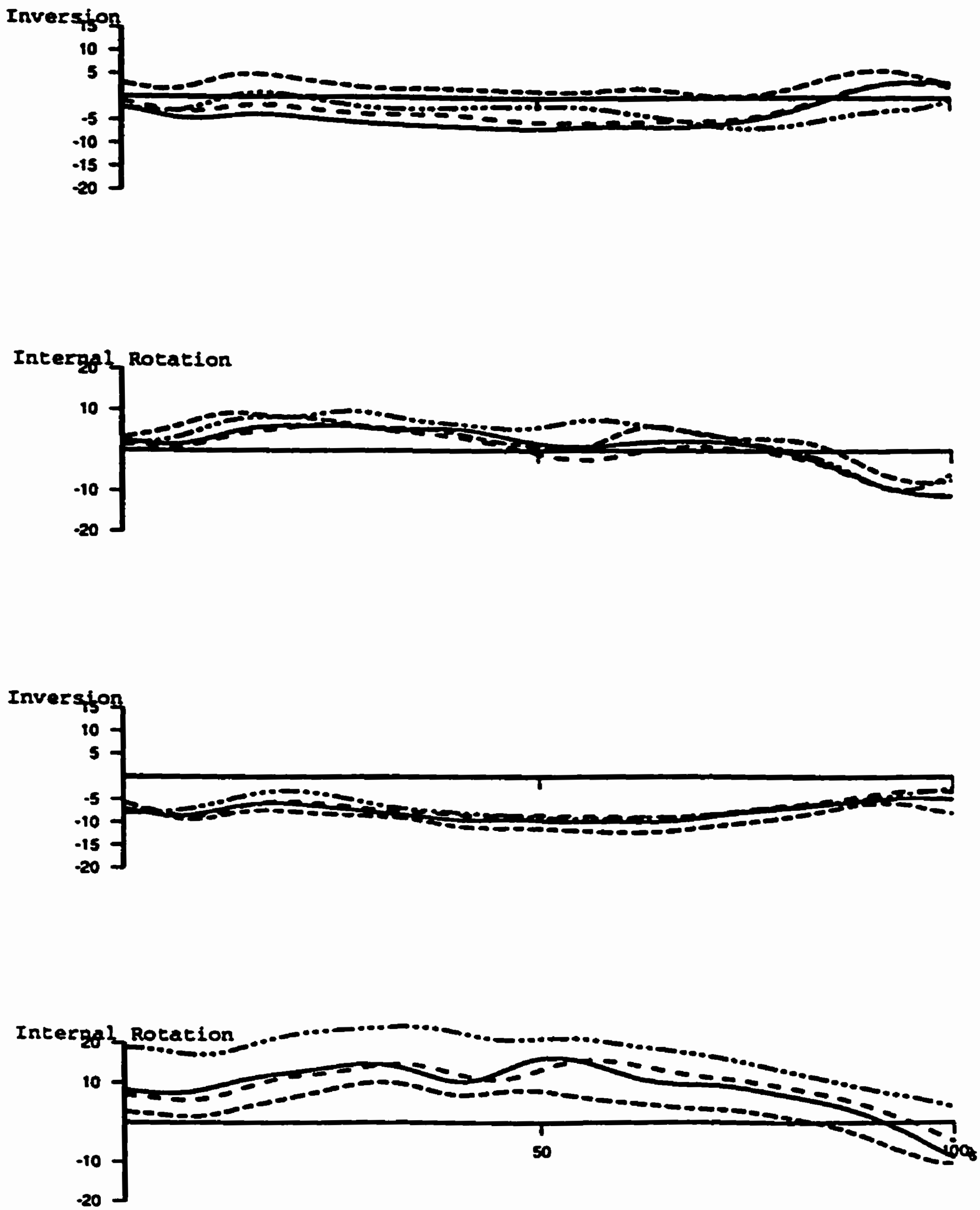
Subject gait curves from adaptation study, normalized from HS to TO.
Top 2 graphs are Subject 3. Bottom 2 graphs are subject 4.
—— Time 0 shoes, ----- Time 0 orthotics, - - - - Time 1 orthotics
- - - - Time 2 orthotics

Appendix H



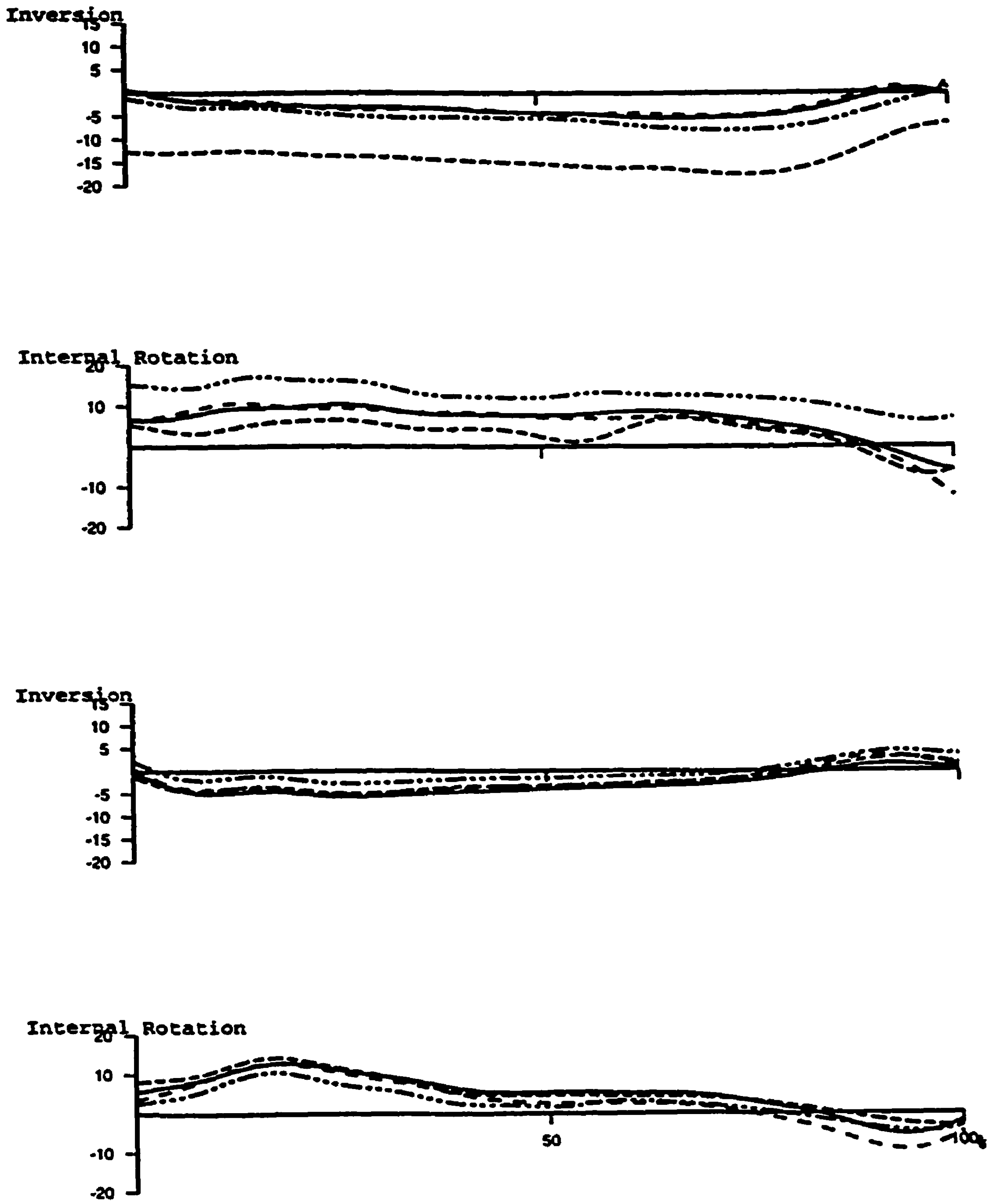
Subject gait curves from adaptation study, normalized from HS to TO.
Top 2 graphs are Subject 5. Bottom 2 graphs are subject 6.
—— Time 0 shoes, ----- Time 0 orthotics, - - - - Time 1 orthotics
- - · - Time 2 orthotics

Appendix H



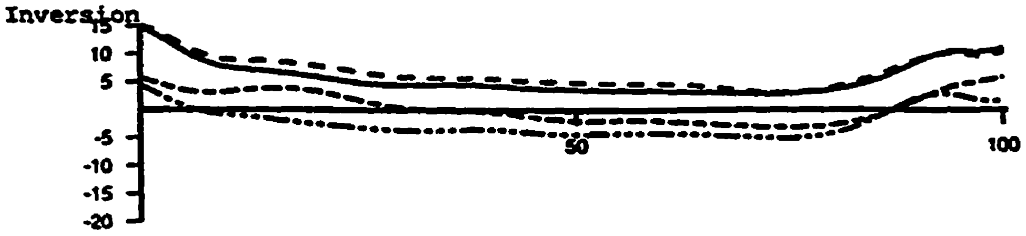
Subject gait curves from adaptation study, normalized from HS to TO.
Top 2 graphs are Subject 7. Bottom 2 graphs are subject 9.
—— Time 0 shoes, ----- Time 0 orthotics, ---- Time 1 orthotics
---- Time 2 orthotics

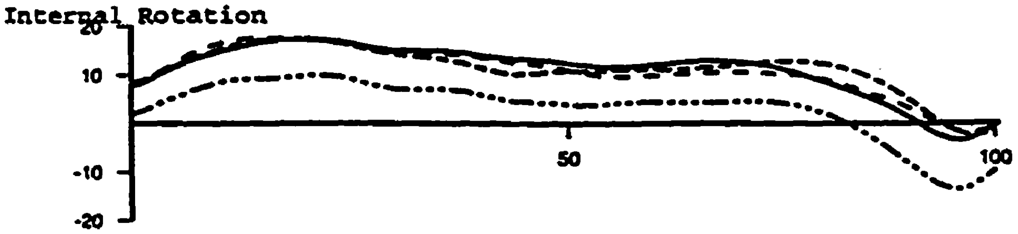
Appendix H



Subject gait curves from adaptation study, normalized from HS to TO.
Top 2 graphs are Subject 11. Bottom 2 graphs are subject 12.
—— Time 0 shoes, ---- Time 0 orthotics, - - - - Time 1 orthotics
- - - - Time 2 orthotics

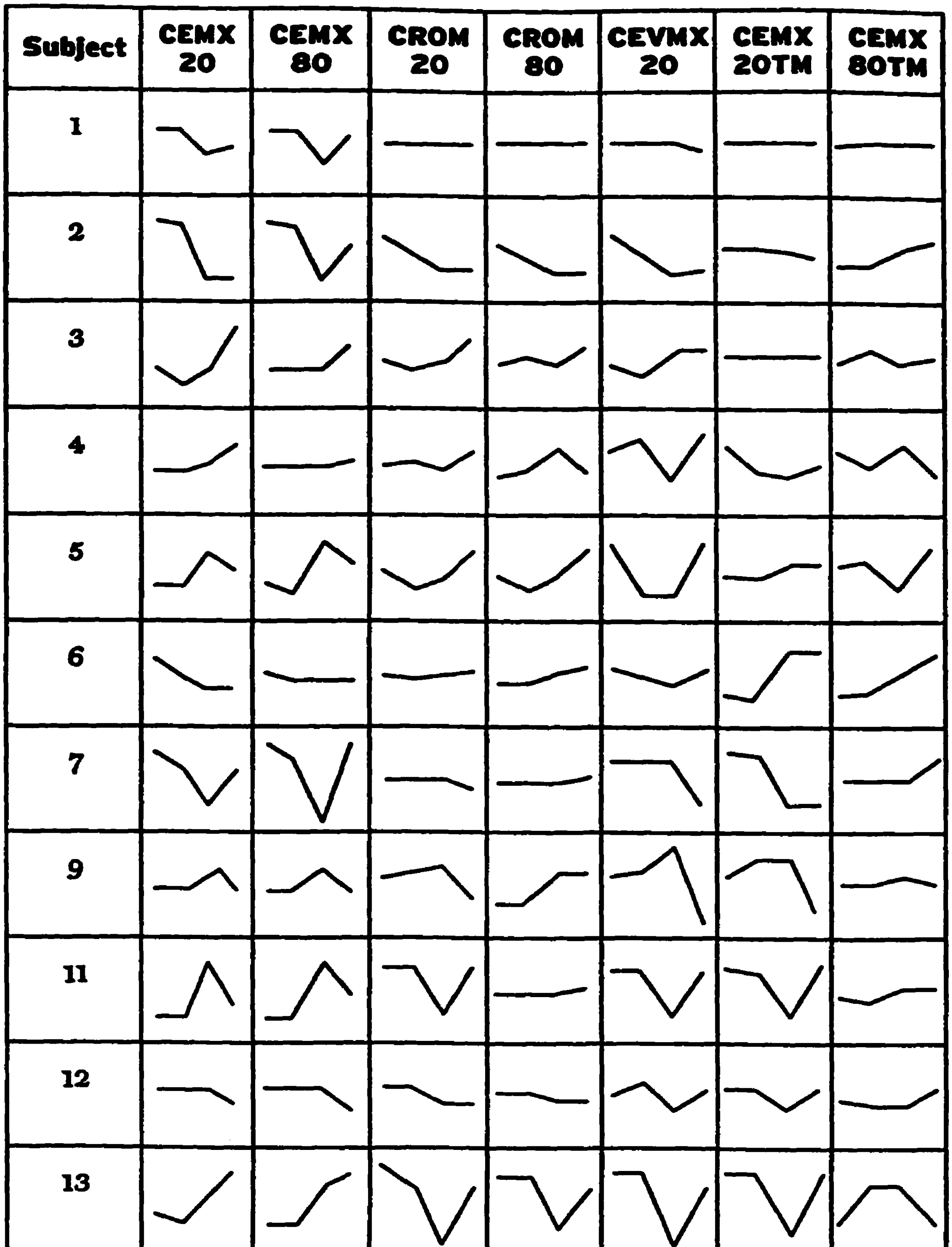
Appendix H





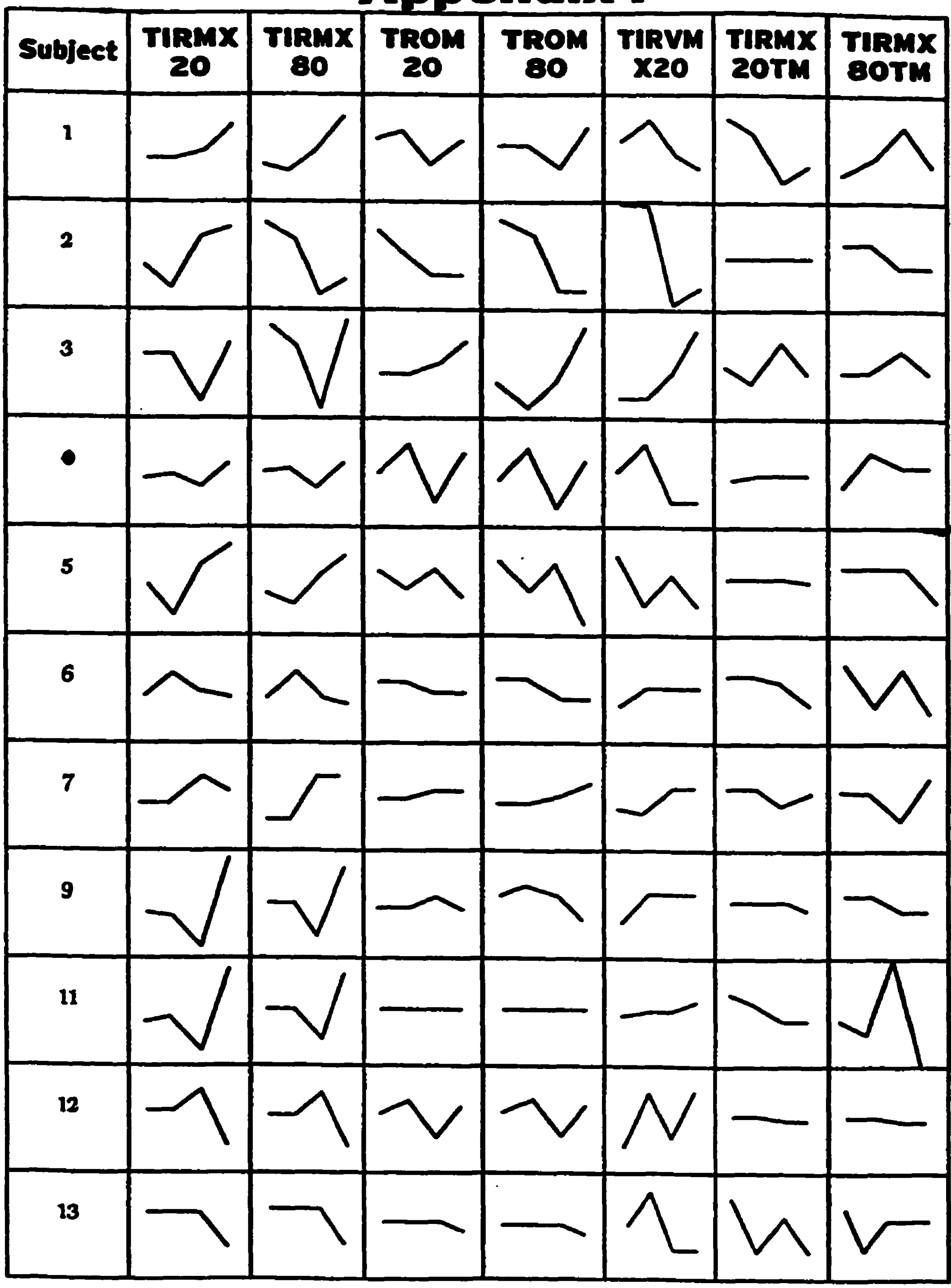
Subject gait curves from adaptation study, normalized from HS to TO.
Top 2 graphs are Subject 13.
—— Time 0 shoes, ----- Time 0 orthotics, ---- Time 1 orthotics
---- Time 2 orthotics

Appendix I



Changes in kinematic variables during one-month of adaptation to foot orthotics. Curve beginning – Time 0 test shoes only. Step 1 – Time 0 test shoes w/orthotics. Step 2 – Time 1 test shoes w/orthotics. Curve end – Time 3 test shoes w/orthotics. Straight line indicates no change ≥ 1 degree, or in the case of timing variables no change greater than 10% of initial value in test shoes only.

Appendix I



Changes in kinematic variables during one-month of adaptation to foot orthotics. Curve beginning – Time 0 test shoes only. Step 1 – Time 0 test shoes w/orthotics. Step 2 – Time 1 test shoes w/orthotics. Curve end – Time 3 test shoes w/orthotics. Straight line indicates no change ≥ 1 degree, or in the case of timing variables no change greater than 10% of initial value in test shoes only.

Appendix J

Subject 1	CEMX 20	CEMX 80	CROM 20	CROM 80	CEV MX20	CEMX 20TM	CEMX80 TM
T1C1	-5.0 *.3*	-7.0 *.3*	5.0 *.5*	7.5 *.4*	-70.0 *5.8*	20.0 *0.4*	43.0 *4.5*
T1C2	-5.0 *.3*	-6.5 *.2*	5.5 *.4*	7.0 *.5*	-67.0 *2.3*	20.0 *0.1*	46.0 *5.2*
T2C2	-2.0 *.3*	-3.5 *.3*	5.0 *.6*	6.5 *.3*	-65.0 *9.4*	19.0 *0.3*	47.0 *7.8*
T2C3	-1.0 *.2*	-5.5 *.3*	5.0 *.3*	7.0 *.8*	-59.0 *5.6*	20.0 *0.3*	45.0 *1.7*

Subject 1	TIR MX20	TIR MX80	TROM 20	TROM 80	TIRV MX20	TIR MX20TM	TIR MX80TM
T1C1	8.5 *.3*	11.5 *.6*	5.0 *.5*	8.0 *.6*	92.0 *18.8*	17.0 *.7*	28.0 *2.3*
T1C2	8.0 *.3*	10.5 *.7*	6.0 *.4*	8.0 *.8*	102.0 *6.7*	16.0 *.4*	33.0 *3.2*
T2C2	10.0 *.6*	13.0 *1.7*	4.0 *.3*	7.0 *1.6*	69.0 *14.1*	7.0 *1.5*	44.0 *8.8*
T2C3	14.5 *.5*	18.5 *1.8*	5.0 *.4*	9.0 *1.9*	51.0 *7.9*	9.0 *1.3*	34.0 *9.4*

Subject 2	CEMX 20	CEMX 80	CROM 20	CROM 80	CEV MX20	CEMX 20TM	CEMX80 TM
T1C1	-8.0 *.2*	-8.0 *.2*	10.0 *.3*	11.0 *.5*	-157.0 *5.6*	13.0 *0.3*	17.0 *3.3*
T1C2	-6.0 *.3*	-6.5 *.3*	7.5 *.6*	9.5 *.4*	-122.0 *6.7*	13.0 *0.4*	18.0 *4.8*
T2C2	-2.0 *.2*	-3.0 *.2*	5.5 *.2*	7.0 *.3*	-100.0 *7.9*	12.0 *0.3*	48.0 *6.4*
T2C3	-2.5 *.2*	-4.0 *.1*	5.5 *.3*	7.0 *.2*	-107.0 *3.3*	11.0 *0.3*	62.0 *5.4*

Subject 2	TIR MX20	TIR MX80	TROM 20	TROM 80	TIRV MX20	TIR MX20TM	TIR MX80TM
T1C1	8.5 *.7*	27.5 *1.0*	14.0 *.8*	33.0 *.9*	254.0 *20.2*	20.0 *.2*	29.0 *.4*
T1C2	6.5 *.7*	25.5 *.4*	12.5 *.8*	31.0 *.7*	254.0 *22.5*	20.0 *.1*	29.0 *.4*
T2C2	11.5 *.2*	11.5 *.3*	11.0 *.4*	11.5 *.5*	118.0 *6.1*	19.0 *.7*	21.0 *1.1*
T2C3	14.0 *.2*	14.0 *.2*	11.5 *.5*	12.0 *.5*	129.0 *5.2*	20.0 *.3*	20.0 *.3*

Quantified results with standard deviation in italics.

Appendix J

Subject 3	CEMX 20	CEMX 80	CROM 20	CROM 80	CEV MX20	CEMX 20TM	CEMX80 TM
T1C1	0.5 *.3*	-1.0 *.3*	6.5 *.3*	8.5 *.3*	-76.0 *2.8*	20.0 *.6*	35.0 *3.4*
T1C2	2.5 *.2*	-1.5 *.3*	5.5 *.3*	9.5 *.4*	-66.0 *5.5*	19.0 *.9*	50.0 *3.2*
T2C2	0.5 *.2*	-1.5 *.2*	6.5 *.3*	8.5 *.3*	-87.0 *5.5*	20.0 *.2*	32.0 *1.4*
T2C3	-5.5 *.3*	-9.0 *.3*	9.0 *.5*	12.5 *.5*	-84.0 *2.9*	20.0 *.2*	37.0 *3.0*

Subject 3	TIR MX20	TIR MX80	TROM 20	TROM 80	TIRV MX20	TIR MX20TM	TIR MX80TM
T1C1	12.0 *.5*	15.5 *.4*	4.0 *.4*	7.5 *.7*	72.0 *7.9*	17.0 *1.8*	39.0 *4.3*
T1C2	12.0 *.7*	14.5 *.6*	4.0 *.7*	6.5 *.6*	70.0 *8.3*	15.0 *2.3*	38.0 *3.7*
T2C2	7.0 *.5*	9.0 *.6*	5.5 *.4*	7.5 *.5*	85.0 *4.4*	19.0 *.5*	46.0 *6.0*
T2C3	13.5 *.5*	17.0 *.5*	7.0 *.6*	10.5 *.5*	107.0 *10.8*	17.0 *2.5*	38.0 *4.6*

Subject 4	CEMX 20	CEMX 80	CROM 20	CROM 80	CEV MX20	CEMX 20TM	CEMX80 TM
T1C1	-3.0 *.2*	-4.5 *.2*	2.5 *.2*	4.5 *.3*	-71.0 *5.8*	10.0 *1.6%*	57.0 *6.5*
T1C2	-2.5 *.1*	-5.0 *.1*	3.5 *.2*	6.0 *.2*	-84.0 *5.6*	8.0 *.3%*	47.0 *1.6*
T2C2	-3.5 *.2*	-5.5 *.3*	1.5 *.8*	8.5 *.5*	-59.0 *7.1*	7.0 *1.2%*	64.0 *2.6*
T2C3	-5.5 *.2*	-7.0 *.1*	4.0 *.2*	5.5 *.1*	-89.0 *5.0*	9.0 *.5%*	40.0 *5.6*

Subject 4	TIR MX20	TIR MX80	TROM 20	TROM 80	TIRV MX20	TIR MX20TM	TIR MX80TM
T1C1	21.5 *.5*	21.5 *.5*	16.0 *.9*	16.0 *.9*	222.0 *6.2*	17.0 *.5*	17.0 *.6*
T1C2	22.5 *.5*	23.0 *.5*	19.5 *.8*	19.5 *.8*	247.0 *8.5*	20.0 *.2*	23.0 *1.3*
T2C2	20.0 *.8*	20.5 *.7*	15.0 *1.3*	15.0 *1.2*	171.0 *11.3*	20.0 *.3*	21.0 *.7*
T2C3	23.5 *.4*	23.5 *.4*	17.5 *.5*	17.5 *.5*	171.0 *4.9*	20.0 *.1*	22.0 *.4*

Quantified results with standard deviation in italics.

Subject 5	CEMX 20	CEMX 80	CROM 20	CROM 80	CEV MX20	CEMX 20TM	CEMX80 TM
T1C1	-2.5 *.4*	-5.0 *.4*	6.5 *.5*	9.0 *.4*	-107.0 *7.4*	15.0 *1.3*	50.0 *1.9*
T1C2	-2.0 *.2*	-4.0 *.3*	5.5 *.3*	7.5 *.3*	-90.0 *4.3*	14.0 *1.3*	57.0 *3.9*
T2C2	-5.5 *.6*	-9.0 *.6*	6.0 *.6*	9.0 *.6*	-92.0 *4.7*	17.0 *1.7*	41.0 *4.5*
T2C3	-3.5 *.3*	-7.5 *.3*	7.0 *.4*	11.0 *.3*	-107.0 *5.0*	18.0 *1.1*	61.0 *3.1*

Subject 5	TIR MX20	TIR MX80	TROM 20	TROM 80	TIRV MX20	TIR MX20TM	TIR MX80TM
T1C1	8.5 *.8*	10.0 *.6*	12.0 *.8*	13.5 *.5*	192.0 *15.8*	20.0 *.3*	31.0 *2.7*
T1C2	6.5 *.6*	9.0 *.7*	9.0 *.4*	12.0 *.8*	144.0 *3.5*	20.0 *.3*	32.0 *2.6*
T2C2	10.5 *.9*	12.0 *.6*	11.5 *1.1*	13.0 *.9*	175.0 *11.1*	20.0 *.3*	31.0 *3.4*
T2C3	13.5 *.3*	14.0 *.4*	8.0 *.5*	8.0 *.6*	140.0 *7.2*	19.0 *.5*	21.0 *1.2*

Subject 6	CEMX 20	CEMX 80	CROM 20	CROM 80	CEV MX20	CEMX 20TM	CEMX80 TM
T1C1	-5.5 *.2*	-7.0 *.2*	5.0 *.3*	6.5 *.3*	-100.0 *4.6*	10.0 *.9*	32.0 *.5*
T1C2	-4.0 *.2*	-6.0 *.3*	4.5 *.2*	6.0 *.3*	-90.0 *3.7*	8.0 *.3*	38.0 *3.0*
T2C2	-3.0 *.2*	-6.0 *.2*	5.0 *.5*	8.0 *.6*	-82.0 *3.1*	18.0 *1.3*	49.0 *4.7*
T2C3	-3.0 *.1*	-5.5 *.3*	6.5 *.3*	9.5 *.3*	-103.0 *5.3*	19.0 *1.1*	58.0 *3.2*

Subject 6	TIR MX20	TIR MX80	TROM 20	TROM 80	TIRV MX20	TIR MX20TM	TIR MX80TM
T1C1	6.5 *.5*	8.5 *.4*	3.5 *.3*	5.5 *.6*	43.0 *4.7*	18.0 *1.0*	46.0 *6.0*
T1C2	9.5 *.7*	11.5 *.5*	4.0 *.5*	6.0 *.4*	52.0 *5.9*	18.0 *.9*	30.0 *4.4*
T2C2	7.5 *.5*	8.5 *.5*	3.0 *.5*	4.0 *.5*	50.0 *7.5*	17.0 *1.4*	50.0 *8.8*
T2C3	6.5 *.5*	7.5 *.7*	3.5 *.4*	4.5 *.6*	51.0 *4.7*	13.0 *1.9*	27.0 *3.4*

Quantified results with standard deviation in italics.

Subject 7	CEMX 20	CEMX 80	CROM 20	CROM 80	CEV MX20	CEMX 20TM	CEMX80 TM
T1C1	-4.5 *.1*	-7.0 *.4*	2.5 *.2*	5.0 *.3*	-54.0 *3.2*	10.0 *1.0*	51.4 *3.6*
T1C2	-3.0 *.2*	-6.0 *.5*	2.0 *.4*	5.5 *.6*	-56.0 *6.1*	9.0 *.8*	50.0 *4.4*
T2C2	1.5 *.4*	-0.5 *.5*	1.5 *1.0*	6.0 *.6*	-54.0 *7.3*	5.0 *.4*	49.0 *9.8*
T2C3	-3.0 *.3*	-7.0 *.5*	1.0 *.2*	8.0 *.6*	-37.0 *3.1*	6.0 *.3*	76.0 *.7*

Subject 7	TIR MX20	TIR MX80	TROM 20	TROM 80	TIRV MX20	TIR MX20TM	TIR MX80TM
T1C1	6.0 *.3*	7.5 *.5*	4.5 *.3*	6.0 *.6*	81.0 *4.7*	19.0 *.5*	32.0 *2.4*
T1C2	6.0 *1.0*	7.0 *1.0*	5.0 *.8*	6.0 *.9*	75.0 *12.4*	19.0 *.6*	30.0 *5.2*
T2C2	9.5 *.6*	10.5 *.9*	6.0 *.6*	7.0 *1.0*	94.0 *7.5*	14.0 *1.0*	21.0 *6.1*
T2C3	8.5 *.7*	10.5 *.6*	6.5 *.8*	8.5 *.8*	97.0 *12.3*	17.0 *.8*	36.0 *4.3*

Subject 9	CEMX 20	CEMX 80	CROM 20	CROM 80	CEV MX20	CEMX 20TM	CEMX80 TM
T1C1	-8.5 *.2*	-10.5 *.3*	1.5 *.2*	5.0 *.3*	-65.0 *6.1*	6.0 *.5*	47.0 *2.3*
T1C2	-8.5 *.2*	-10.0 *.3*	3.0 *.2*	5.0 *.5*	-72.0 *6.0*	8.0 *.3*	47.0 *6.3*
T2C2	-10.0 *.3*	-13.0 *.3*	4.0 *.2*	7.5 *.3*	-95.0 *7.4*	8.0 *.3*	53.0 *3.5*
T2C3	-8.0 *.2*	-9.5 *.2*	0.0 *.0*	7.0 *.3*	-21.0 *5.9*	1.0 *.5*	46.0 *6.6*

Subject 9	TIR MX20	TIR MX80	TROM 20	TROM 80	TIRV MX20	TIR MX20TM	TIR MX80TM
T1C1	12.5 *.4*	17.5 *.8*	5.5 *.5*	10.5 *.5*	86.0 *9.4*	20.0 *.1*	48.0 *2.2*
T1C2	11.5 *.5*	17.0 *.6*	6.0 *.7*	11.5 *.9*	99.0 *12.1*	20.0 *.3*	49.0 *3.5*
T2C2	8.0 *.7*	11.5 *.5*	7.0 *.7*	10.5 *.6*	96.0 *8.2*	20.0 *.2*	33.0 *2.3*
T2C3	22.0 *.3*	24.5 *.3*	5.0 *.2*	7.5 *.3*	94.0 *5.2*	18.0 *1.7*	33.0 *1.2*

Quantified results with standard deviation in italics.

Subject 11	CEMX 20	CEMX 80	CROM 20	CROM 80	CEV MX20	CEMX 20TM	CEMX80 TM
T1C1	-3.0 *.2*	-6.0 *.3*	3.5 *.3*	6.5 *.3*	-55.0 *3.0*	19.0 *.9*	64.0 *4.0*
T1C2	-2.5 *.2*	-5.5 *.3*	3.0 *.3*	6.0 *.3*	-56.0 *4.4*	17.0 *1.5*	59.0 *5.0*
T2C2	-13.5 *.2*	-17.5 *.2*	1.0 *.3*	5.5 *.3*	-27.0 *12.2*	13.0 *2.4*	71.0 *2.9*
T2C3	-4.0 *.1*	-8.0 *.3*	2.5 *.4*	7.0 *.3*	-47.0 *4.9*	19.0 *1.0*	73.0 *1.0*

Subject 11	TIR MX20	TIR MX80	TROM 20	TROM 80	TIRV MX20	TIR MX20TM	TIR MX80TM
T1C1	10.0 *.5*	11.0 *.5*	4.0 *.5*	5.0 *.5*	63.0 *5.5*	17.0 *1.0*	27.0 *3.0*
T1C2	11.0 *.4*	11.5 *.4*	4.0 *.4*	5.0 *.5*	68.0 *6.7*	14.0 *.8*	24.0 *3.4*
T2C2	7.0 *.6*	8.0 *.6*	4.0 *.4*	5.0 *.4*	70.0 *7.9*	11.0 *3.0*	50.0 *6.7*
T2C3	17.5 *.5*	18.5 *.6*	3.5 *.6*	4.5 *.6*	78.0 *13.8*	11.0 *2.5*	13.0 *3.2*

Subject 12	CEMX 20	CEMX 80	CROM 20	CROM 80	CEV MX20	CEMX 20TM	CEMX80 TM
T1C1	-5.0 *.1*	-6.0 *.1*	4.5 *.2*	5.5 *.2*	-93.0 *2.8*	16.0 *1.8*	27.0 *.8*
T1C2	-4.5 *.1*	-5.5 *.1*	5.0 *.2*	6.0 *.3*	-105.0 *3.3*	17.0 *1.7*	25.0 *1.9*
T2C2	-4.5 *.1*	-5.0 *.1*	3.5 *.3*	5.0 *.2*	-81.0 *3.6*	8.0 *1.3*	25.0 *1.9*
T2C3	-2.0 *.1*	-3.0 *.2*	4.0 *.1*	5.0 *.2*	-94.0 *3.1*	12.0 *1.7*	30.0 *1.9*

Subject 12	TIR MX20	TIR MX80	TROM 20	TROM 80	TIRV MX20	TIR MX20TM	TIR MX80TM
T1C1	13.0 *.5*	13.0 *.5*	7.5 *.5*	7.5 *.5*	79.0 *3.7*	18.0 *.3*	18.0 *.3*
T1C2	13.0 *.3*	13.0 *.3*	9.5 *.6*	9.5 *.6*	104.0 *4.4*	18.0 *.5*	18.0 *.6*
T2C2	14.5 *.7*	14.5 *.7*	6.5 *.7*	6.5 *.7*	85.0 *8.2*	17.0 *.4*	17.0 *.5*
T2C3	11.0 *.3*	11.0 *.3*	8.0 *.3*	8.0 *.3*	100.0 *6.2*	17.0 *.2*	17.0 *.2*

Quantified results with standard deviation in italics.

Subject 13	CEMX 20	CEMX 80	CROM 20	CROM 80	CEV MX20	CEMX 20TM	CEMX80 TM
T1C1	6.0 *.2*	2.5 *.5*	9.0 *.4*	12.0 *.5*	-114.0 *6.4*	20.0 *.1*	60.0 *5.6*
T1C2	8.0 *.3*	3.0 *.3*	7.5 *.3*	12.0 *.4*	-108.0 *2.7*	20.0 *.2*	73.0 *.5*
T2C2	3.0 *.2*	-3.0 *.3*	3.0 *.2*	9.0 *.5*	-58.0 *4.3*	11.0 *1.7*	74.0 *.8*
T2C3	-2.5 *.2*	-5.5 *.4*	7.0 *.3*	10.0 *.4*	-95.0 *3.6*	20.0 *.2*	60.0 *5.8*

Subject 13	TIR MX20	TIR MX80	TROM 20	TROM 80	TIRV MX20	TIR MX20TM	TIR MX80TM
T1C1	17.5 *.3*	17.5 *.3*	10.0 *.6*	10.0 *.6*	115.0 *10.0*	20.0 *.4*	21.0 *1.1*
T1C2	18.0 *.2*	18.0 *.2*	10.0 *.4*	10.0 *.4*	147.0 *10.5*	16.0 *1.3*	16.0 *1.3*
T2C2	17.5 *.4*	18.0 *.4*	9.5 *.5*	9.5 *.5*	99.0 *6.7*	18.0 *.7*	19.0 *.9*
T2C3	10.0 *.6*	10.5 *.5*	8.5 *.6*	8.5 *.7*	101.0 *3.7*	16.0 *1.3*	18.0 *1.7*

Quantified results with standard deviation in italics. Value of independent variables with standard error.
Values for CEMX20 & 80, TIRMX20 & 80, CROM20 & 80, TROM20 & 80 are to nearest 0.1°. Values for CEVMX20 & TIRVMX20 are in degrees/sec. To 0.1°. Values for CEMX20TM & 80TM, TIRMX20TM & 80TM are in per cent of gait normalized from heel-strike to toe-off.