MOBILITY CHARACTERISTICS OF TOTAL ANKLE REPLACEMENTS

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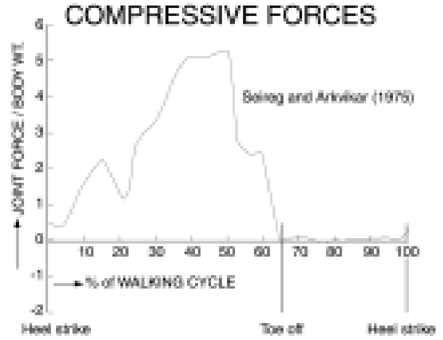
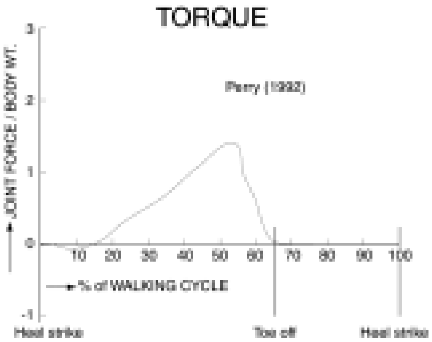
INTRODUCTION

Ankle joint replacement is again emerging as an alternative to arthrodesis in the surgical treatment of ankle joint arthritis. Restoration of normal ankle joint function through arthroplasty can result in relief of pain and return of normal gait biomechanics. Despite promising early results in the 1970's, long-term follow-up studies have been fraught with high failure rates leading to their abandonment. Prosthetic loosening has been the predominant cause of failure with rates ranging between 52% and 95% at 10 years.[3,10,11,12] This has been linked to the excessive intrinsic constraint offered by these systems, often in conjunction with compromised subtalar joint motion and alignment.[6] To be successful, prostheses need to be able to withstand the considerable forces which act across the ankle during normal walking while allowing for a functional range of motion. Contemporary ankle replacement designs seek to offer this balance without being excessively constrained, thereby decreasing the risk of loosening.[1,4,5,8]

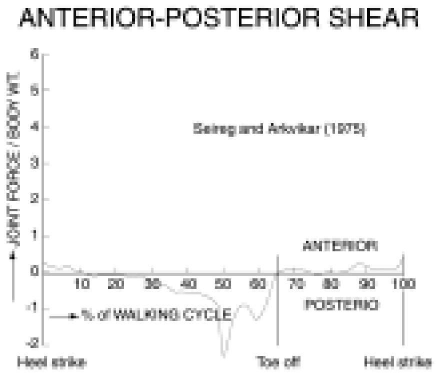
This study characterizes total ankle replacement devices in terms of the force generated during a prescribed displacement. The four systems evaluated include the Agility (DePuy Inc.), Buechel-Pappas (Endotec, Inc.), STAR (Link Orthopaedics, Inc.) and TNK (Kyocera Corporation). Currently, only the Agility system is available for clinical use in the United States, with the remaining representing a growing international presence.

THE MECHANICAL ENVIRONMENT


COMPRESSIVE FORCES


TORQUE

Implant design must accommodate the joint forces encountered during walking. Ground reaction, gravitational, ligament and muscle forces produce compressive, shear and torsional loads at the ankle.


ANTERIOR-POSTERIOR SHEAR


MEDIAL-LATERAL SHEAR

INTRINSIC CONSTRAINT

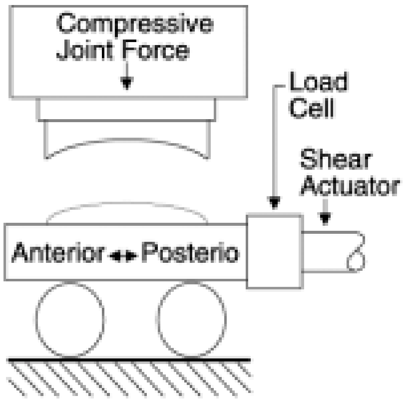
Stability is achieved in total ankle replacements through geometric variation of the condylar surfaces. The intrinsic constraint of an implant system is defined as the capacity of the implant to limit rotational, anterior-posterior and medial-lateral displacements to within normal ranges. In the absence of gross material deformation, intrinsic constraint due to geometric variation may be described in terms of the shear forces and torques which act orthogonal to the physiologic compressive loads between the tibial and talar components.

METHODS AND MATERIALS

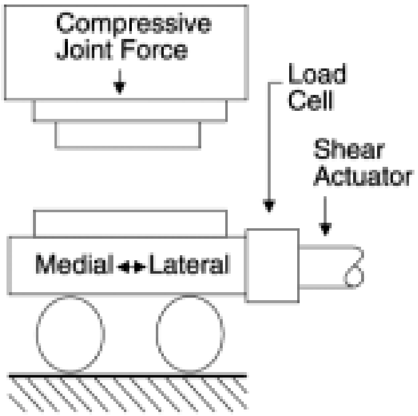
A dynamic testing system capable of applying biaxial loads (Instron Testing Machine, Model 1115, Instron Corporation, Canton, Massachusetts) was utilized to assess the intrinsic performance characteristics of four total ankle replacements. Anterior, posterior, medial, lateral and rotational constraints were determined for each design under a compressive load consistent with normal walking gait.[9] *A compressive load of 5 x body weight and 10 degrees flexion was chosen to represent a position of gait where maximum shear forces act in the posterior and lateral directions as well as in rotation.*[7,9] *Anterior and medial shear forces are presented at the same gait position for completeness. A body weight of 163 lbf was used in this evaluation, which corresponds to the average for a 60-year old, 5'8" male subject.*[2]

ANTERIOR-POSTERIOR AND MEDIAL-LATERAL SHEAR TESTING

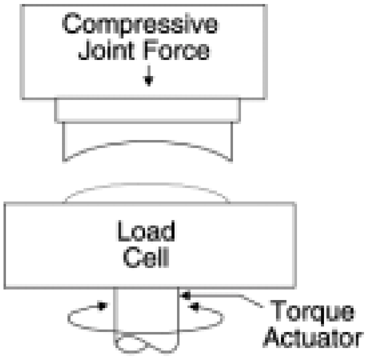
Three ultra-high molecular weight polyethylene (UHMWPE) tibial components were evaluated in each test direction for each system. Under an in vivo *compressive load, shearing displacements were applied to the system until implant subluxation. Anterior, posterior, medial and lateral subluxation is defined as the dislocation of the talar component relative to a stationary, tibial plateau. The shear forces determined provide a measure of the maximum ability of the ankle design to constrain displacement during gait.*



Anterior-Posterior Test Assembly



Medial-Lateral Test Assembly



Rotational Test Assembly

ROTATIONAL TESTING

Under an in vivo *compressive load, the system was rotated both internally and externally in the transverse plane and the torque versus angular displacement recorded. Three UHMWPE tibial components were evaluated for each system. These results provide a measure of the ability of the ankle design to constrain rotation during gait.*

RESULTS

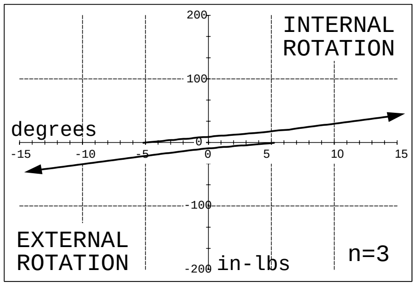
The graphs presented for each design are the force-displacement curves measured in the four directions (anterior, posterior, medial and lateral). The rotation plots represent the amount of torque produced during angular displacement of the talar component. The values reported are the average, constraint forces for each total ankle design, (n = 3).

In general, the graphs provide a visual description of the mobility and constraint offered by each total ankle design. All plots begin well before neutral and proceed in the direction of testing. For example, the testing of posterior constraint starts with the joint contact significantly anterior of neutral and proceeds in the posterior direction.

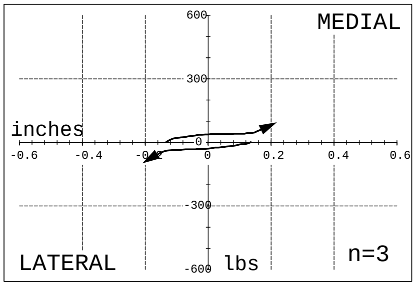
The maintenance of a relatively low shear force over a defined displacement is indicative of low constraint motion such as sliding, with only friction providing resistance. This frictional resistance is characteristic of sliding between the tibial and UHMWPE components as well as sliding between the UHMWPE and the talar components when the condylar geometry is flat. Conversely, rapidly increasing constraint is evidence that the talar component has engaged a sloped region of the UHMWPE component.

AGILITY

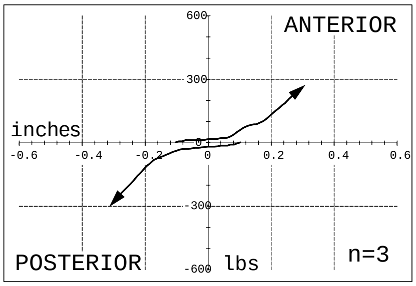
Rotational Constraint



M-L Constraint

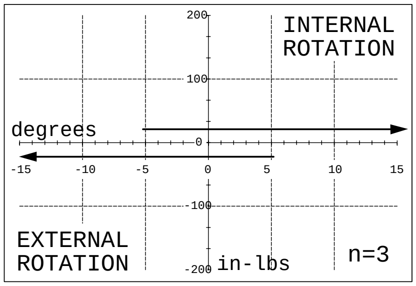


A-P Constraint

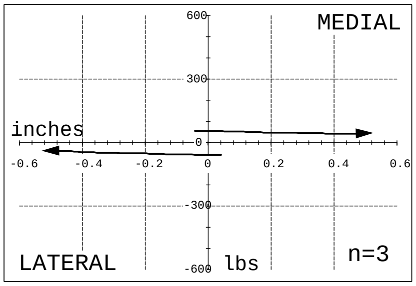


BUECHEL-PAPPAS

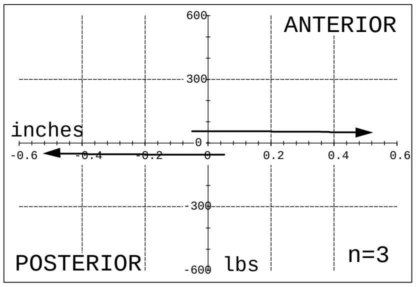
Rotational Constraint



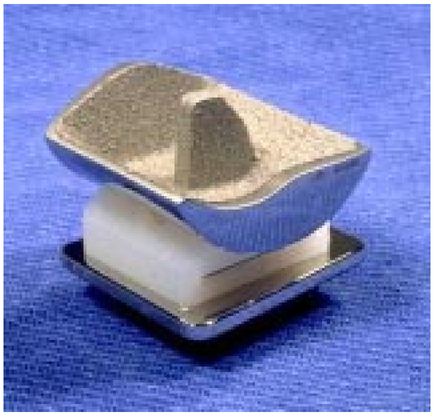
M-L Constraint



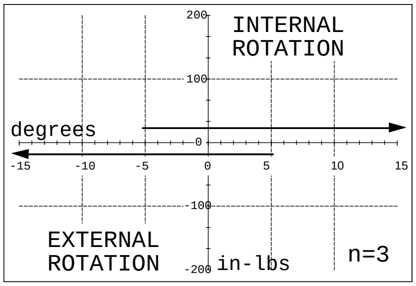
A-P Constraint



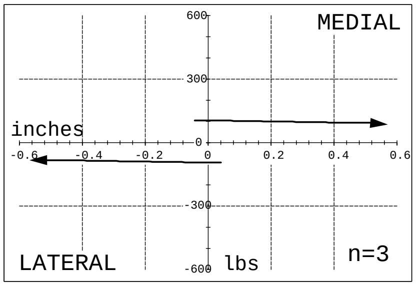
STAR



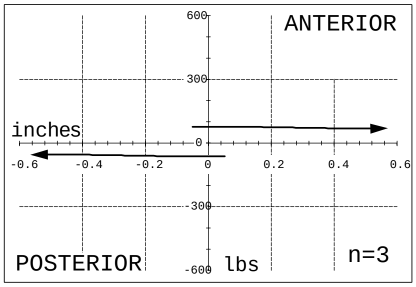
Rotational Constraint



M-L Constraint

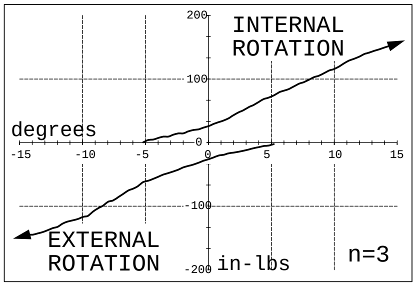


A-P Constraint

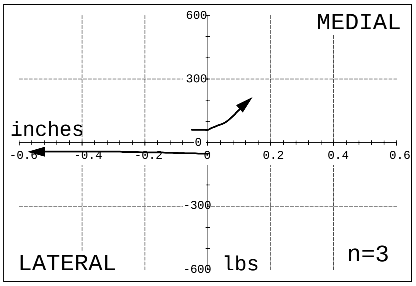


TNK

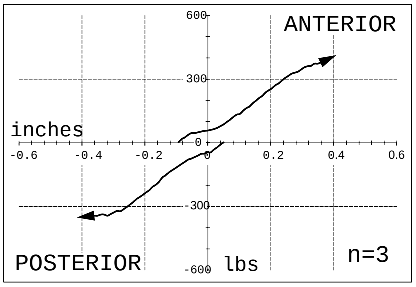
Rotational Constraint



M-L Constraint



A-P Constraint



DISCUSSION

The significance of this study lies in the analysis of mobility offered by four total ankle replacements, each system providing instrinsic constraint through a different mechanism. The degree of design mobility or unconstrained displacement between the talar-UHMWPE and tibial-UHMWPE components is summarized for each system in Table 1.

System Name	*Rotational Displacement*	*Medial-Lateral Displacement*	*Anterior-Posterior Displacement*
Buechel-Pappas	∞	∞	∞
STAR	∞	∞	∞
Agility	*~0 in*	*0.27 in*	*~0 in*
TNK	*~0 in*	*~0 in - Medial* *∞ - Lateral*	*~0 in*

Table 1

By comparison to the highly constrained, first generation ankle replacements, the current systems promote load sharing through displacements between the tibial and talar components. Simply put, these designs should allow the torques and shear forces of gait to be transferred via displacements to the soft tissues in a fashion similar to the normal ankle. The potential advantages to load sharing are many. Load sharing reduces loosening stresses transferred to the implant-bone interface and promotes soft tissue strengthening. These tissues, unlike the inert prosthesis, have the capacity to respond and remodel to the challenges of expanding activities as the pain-free patient rehabilitates. Finally, load sharing may well reduce articular wear of these devices by reducing joint loads. Thus, in general, soft tissue involvement should be encouraged in order to decrease the dependency on intrinsic constraints afforded by condylar geometry.

The four designs studied were divided into two classifications. The first group, Buechel-Pappas and STAR, permit unlimited motion in all of the directions evaluated by utilizing an UHMWPE insert which is unconstrained, (i.e., flat-on-flat) on the tibial tray surface. Additionally, the UHMWPE component conforms with the curved articulating geometry of the talar component and thus, the force-displacement curves represent the frictional resistance of the UHMWPE-tibial tray interaction only. Because of the mobility these two designs offer, competent soft tissue structures are a necessity for maintaining a stable articulation and load sharing is promoted. Also, the UHMWPE-talar articulating geometries in this group are able to compensate for inversion-eversion tilting. Slight positional malalignment of the components should not significantly affect the expected in vivo *service life of the device. In addition, this compliance to position, within the mobility displacement envelope, which is defined by the soft tissue structures and device interaction, should allow these designs to function in patients with minor aberrant gait patterns.*

The Agility and TNK designs comprise the second group and represent more constrained total ankle replacement designs as the UHMWPE component is locked to the tibial tray. They both permit internal-external rotation within a normal physiologic range (approximately -3 degrees to +5 degrees). The resulting torques measured are seen to increase with increasing rotational displacement, which is indicative of the geometrical interaction of the UHMWPE-talar component interface. It is important to point out that the torques measured within this rotational envelope are minimal, which should promote the maintenance of implant fixation. For the medial-lateral and anterior-posterior test directions, these systems utilize build-ups (i.e., steep walls) and articulating curvatures to resist translation and ultimate subluxation. While these designs promote effective load sharing within the normal, physiologic range of motion, they also address the issue of potential increasing tissue incompetency with time in vivo *and ultimately, serve as a compensatory constraint mechanism when the envelope is exceeded.*

CONCLUSION

While analyzing total ankle replacements it is important to appreciate the actual displacements allowed by the geometric constraint of each design. Within the envelopes of normal displacement the systems studied demonstrate relatively low force and torque values which should contribute to their in vivo longevity. The one exception is the medial displacement realized in the Kyocera design, however, only clinical reports will gauge the significance of this finding. It is important to appreciate the dramatic reduction in device constraint realized by these contemporary designs in comparison to first generation devices. Clinical longevity of total ankle arthroplasty is dependent upon a correct balance between the intrinsic mobility allowed by design geometry and patient's presenting pathology.

These ongoing laboratory evaluations assist an understanding of the anticipated performance of contemporary total ankle replacements. The results are intended to aid the surgeon in device selection when considering patient factors. Further, they provide the manufacturer with design criteria and assist regulatory agencies in determining the safety and efficacy of specific ankle designs.

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