Posterior stabilized knee design biomechanical considerations

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ABSTRACT

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Numerous posterior stabilized knee systems are available for primary and revision total knee arthroplasty. Design of these systems requires an understanding of the articulating geometries and kinematic/kinetic biomechanical considerations of the normal knee. The findings for the normal knee are integrated into the design of a prosthetic system.

The natural femoral, tibial and patella articulating geometries are defined to enable subsequent kinematic and kinetic analyses. The articulating geometries are characterized from review of anthropometric studies of the tibiofemoral and patellofemoral joint.

The kinematic analysis of the natural knee defines knee motion in terms of rotation, adduction/abduction, range of motion and femoral rollback. Typical activities for total knee recipients are characterized under these headings. Instant center theory is also applied to the natural knee as it facilitates linking natural knee motion and prosthetic motion analysis. Natural knee kinetics for the gait cycle is characterized. The maximum gait cycle compressive and shear loads and knee motions attained from clinical studies using force plate, cinematography and computer optimization techniques are reviewed. The resultant loads and motions obtained from the studies form a benchmark used to establish laboratory testing parameters.

The kinematic and kinetic analysis for generic posterior stabilized design is

studied. Interaction of the femoral cam, tibial spine, femoral condyles and tibia plateau geometry are reviewed for a proposed and existing posterior stabilized geometry. Additional posterior stabilized design issues including: subluxation resistance, range of motion, bone conservation for the femoral housing resection, internal/external femoral rotation, tibial polyethylene insert modularity with the tibial tray and tibial polyethylene insert conformity with the femoral condyles are reviewed. A survey of designs on the market indicates a wide range of results for bone conservation for the femoral housing resection, internal/external rotation, and degree of conformity.

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This thesis is dedicated to my parents,
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1. INTRODUCTION

The scope of this thesis is limited to biomechanical considerations for posterior stabilized knee design and pertinent background material. Posterior stabilized (PS) knee prostheses are used in primary total knee arthroplasty (TKA) or revision TKA to alleviate pathological conditions of one or all three compartments of the knee joint. Namely; the medial and lateral tibiofemoral compartments and the patellofemoral compartment. These pathological conditions include rheumatoid arthritis (RA), degenerative osteoarthritis (OA) and traumatic arthritis.

Knee designs used in primary TKA are generically referred to as tricompartmental and typically consist of a metallic femoral component, metallic tibial tray used to support a polyethylene tibial bearing surface (referred to as the tibial insert) and a patella component of all polyethylene design or a composite consisting of polyethylene and metal. The first tricompartmental knee designs date back as early as 1974 and included the Total Condylar, Duopatella and Townley Design. [1] These designs were unlike the current posterior stabilized designs in that they were posterior cruciate sparing devices. Posterior stabilized knee prostheses are also tricompartmental with most incorporating a polyethylene tibial spine and a transverse femoral cam (see Figure 1).

The term "posterior stabilized" is coined from the contact of the transverse femoral cam on the posterior aspect of the tibial spine. This interaction between the femoral cam and tibial spine provides knee joint stability normally afforded by an intact posterior cruciate ligament. This stability provides resistance to posterior tibial subluxation (see Figures 2 and 3).

The first posterior stabilized prosthesis was developed in 1978, at the Hospital of Special

Surgery by John Insall, M.D. and Albert Burstein, Ph.D. The posterior stabilized prosthesis was a modified version of the Total Condylar design. In order to appreciate why the Posterior Stabilized prosthesis was pursued, one should become acquainted with the Total Condylar design rationale.

The Total Condylar was designed to permit excision of both cruciate ligaments because it permits easier correction of fixed deformity resulting from the pathology by enhancing surgical exposure. The developers reasoned that enhanced exposure reduced the difficulty of ligamentous release to achieve correct ligament tension in flexion. Improper ligament tension may result in excessive laxity in flexion which in turn can cause posterior tibial subluxation (Figures 2 and 3). These factors coupled with approximately ¼ of patients with a Total Condylar prosthesis unable to climb stairs normally and/or with a range of motion of only 90° led Insall and Burstein to consider modifications to the Total Condylar[2].

As previously stated, the modifications included the addition of the femoral cam and tibial spine to prevent posterior tibial subluxation. Insall and Burstein also revised the center of curvature of the prosthesis to permit more normal knee motion which achieved greater flexion. To better approximate normal knee motion the inventors created a femoral cam/tibial spine interaction along with the tibiofemoral articulation that closely approximated the instant center of rotation for the normal knee. The concept of instant center will be covered later in the text.

Since the development of this first Posterior Stabilized prosthesis, at least ten additional designs have been marketed using one variation or another of the transverse femoral cam and tibial spine contact. These include the:

Kinematic™	Omnifit™	Continuum™
Kinemax™	PFC™	AMK™
S-ROM™	Insall-Burstein II™	AGC™
Ortholoc II™	Lacey™	Genesis™

Each claims its advantages or list of features similar to the others.

2. ARTICULATING GEOMETRIES

2.1 Introduction

Posterior Stabilized knee design is intended to provide a patient with the ability to perform normal daily living activities. To design the prosthesis, the daily activities are usually studied in a biomechanical framework of motion and force analysis. However, prior to biomechanical analysis the tibiofemoral and patellofemoral articulating geometries need to be defined to permit positioning of a femoral cam and tibial spine geometry that will impart desirable motion and force profiles to yield long term clinical results for the prosthesis.

2.2 Femoral Articulating Geometry

Femoral Geometry - The Sagittal Plane Profile

Definition of the sagittal profile of a femur or "J" curve comes from anthropometric studies performed on many specimens of human femorals. The underlying premise in these studies and with development of a prosthetic J curve is to duplicate normal anatomy. Actually, the same premise is usually pursued for the entire design of any prosthetic device. It should be noted that recent work in kinematic analysis is fine tuning this philosophy. Specifically, some investigators are taking into account the effect of soft tissues removed during a total joint arthroplasty and examining this motion.[3] Studies have shown that with this soft tissue removed during the arthroplasty, kinematics are altered and compensated for by a patient. Since the kinematics are altered, the designer could design for the altered motion as long as it doesn't restrict function for normal activities. By designing for the compensated or altered motion, less force is imparted to the prosthetic/bone interface thereby theoretically increasing implant longevity.

Since the aforementioned work is preliminary (less than ten patients with prosthesis have been analyzed), the more traditional approach of fitting a J curve to normal anatomy will be explored. Additionally, this is the standard practice of virtually every implant marketed and the compensated motion analysis study cited above utilized prostheses designed to duplicate normal anatomy and motion. To change the J curve philosophy may result in motion other than that observed for the patients already studied.

Studies that have been conducted on anthropometric attributes of human femurs include the work of Erkman[4], et.al, Seedhom[5], et.al, and Yoshioka[6], et. al. Many other studies have been conducted, however, the three that are cited convey the essence of surveyed studies. It is noted that these studies provide information on the relationship of the anterior-posterior and medial-lateral width ratios, intercondylar notch area and the transepicondylar axis. All these parameters are important in the design of a posterior stabilized prosthesis since they relate to implant geometry which effects implant coverage of resected bone.

Specifics as to how the "J" curve are defined is best discussed in Erkman's work. He and associate, P.S. Walker measured lateral views of femurs and fitted the load bearing area of the femur with either two tangent circular arcs, an ellipse, two non-tangent arcs, an archimedean spiral and an equiangular spiral. The best fit was attained from the two tangential circular arcs.

The "J" curve of most femoral components on the market today use three radii on the lateral aspect where Erkman and Walker used two for the load bearing area of the femur (see Figure 4, radii R_3, R_4, and R_5).

Most femora also use two other radii (Figure 5, radii R_1 and R_2) to define geometry proximal to the tibiofemoral load bearing area. The trend is therefore to designate five lateral and five medial condyle radii.

Femoral Geometry - The Coronal Plane Profile

In the coronal or frontal plane, prosthetic articulation is either radius on radius or flat on flat (see Figures 5 and 6). A discussion of flat on flat versus radius on radius articulations goes beyond the scope of the J curve and relates to interchangeability issues between femoral components with polyethylene tibial inserts as well as contact stress imparted to the polyethylene tibial insert during adduction/abduction motions.

2.3 Tibial Articulating Geometry

The normal tibia has a posterior downwardly inclined slope of approximately 7 to 10°. This slope creates an uphill effect which needs to be overcome if the femur is to sublux anteriorly on the tibia.

This uphill effect gives added stability to the normal knee joint to resist the large anterior shear forces present during activities such as descending stairs and the gait cycle. In the normal knee, shear forces are also resisted by the posterior cruciate ligament, the collateral ligaments, the quadriceps muscles/patella tendon, and the interaction of femoral articular cartilage with the tibial menisci.

Most posterior stabilized designs attempt to duplicate the posterior slope of the natural tibia to get the benefit of the uphill effect in resisting posterior tibial subluxation. This is done either by resecting the tibia at a 7 to 10° angle or building a slope into the polyethylene tibial insert articular surface or a combination of both.

2.4 Patellofemoral Articulating Geometry

The anatomic patella shape is nearly oval and has two sections called the medial and lateral facets. The interaction of these facets form a ridge which is located off center toward the medial side. This ridge rides in the trochlear groove during extension and the medial facet articulates predominately with the intercondylar notch during flexion.

The patella is part of the extensor mechanism of the knee and also functions to distribute the compressive forces developed during extension onto the anterior surface of the femur. Figures 7 and 8 illustrate how the patella serves to increase the moment arm of the quadriceps muscle group by increasing the distance from the tibiofemoral instant center to the patella tendon.

To develop a prosthetic patella articulation, one must develop an understanding of the trochlear groove geometry. In the lateral view this geometry is often modelled as a series of radii or one radius on a prosthetic device. The intent in TKA is to duplicate the natural articulation to yield the same extensor mechanism biomechanics. Increasing the moment arm increases the force on the patella implant while decreasing the moment arm will weaken the extensor mechanism. This is why most prosthetic systems not only try to mimic the trochlear groove geometry but also attempt to replace precisely what is resected from the patellar bone with the patellar prosthesis.

Normally, prosthetic patellas are domed shaped. This is effectively a sphere cut by a chord. Variations include flared domes that include a flat region adjacent to the radial region which may reduce contact stress when the device articulates in the intercondylar notch area of the femoral prosthesis.

3. KNEE KINEMATICS

3.1 Introduction

Knee biomechanics involves motion and force analysis. The motion analysis is referred to as kinematics and the force analysis is referred to as kinetics.

3.2 Knee Kinematics

The motion between the articulating surfaces of the tibiofemoral and patellofemoral joint has been described using the instant center theory. It will be shown later in the text that this theory forms the basis of a popular posterior stabilized design. The following discussion of instant center theory is developed from Nordin and Frankel's discussion.[7]

3.2.1 Instant Center Theory - Tibiofemoral Articulation

The instant center theory was developed by Reuleaux and analyzes the predominate motion of this articulation which occurs in the sagittal plane. The motion is referred to as flexion and extension or range of motion. Figure 9 from Nordin and Frankel displays the technique applied between 80° and 90° of flexion. The motion of the femur on the tibia is tangential to the tibial articulating surface for a normal knee.

If this analysis were carried out for 10° increments in flexion angles, the resulting instant center pattern resembles a semicircular geometry. Specifically, the center of rotation at a given instant is perpendicular to the common tangent through the contact point between the tibial and femoral articulating surfaces.

Further analysis of the instant center of the normal tibiofemoral articulating surfaces indicates that the femur both slides and rotates on the tibial condyle during flexion and extension. This can be seen in figure 10 from Kapandji where the motion of sliding and rotation is deduced by examining the effect of pure rotation, pure sliding and the combination of sliding and rotating.[8] This motion is referred to as rollback.

It is interesting to note that the instant center pattern resulting for an abnormal knee is caused by motions which are not tangential to the tibia. The effect of abnormal instant centers resulting from ligamentous or soft tissue damage causes the tibiofemoral joint to either distract or compress with further flexion versus a normal instant center which promotes gliding, sliding and rotation at the tibiofemoral interface (see Figure 11).

An example of resultant instant center path for non tangential motion is shown in figure 12 from Nordin and Frankel. This is a 35 year old male with a bucket handle tear of the meniscus. The instant center jumps at full extension of the knee.

3.2.2 Screw Home Mechanism

For a normal tibiofemoral articulation during extension to flexion, the medial meniscus reportedly displaces 4 - 6 mm posteriorly while the lateral meniscus displaces 10 - 12 cm[8]. The unequal displacement of meniscus can be further deduced as unequal displacement of the tibiofemoral contact point in each compartment. This results in a rotation of the tibia relative to the femur. This rotation is referred to as the "screw home mechanism" and is described as the tibia externally rotating during extension and internally rotating during flexion.

The rotation occurs due to the aggregate effect of soft tissue linkage and the patella and femoral interaction. The term "screw home" is specifically coined from the fact that in full extension the knee returns to a "locked" or "tightened screw" due to the tightening of the cruciate ligaments, collateral ligaments and the interaction of the tibial spine with the intercondylar notch of the femur. The cruciates have been characterized as acting dependently throughout the range of motion in a manner similar to a four bar linkage[9]. It is primarily this interaction that causes the rotation of the tibia relative to the femur. Due to the positions of ligament attachments, the resultant motion is rotation and translation of the tibia, thus the screw home effect.

Most total knee replacements involve excision of the anterior cruciate ligament while all involve removal of the meniscus. From the forgoing discussion on the role of the anterior cruciate ligament interaction with the posterior cruciate ligament during the screw home mechanism, it is not hard to imagine that prosthetic knee motion is altered relative to normal knee motion. This is precisely what the work of Banks et al., illustrated during fluoroscopic studies of a prosthetic knee which involved excision of the anterior cruciate ligament and meniscus[3]. Their findings illustrated that the tibia rotated externally during extension which is similar to the normal knee during extension. However, they found that the prosthetic femoral component moved posteriorly during extension versus anterior during extension as in the normal knee. They characterized this motion as "paradoxical" implying the same rotation but opposite translation. Through discussion with Banks, another prosthetic knee design involving anterior cruciate ligament excision has been investigated and yielded the same paradoxical motion.

With these results, coupled with the fact that a posterior stabilized prosthesis involves anterior cruciate ligament, meniscus and posterior cruciate ligament removal, it becomes an interesting point concerning what prosthetic motion actually results. As discussed previously, the goal of most prosthetic designs is to simulate normal knee kinematics. With this study, it has become apparent that posterior cruciate ligament retaining devices do not appear to simulate normal knee motion but rather an anterior cruciate ligament deficient motion. Therefore, one could theoretically challenge this basic premise of normal motion purported by most prosthetic designers. Further, one may challenge the clinical necessity to duplicate normal knee motion with a prosthetic design because clinically most prosthesis provide ample range of motion and stability for patients during normal activities. Obviously this argument can be brought to posterior stabilized designs. It would be an interesting fluoroscopic study to determine the motion resulting for a posterior stabilized design.

3.2.3 Instant Center Theory - The Patellofemoral Joint

The patellofemoral joint can also be analyzed using instant center theory. Nordin and Frankel indicate that from full extension to full flexion, the patella glides (slides and rotates) on the femur 7 cm.[7] Figure 13 from Nordin and Frankel illustrates the instant center theory applied to the patella between 75 and 95° of flexion. Similar to the tibiofemoral instant center analysis, the entire instant center curve for the patellofemoral articulation can be deduced by using x-ray analysis at flexion angle increments.

3.2.4 Knee Motion Definition and Normal Activity Classification

Knee motion occurs in three planes; the frontal (or coronal), the sagittal and the transverse (or horizontal). Motion in the sagittal is defined as range of motion or extension and flexion. Transverse plane motion is called internal and external rotation. Frontal plane motion is referred to as adduction and abduction.

In the normal knee, all three motions occur simultaneously during normal daily living activities. It is interesting to note that early prosthetic designs such as the Geupar or Waldius were hinged prosthesis and only permitted flexion and extension. These designs were prone to early mechanical fatigue or fixation fatigue failure due to the high rotational and adduction/abduction loads imparted to the bone interface during normal activities for TKA patients.

The following is a description of primary knee motions:

Range of Motion

The normal knee permits from 6 - 9° of hyperextension and up to 140° of flexion.

Rotation

In full extension, the normal knee rotation is virtually restricted by the soft tissue (refer back to the screw home mechanism discussion) and by tight clearance between the tibial spine and intercondylar notch. When assessed with the tibia under no compressive loading (as with a patient on a table and no active resistance- also referred to as passive assessment), rotation increases with increase in the flexion angle. At approximately 90° of flexion, passive rotation is at a maximum of 45° external and up to 30° internal rotation.[7] Beyond 90° flexion, the soft tissues (collaterals, cruciates and posterior capsule structures) attenuate further increase in internal or external rotation.

Adduction/Abduction

This motion is resisted primarily by the collateral ligaments. As with rotation, adduction and abduction are essentially $\pm$ 0° at full extension lending stability to the knee when standing. Passive adduction and abduction increase as the flexion angle increases up to 30° and then decreases as flexion angle continues to increase.[7]

Quantifying Normal Activities

The scope of normal activities in this section are limited to those a total knee patient requires namely; walking, stair climbing, sitting and lifting object. Activities such as running and deep knee bends have been omitted since it is generally understood in the orthopaedic community that these activities will cause premature implant failure or pain.

There have been numerous studies to analyze these activities for the normal and prosthetic knee in terms of range of motion, rotation and adduction and abduction. The following synopsis is for normal knee motion and is a condensed version of the summary presented by Nordin and Frankel[7] and the work of Kettlecamp[10] and Laubenothal[11].

Activity	Range of Motion
Gait	0 to 67° in the swing phase 0 to 20° in the stance phase
Stair Climbing	0 to 83
Sitting	0 to 90°
Lifting	0 to 117°

Since the majority of implant work cycle comes from the gait cycle (see figure 14), most research on internal/external rotation and adduction/abduction have concentrated on this area. Additionally, an electrogonimetric study of rotational and adduction/abduction motion suggest that the results are sensitive to initial foot position which in itself was found to be subjective.[8] Therefore, rotational and adduction/abduction discussion is limited to gait.

Gait

Internal/External Rotation	-	7.2^0 average internal rotation [10] (see a) 6.1^0 average external rotation [10] (see b)
Adduction/Abduction	-	8.4^0 maximum average adduction 2.8^0 maximum average abduction

a. internal rotation occurs during flexion in the swing phase[7]
b. external rotation begins during extension in the stance phase just before heel strike[7].

3.3 Knee Kinetics

3.3.1 Background

Kinetic analysis of the knee joint involves calculating the joint reaction forces necessary to resist the loads imparted to the foot from contact with the ground during dynamic activities such as walking, running and jumping. Burstein defines the joint reaction force as the result of the "functional loading" from ambulatory processes.[20]

3.3.2 Static Analysis

To determine the joint reaction loads, one must first determine whether the loading is static or dynamic. A static load situation implies that the loads imparted from inertial effects of the leg accelerating or decelerating are negligible or are non existent and are therefore ignored. The static joint reaction force is determined by indirect means (as are the dynamic joint reaction forces) since an instrumented prosthetic knee placed in vivo is not yet available. The indirect determination of the joint reaction force involves using free body diagrams, a knowledge of which muscle groups primarily resist the motion and a knowledge of the point of application of the joint reaction force. Consider the following example of a person standing on a step with the knee flexed to calculate the joint reaction force which is actually the force acting on the tibia due to a person's body weight (W) (see Figures 15 and 16).

Since this is a static analysis, the vector for "J" must also pass through point "O" to ensure all forces in the free body are concurrent, that is not causing any couple or moment. With the knowledge of vector directions for J, P and W along with the know value of W, the magnitude of J and P can be determined using graphic techniques (see Figure 17).

3.3.3 Dynamic Analysis

Forces imparted during customary patient activities require dynamic analysis since inertia effects of the lower limb are involved. Dynamic analysis involves application of Newton's Second Law of Motion for non-equilibrium conditions. Simply stated this is $F = MA$ or for angular motion $T = I\alpha$ where:

F = Force
A = Acceleration
I = Mass Moment of Inertia
M = Mass
T = Torque
α = Angular Acceleration

It is possible to calculate the joint reaction force for an ambulatory activity by first assessing the angular acceleration (α) of the lower limb using cinematography, photography or electrogoniometry. The mass moment of inertia (I) can be calculated or approximated using elementary mechanics (generally this data is available in the literature). The torque T can therefore be solved from using $T = I\alpha$. In the example of the patella tendon transmitting the force from the quadriceps muscle group to extend the knee during swing phase of gait, and the knowledge of instant center of rotation of the tibiofemoral joint, one can determine the joint reaction force. Specifically, assume r is the perpendicular distance between the instant center of rotation for the knee and the line of application of the patella tendon for the same instant where the angular acceleration was determined. The patella tendon reaction force (P) is the torque divided by the moment arm; $P = T/r$ (see Figure 18).

If the radial acceleration (versus the angular acceleration) is considered to be zero (this occurs when the leg is nearly vertical during gait), then the joint reaction force J can be found by subtracting the lower limb weight from the value of P. If the radial acceleration was not zero, the lower limb would tend to be pulling the tibia from the femur in the opposite direction of P. The joint reaction force would then be found from:

$$J = P - MA - W$$

Where: M = Mass of Lower Limb
A = Radial Acceleration of Lower Limb from Upper Limb
W = Weight of Lower Limb

This type of analysis represents a simplified approach for calculating joint reaction force. The next section deals with a review of a more complex approach to solve for joint reaction forces since more muscles are included in the analysis.

3.3.4 TibioFemoral and PatelloFemoral Joint Reaction Forces for Ambulatory Activities

In 1968, Morrison developed a method to analyze joint reaction forces in the knee[13]. Morrison attempted to determine these forces for normal gait on a level surface by considering several factors including:

- 12 subjects
- A force plate to measure the foot to ground reaction force similar to that used by Paul[14] in his analysis of the hip joint reaction forces. This force plate would sense six component forces including F_x, F_y, F_z, M_x, M_y, M_z, where F indicates force and M indicates moments for the three orthogonal axis.
- Cinemaphotography to record the relative acceleration of body segments. This method was also adopted from Paul's work and involved filming skin markers.
- Electromyographic data was recorded during gait to ascertain which muscle or muscle groups were active at a given instant during gait.
- The force plate, cinemaphotography and electromyographic data were synchronized.
- The external force system acting on the knee joint was calculated from the data at 1/50 second intervals. This analysis reportedly adopted the methods used by Bresler and Frankel[15]. This involved calculating the resultant forces and moments transmitted between body segments where moments are transmitted by tension in the ligaments and muscles. The electromyographic signals permit determination of which muscles are active so that with simplifying assumptions to ease solution of statically indeterminate systems of equations, the joint reaction forces were

calculated. A single cadaver specimen was analyzed to help determine an average line of action of muscle and ligament forces relative to anatomic landmarks.

Morrison results analyze the anterior-posterior force on the joint = R_x, the compressive force R_y and the medial-lateral shear load R_z. He also determined quadriceps, gastrocnemius, hamstring, and ligamentous loads in the joint.

The joint force is the vector sum of R_x, R_y and R_z. The value of R_y (the compressive load was found to have a mean maximum, of 3.03 times bodyweight but was calculated as high as 4.0 times bodyweight. Figure 19 adopted from Morrison gives a typical force (R_y) versus gait cycle profile. Peaks at a, b, and c were typical.

In 1969 Morrison published a continuation to this study where he analyzed the joint reaction loads for other ambulatory activities including ascending and descending a ramp and stairs[16]. Table 1 highlights these findings as well as those of other investigators.

In 1975, Seireg and Arvikar published results of a mathematical analysis of the joint reaction forces of the lower extremity[17]. The knee joint only is included in this discussion. Their work included the following background and assumptions to find a solution.

- The orientation and points of muscle/ligament insertions and origins were obtained using anatomic data from Braus[18]. Body segment weights and centers of mass used data from Hanavan[19].
- The analysis accounted for 31 muscles in the lower extremity in a quasistatic nature which implied that inertial forces and moments were neglected.
- The model yielded 42 equilibrium equations wherein an optimization program was

employed to solve the statically indeterminate system. The objective function involved minimizing the weighted sum of all muscle and ligament forces. The thought here is to minimize the work necessary to ambulate.

- The resultant theoretical muscle loads were checked against experimental electromyographic (EMG) data for subjects in normal gait. Seireg et,al., indicated that in general, there was "good correlation" between EMG pattern and muscle force as a function of the corresponding point in the gait cycle.
- The quasi-static walking solution to the problem can be modified for a dynamic situation via the addition of appropriate equations in the analysis.
- Figure 20 adapted from Seireg et.al., graphically illustrates the solution achieved for the optimization problem.

These two references have been reviewed in depth to illustrate the complexity of calculating knee joint reaction force without the use of in vivo insertion of an instrumented knee joint. The variance of maximum calculated compressive joint reaction loads of 3.03 times body weight for Morrison and over seven times body weight for Siereg et.al., suggests that an instrumented knee would be invaluable to more definitely obtain joint reaction loads. This obviously facilitates the design of a prosthetic device since it would properly characterize the tibiofemoral loads, tibial tray to tibia loads and patellofemoral loads. Table 1 adopted from a Dartmouth research effort summarizes most of the pertinent available literature on maximum compressive joint reaction forces for normal ambulatory activities.

TABLE 1

Maximum Compressive Joint Forces For Various Daily Activities

TIBIOFEMORAL

Activity	Morrison '70	Dumbleton	Unknown	Seedhom & Wright '84	Maquet '84	Paul '76
Walking	3.4 x BW	3.2 x BW			5 x BW	3 x BW
Up Ramp	4.5 x BW					4.4 x BW
Down Ramp	4.5 x BW					4.4 x BW
Up Stairs	4.8 x BW		4.4 x BW			4.4 x BW
Down Stairs	4.3 x BW		4.9 x BW			4.9 x BW
Rise Chair				3.2 x BW		
Knee Bend						4.2 x BW

PATELLOFEMORAL

Activity	Morrison '70	Reilly-Martens '67	Seedhom Wright '84	Reilly & Martens '72
Walking	0.7 x BW	0.5 x BW		
Up Ramp	1 x BW			
Down Ramp	2 x BW			
Up Stairs	2.8 x BW	3.3 x BW		1.7 x BW
Down Stairs	2.8 x BW			1.7 x BW
Rise Chair			4.3 x BW	
Knee Bend		7.6 x BW		2 x BW

Abduction and adduction moments are discussed in some of the references in Table 1. The joint reaction forces resulting from abduction and adduction moments are not discussed in this text since it is the general consensus of most posterior stabilized prosthetic designs that these loads are resisted by the soft tissue structures. Since the collateral ligaments primarily resist these moments and it is generally agreed upon that the collaterals are intact when using a posterior stabilized prosthesis, the aforementioned design consensus has validity. In the event the collateral are not intact, a more constrained prosthetic device generally referred to as a total condylar constrained implant is utilized. This prosthesis resists adduction and abduction moments normally resisted by the collateral ligaments by virtue of contact with the medial and lateral aspects of the tibial spine with the interior femoral housing walls.

4. POSTERIOR STABILIZED DESIGN ISSUES

4.1 Background

This section involves integrating the biomechanical background previously discussed with some of the current PS designs on the market. The biomechanical factors reviewed include: instant center and femoral rollback analysis, femoral rollback design methodology, range of motion, subluxation resistance and patella clearance with the anterior tibial spine. Additional consideration is given to rotation, bone conservation, assembly methods of polyethylene tibial inserts into tibial trays, articulating surface conformity and tibial tray design.

4.2 Instant Center and Femoral Rollback Analysis

Many of the current PS prosthetic knee systems are designed to provide forced femoral rollback from the tibial spine and femoral cam interaction. The basic premise is to duplicate the femoral rollback present in the normal knee since it is believed that this will provide patients with normal kinematics and result in favorable patellofemoral and tibiofemoral joint reaction force profiles for the prosthetic device. This still is the basic premise of design for both cruciate sparing and sacrificing devices despite the previously cited work of Scott et. al.[3] regarding femoral movement in a prosthetic device actually being femoral "roll forward" (versus rollback) based on fluoroscopic analysis.

The Insall-Burstein Posterior Stabilized Knee system was among the first developed and is designed to position the instant center of rotation for flexion angles greater than 40° in the posterior region of the tibial anterior-posterior centerline[20]. This is presumably desirable because it permits greater flexion by not over stuffing the patellofemoral joint in late flexion due to the femur being located too anteriorly relative to the tibia. Over stuffing implies the tension in the quadriceps mechanism is increased.

Burstein also postulates other advantages to maintain the instant center and tibiofemoral contact point in the posterior aspect of the tibial plateau for flexion angles greater than 40°[20]. These comments are summarized from the cited reference and also justify why the Insall-Burstein knee system incorporates a single anterior-posterior radius on the tibial insert.

* Burstein postulates that if normal forces (forces acting perpendicular to the point of contact) acting on the natural joint surfaces deviate by greater than 8° from the true normal, then the cruciate ligaments will incur load.

* Since literature findings (not specifically cited by Burstein) indicate that cruciate loads do not exceed one quarter of the normal load for ambulatory processes, Burstein concludes this permits the normal force angular deviation to increase from 8° to 22° (See Figure 21). This implies that a combined normal and cruciate force can be replaced by a single force oriented at 22° from the tibial axis. Burstein is therefore postulating the natural knee tibial articulating surface (meniscus and cartilage) as being equivalent to a surface with a single radius having an included angle of 22°. Since the prosthetic Insall-Burstein tibial component radius exceeds the postulated 22° included angle equivalent of the natural knee, Burstein acknowledges that supplemental mechanisms are required to provide the equivalent cruciate stabilizing force (see Figure 22). He accomplished this via two mechanisms:

a. Femoral cam and tibial spine interaction resisting the anterior shear loads the posterior cruciate would resist.

b. For flexion angles greater than 40°, the instant center of rotation is maintained in the posterior region of the tibia via the cam and condylar surface contact profiles. (Posterior condylar contact is desirable as it promotes more flexion.)

By maintaining posterior tibiofemoral contact at flexion angles greater than 40°, Burstein has essentially reduced the 42° included angle of the tibia for 21° (only for flexion angles greater than 40°) and via the analysis used before, has limited the shear loads (normally resisted by the cruciate) to no greater than 1/4 the normal force. The net effect is the worst case combined normal and cruciate (shear) loads are modelled as one force with a 22° resultant angle from the vertical tibial axis. As seen in Figure 23 the resultant load runs through the stem.

Many devices marketed today use the theory developed by Burstein. The technical literature on these devices discuss how they maintain similar tibiofemoral contact points as a function of flexion angle. This technical literature therefore refers to the posterior femoral rollback as being similar to the Insall-Burstein system. Since the Insall-Burstein system has enjoyed a relatively high survivorship rate and good to excellent knee scores since its inception, it is not difficult to acknowledge it is the gold standard and other designs tend to be similar to it. It should be pointed out that the other devices which are marketed as having similar posterior shift of the tibiofemoral contact point with increasing flexion (i.e. femoral rollback), generally fail to discuss the relationship between the normal and shear loads imparted to the tibial component. Since all posterior stabilized designs essentially have equivalent "J" curves and use dished (versus flat) tibial articular surfaces, it would stand to reason that the relationship of normal and shear loads would also be approximately equivalent to the Insall-Burstein system. (This refers to the shear loads not exceeding ¼ the normal loads and as previously discussed, is a function of the included angle of the tibial insert for flexion angles greater than 40°.) Perhaps this discussion is omitted in most technical information from manufacturers due to its complexity and the manufactures rely more upon the clinical success of the Insall-Burstein system.

Up to now the discussion in this section has dealt with the theoretical attributes of why the Insall-Burstein system and successor systems desire to have the instant center profile posterior to the centerline of the tibial component. The remainder of this section deals with experimentally evaluating the Insall-Burstein prosthesis for the instant center profile. In order to determine the instant center profile, a laser scanning device was used by the author to record the contour of the implant as computer data. The data was then converted to an IGES format and translated into a CAD database (Computervision - CV-4) for subsequent sectioning of the polyethylene tibial insert and femoral surfaces. The instant center of rotation profile was solved and is illustrated in Figure 24 for flexion angles of 45, 90, 105 and 120°. It is interesting to note that this analysis confirms Burstein's theory wherein the instant center profile is posterior to the anterior-posterior centerline of the tibia.

Also noteworthy is the fact that the Insall-Burstein design as well as the PFC™ and Genesis™ designs have a continuous posterior displacement of the tibial and femoral contact point as the flexion angle increases. (Note: technical literature of other designs was not specific enough to determine whether this was true).

All designs do not employ this methodology. The AMK® is theoretically designed to have contact between the femoral cam and spine of the tibial insert at approximately 25° of flexion. (This is when the femoral condyle/tibial articular surface contact point is approximately at the centerline of the tibial anterior-posterior dimension and when the anterior shear loads in gait are large enough to cause the femoral component to move anteriorly thereby causing the femoral cam to contact the tibial spine.) From 25° to approximately 45° flexion, the femoral component does go through a continuous posterior displacement (until it is 6 mm posterior to the tibial anterior-posterior centerline for the size 3 component). The 45° flexion angle is in the vicinity of the greater flexion angles required in the load carrying portion of the gait cycle. Note that the gait cycle accounts for approximately 90% of the average duty cycle which an implant goes through. (The balance being stair climbing/descending, sitting/resting etc.). From approximately 45° to 120° flexion, no further posterior displacement of the femoral component occurs by virtue of the origin of the femoral cam being the same as the origin of the femoral condyle used during articulation from 45° to 120° (see Figure 25). One may question the potential for wear of the polyethylene tibial insert by dwelling in the same area from 45° to 120°. However, as previously stated, a low portion of the implant's duty cycle involves flexion angles greater than 45°.

It is also interesting to note that the more recent designs of posterior stabilized prostheses have been reducing the amount of femoral rollback. Table 2 is a summary of this trend. The first three entries are among the most recent designs on the market.

TABLE 2

Femoral Rollback

System	Approximate Femoral Rollback at 120° Flexion (mm) Measured Relative to Tibial A-P Centerline*
AMK® - DePuy	6.0[a]
PFC - Johnson and Johnson	8.0[b]
Kinemax - Howmedica	10.0[c]
IB I and IB II - Zimmer	13[d]
Ortholoc II	21[e]
Omnifit - Osteonics	12[f]

* Data applies to mid size components.
a. The data was obtained from Computer aided design layout data for size 3.
b. From technical literature on product[21].
c. From technical literature on product[22].
d., e., f. Data obtained from Fuji contact film study - center of pressure zone used at 120° flexion.

The potential negative side of reducing femoral rollback has been surmised by many to be reduced maximum flexion. The natural tibiofemoral articulation reportedly involves some 4-6 mm medial posterior meniscus movement and the lateral meniscus some 10-12 mm posterior translation. Earlier PS designs have used values in the neighborhood of 12 mm. Another possible reason was discussed by Burstein wherein he advocates maintaining an instant center profile in the posterior aspect of the tibia for better flexion.[20]

It is important to note that the rollback recorded in Table 2 assumes no rotation while the 4-6 mm medial and 10-12 mm lateral meniscus movement indicates rotation since each compartment is undergoing different translation. This could be thought of as the "screw home mechanism". Obviously with rotation, all table values would increase for one compartment and decrease for the other.

Clinical results on the AMK® with only 6.0 mm femoral rollback have shown no detrimental effect of reducing rollback. The average range of motion obtained in one clinician's use has been 110°.

4.3 Femoral Rollback Design Methodology

Once one has determined the amount of posterior femoral rollback versus flexion angle criteria desired for a prosthesis it is an exercise in curve fitting to develop a femoral cam and tibial spine profile. However, certain criteria must be set to develop these geometries, namely:

a) the femoral J curve

b) the tibial polyethylene articular geometry which interfaces with the J curve

c) either a preconceived notion of the femoral cam geometry (i.e., circular or a series of radii that are manufacturable), or a preconceived idea of the posterior aspect of the tibial spine (i.e., vertical or angled).

Assume the femoral cam geometry and position are given. To generate the resulting tibial spine for a given femoral rollback profile, the femoral cam position must first be recorded. This is found by properly positioning the femoral component on the tibial articulating surface based on the femoral rollback profile/flexion angle. With all femoral cams positioned on one layout, a curve is drawn tangent to the all femoral cams. This curve represents the posterior aspect of the tibial spine (Figure 26).

It's also worthwhile noting that the posterior aspect of the generated tibial spine may not always be readily manufacturable. This usually applies to those designs which are not easily machined since most manufactures do not mold polyethylene. In these situations the designer may use several options.

a) Deviate from the initial femoral rollback profile in whatever flexion range necessary (i.e., early, mid or late) and adjust the posterior aspect of the spine for manufacturability/machinability.

b) Change the femoral cam to yield a more manufacturable tibial spine.

A final note on rollback is that most posterior stabilized designs incorporate a femoral cam positioned in the posterior aspect of the femoral component and a tibial spine with the posterior aspect of the spine positioned posterior to the a-p centerline of the tibia.

4.4 Range of Motion

The range of motion for a bench top tested PS design is a function of the J curve, tibial articular surface for the J curve and the interaction of the femoral cam (s) and the tibial spine. Range of motion includes hyperextension and flexion/extension.

Hyperextension

Some devices have a "physical stop" created by the contact between the anterior portion of the tibial spine and the femoral component at the maximum hyperextension angle. The area of the femoral component which contacts the spine is the base of the patella track forming the anterior border of the intercondylar notch. This can also be referred to as the anterior cam. The technical literature for some designs define this as the point where hyperextension ceases, whereas other designs indicate that a continued cam action may continue with the anterior spine and afford further hyperextension (see Figures 27 and 28).[23]

It is important to note that for designs which follow the principle outlined for the AMK® wherein a hyperextension movement is permitted after contact between the anterior cam and tibial spine the hyperextension should be assessed relative to:

a) The required hyperextension for a normal knee (Kapandji[8] indicates that this has been measured from 6° to 9°)

b) The tibiofemoral contact point. The more a prosthesis of this type is put into hyperextension the further anterior the contact point between the tibial and femoral condyle moves until it is not anatomically possible to move anterior any further.

Therefore, caution should be exercised when assessing hyperextension to ensure that at approximately 5° hyperextension, the tibiofemoral contact point is within a few millimeters of the anterior-posterior centerline of the tibia. This has been considered the approximate area of tibiofemoral contact observed for normal knees in hyperextension when assessed intraoperatively.

Flexion

Most posterior stabilized designs provide at least 120° of flexion. This is more than adequate to cover the necessary upper limit of flexion necessary to perform typical patient activities outlined in the kinematics section. Recall that activities such as sitting and rising from a chair or lifting an object require range of motion greater than 90° and less than 120°. If a patient were to flex beyond 120°, several things can happen:

a) The superior aspect of the posterior femoral condyle may create high loads on the tibial insert because the tibiofemoral contact area is decreasing to an edge contact.

b) The posterior aspect of the femoral bone may contact the tibial insert precluding further flexion.

c) The relationship between the patella track on the femoral component and the femoral rollback may block further flexion due to an over tightened patellofemoral joint.

4.5 Subluxation Resistance

Recall that subluxation is either the anterior displacement of the femur relative to the tibia or posterior displacement of the tibia relative to the femur caused by the lack of ligamentous stability to resist the anterior shear loads on the femur during ambulatory processes. For the purposes of this section, subluxation resistance is characterized as the femoral displacement necessary to cause the femoral cam to jump over the top of the tibial spine at a given flexion angle.

The logical points to evaluate subluxation resistance are at those recorded in the literature or those learned from personal correspondence with physicians as being troublesome. From discussion with physicians, one troublesome point seems to be at approximately 90° flexion when the lower extremity is free-hanging, permitting the tibial and femoral articular surfaces not to be in contact nor under any compressive load. Depending upon the ligamentous laxity and prosthesis type, this angle of flexion and loading condition has been reported as causing the femoral cam to ride over the top of the tibial spine for posterior stabilized prostheses. It therefore becomes important to maximize the superior femoral translation to help alleviate subluxation under these conditions. Other potential instability can occur in the early part of flexion when the cam of some designs is contacting high on tibial spine. Consider the Insall-Burstein design at approximately 25° of flexion in a knee where ligamentous instability caused by improper flexion-extension gap balancing permits the femur to be unstable on the tibia in the anterior-posterior direction. Examination of the anterior shear load at 25° flexion in the gait cycle on the leg in the stance phase suggests the shear loads are appreciable. Figure 29 indicates that at 30° flexion under non-properly balanced collateral ligaments, the femoral cam could ride over the tibial spine.

Subluxation resistance is dependent on several factors including:

a) The cam position and geometry.

b) The posterior rollback desired in a design as it affects the cam position and geometry.

c) The tibiofemoral condylar surface geometry as they also relate to a and b.

d) The height of the tibial spine.

4.6 Patellar Clearance With the Tibial Spine

Patella clearance with the tibial spine is desirable because it prevents polyethylene (patella) on polyethylene (tibial spine) contact which causes wear debris. This wear debris can lead to premature failure from mechanical or osteolytic failure of the joint or surrounding tissue, respectively.

To analyze this aspect of a PS design requires a designer with the help of the surgeon and x-ray analysis to examine the flexion/extension of the joint. This is usually first performed with computer aided design layouts, therein incremental flexion angles are represented and the "normal" patella position/orientation is imposed on the layout. From these layouts the designers can determine an anterior tibial geometry which would not impinge on the patella. The analysis should next consider the attributes which would reduce the clearance between the two surfaces. These include but are not limited to:

a) Rotation of the femoral component.

b) Patella alta or baja caused by surgical movement of the joint line. Patella alta refers to the patella being more superiorly located then normal relative to the joint line. Patella baja refers to a more inferior than normal patella location relative to the joint line.

c) The anterior-posterior positioning of the tibial insert/tray resulting from surgical implantation. Anterior positioning of the tray would likewise move the tray anteriorly and increase the likelihood of the spine contacting the patella.

d) The polyethylene thickness between a metal stabilizing post and anterior border of the spine.

4.7 Rotation

The rotation of a PS design or any other prosthetic knee design can be assessed using simple benchtop methods or with more elaborate servo-hydraulic devices such as an MTS machine which is designed to give the torque required to produce a certain rotation under a given compressive load. A review of designs using a simple benchtop method involving a protractor at flexion angles where the femoral cam component is in contact with the tibial spine indicates most designs yield a minimum of 6° to 7° internal and external rotation at 90° flexion. The rotation is considered completed when the inside femoral housing contacts opposing anterior and posterior corners of the tibial spines or when the femoral condyles contact the extreme limits of the tibial articular surface.

In full extension, the benchtop method relies on tactile feedback to sense when "appreciable" rotational resistance is encountered. In extension a minimum of 6 to 7° of internal/external rotation was found for the designs surveyed. Table III gives a summary of designs characterized with the benchtop method or from data attained from manufacturers technical literature.

TABLE 3

Internal/External Rotation

Design	At Extension (degrees)	At 90 Flexion (degrees)
Insall-Burstein	7	7
PFC	10	10
AMK	10	12
Ortholoc II	>20	>20

Recent PS designs have offered an increase in the available rotation. This is afforded by the clearance between the tibial spine and inside femoral housing wall. It is also related to the profile of the tibial articular surface. Generally, the deeper the radial contour goes into the tibial insert (relative to the lateral view), the greater the resistance to femoral rotation. Figures 30 and 31 demonstrate this to the extremes of current posterior stabilized designs. Figure 30 is the Insall-Burstein polyethylene tibial insert design which has a deep radial profile in the sagittal plane and offers less rotation than the Ortholoc II polyethylene tibial insert design in Figure 31 which is essentially flat in the lateral view. As can be surmised, the radiused or dished designs limit rotation either by tibial articular surface/femoral condyle contact or tibial spine edges/femoral cam contact.

It is also interesting to note that the radial profile (relative to the sagittal view) causes greater lengthening potential for the collateral ligaments as the femoral component goes into more rotation. This is due to one condyle riding up the anterior radius while the other is riding up the posterior radius. Whether the increased collateral ligamentous tension becomes the operative anti-rotational mechanism is dependent on the amount of rotation necessary and ligament tension in the collaterals during flexion-extension gap balancing. The Ortholoc II design which has virtually unrestricted internal/external rotation from mechanical means, utilizes the collateral ligaments as the primary soft tissue structures to limit rotation.

Most recent PS designs have also been adopting an "hourglass" geometry in the design of the posterior femoral cam and tibial spine. The intent is to prevent the edge loading that occurs when a linear cam and spine profile are taken through rotation. Figures 32 indicates the edge loading for a linear cam/spine contact in rotation while Figure 33 indicates how the hourglass design eliminates edge loading and yields a contact zone on the entire posterior tibial aspect. The effect is to reduce the localized load and therefore the stress on the polyethylene tibial spine thereby reducing the potential for polyethylene wear and resultant debris into the joint space.

Figure 34 is a posterior stabilized retrieval indicating the effects of edge loading between the posterior aspect of the tibial spine and femoral cam as well as between the anterior margins of the tibial spine and femoral condylar surface. The insert material is a carbon fiber reinforced polyethylene which is no longer marketed due to its greater tendency to dissociate (when compared to conventional polyethylene) under normal loads.

Examination of Insall-Burstein tibial retrievals manufactured from conventional polyethylene indicated less dramatic deformation of tibial spine, however deformation was noted. This suggests that more than 6° to 7° internal/external rotation may be required in a posterior stabilized design. It is also important to note that when the rotation reaches its maximum, the tibial tray/bone cement interface is subjected to unnecessary torsional loads. Therefore, the recent trend in posterior stabilized design to provide 10° internal/external rotation may have validity. Proponents of this much rotation include the AMK®, PFC, AGC, Ortholoc II and Kinemax as indicated in manufacturer's literature.[21,22,24]

4.8 Bone Conservation

This section deals with the volume of bone required to accommodate the femoral housing. It does not include the additive effects of the bone volume required to resect the anterior-posterior box profile of an implant. Generally all implant systems are comparable in anterior-posterior box resected bone volume since all implants have distal and posterior thicknesses of 8 - 10 mm on average within a given system. The intent of most systems is to replace the resected bone while providing a balanced flexion-extension gap and proper knee valgus alignment. The valgus alignment is to ensure that the mechanical axis passes through the medial-lateral centerline of the joint. (See any typical total knee surgical technique for a discussion of alignment).

The objective is to reduce the resected bone for the femoral housing for several reasons.

a) The broader the distal and chamfer area contact between femoral implant and bone, the less load/unit area on the supporting bone.

b) The more bone remaining, the stronger the integrity of the distal femur.

c) In the event of revision of a posterior stabilized prosthesis, more bone stock usually implies less difficulty for the revision (i.e, it may avoid the need for bone graft or intramedullary stems for stability).

The volume of the femoral housing does not imply the volume of bone resected from the femur is the same. To better understand this, Figures 35 and 36 are provided for reference relative to the following discussion.

As can be seen in Figure 35, the natural femur is relieved in the area of the femoral housing by virtue of the anatomy of the intercondylar notch. The notch accounts for a sizeable portion of the femoral housing volume. It is also seen that the notch displaces more bone volume in the posterior aspect of the femur versus the anterior aspect. This is one factor that accounts for most posterior stabilized designs having a lower anterior femoral housing surface than posterior surface.

Recent posterior stabilized designs have addressed reduction of the bone volume resected in a number of ways. The Insall-Burstein II posterior stabilized design uses a femoral housing that requires less bone be resected than the first version of the Insall-Burstein I design. It is not clear if this was accomplished by changing the position of the posterior cam more distally or reducing the diameter of the cam or a combination of both or reducing wall thickness. Whichever method was used has resulted in the superior surface of the femoral housing being closer to the distal implant surface.

A more recent design, the AGC PS, has eliminated the need for any femoral housing resection. This was accomplished by placing the femoral cam between the posterior runners in a manner that it does not violate the anterior-posterior box. The tibial insert therefore does not need a spine, rather it has a curved depression to handle the femoral cam (see Figure 37). The posterior femoral rollback profile versus flexion angle that results for this device nor subluxation height resistance was not available to the author to evaluate the feasibility of this design.

Another recent design, the Genesis posterior stabilized, at first appearance has a posterior cam/tibial spine design that would require a great deal of bone resection due to the height of the tibial spine. Technical literature for this product indicates a small amount of required resection is due to the extreme posterior placement of the tibial spine and femoral cam. The implication is that the only posterior bone is removed which doesn't require excessive resection due to the geometry of the intercondylar notch. Additional review of the Genesis technical literature reported the Genesis implant required 37.5% less bone removal than the Insall-Burstein II due to a smaller housing and posterior housing location. The reference does not indicate which sizes were compared.

Perhaps the most significant clinical related aspect of the femoral housing size is that the lower and narrower the profile, the less tendency to split femurs during implantation.

4.9 Assembly of Polyethylene Tibial Inserts into Tibial Trays

Current posterior stabilized designs utilize the modular feature of securing various thicknesses of tibial inserts to tibial trays. Some systems require the tibial tray dimensions be the same as the polyethylene tibial insert (in the anterior-posterior and medial-lateral directions) while others permit any combination of trays and inserts to mate.

The manner in which the tibial insert loads to the tibial tray relates directly to the surgical ease to implant a device. Modular posterior stabilized designs use two possible directions for tibial polyethylene insertion onto the tray. Namely:

a) The polyethylene insert is loaded from the front, that is, from anterior to posterior where it is then locked in place with either a combination of undercuts or dovetails, fixation posts or pegs, or interference fits (see Figures 38 and 39).

b) The insert is loaded from the side, that is, from medial to lateral or lateral to medial where it is then locked in place (see Figure 40).

Both offer the advantage of modularity which reduces the inventory costs associated with one tray for every insert thickness. However, the front loading polyethylene tibial insert provides a surgical advantage over the side loading polyethylene tibial inserts since it is possible to assemble the front loading type after the tibial tray is positioned by simply placing the femur in flexion. The side loading polyethylene tibial insert does not permit this because the femoral condyle obstructs the tibial spine. The result is that the polyethylene tibial insert must first be attached to the tibial tray and then implanted. The underlying premise is the femoral component is implanted first otherwise the ligamentous laxity would be excessive since the femoral cam must be made to move anterior to posterior over the tibial spine.

4.10 Articulating Surface Conformity

The relationship of the tibial articular surface and femoral articular surface in the sagittal plane has been previously described. The sagittal geometries of the tibial insert and femoral component in conjunction with the tibial spine geometry/position and femoral cam geometry/position determine the femoral rollback. The issue in this section is what are the other effects of increasing or decreasing anterior-posterior polyethylene tibial insert/femoral condyle conformity as well as medial-lateral conformity. It should be noted that conformity, as discussed here, implies matched radii in the anterior-posterior or medial-lateral plane. Increasing the anterior-posterior and medial-lateral radial conformity between the tibial insert and femoral condyle results in:

a) A reduction of the available rotation of the femoral component on the tibial component. To visual this, it is worthwhile considering the available rotation of a femoral component on a flat plate versus a plate that has two depressions both with anterior-posterior and medial-lateral radii. Intuitively, one should see that the flat plate will not restrict the rotation while the dual radii depression will.

b) Increased conformity increases the torsional stresses imparted through the tibial insert to the tibial tray and therefore between the bone cement and bone interface. This results from the resistance to femoral rotation coming from the conforming nature of the insert.

c) Increased conformity lowers the contact stresses imparted to the polyethylene. This is apparent when using the analogy of the femoral component as a radius setting in the depression (radii) versus on a flat plate.

Parametric finite element studies and elasticity solution studies performed by Bartel[25] suggest that an increase in conformity in the medial-lateral direction has more effect than in the anterior-posterior to reduce contact stress, shear stress and von Mises stress. Bartel's work involved varying conformity of both medial-lateral and anterior-posterior radii between the femoral component and tibial insert. Associated variables to reduce polyethylene stress included the polyethylene thickness (Bartel found a minimum of 6 to 8 mm's of polyethylene is advised for a composite metal tray/modular polyethylene insert) and cyclic fatigue. The fatigue is caused by the femoral rollback induced movement of compressive and tensile stresses on the polyethylene tibial insert since the femoral component tends to indent the polyethylene tibial insert. It is worthwhile noting that there has been much work done in the study of the effect of the cyclic fatigue of various grades of polyethylene (actually ultra high molecular weight polyethylene UHMWPE) and how it relates to surface damage to the polyethylene.[26,27] This surface damage includes pitting and delamination while creep is also present. The debris resulting from these processes results in mechanical failure of the prosthesis as well as osteolytic reaction. The scope of this thesis deals mainly with the geometry related issues of posterior stabilized design rather then an in depth review of retrieval analysis of failed or worn posterior stabilized components. Retrieval analysis is an extensive topic and is covered only briefly in the text as more material is preferentially related regarding design.

As can be surmised, the tibiofemoral joint conformity represents an optimization problem wherein high conformity lowers polyethylene stresses but imparts high loads on the fixation interface caused by torque from femoral rotation. The clinical data supports that the lower limit of conformity selected should yield 6° to 7° of internal and external rotation. This is based on the Insall-Burstein design clinical findings showing no significant radiolucencies developing at the cement interface of the tibial tray[2].

The patellofemoral joint conformity is not as design sensitive as the tibiofemoral joint. As a general rule the radius used in the femoral trochlear groove is the same value as the patella radius. The amount of conformity between the patella and the femoral component which is actually present relates to manufacturing tolerances. Some prostheses use a grinding process to insert the trochlear groove while others rely on hand polishing of a near net casting. Either way imposes manufacturing tolerance as does the machining or molding process for the spherical radial profile of typical patella component. Depending upon the mismatch in conformity and material properties for the particular grade of polyethylene selected for the patella, the patella loadings can result in deformation that may cause delamination of the patella.

4.11 Tibial Tray Design

Up to this point the front or side insertion of the polyethylene tibial insert onto the tibial tray and the inclusion of a stem for stability have been discussed. Other tibial tray design parameters include:

a) The tray material - generally either Ti-6Vi-4Al or CoCr alloy (either ASTM F-75 (cast) or F-799 (wrought).

b) The tray thickness.

c) The stem location and geometry.

d) The capability of the tray to accept modular stems.

e) The number of tray sizes.

f) The fixation interface geometry of the tray.

Item a, the choice of material for the tray generally involves a discussion of material stiffness. Since the stiffness of Ti alloy is significantly less than CoCr alloy, many manufacturers promote it since it will reduce stress shielding of the resected bone.

However, any discussion of stiffness must also consider the geometry (or thickness) of the tray to get a true comparison. Some manufacturers also choose Ti alloy due to its superior ingrowth capability when compared to CoCr. Specifically, Ti alloy trays fitted with a Ti porous surface for ingrowth have shown superior ingrowth compared to CoCr alloy trays fitted with CoCr porous surfaces. Ti alloy trays therefore have better biocompatability than CoCr alloys in a non-cemented mode. It should be noted that the authors understanding of the posterior stabilized market is that most tibial trays are implanted using cement on the underside and proximal stem region of the tibial tray.

An additional factor necessary to assess the use of CoCr alloy or Ti alloy is machinability. In this regard Ti alloy trays have the advantage of easier machinability.

The tray thickness is an issue as it relates to available polyethylene tibial insert thickness. Based upon Bartel's work[25], 6 mm minimum insert thickness is desirable to help reduce stresses and promote greater insert fatigue life. Generally a surgeon wishes to minimize the amount of tibial bone resected while maintaining the joint line. It is therefore apparent that the minimum safe tray thickness is the design parameter. The 2% yield strength of Ti-6-4 alloy is 115 ksi while that of CoCr alloy (cast F-75) is 65 ksi[27]. The fatigue strength of each alloy is 60 ksi and 45 ksi, respectively[27]. Acknowledging that Ti alloy is much more notch sensitive then CoCr alloy, the fatigue strength value of Ti alloy trays must be considered. A review of tibial tray thicknesses from various manufacturers varies from 3.1 mm to 5.7 mm. These designs are generally submitted to 10^6 cycles of fatigue testing at gait cycle loads (3X body weight) and therefore represent acceptable tray thicknesses. The resulting minimum tray/insert thicknesses are 8 mm. It is therefore evident that some 8 mm composite thickness have as little as 3.3 mm poly thickness. A recent trend in the market is to provide composite tray/insert thicknesses starting at 10 mm thereby providing the 6 mm minimum recommended by Bartel.

The stem location on a tray is dictated by the position of the tibial intramedullary canal and the slope of tibial resection resulting from the instruments provided with the implant. Some designs advocate a 0° tibial posterior slope while others advocate a 5° to 7° tibial posterior slope.

The stem geometries are either cylindrical, tapered or that illustrated in Figure 41. Most stems include flat regions to better resist the rotational or torsion loads imparted to the tibial insert. Additionally, most trays include a means to attach modular stems usually via a morse taper and/or screw thread. These stem extensions provide added support to the tray as they also distribute the loads into the intramedullary canal.

The number of tray sizes relates to the cortical coverage that the tray provides. To resist subsidence, it is desirable to have the tray positioned above as much cortical bone as possible rather than solely over the weaker cancellous bone structure. Assuming an anatomic perimeter shape, the more sizes a tray offers, the greater the potential to provide cortical coverage. It is interesting to note that earlier tibial tray designs, particularly of the all polyethylene variety (which included an integral polyethylene stem) were reported to fail at a relatively high rate. This can partially be attributed to the lack of available sizes and non anatomical geometry that resulted in negligible cortical support of the tibial tray.

The depth of resection can be ruled out as affecting the bone strength based upon the work of Belec.[28] This work indicated there was no statistically significant deterioration of bone properties of a resected tibia when examined between 2 mm distant slices. This work involved converting CT bone data density into bone properties.

The fixation interface geometry of a tibial tray refers to the inferior side of the tray. Specifically, in a posterior stabilized application which is primarily a cemented application, does the tray include a means to augment cement interdigitation? This can be accomplished via a pattern involving peaks/troughs or some type of standardized undercut to permit cement to bond to something other than a flat smooth undersurface. Since the compressive, shear and rotation loads imparted to a tray can be substantial, any additional means to improve the cement bond to the tray are desirable.

5. SUGGESTED TESTING FOR PROSTHETIC DESIGNS

Following design and prototyping of any prosthetic device, it is strongly recommended to conduct laboratory tests to evaluate the safety and efficacy of the design. The testing usually involves a protocol verifying design attributes based upon biomechanical analysis or generic prosthetic attributes usually required by the Food and Drug Administration medical device regulations to authorize a manufacturer to sell this product. This discussion includes recommended tests falling under both categories.

Tibial Spine Loading

Review of the literature revealed that the anteriorly directed shear loads acting in the knee joint were calculated as 1.3 times body weight by Morrison and 2.1 times body weight by Seireg.[25,27] A suggested test involves potting the tibial tray and tibial insert components and loading the spine anteriorly with a minimum of 2.1 times body weight. This is usually performed with an MTS machine or other servohydraulic device at a high frequency. Recommended test duration is usually that simulating ten years or ten million cycles.

Rotational Laxity

This test is designed to assess the available internal and external rotation afforded between the femoral and tibial components. The test can be performed using either tactile feedback or more elaborately with a dual axis MTS type machine. One axis would provide a compressive load between the components while the other measures the resistance torque for a given rotation angle.

Medial-Lateral and Anterior-Posterior Laxity

The test involves assessing the translation permitted shift between the tibial and femoral component in the medial/lateral and anterior/posterior direction. Most designs provide at least 1 to 2 mm of medial-lateral laxity before the spine and inner femoral housing walls contact. Medial/lateral laxity permits surgical misalignment and is often an indication of available rotation. The anterior/posterior laxity is a function of when the femoral cam and tibial spine are designed to contact.

Contact Area

This static test is usually performed using pressure sensitive film and involves the tibiofemoral and patellofemoral contact. The test is performed at various flexion angles with larger contact areas being desirable as it usually implies lower contact stresses on the polyethylene components. Of particular interest is the contact area of the patellofemoral joint as the patella transitions from the trochlear groove to the intercondylar notch. Contact area studies are often supplemented with finite element modelling analysis as well. This permits determination of principle and von Mises stresses in the polyethylene tibial insert.

Modular Component Testing

For systems including modular tibial trays, polyethylene tibial inserts and modular stems, a fatigue test simulating in vivo loads is used to verify the locking integrity.

6 CONCLUSION

Appropriate design of a posterior stabilized prosthesis requires an understanding of the kinematics and kinetics of the normal knee. However, to attain this understanding of the normal knee first requires the geometry of the natural tibiofemoral and patellofemoral joints be characterized. Fortunately, the literature has numerous anthropometric studies to facilitate this analysis.

Kinematic design of the posterior stabilized prothesis is primarily based upon developing an understanding of the interaction of the femoral cam with the polyethylene tibial spine simultaneous to the femoral condyles articulating on the polyethylene tibial plateau. Studying this interaction was best simplified using two dimensional lateral profiles of the prosthetic femoral and tibial components.

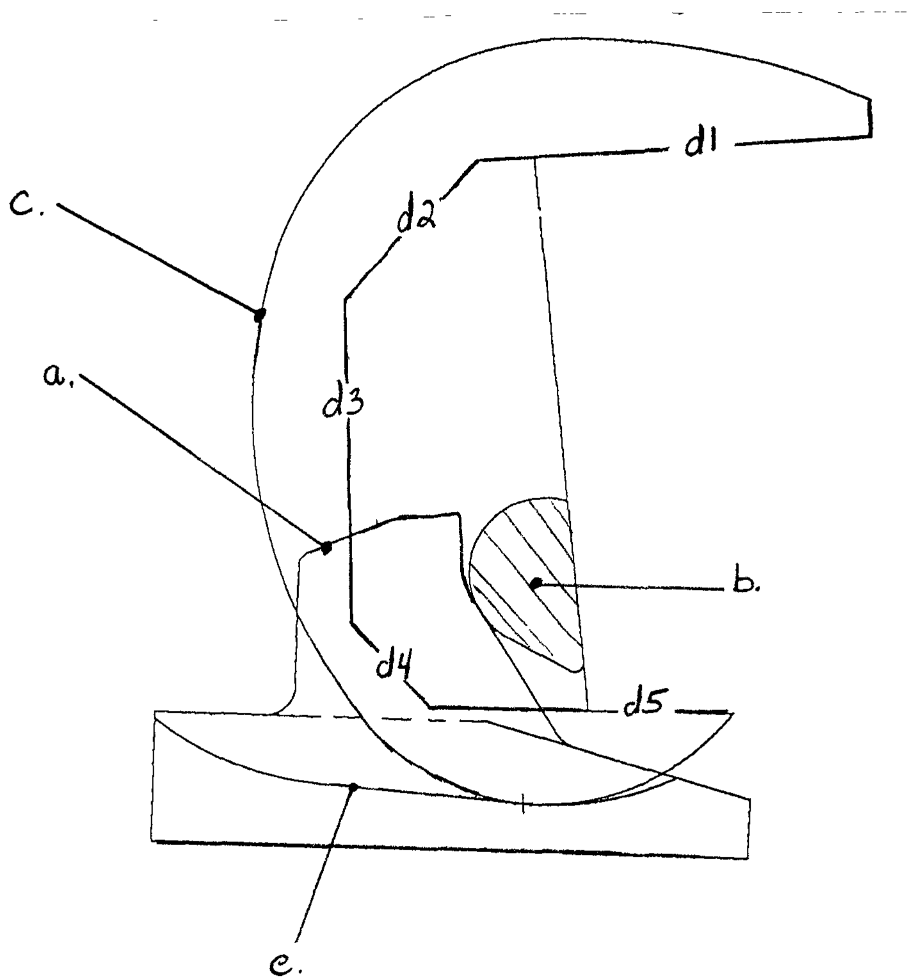
The kinetic analysis of the posterior stabilized prosthesis is best performed both analytically and empirically. A review of the literature enabled the resolution of the maximum anticipated compressive and shear loads for the gait cycle which represents approximately 90 percent of the duty cycle on the implant. Integration of the kinetic and kinematic data enables a well founded prosthetic design for the relative motions of the components and the joint reaction forces acting on the prosthesis. The knowledge of joint reaction force magnitude and direction enables the laboratory or empirical testing of the design.

Of the additional posterior stabilized design attributes surveyed in this text, relative conformity between the femoral condyle and polyethylene tibial insert, internal-external rotation, and the volume of bone removal required for the femoral housing resection, yielded a significant range of results among current posterior stabilized systems.

It is worthwhile noting that the current posterior stabilized knee market represents approximately ten percent of all total knee replacements performed in the USA. With the knee market expected to double in the next ten years to over 200,000 procedures per year, this equates to a substantial number of posterior stabilized prosthesis being implanted.

The controversy in total knee surgery of whether to remove the posterior cruciate and use a posterior stabilized device or keep the cruciate and use a cruciate spacing device, continues. However, for those surgeons who encounter a detrimentally attenuated posterior cruciate and desire the assurance of more anterior-posterior stability, the posterior stabilized device remains viable option.

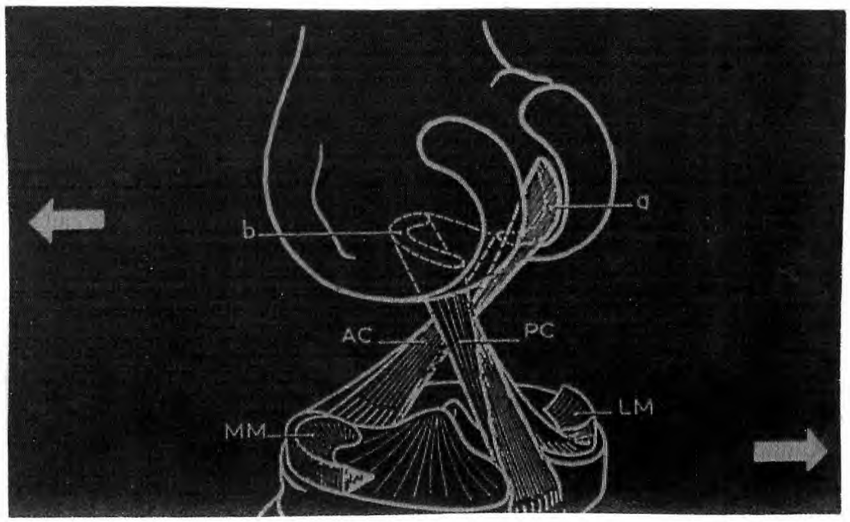
APPENDIX



Posterior Stabilized Knee Prosthesis

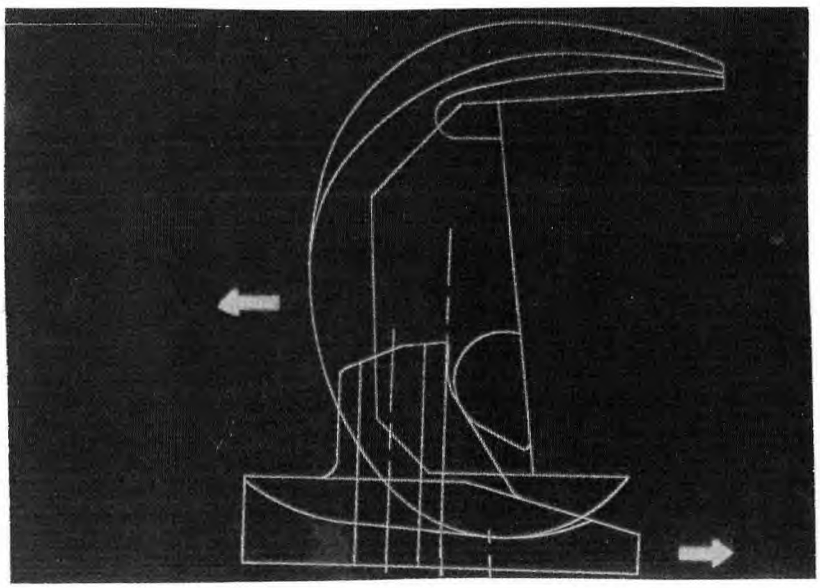
Figure 1

a. Raised tibial spine
b. Femoral transverse cam
c. Femoral condyle
d. A-P box (d1=anterior flange, d2=anterior chamfer, d3=distal surface, d4=posterior chamfer, d5=posterior flange)
e. Polyethylene tibial insert articular surface



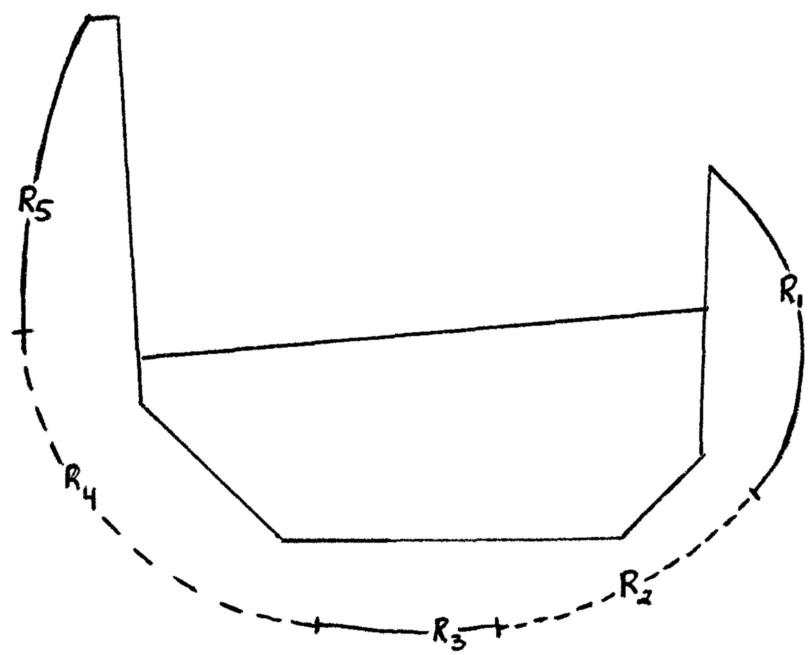
Posterior Tibial Subluxation Motion in the Normal Knee

Figure 2 Posterior tibial subluxation occurs when the tibia moves posterior to the femur due to the anterior shear loads on the femur. The arrows indicate the relative motions of the femur and tibia during subluxation.
ACL anterior cruciate ligament
PCL posterior cruciate ligament
LM lateral meniscus
MM medial meniscus
(Adapted from Kapandji, 1974)



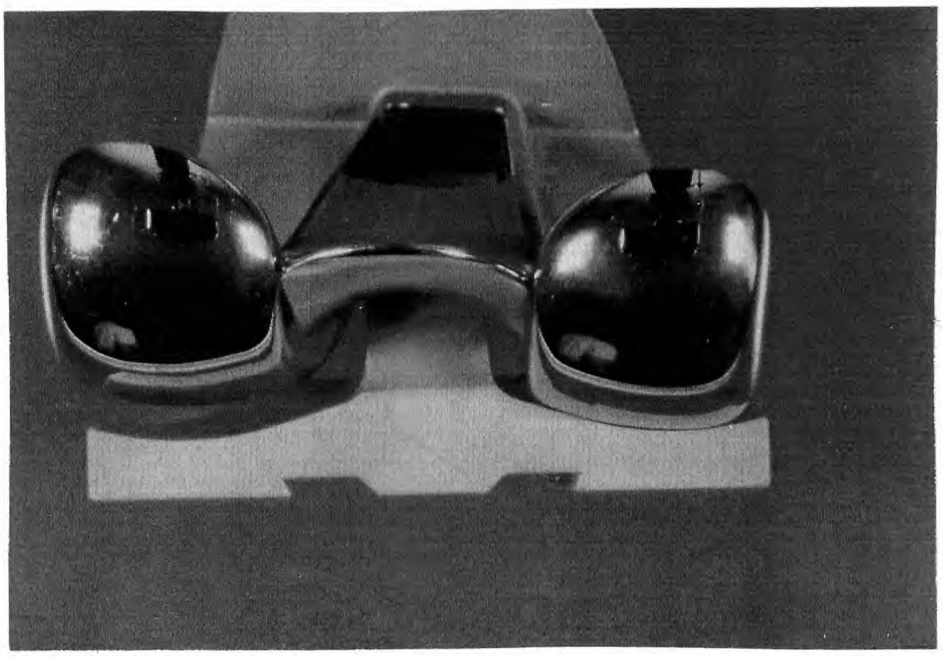
Resistance to Tibial Subluxation for a Prosthetic Design

Figure 3 Just as the posterior cruciate ligament resists posterior movement of the tibia relative to the femur, the interaction of the tibial spine and the femoral transverse cam do likewise.
a. Tibial spine
b. Femoral transverse cam



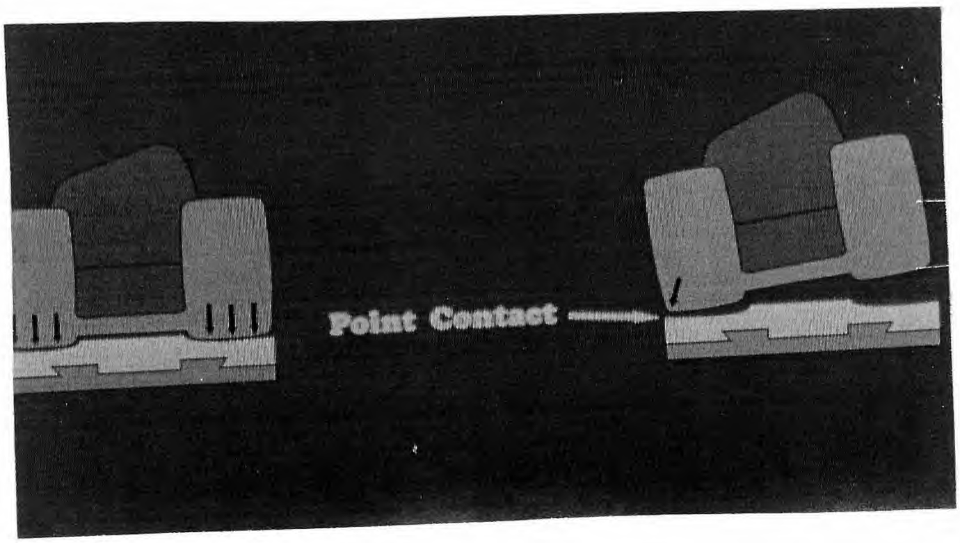
Prosthetic "J" Curve

Figure 4 In the lateral view, most posterior stabilized prosthesis are constructed from four or five tangent radii (R_1 through R_5)



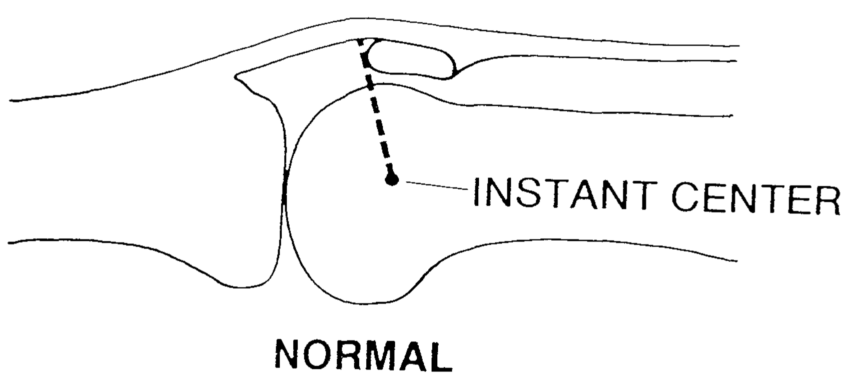
Tibiofemoral Articulation - Radius on Radius

Figure 5 Note the theoretical line contact maintained with the adduction or abduction load illustrated above in the frontal view of the radial femoral profile on the radial tibial insert articulating surface profile.



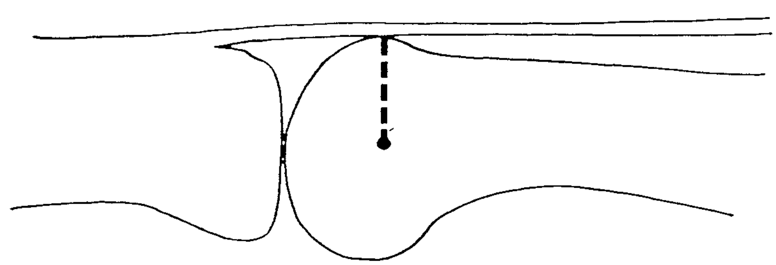
Tibiofemoral Articulation - Flat on Flat

Figure 6 The flat femoral condyle is articulating on the flat tibial insert articular surface. Note that during adduction or abduction loading of the joint a theoretical edge or point contact occurs. This can result in high stress in the polyethylene tibial articular surface promoting mechanical failure.



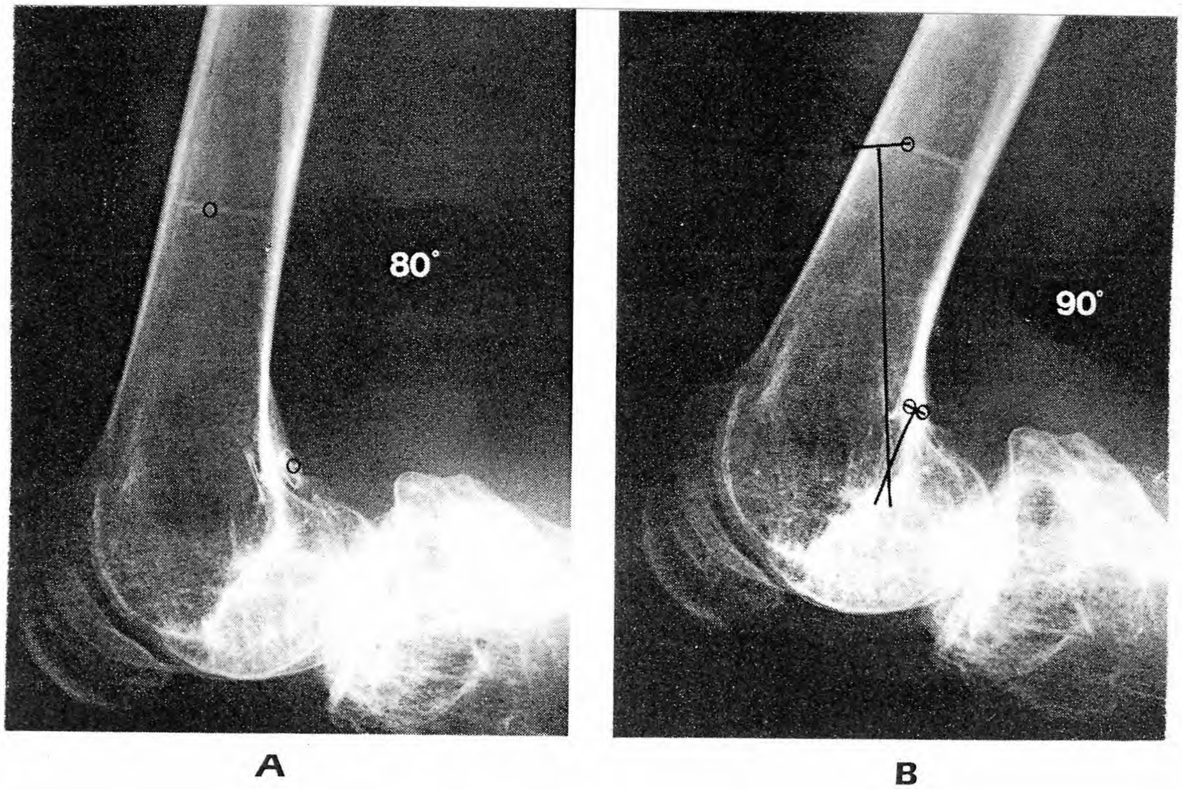
Normal Quadriceps Muscle Moment Arm

Figure 7 The quadriceps muscle moment arm (represented by the dashed line) in a normal knee extends from the instant center of the tibiofemoral joint to the patellar tendon attachment to the patella (from M. Nordin, V. Frankel: Basic Biomechanics of the Musculoskeletal System, 2nd Edition. Philadelphia, Lea & Febiger, 1989. Reprinted with Permission).



Quadriceps Muscle Moment Arm After Patellectomy

Figure 8 The moment arm is reduced without the patella. This requires more quadriceps force to provide an extension torque comparable to that resulting for the normal moment arm (from M. Nordin, V. Frankel: Basic Biomechanics of the Musculoskeletal System, 2nd Edition. Philadelphia, Lea & Febiger, 1989. Reprinted with Permission).

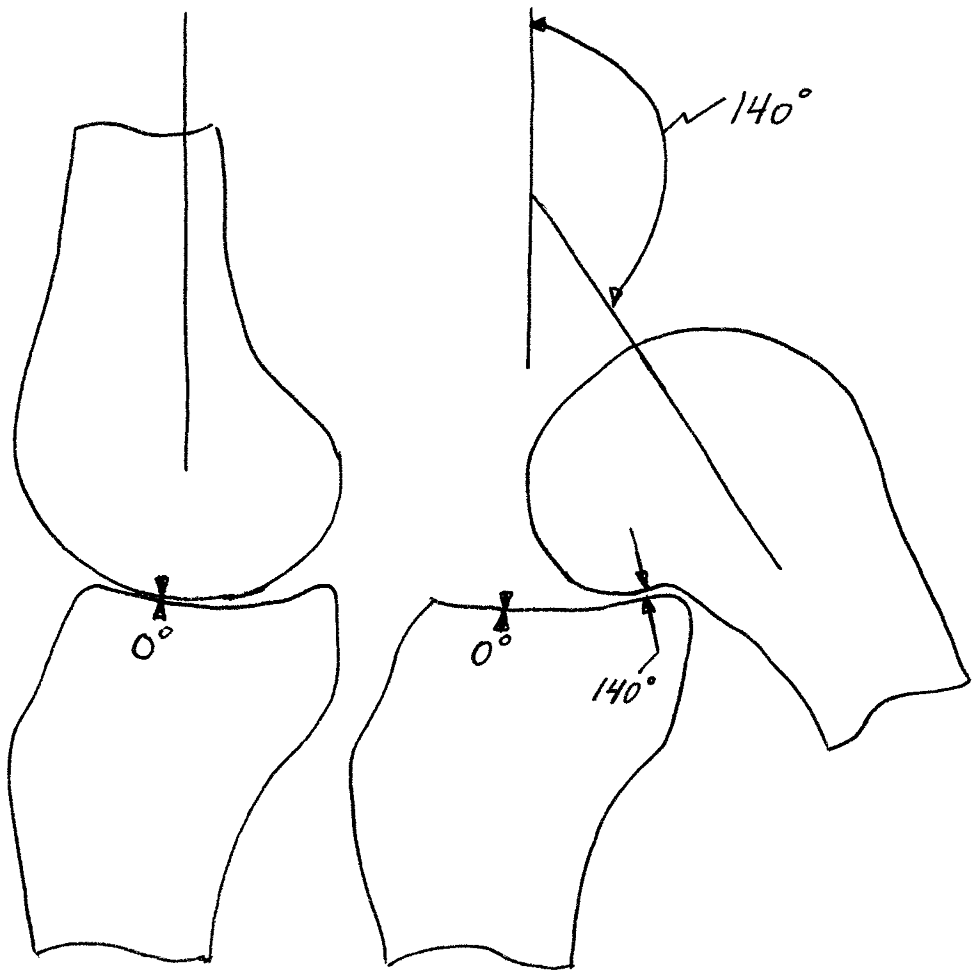


Determining the Tibiofemoral Instant Center

Figure 9

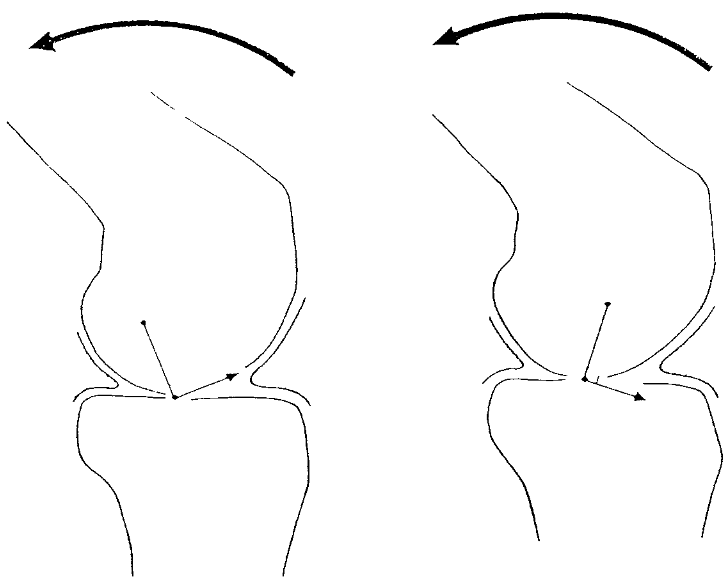
A. Two easily identifiable points on the femur are designated on a roentgenogram of the knee flexed at 80°.

B. The roentgenogram is compared with a roentgenogram of the knee flexed at 90°, on which the same two points have been indicated. The images of the tibiae are superimposed, and lines are drawn connecting each set of points. The perpendicular bisectors of these two lines are then drawn. The point at which these perpendicular bisectors intersect is the instant center of the tibiofemoral joint for the motion between 80 and 90 degrees of flexion (from M. Nordin, V. Frankel: Basic Biomechanics of the Musculoskeletal System, 2nd Edition. Philadelphia, Lea & Febiger, 1989. Reprinted with Permission).



Femoral Rollback

Figure 10 The motion of the femur on tibia is referred to as rollback and is a combination of rolling and sliding. (Adapted from Kapandji, 1974.)

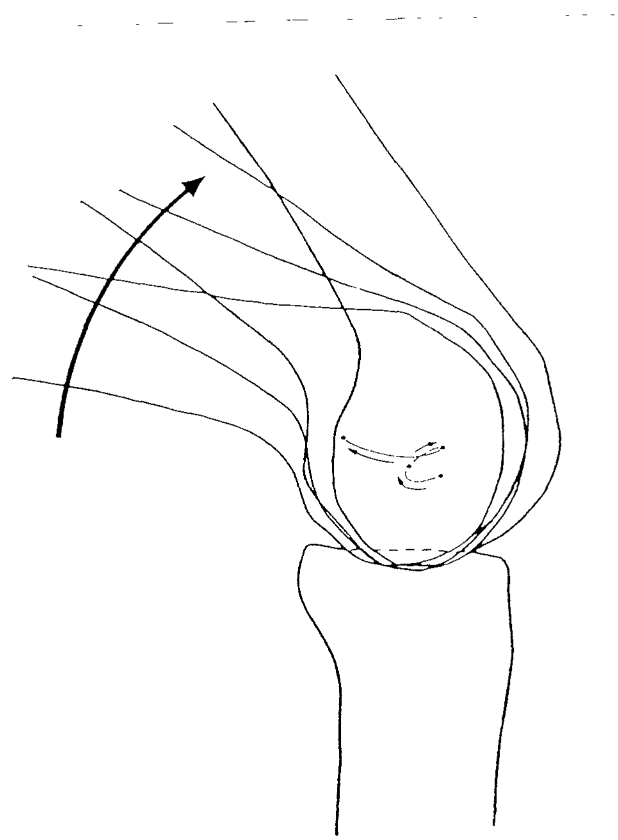


Displacements for Abnormal Instant Centers

Figure 11 Surface motion in two tibiofemoral joints with displaced instant centers. In both joints the arrowed line at right angles to the line between the instant center and tibiofemoral contact point indicates the direction of displacement of the contact points.

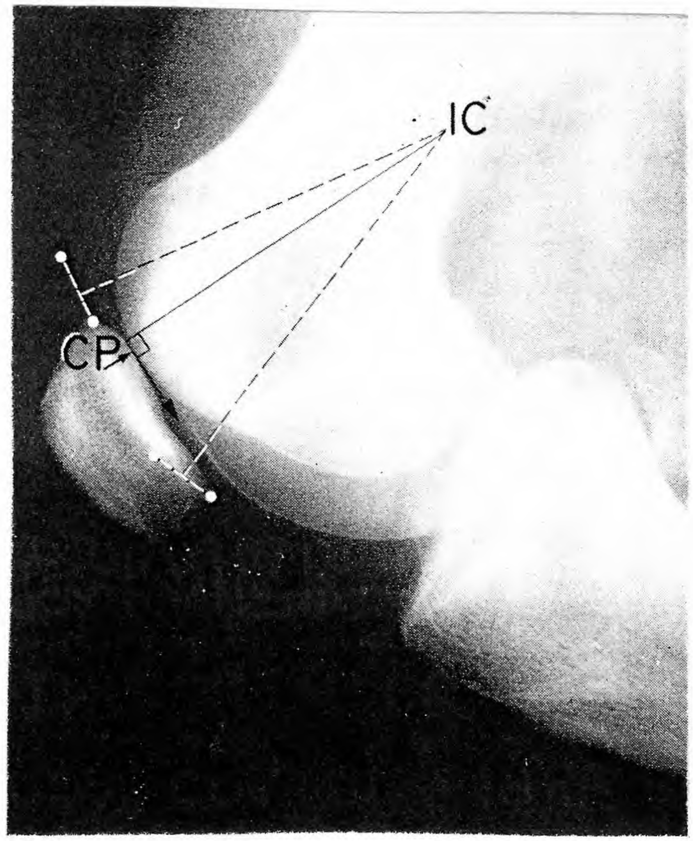
A. The small arrow indicates that with further flexion the tibiofemoral joint will be distracted.

B. With increased flexion this joint will be compressed (from M. Nordin, V. Frankel: <u>Basic Biomechanics of the Musculoskeletal System, 2nd Edition.</u> Philadelphia, Lea & Febiger, 1989. Reprinted with Permission).



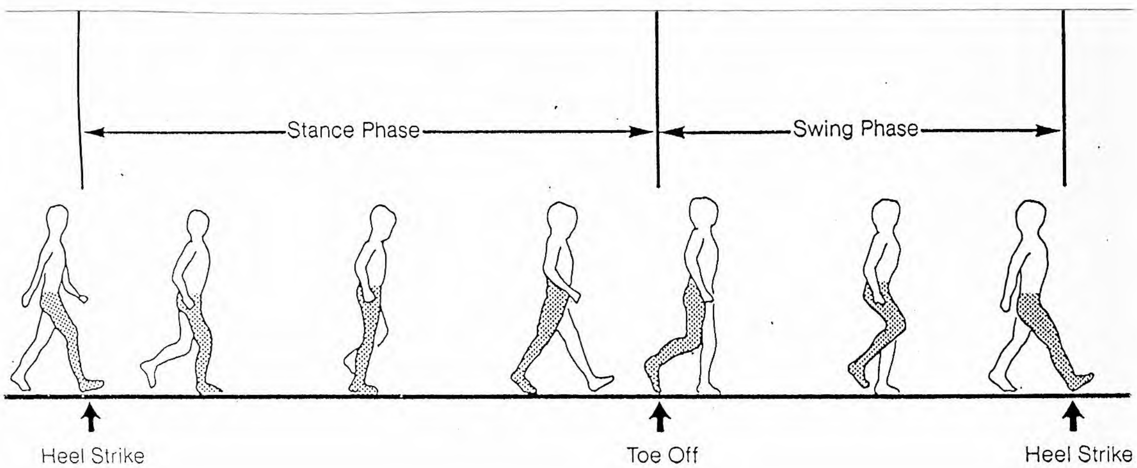
Abnormal Instant Center Profile

Figure 12 Abnormal instant center pathway for a 35 year old man with a bucket handle derangement. The instant center jumps at full extension of the knee (from M. Nordin, V. Frankel: Basic Biomechanics of the Musculoskeletal System, 2nd Edition. Philadelphia, Lea & Febiger, 1989. Reprinted with Permission).



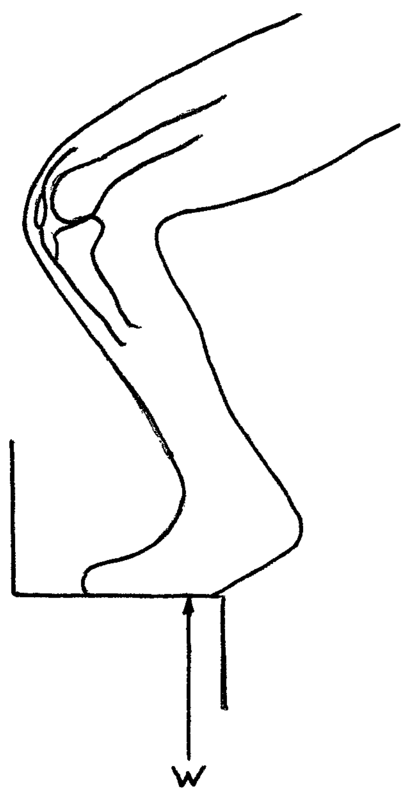
Patellofemoral Joint Instant Center

Figure 13 After the instant center (IC) is determined for the patellofemoral joint for the motion from 75 to 90 degrees of knee flexion, a line is drawn from the instant center to the contact point (CP) between the patella and the femoral condyle. A line drawn at right angles to this line is tangential to the surface of the patella, indicating gliding (from M. Nordin, V. Frankel: Basic Biomechanics of the Musculoskeletal System, 2nd Edition. Philadelphia, Lea & Febiger, 1989. Reprinted with Permission).



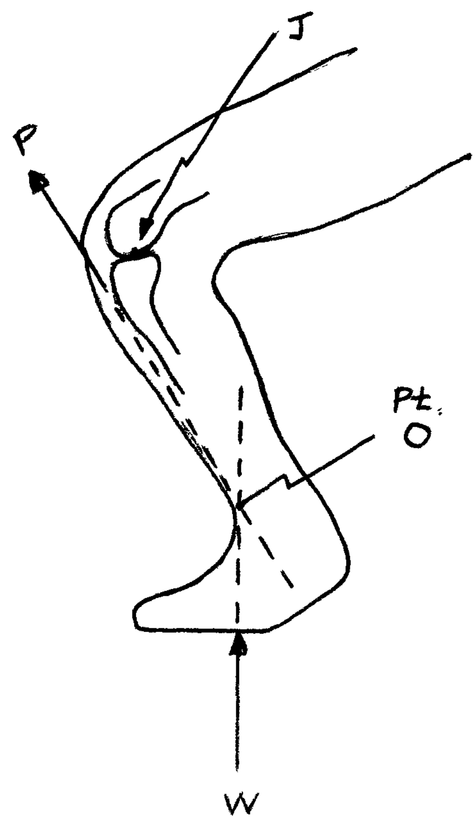
The Human Gait Cycle

Figure 14



One Legged Stance on Stair Step

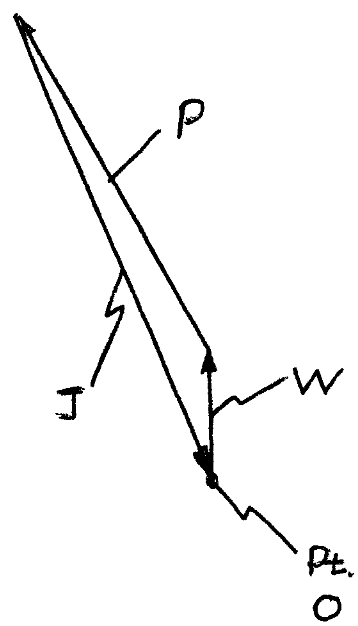
Figure 15 "W" is the ground reaction force since we are assuming the person is standing on one leg on a stair step. (Adapted from Ingwersen, 1974).



Free Body Diagram of One Legged Stair Stance

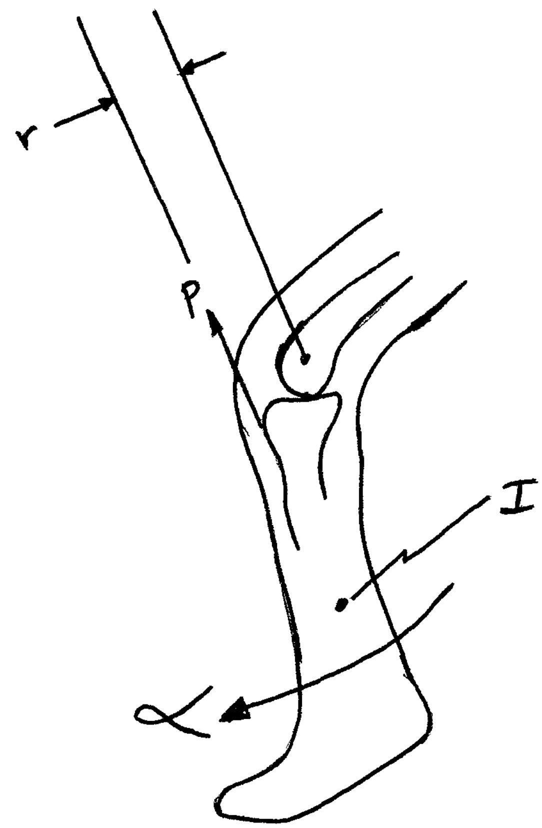
Figure 16

"P" is the line of action of the tension in the patella tendon resulting from the quadriceps muscle group resisting further flexion of the knee.
"J" is the joint reaction force; at this time only the point of application is known. The point of application of "J" is determined from x-ray analysis using instant center techniques previously discussed.
"O" represents the intersection of vectors P and W.
(Adapted from Ingwersen, 1974).



Graphical Determination of Joint Reaction Force

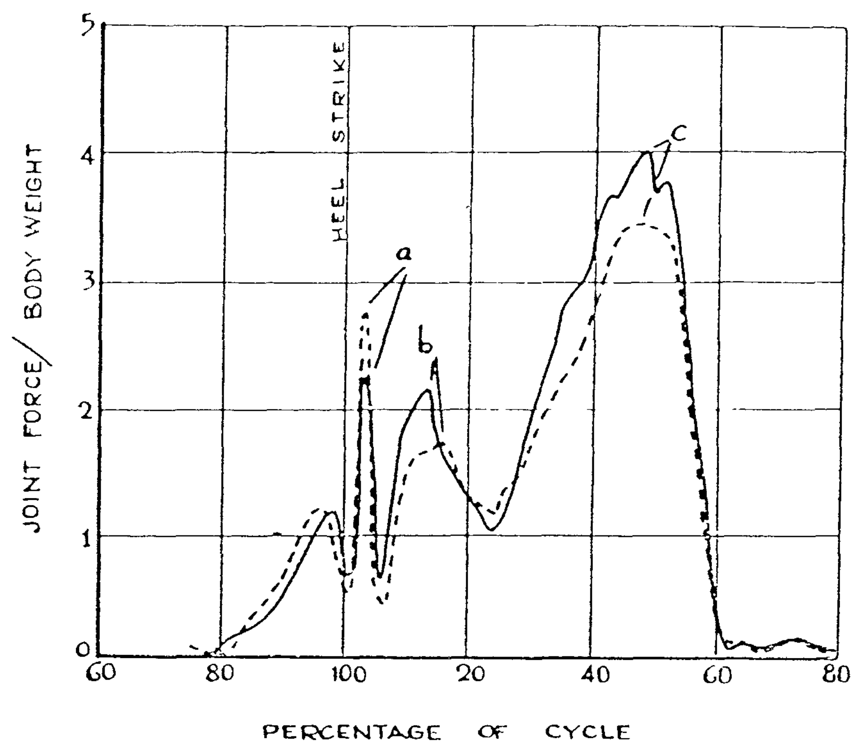
Figure 17 Graphical analysis of the forces implies that the head and tail of vectors must have a common point to permit all forces to sum to zero to satisfy equilibrium in the X and Y directions. Scaling of this figure will permit the magnitude of P and J to be determined. (Adapted from Ingwersen, 1974).



Dynamic Force Analysis Diagram

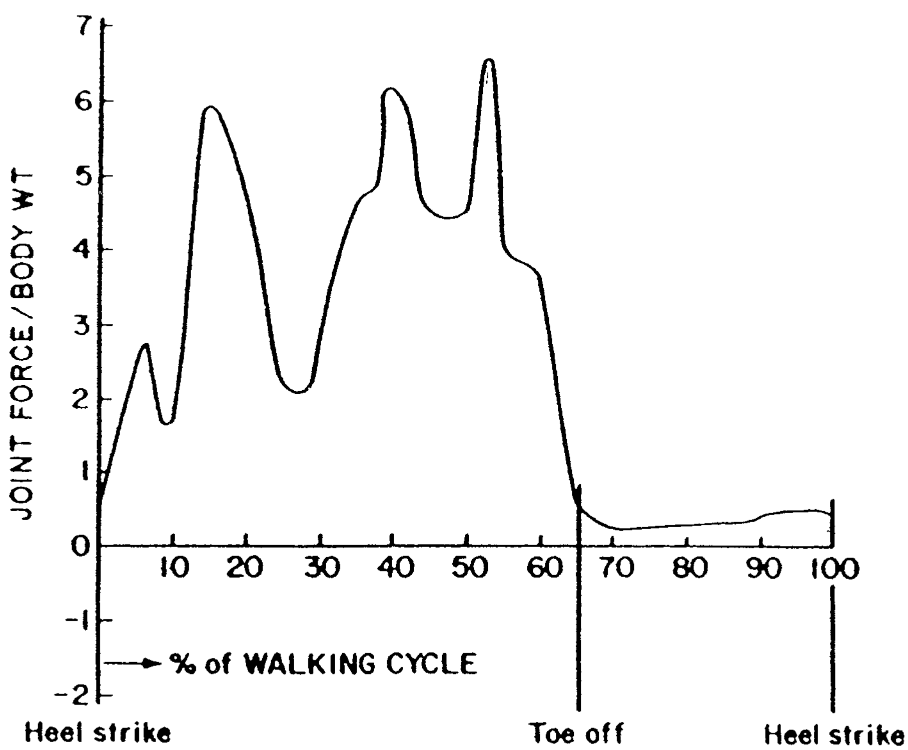
Figure 18

"r" is the quadriceps muscle force moment arm.
"P" is the force acting in the patellar tendon
"I" is the mass moment of inertia of the lower limb
"α" is the angular acceleration of the lower limb at the instant of interest
(Adapted from Ingwersen, 1974).



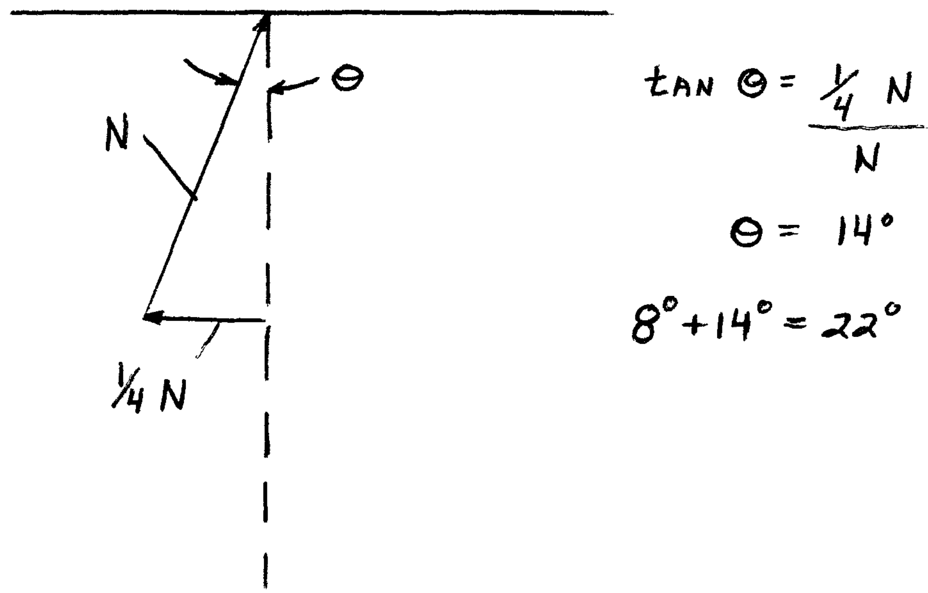
Joint Reaction Force for Gait per Morrison (1968)

Figure 19 The force illustrated is the "compressive" joint reaction force.
(From Morrison J.B., "Bioengineering Analysis of Force Action Transmitted by the Knee Joint." *Biomedical Engineering*. April (1968): 164-170.)



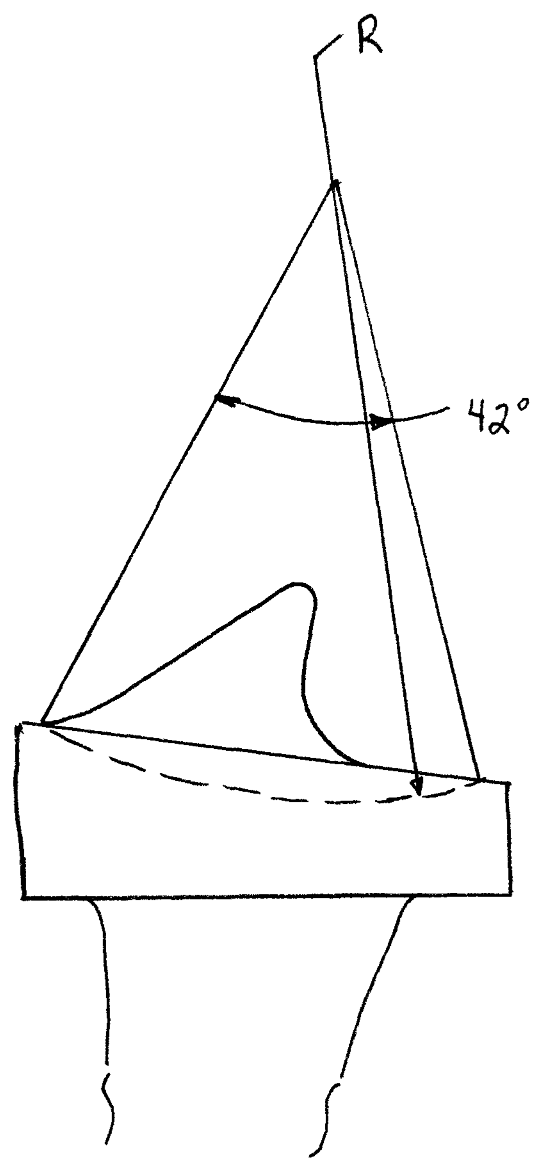
Joint Reaction Force for Gait per Seireg and Arvikar (1975)

Figure 20 Note that the peak compressive joint reaction force is approximately seven times body weight. (Adapted from Seireg and Arvikar, 1975).



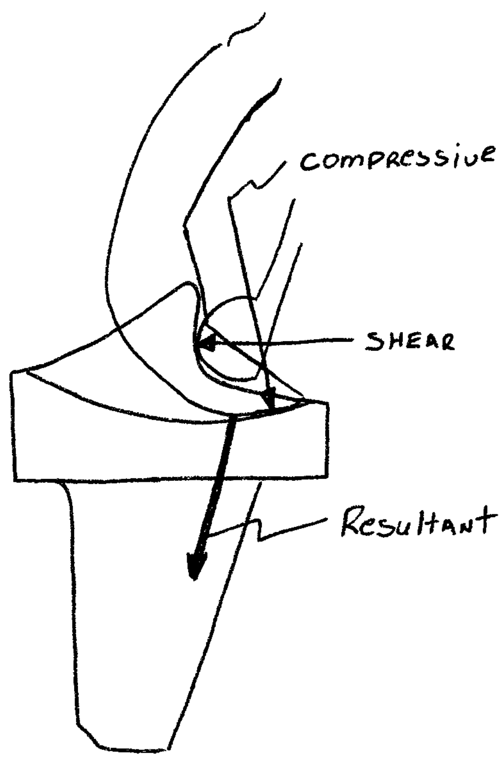
Free Body Diagram of Burstein's Theory

Figure 21
"N" signifies the normal force
¼ "N" signifies the maximum cruciate force per literature reviewed by Burstein.



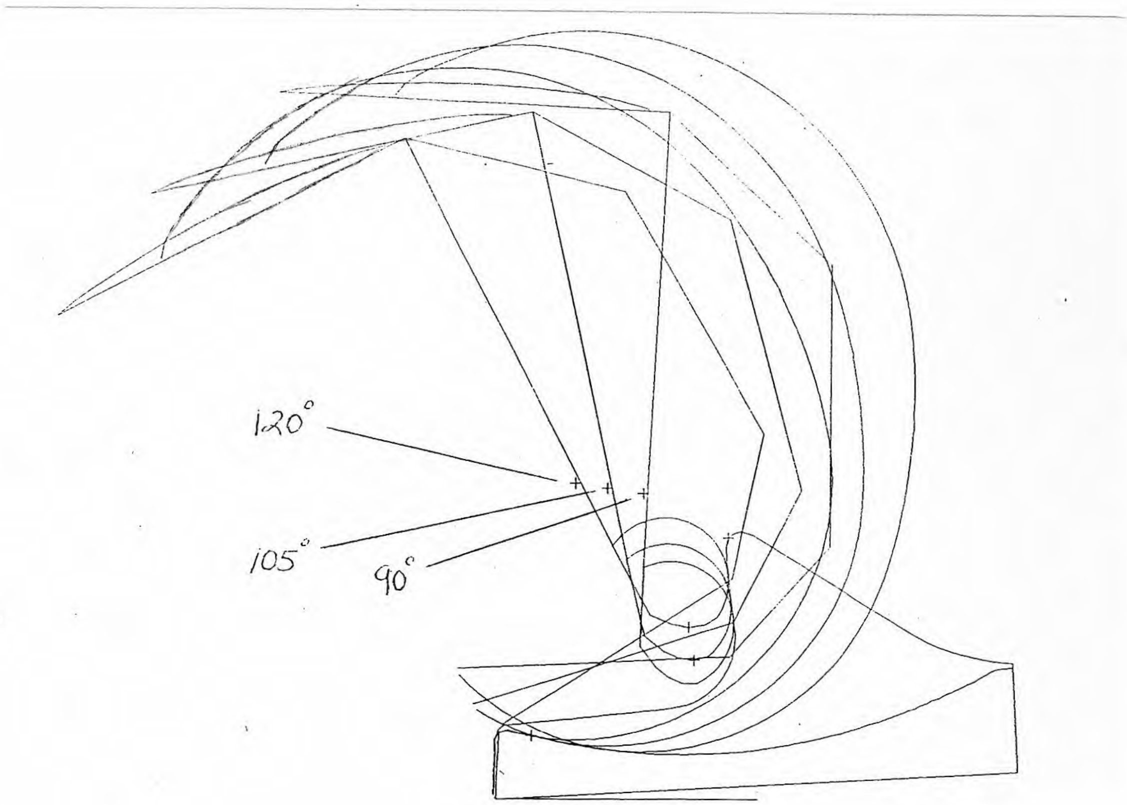
Insall-Burstein I Tibial Component - Lateral View

Figure 22 The Insall-Burstein I posterior stabilized design utilizes a tibial articulating surface consisting of a single anterior-posterior radius with an included angle of 42° (Adapted from Insall, 1984).



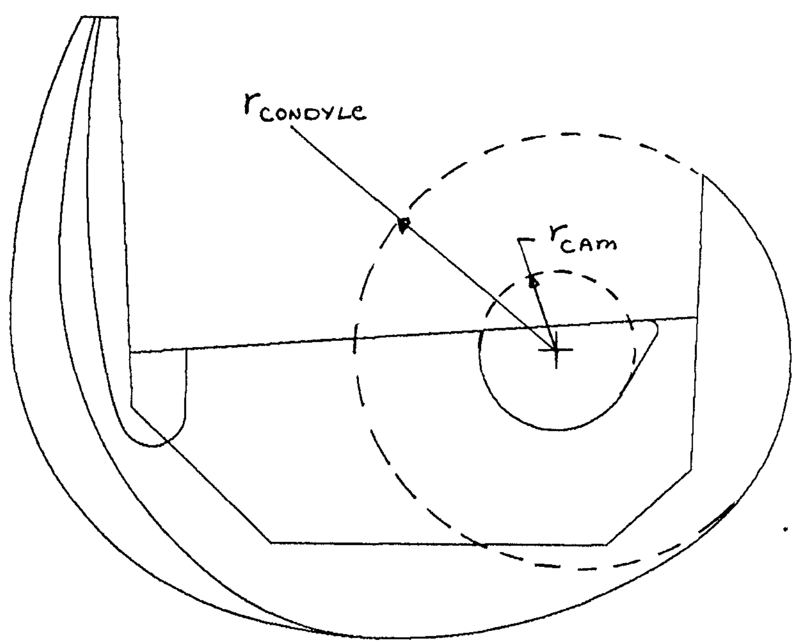
Resultant Force for Tibial Component of the Insall-Burstein

Figure 23 The resultant force of the compressive and shear loads is designed to act through the stem of the prosthesis. (Adapted from Insall, 1982).



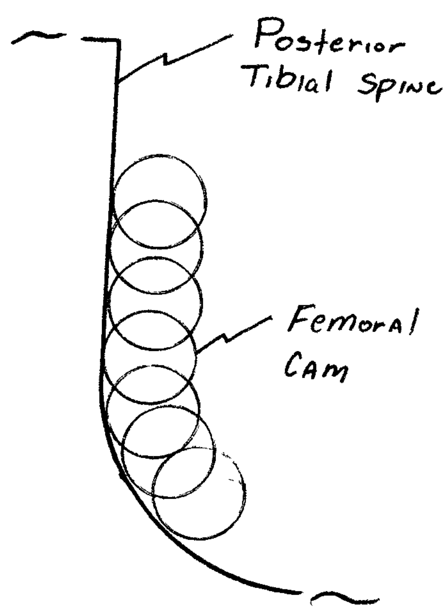
Instant Center Analysis of Insall-Burstein II

Figure 24 The lateral profile of the components was generated from laser scanning techniques where the data was recorded as a series of points. Through computer aided design techniques, the instant centers were found.



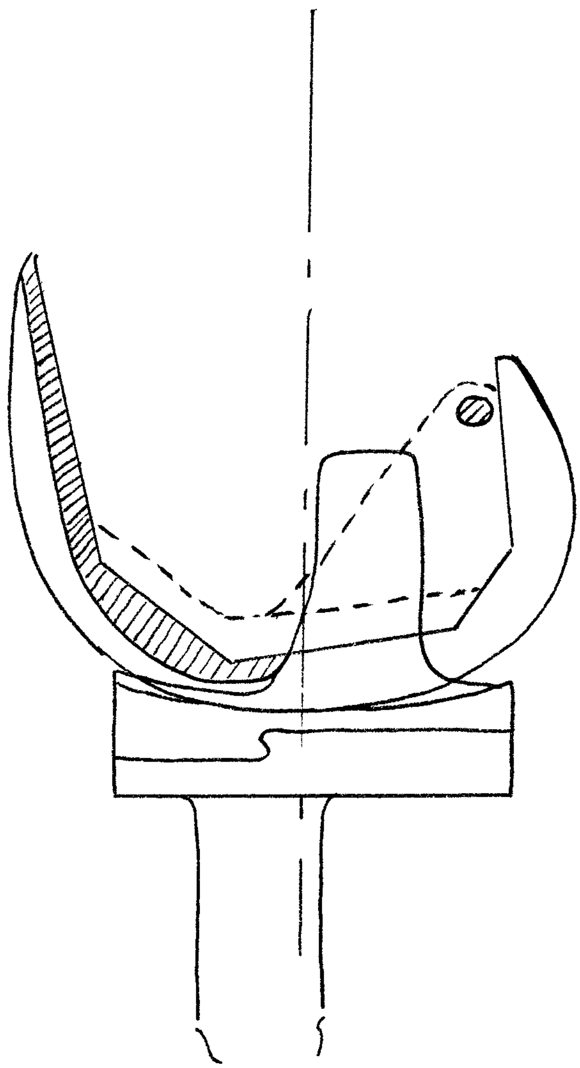
AMK® Posterior Stabilized Prosthesis

Figure 25 Since the origin of the femoral cam radius and femoral condyle radius active from 45 - 120° flexion are the same, the effect is that contact point on the polyethylene tibial insert is the same from 45 to 120° flexion.



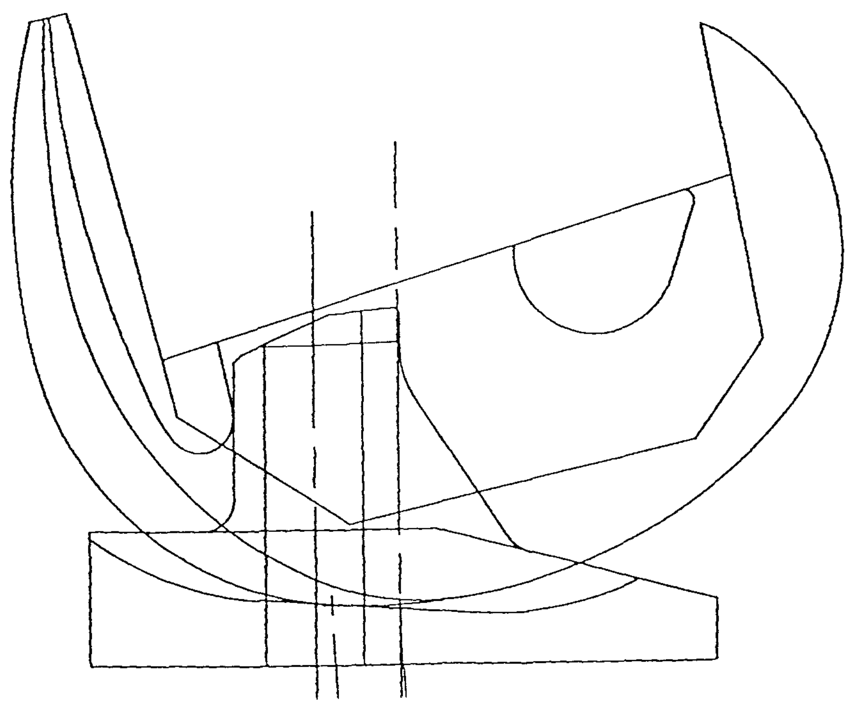
Generating Posterior Surface of Tibial Spine

Figure 26 Layout illustrating a curve which is tangent to all femoral cam positions at the indicated flexion angles. This curve represents the posterior aspect of tibial spine.



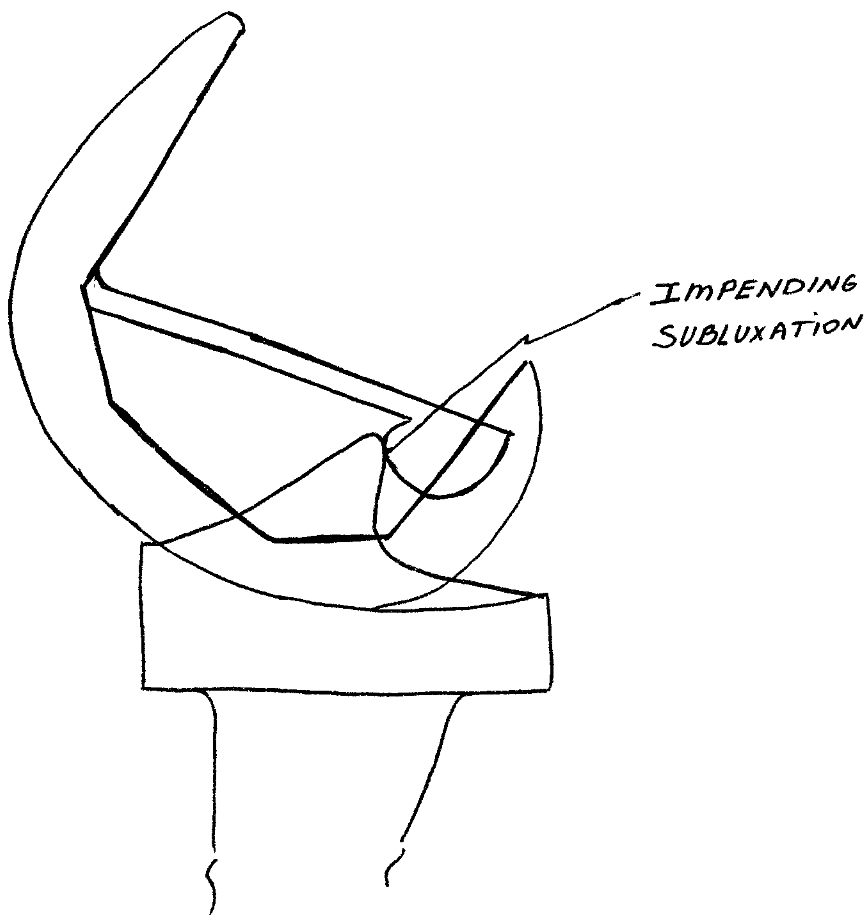
Genesis Prosthesis in Hyperextension

Figure 27 The Genesis design is an example wherein the hyperextension is theoretically designed to cease at anterior spine/intercondylar notch contact. (Adapted from manufacturer's literature).



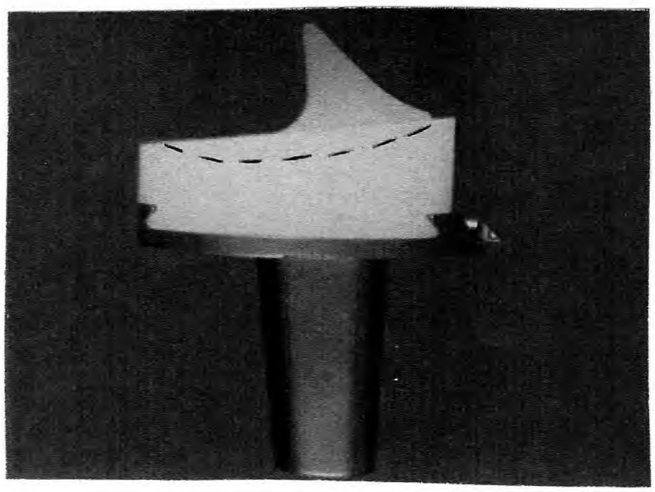
AMK® Prosthesis in Hyperextension

Figure 28 The AMK® is designed to permit further hyperextension when the anterior spine contacts the anterior femoral cam (this cam is a fillet radius fitted between the patellar track and intercondylar notch).



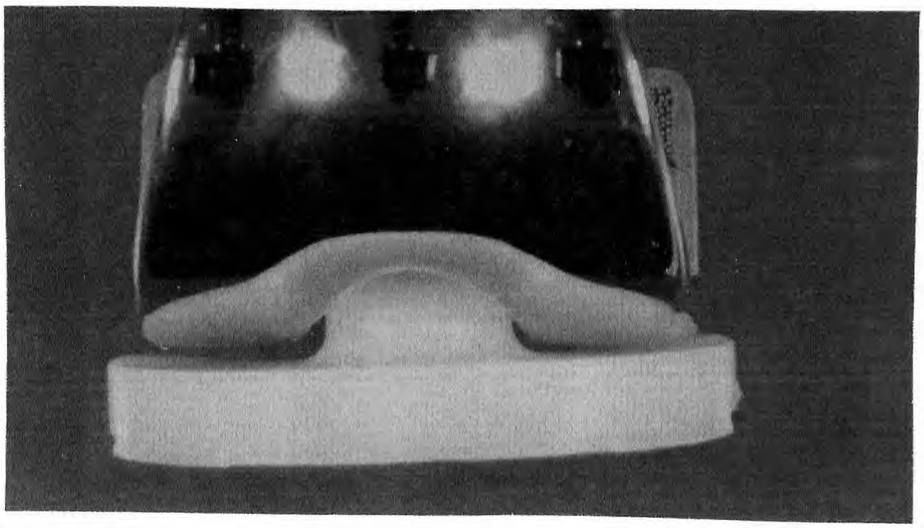
Subluxation Potential of Posterior Stabilized Prosthesis

Figure 29 Ligamentous instability may permit the femoral component cam to ride over the tibial spine under normal shear loads causing posterior tibial subluxation.



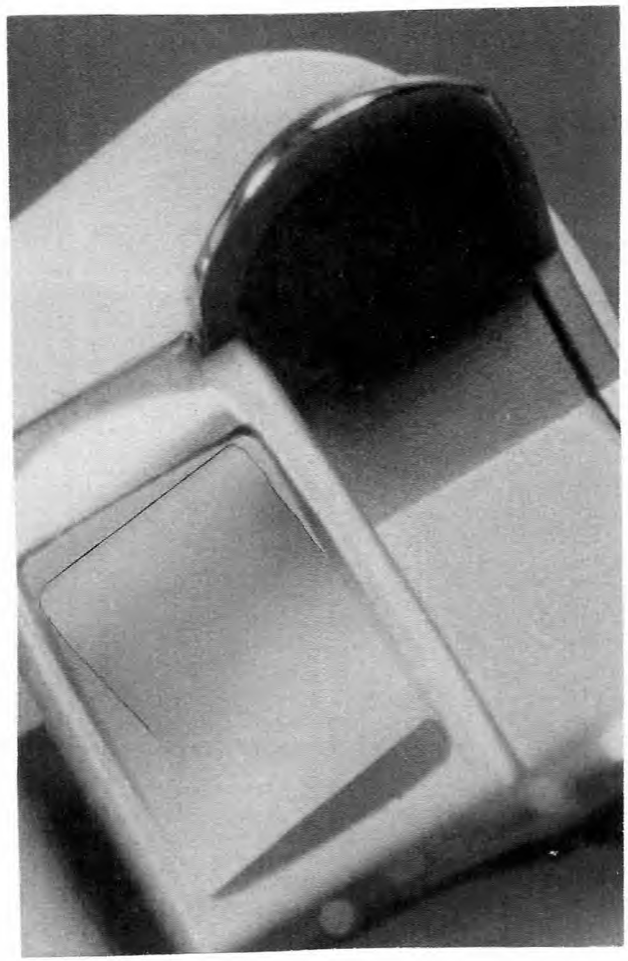
Lateral View of Insall-Burstein Prosthesis

Figure 30 The dashed line represents the deep radial profile of the articular surface.



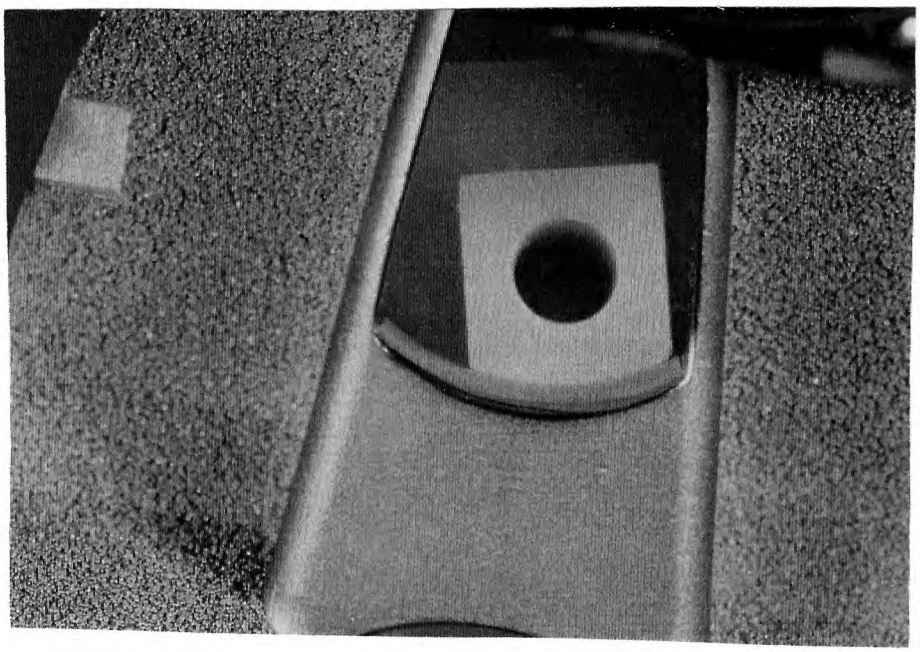
View of Ortholoc II Prosthesis

Figure 31 Note the relatively flat profile of the articular surface.



Linear Cam and Spine

Figure 32 Linear cam and posterior tibial spine indicating edge loading when in rotation.



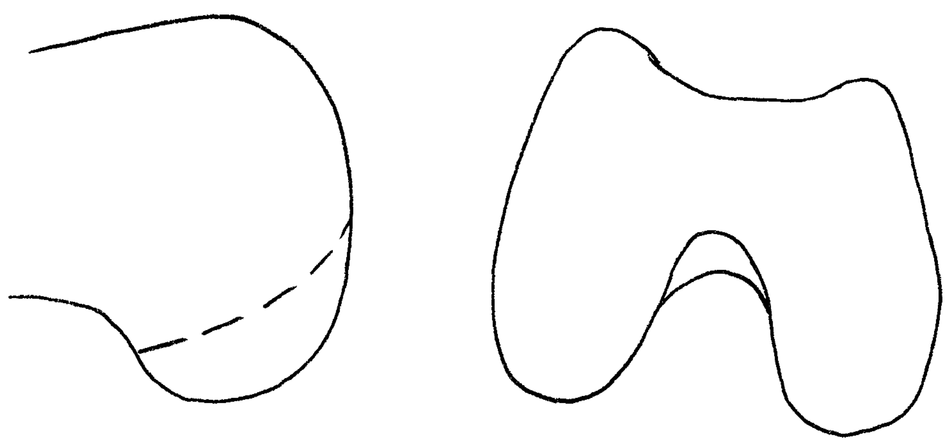
Radial Cam and Spine

Figure 33 Hourglass cam and posterior spine indicating large contact zone when in rotation.

Insall-Burstein Retrieval

Figure 34 Insall-Burstein retrieval with the tibial insert manufactured from carbon fiber reinforced polyethylene. Note the wear at the anterior and posterior margins of the tibial spine.

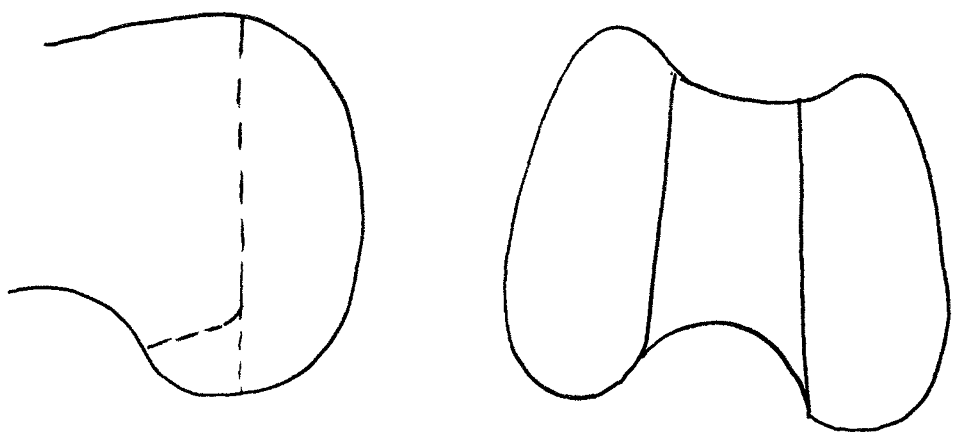
Anterior



Posterior

Distal Femur Prior to Housing Resection

Figure 35 Note that the intercondylar notch is largest posteriorly.

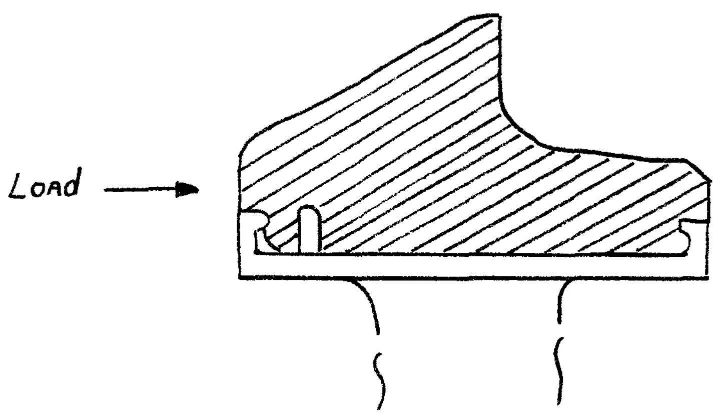


Distal Femur with Typical Resection for Femoral Housing

Figure 36 Note that the volume of bone resected from the natural femur is greater anteriorly due to the geometry of the natural intercondylar notch.

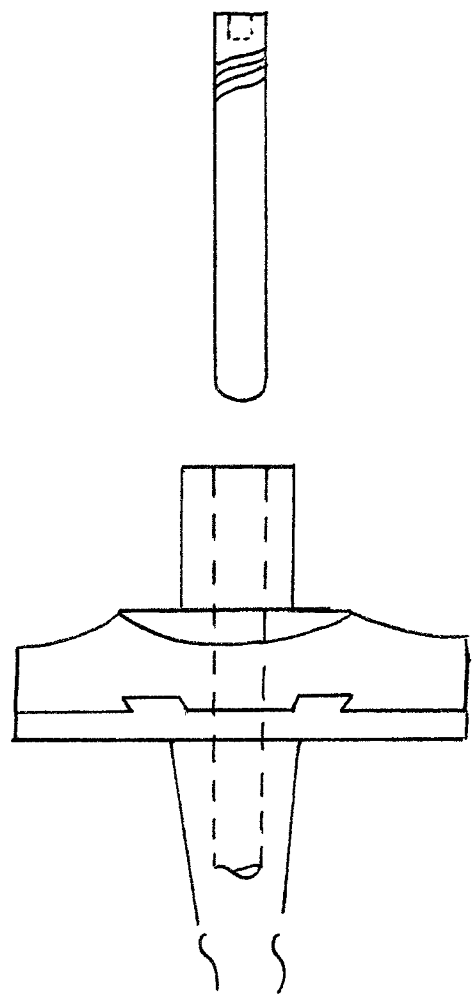
AGC Posterior Stabilized Prosthesis

Figure 37 The tibial component does not use a conventional tibial spine rather it has a trough. The femoral cam does not violate the anterior-posterior box.



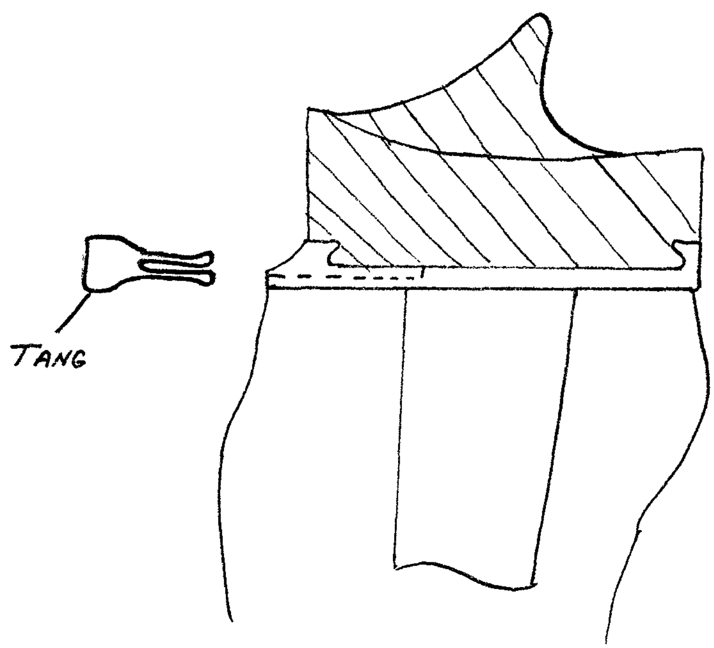
Front Loading Tibial Insert With Undercut

Figure 38 The tibial insert is loaded from the anterior to posterior direction and locks in place due to an interference with the metallic ridge of the tibial tray.



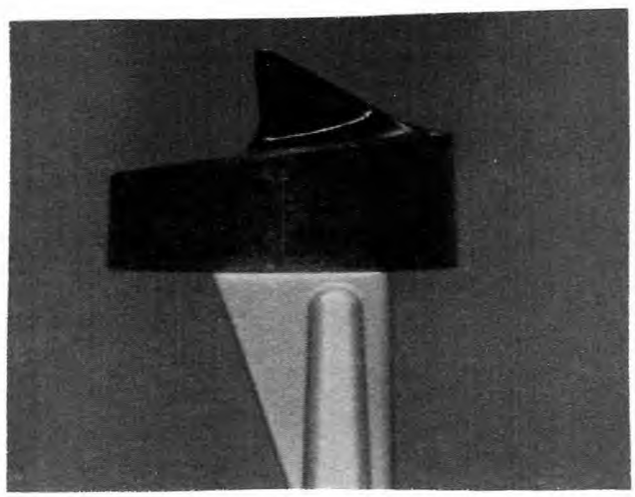
Front Loading Tibial Insert with Dovetail/Pin

Figure 39 The tibial insert is loaded from anterior to posterior and locked in place with a pin.



Side Loading Tibial Insert with Dovetail/Tang

Figure 40 The tibial insert is loaded medial to lateral using dovetails and locked in position using a fixation tang.



Typical Posterior Stabilized Stem Geometry

Figure 41 This is a lateral view of the stem representing a geometry common to the Insall-Burstein system and AGC system. The shape is designed to resist torsional loads.

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