ON THE DESIGN PROCEDURE OF AN ARTIFICIAL KNEE JOINT

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A Major Technical Report
in
Department of Mechanical Engineering
Faculty of Engineering

Presented in Partial Fulfillment of the Requirement of the Degree of Master of Engineering at Concordia University

Montreal, Canada

January 1979

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ABSTRACT

ment in the design of a prosthesis but it should be considered along with other requirements such as the range of movement and the stress levels in the implant. However, to design a future knee prosthesis one must begin with an understanding of the nature of the normal knee joint, its range and rate of movement, the loads transmitted by the articulating surfaces, the contact stresses and the source of stability; and the ways in which these factors are affected by disease.

In the selection of materials for a prosthesis, the environment, compatibility of the materials and their wear products with the body and fixation problems must be considered and also the rate of wear should be minimal to provide adequate life to the prosthesis.

Finally, the problems of communication have to be overcome; the engineer must appreciate the surgery and clinical
evaluation associated with the artificial knee joint and problems facing the surgeon, whilst the surgeon must communicate
adequately with the engineer and understand the design approach,
materials selection and production techniques and the need for
careful evaluation of the characteristics of individual components and the complete prosthesis in standard laboratory
before surgery can proceed.

ACKNOWLEDGEMENTS

M.O.M. Osman, for his guidance throughout all stages of this report. Special thanks to my friend, Anne Marie de Passille for her help and encouragement.

LIST OF SYMBOLS

•		
. a	moment arm of muscle force	
A _{CX}	anterior cruciate ligament force componen	nt
, ' ä x	the linear acceleration of limb-segments	
c `	bearing .compression.force	
c_1	moment in lateral joint compartment	1
C _m	load in medial joint compartment	·
$c_{\mathtt{r}}$	cruciate ligament force	,
Dg	moment arm due to G	
$ m f p_h$	moment arm due to H	•
. D ^d	moment arm due to Q	• ,
F×	antero-posterior shear force	• •
F _Y	Vertical force	
Fz	medio-lateral shear force	
F _{xk}		, 9
Fyk Fzk	three forces of orthogonal tibial axes in of the knee joint centre	itersecting
G	gastrochemii muscle force	
H .	hamstrings muscle force	*
ı	the mass moment of inertia of segments	
٥L	lateral collateral ligament force	
M .	tensile force in the medial collateral li	gament
MX		•
M _. y	moments in the sagittal plane	•

List of Symbols (cont'd)

M _{xk} M _{yk}	three moments of orthogonal, tibial axes inter-		
M _{zk}	secting at the knee joint centre		
Pcx	posterior cruciate ligament force component		
Ω	quadriceps muscle force		
T .	muscle force (Q, G & H)		
Ty	Y _k component		
W	knee condylar width		
w	weight of the shank and foot		
x.	distance of Fx from knee centre		
\\$	distance of Fy from knee centre		
Y _k	ground to foot force		
, °	centre of joint pressure		
$\alpha_{\mathbf{z}}$	the angular accelerations		
ex	angle of inclination		

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CHAPTER 1

INTRODUCTION

1 - Introduction

The knee joint is one of the most highly loaded, and possibly one of the most highly stressed, human synovial joints. In normal activities such as walking, running, climbing stairs and getting in and out of chairs the load put on the human knee joint can exceed five times the weight ofthe body. Although, large numbers of people make further demands on the knee in participating in such sports as football, soccer, tennis and long-distance running. It is no wonder that many people go into their later years with one knee or both knees so badly deteriorated as to be crippling.

It is now possible to replace such a knee with a mechanical device that imitates the subtle and complex motion of a natural knee. To many people, the incorporation of medicine and engineering conjures up visions of the popular television programs, Six Million Dallar Man and The Bionic Woman. Although the power bestowed upon these heroes through their electronic senses and their mechanical limbs is entertaining, it is still far from being a reality. Bionic, in the popular sense, is correctly termed biomedical engineering, the application of engineering principles to medical and biological problems.

Perhaps in some distant future this research will result in

the ultimate body, but for the present, scientists are concerned with less spectacular, but more urgent problems. One active area of study has come about as a result of orthopaedic surgeons searching for new ways to help people crippled by joint disease.

It is not infrequently subjected to distress resulting from disease or injury and the call for satisfactory replacement joints has been growing stronger in recent years. In the early 1950's, a British orthopaedic surgeon, Dr. John Charnley, developed the first successful artificial hip. The remarkable results in mobolizing patients with severe rheumatoid arthritis marked a new approach to this medical problem. Other surgeons, most notably, Dr. Borge Walldius of Sweden and Dr. L.G.P. Shiers of England, developed artificial knees. However, unlike the hip, which is a simple ball-and-socket joint (Figure 1-1), the knee is a very complex structure.

The design of the first replacement knees was essentially a hinge (Figure 1-2), which replaced most of the bone and tissue surrounding the joint. Although this procedure is still useful in cases of severely damaged knees or in particularly complex situations, it is considered excessive for many diseased joints with less structural involvement. The operation requires the removal of too much healthy tissue and leaves a joint which does not function naturally. (3)*

^{*}Numbers in brackets refer to references at the end of this work.



Figure 1-1 A modern version of the first successful artificial hip (from Reference 3).

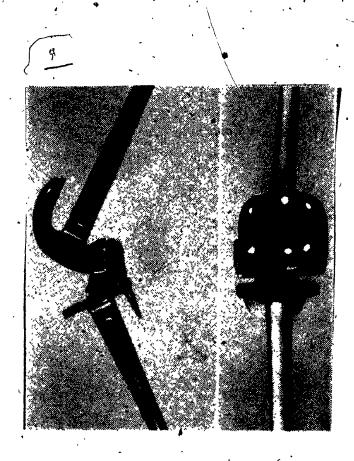


Figure 1-2 The first design of an artificial knee (simple hinge) (from Reference 3).

It was not until 1968 that Dr. Frank Gunston of Winnipeg, an engineer and orthopaedic surgeon, revolutionized the concept of knee joint replacement. Instead of substituting an entire knee, separate pieces of special alloy stainless steel and wear-resistance plastic were implanted to replace only the damaged joint surfaces (Figure 1-3). This left most of the surrounding tissue intact, while providing the patient with an increased mobility and relief from pain.

Improvements in design, materials and surgical methods have advanced the artificial knee to the point where it can provide substantial benefits to a person suffering from severe arthritis. Arthritis literally means 'joint inflammation'. The term is applied to nearly a hundred diseases, all of which have as symptoms persistent or recurring pain, stiffness and swelling in one joint or more. The number of people thus afflicted has been estimated by the Arthritis Foundation as 363 million, or 10 per cent of the world's population. Among them are more than 50 million people in the United States, of whom some 20 million require medical care and 3.5 million are significantly disabled. (6)

In recent years much work has been done to define the ideal artificial knee. The question at issue includes the amount of relative motion to be provided between femoral and tibial component, the materials to use on load-bearing surfaces,



Figure 1-3 The Gunston artificial knee (from Reference 3).

ing of the patellofemoral joint, the amount of bone to be removed and the criteria for choosing patients. More than 80 designs for artificial knees are estimated to be available in the United States and abroad. Many of them differ slightly in configuration and function, so that one must entertain misgivings about this proliferation. The situation does, however,

A recent survey under the Rehabilitation Engineering
Program of North Western University indicates that 80,000
total hip replacements and 30,000 knee replacements were performed in the United States in 1976. Surgeons responding that they would do 1.12 times as many hip and 1.76 times as many knee replacements if more reliable prostheses were available.

reflect the intense effort devoted to the design of knee re-

placements.

The major cause of failure of artificial knees is loosening, which is the loosening of the attachment of implants to bones (Figure 1-4). Certainly the frequency and severity of loosening increase with time, and one can say that the trouble is quite likely to occur in patients who are either active or heavy and thus put great demands on a prosthesis. (6)

However, this report will show the procedure of designing an artificial knee joint, such as the clinical background, the geometry, movement and loads encountered in the knee, the

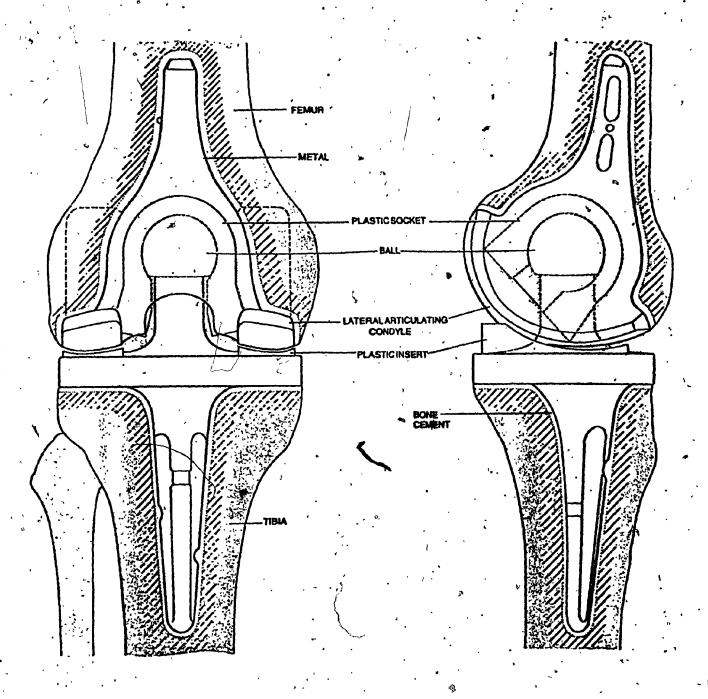


Figure 1-4 Attachment of prosthesis components to Femur and Tibia from front and side view (from Reference 6).

general range of design objectives with possible mechanical solutions and finally the mechanical and tribological properties of current prosthetic materials and wear of protheses.

CHAPTER 2

FUNCTIONAL ANATOMY, ANATOMY OF DISEASED JOINTS, GEOMETRY, 'MOVEMENT, AND LOAD ON THE KNEE JOINT

2 - Functional Anatomy, Geometry, Movement and Load on the Knee Joint

Before the bio-engineer can consider the optimum form of an artificial knee or any other joint, he needs to understand the anatomy of the natural joint, its range and rate of movement, the load transmitted by the articulating surfaces, the contact stresses and the source of stability, and the ways in which these factors are affected by disease. In addition, he needs to be aware of the environmental conditions which any prosthesis will encounter, since these may influence material selection.

Descriptive anatomy rarely presents an adequate statement of overall joint geometry and surface curvature to enable contact stresses to be calculated, even if the loads and mechanical properties of the bone and cartilage, structure are adequately understood.

2-1 Functional Anatomy of Knee Joint

The knee joint is capable of large rotations in the sagittal plane only. With the exception of positions of acute flection (i.e. 900+) rotations about the long axis of the shank and in the coronal plane are restricted to a few degrees by restraint due to the ligaments of the joint.

For most activities, therefore, the mechanics of the knee joint can be compared to a simple hinge. Rotation at the knee such as changes in relative angular position of the shank and thigh are controlled by forces developed in the muscles acting across the joint (Figure 2-1).

These muscles can be classified into three main groups, namely:

- (a) Quadriceps femoris: including rectus femoris, vastus medialus, vastus intermedius, vastus lateralus. These muscles tend to extend the knee.
- (b) Hamstrings: including long head of biceps; short head of biceps, semimembranosus, semitendinosos. These muscles tend to flex the knee. Gracilis, an adductor of thigh, and sartorios may also assist the hamstrings in flexing the knee.
- (c) Gastrocnemius: including gastronemius medial head, gastronemius lateral head, plantaris. These muscles tend to flex the knee.

Tensor fasciae latae and gluteus maximus, which by tightening the iliotibial tract resist aduction of the knee, and popliteus which unlocks the knee joint at the beginning of flexion, do not fall naturally into any of the three groups and were omitted from the analysis. (7)

The basis for classification is that all muscles in a group have confluent lines of action. It is stated that muscles

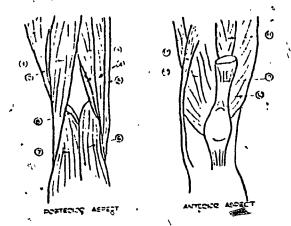


Figure 2-1 Muscles controlling the knee joint (from Reference 8).

1 - Biceps long head, 2 - Biceps short head, 3 - Semitendinosus, 4 - Semimembranosus, 5 - Gracilis, 6 - Gastrocnemius med. head, 7 - Gastrocnemius lat. head, 8 - Plantaris, 9 - Rectus femoris, 10 - Vastus lateralis, 11 - Vastus intermedius, 12 - Vastus medialis, 13 - Sartorius

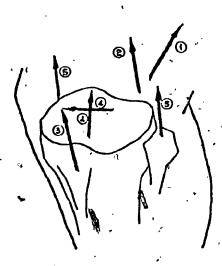


Figure 2-2 Simplified muscle and ligament system acting at the knee joint (from Reference 8).

1 - Hamstrings, 2 - Gástrocnemius, 3 - Quadriceps femoris, 4 - Cruciate ligaments, 5 - Collateral ligaments

with a group of classified act synchronously in controlling joint movement.

The muscles acting across the knee joint can therefore be so grouped for the purpose of force analysis. It was assumed that the direction of resultant force in a muscle group remained constant regardless of the intensity of muscle action. To obtain a solution for force action at the knee joint a functionally equivalent simplified muscle and ligament system was devised in the light of the experimental information and analytical techniques available. This simplified system consisted of the three muscle groups as defined and the four ligaments which act across the joint, (Figure 2-2). (8)

In the analysis undertaken to assess tensions in the muscle groups and ligaments, it is necessary to calculate their lines of action relative to the knee joint centre. These are obtained as follows. An amputated limb is dissected and measurements of muscle and ligament origins and insertions at the knee joint are made directly. Muscle origins on the pelvis are measured from a skeleton. In the case of the hamstrings, and gastrochemius muscle groups an equivalent origin and insertion is developed from measurements on individual muscles of the group. Values thus obtained will apply to subjects under appropriate scaling factors. The line of action of a

muscle group or ligament is takne to be the line joining its origin and insertion.

The quadriceps femoris muscle group acts on the shank through the patellar ligament. The line of action of the patellar ligament relative to the tibia was found to vary with the angle of the knee joint.

Although the hamstrings and gastrocnemius muscle groups produce moment action in the same direction at the knee joint, the two groups function at different stages of the walking cycle.

2-2 Anatomy of Diseased Joints

At present, usually all total replacement operations are performed on joints suffering from one or another form of arthritis, at the knee, rheumatoid arthritis is encountered considerably more often than is esteoarthrosis. In any knee which is a candidate for total replacement, degeneration or loss of articular cartilage can therefore be assumed to have occurred, at any joint, the obvious purpose of total replacement therapy is to provide new bearing surfaces. At any joint, and particularly at the knee, increasing severity of arthritis often brings other anatomical abnormalities which must be considered in design of any replacement. These may be classified, from the functional viewpoint, as follows.

2-2-1 Reduced Ranges of Voluntary Movement

Voluntary movement may be restricted by pain, the relief of which is one of the chief objectives of replacement therapy. Since articular cartilage has no nerves, the source of pain signals must be in the subchondral bone or other trissues, the implications for the design of replacement prostheses are discussed below.

In other respects, the restriction of voluntary movement is for practical purposes a deformity, and will be considered as such below.

2-2-2 Stiffness

Stiffness is commonly observed in arthritic joints. It may result from deformity of the subchondral bone, from scarring of the capsule, or from involuntary spasm of the muscles controlling the joint, presumably as a protective device.

2-2-3 Deformity.

Deformity at a knee joint can occur about three major axes, being observed as flexion deformity, valgus or varus deformity, or torsional deformity. Mild deformity may be caused by contraction of the posterior capsule. Severe flexion deformity of long duration may additionally involve collapse of the load-bearing areas of the tibial and femoral condyles with the knee in flexion, if this is so, attempts to correct

deformity lead to mechanical interference between the intercondylar eminence on the tibia and the intercondylar notch on
the femur which, not having been loaded in compression, have
not collapsed with the loaded areas of the condyles.

Valgus deformity often involves collapse of the lateral condyles of the tibia and femur, and varus deformity that of the medial condyles.

Torsional deformity is encountered, but more than about ten to fifteen degrees is unusual.

2-2-4 Instability

Instability can occur in the same modes as deformity; and the two are sometimes found together, e.g. a knee which has a valgus deformity is likely to be displaced further into valgus on the application of compressive load in standing, and this additional displacement, being involuntary, must be regarded as an instability. The existence of instability implies slackness in soft tissues, e.g. the medial collateral ligament and medial capsule in vilgus instability, or the posterior capsule in genu recurvatum.

2-2-5 Cancellous Bone of Doubtful Strength

In sever ostebarthrosis the subchondral bone may be deformed and may contain cysts, but observation suggests that its general strength is not lower than that of normal bone.

In rheumatoid arthritis, however, observation suggests that the cancellous bone is significantly weaker than normal, and the collapse of load-bearing areas, or penetration of a tibial condyle by a femoral condyle, is consistent with this.

Obviously, some of these factors of abnormalities are related in that they are consequences of the disorganization of some of the tissues forming the joint, but this discussion is concerned with the functional consequences and not the causes.

A successful replacement procedure will enable as many of these abnormalities as are present to be corrected to extents which will unable the patient to lead an acceptable life.

It is clear also that the correction of some or all of the abnormalities mentioned above will require the design of a procedure of which the prosthesis itself is a part. Obviously, some less severely disorganized knees will present fewer abnormalities, and may be successfully treated with simpler prostheses and procedures, but for some time to come total replacement is likely to be reserved primarily for severely disorganized knees, and the designer must, therefore, consider these first, in the reasonable expectation that if a severely disorganized knee can be treated then so can a less severely disorganized one.

2-3 Geometry of the Knee Soint

The essential features of the knee joint are shown in Figure 2-3. Articulation and load transmission between the femur and tibia are effected at the lateral and medial condyles, with a further important bearing area being provided by contact between the patella and the femur, The major muscle groups associated with the knee are the quadrieps, the hamstrings and the calf muscles. The ligament systems depicted in Figure 2-4 show that, in addition to the lateral (fibular) and medial ligaments, important anterior and posterior cruciate ligaments cross-connect the femur and tibia. (9)

To show the geometry of the articulating surfaces in the natural knee, an acrylic plastic model of the femoral and tibial condyles was used and sectioned to yield contours in saggital plane as shown in Figure 2-5. (10)

The spiral profile of the medial femoral condyle in which the radius of curvature increase from front to rear as shown, but it is worth noting that the curvature of the lateral femoral condyle is more nearly uniform over the normal articulating region. The medial tibial condyle exhibited some concavity in both the anterio-posterior and medio-lateral directions, thus providing congruity with the opposing femoral condyle, but the lateral tibial condyle was unexpectedly found to have some convexity in the anterior-posterior direction.

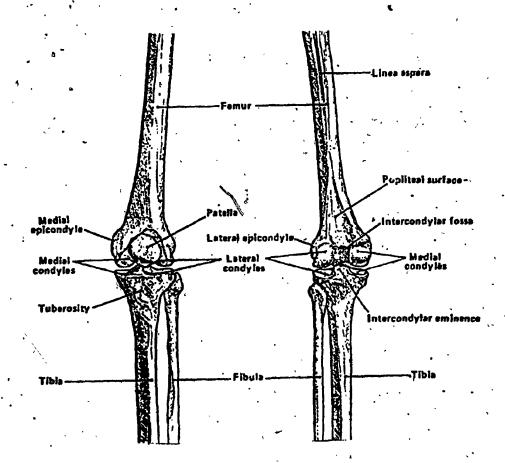


Figure 2-3 Main skeletal structures of a human knee joint (from Reference 9).

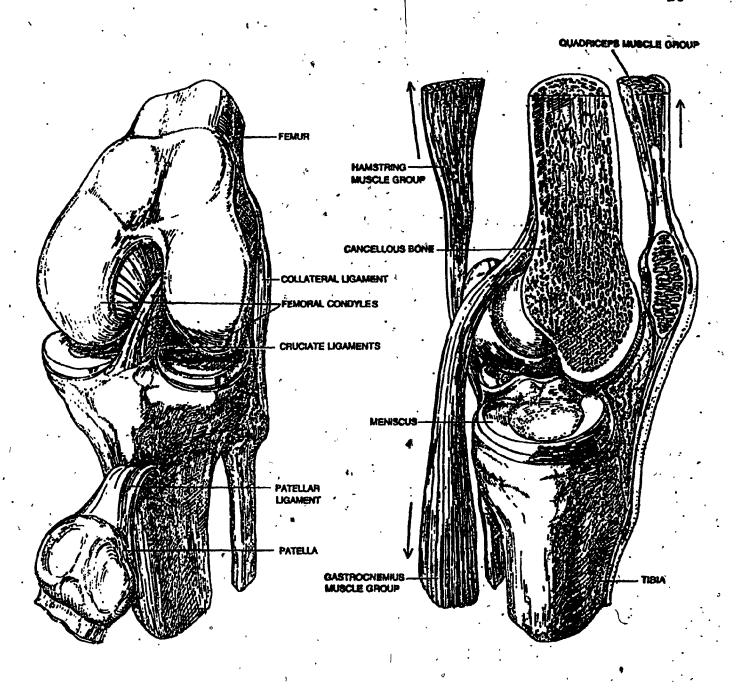


Figure 2-4 Views of normal knee joint from the front with the arrangement of the ligaments and the side with the muscle groups that control the knee (from Reference 6).

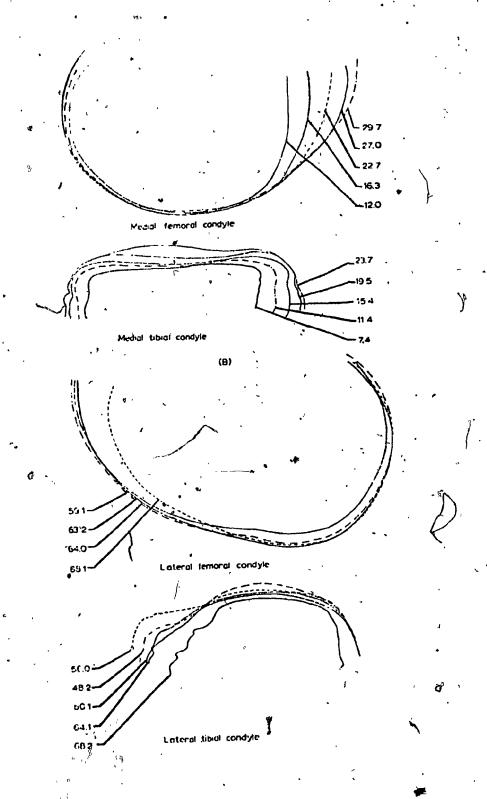


Figure 2-5 Contours of sections of the knee joint in the sagittal plane. Distance of the planes of the contours, from a reference plane, are indicated on the individual contours, in mm (from Reference 10).

2-4 Movement of the Knee Joint.

whilst the dominant movement in the natural knee is undoubtedly flexion-extension (Figure 2-6), small but significant rotations are encountered and tolerated in both steady walking in a straight path and in turning. The very large range of flexion required for simple activities like walking and rising from a chair at once ensures a unique characteristic for the natural knee and a sever design requirement for adequate replacement joints. In level walking maximum values of knee flexion range from about 60° to 70°, whilst in rising from chairs the angles can exceed 100° and may even reach 120°. In ascending or descending stairs the maximum flexion is normally between 90° and 100° (Figures 2-7, 2-8 and 2-9).

Rotation at the knee joint, both about the long axis and in sense of ad-abduction, has been demonstrated in several studies of gait, and in those studies rotations of the tibia relative to the femur about the long axis appear to lie in the range 5° to 10°, with the maximum value in the walking cycle being achieved at the end of the swing phase, whilst a total range of 17° in ad-abduction has been observed. A full description of the kinematics must obviously include the phase relationships of these different rotations, but the order of magnitude of the relations is as stated above. (12)

In design of an artificial knee, it is very important

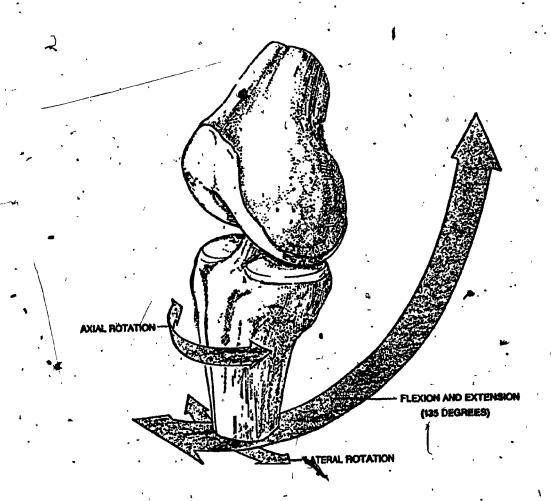
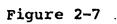
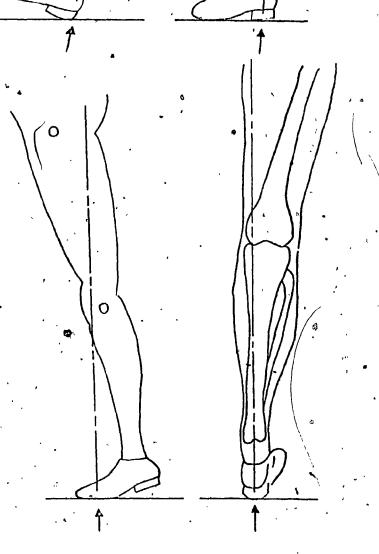


Figure 2-6 Triaxial motions of the normal knee joint (from Reference 6).

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Lateral and A/P views (of the leg in relaxed walking (from Ref-erence 12).



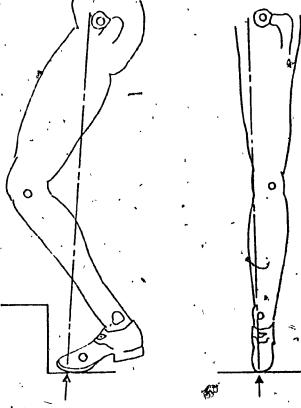
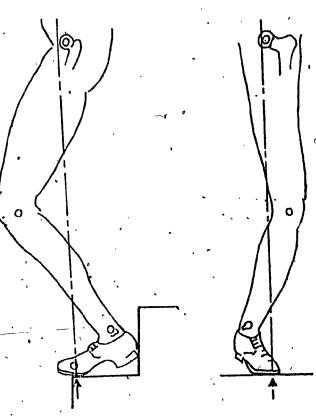
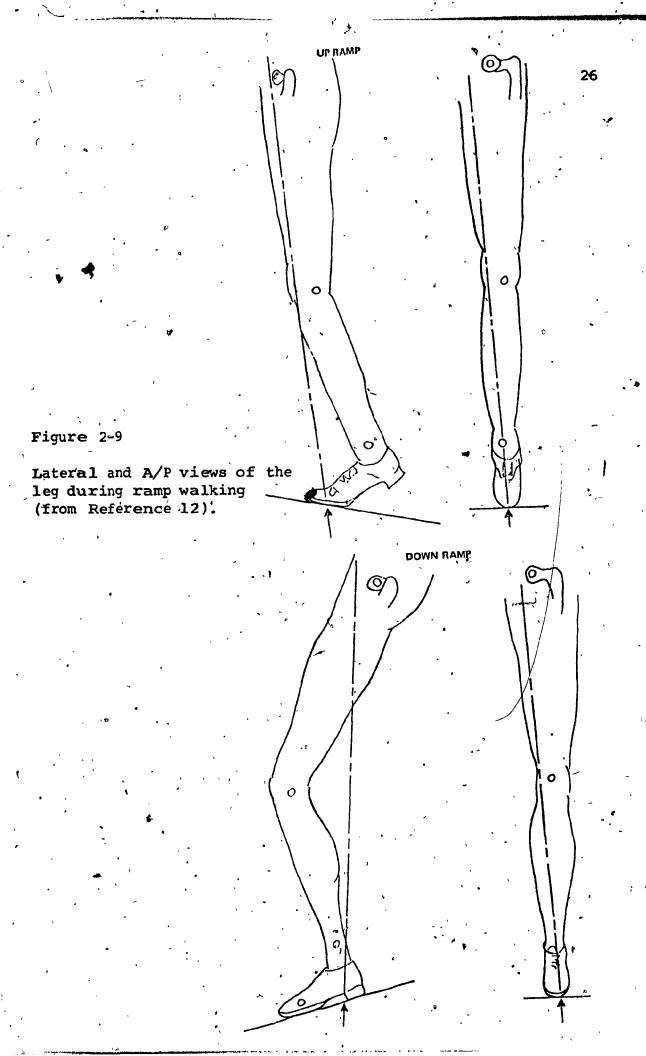


Figure 2-8

Lateral and A/P views of the leg during stair ascent and descent (from Reference 12).

DOWN STAIRS





to be aware of the ability of the natural knee to accomodate these remarkable angles of flexion and rotation.

2-5 Loading on the Knee Joint

Human locomotion is an extremely complex phenomenon.

Because walking is a three-dimensional activity creates major difficulties in the analysis of force actions transmitted between limb segments. Although the main effects of locomotion are in the plane of progression neglect of lateral and rotatory displacement will introduce major errors in joint force computation.

By static analytical method and using a planar force system, could calculate the magnitude and direction of the resultant force transmitted at the hip for individuals standing on one leg. This configuration does not, however, closely correspond to the single support phase of the gait cycle (Figure 2-10) and extrapolation of moments and forces must be made with caution. (11)

The resultant joint force at the hip or knee is calculated by considering the appropriate limb segment as a free
body at conditions of equilibrium. The maximum joint loading
occurs at the stance phase only and for knee may be two to four
times body weight. Swing phase loading is small by comparison,
and is due entirely to the effects of gravity and inertia acting

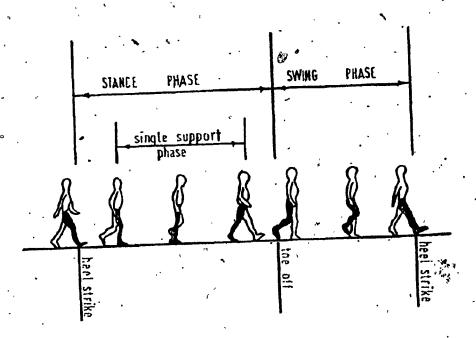


Figure 2-10 The gait cycle. The stance phase involves approximately 60 per cent of the gait cycle. During the single support portion of this phase body weight is supported entirely by the weight-bearing limb (from Reference 14).

on limb segments. Since effect of swing phase load is very small at the knee, it can be omitted for the stance phase without any serious change in the analysis.

2-5-1 Experimental Technique

Skin markers were placed on each subject overlying the anterior superior iliac spine and bony prominence of the greater trochanter at the hip together with markers located anteriorly and laterally corresponding to the center of rotation of the knee and ankle (Figure 2-11).

During a walk a continuous record of the ground-tofoot forces and moments at the force plate is made.

The subject will be photographed from the front and side by two synchronized Paillard Bolex H-16 cameras at 50 frames per second. At the completion of a test the film will be re-exposed to a grid of five-inch squares placed at the force plate center to allow measurements to be made of marker positions in relation to the grid.

2-5-2 Theoretical Analysis

From Figure 2-12 the external force system acting at the knee, the moment in the sagittal plane is:

$$M_{Z} = F_{Y} \cdot X - F_{X} \cdot \overline{Y}$$
 (1)

the effect of M₂ is to flex or extend the shank about the

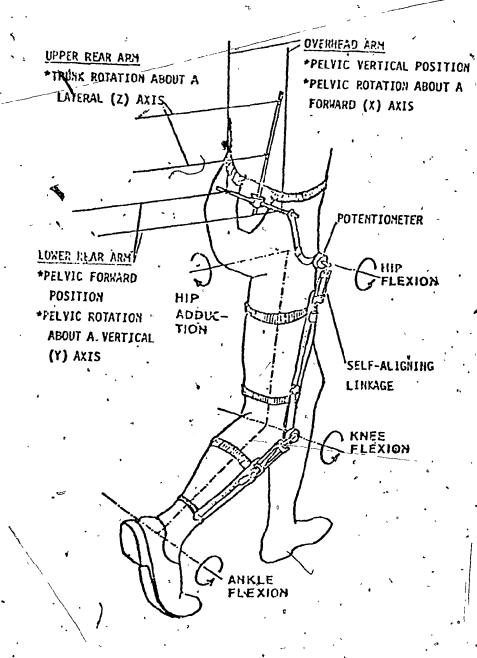


Figure 2-11 System of motion measurement (from Reference 15).

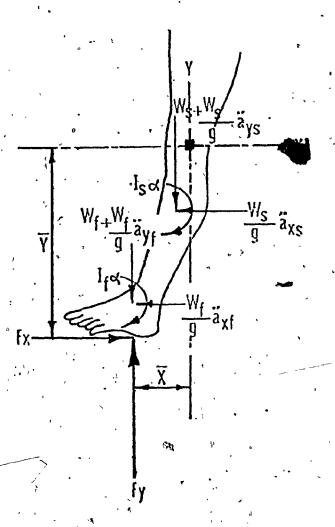


Figure 2-12 Ground force, acceleration and gravitational effects. The external forces and moments acting on the foot and shank in the sagittal plane are illustrated. Inertia and gravitational effects are ignored in the calculation of knee moment (from Reference 14).

Z-grid axis through the knee joint center. Similarly, M_X
tends to abduct/adduct and M_Y rotates the shank about their respective axis.

Forces acting on the shank and foot are F_x , anteroposterior shear force; F_y , Vertical Force; and F_z , mediolateral shear force. The external force actions (F_x, F_y, F_z) and M_x , M_y , M_z) calculated relative to the grid axis system are resolved into component corresponding to a set of orthogonal tibial axes intersecting at the knee joint center, expressed as three forces, F_{xk} , F_{yk} , F_z and three moment M_{xk} , M_{yk} , M_{zk} . For equilibrium the external force actions at the knee must be balanced by force actions occurring in muscles, ligaments and at the bearing surface (Figure 2-13).

In general, there are more unknown force actions than equilibrium equations. A full solution can be made, however, from assumptions derived in considering the functional anatomy of the knee joint.

It is assumed, for example, that the main function of the cruciate ligaments is to resist antero-posterior displacement of the tibia. A tensile force in one ligament implies the force action in the other. The cruciates are assumed not to transmit moments in either the sagittal or frontal planes.

The force equation is:

$$A_{CX} = P_{CX} = F_{XK} = 0 \qquad (2)$$

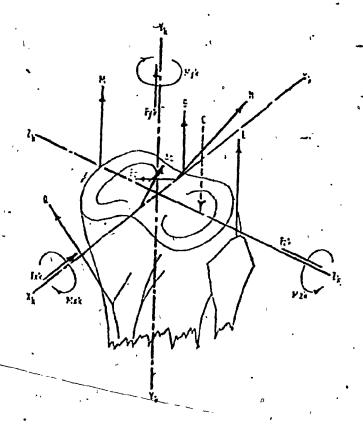


Figure 2-13 Knee joint force model, where F_{xk}, F_{yk}, F_{zk} and M_{xk}, M_{yk}, M_{zk} represent applied forces and moments. Reactive muscle ligament and bearing forces are:

M - medial collateral ligament;

L - lateral collateral ligament;

A_c - anterior cruciate ligament;

P_C - posterior cruciate ligament;

Q - quadriceps force action;

H - hamstring;

G - gastrocnemii;

C - bearing force.

(from Reference 14)

where A_{CX} and P_{CX} are forces components of the anterior and posterior cruciate ligament parallel to the tibial plateau and F_{XK} is the net force action on the shank which include muscle and ground-to-foot component resolved parallel to the plateau.

The cruciate ligament force is:

$$\phi$$
 $c_r = A_{cx} \text{ or } P_{cx}/cos\theta_x$

where $\theta_{\mathbf{x}}$ is the angle of inclination of the cruciate ligament to the tibial plateau

when $A_{CX} > 0$ it is assumed that $P_{CX} = 0$ and therefore

 $A_{CX} = \sum_{i=1}^{n} F_{XX}$, a similar solution is made for P_{CX} .

Rotations at the knee in the sagittal plane are controlled primarily by three muscle groups:

- Q, quadriceps (knee extendors)
- G, gastrochemii (knee flexors)
- H, hamstrings

It is assumed that when M_{Zk} is acting to flex the knee a force action occurs in the Q for equilibrium and that action occurs in the flexors. The opposite assumption is made when moment M_{Zk} act to extend the shank.

The equations for calculation of muscle force are:

When Q = 0, G & H = 0

When G or H = 0, Q = 0

Therefore $Q = M_{zk}/D_q$ or $G \& \text{ or } H = M_{zk}/D_q$ or D_h (3)

Where Q, H & G are force reaction in the muscle groups D_q , D_h & D_g their respective moment arms measured from the knee joint center. The collateral ligaments resist moments which tend to abduct or adduct the tibia. Abduction of shank will be resisted by a tensile force in the medial collateral ligament M and a bearing compression force C (Figure 2-14).

As the abduction moment increases in magnitude the resultant joint force C and its point of application, the center of joint pressure Z_O, will shift towards the lateral joint compartment. The opposite situation (Figure 2-15) occurs when an adduction applied to the tibia.

Assume the limiting value of $Z_0 = W/4$ where W= Knee condylar width

There are three possible solutions for $z_o: \sim$

If
$$Z_0 \searrow W/4$$
 then $M = 0 \& L = 0$ (4)

If
$$Z_0 \left(-W/4 \text{ then M}\right) O \& L = 0$$
 (5)

If
$$-W/4\sqrt{Z_0}\sqrt{W/4}$$
 then $M = L = 0$ (6)

the first two solutions imply one point bearing contact between femoral and tibial candyles with the resultant joint force C concentrated in the medial plateau for the first case and in the lateral compartment for the second. Two point contact occurs for the third solution and the total load C will be distributed proportionately as $C_m & C_1$ in the medial and lateral joint compartments.

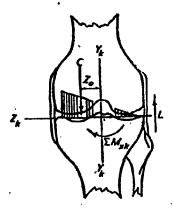


Figure 2-14 Abduction loading of the shank. When the applied moment tends to abduct the shank the centre of joint pressure Z_o shifts into the lateral joint compartment and the moment is resisted by a medially located bearing force C and a tensile force in the lateral ligament (from Reference 17).

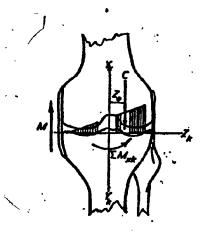


Figure 2-15 Adduction loading of the shank. This is the opposite situation to that illustrated in Figure 2-14 (from Reference 17).

In general there are two-equilibrium equations from Figure 2-

$$C.Z_0 + L.W/2 - M.W/2 - T.a + M_{xk} = 0$$

(7)

and

$$M + L + T_V - C + F_{Vk} = 0$$

(8)

where C = resultant joint bearing force

 z_o = center of joint pressure

M = Medial collateral ligament force

L = Lateral collateral ligament force

T = Muscle force (Q, G & H) and T_y the Y_k component

a = moment arm of muscle force

 $F_{yk} = Y_k$ ground to foot and carciate force component

 M_{xk} = applied abduction/adduction moments.

A valid solution for C, M and L can be made for all possible loading conditions during the stance phase from equations 4, 5, 6, 7 and 8.

2-5-3 Inertia and Gravitational Effects

If the effect of gravity and inertia is included in the analysis the moment equation in the plane of progression (Sagital plane) (Figure 2-12) is:

$$M_{zk} = F_{y}.\overline{X} - F_{x}.\overline{Y} - W(X_{k} - X_{s}) - W/g. \text{ ay}(X_{k}-X_{s})$$
$$+ W/g. \text{ a}_{x}(Y_{k} - Y_{s}) + I. \alpha I. \alpha_{z}$$

Where W represents the weight of the shank and foot, a and

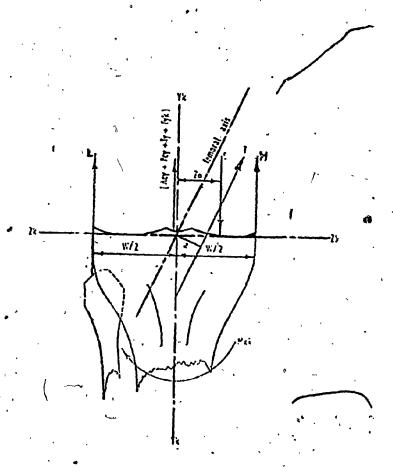


Figure 2-16 Force actions at the knee joint for conditions of equilibrium (from Reference 14).

the linear acceleration of limb segments, I the mass moment of inertia of segments and α the angular accelerations.

The fore and aft moment for a normal subject during a "fast" walk calculated with and without gravitational and inertia effects is shown in Figure 2-17. It is apparent that the effect of these terms on computed sagittal plane moments is small for the stance phase, and can safely be omitted from joint force computations.

rigure 2-18 shows the joint force results from four normal subjects for the activity of level walking. Both limbs in each subject were tested. The average maximum bearing force transmitted at the knee was 3.5 times body weight. There are three peak loads a, b, c which correspond to hamstring, quadriceps and gastrochemius force actions. The relative magnitude of the peaks varied for different subjects but exhibited similar characteristics for each individual with repeated testing. (12)

rigure 2-19 shows the center of joint pressure for all normal subjects was located in the medial joint compartment throughout most of the stance phase.

Cruciate ligament force varied in magnitude from 34 to
134 pounds (Figure 2-20). For most subjects the anterior
cruciate ligament transmitted load during the early part of the
stance phase and the posterior cruciate towards the end of

Figure 2-17

Comparison of total force and aft knee moment with moment due to ground reactions. Sagittal plane moments with and without acceleration effects are illustrated for a normal subject (from Reference 14).

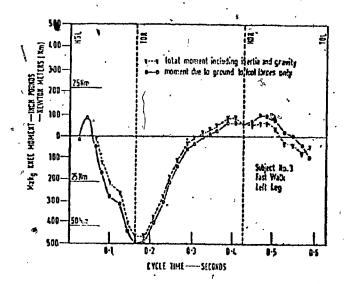
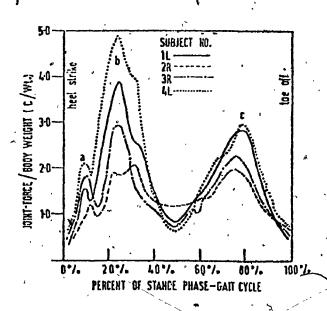


Figure 2-18

Knee joint bearing force-normals. The bearing curves for normal subjects are illustrated. The a, b and c peaks correspond to hamstring, quadriceps and gastrocnemuis force actions. (from Reference 14).



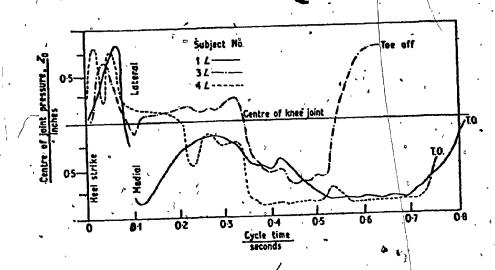


Figure 2-19 Variation of center of joint pressure. The center of joint pressure tends to be located in the medial joint compartment during weight bearing in normal individuals (from Reference 17).

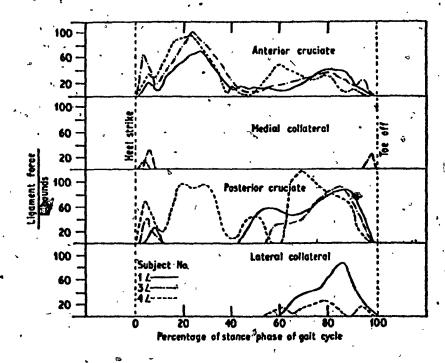


Figure 2-20 Ligament force actions in normal limbs. The magnitude and phasing of knee ligament force actions during the stance phase of the gait cycle (from Reference 17).

the cycle. Almost no force occurred in the medial collateral ligament during weight bearing.(13)

Force actions at the knee were calculated for three polio, five osteoarthritic and six rheumatoid arthritic patients. The joint force of paralytic limbs are shown in Figure 2-21 and are typical for all pathological limbs tested.

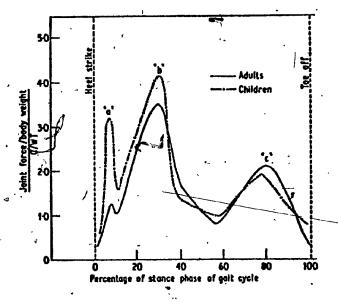


Figure 2-21 Knee joint bearing force in paralytic limbs.
The a, b and c force peaks are blunted and joint force tends to approach body weight (from Reference 17).

3- General Design Procedure

To design any piece of equipment, we could start in several ways, as indeed the design itself may have developed in different ways, but for purposes of discussion, it is simplest to start from the requirements, to examine their implications, to outline possible solutions, and then, so far as possible, to compare the merits of the possible solutions. In practice, this comparison will be based partly on laboratory testing and field trials of limited numbers of chosen designs.

In this case, a good design for a knee joint is a treatment which will result in freedom from pain, sufficient ranges of motion for the activities of daily living, the correction of deformities or instabilities, and a working life for the prosthesis at least as long as the patient's own expectancy of life. The surgeon needs a practicable insertion procedure and an acceptable salvage procedure for use if necessary and the treatment should be done at a cost of no higher than necessary. These aspects of the procedure are discussed as follows. (15)

3-1 Freedom from Pain

Freedom from pain would be expected to require the replacement of both rubbing surfaces, and this expectation is confirmed by widespread observation at the hip. It must be

CHAPTER 3

GENERAL PROCEDURE TO DESIGN AN ARTIFICIAL KNEE FOINT

said that at the knee pain is often eliminated, or reduced to tolerable levels, by replacing only the tibio-femoral joint and leaving the patello-femoral joint either with both cartilage surfaces present or with the posterior face of the patella working against the anterior surface of a femoral component. Usually no knee replacement prosthesis used to replace both joints, although some are developed which do, Some employ a single femoral component which provides the bearing surface at both the tibio-femoral and patello-femoral contacts. Thus, it may be said that the tibial and inferior femoral bearing surfaces must be replaced, and that the pat-. ellar and anterior femoral surfaces should be in a so far unknown proportion of patients. If the obvious source of pain has been removed, loosening of one or more components is the other possible cause of pain which must enter into engineering considerations.

3-2 Sufficient Ranges of Motion

The natural knee is now well-known to be a three-dimensional joint, the three rotational degrees of freedom in which are linked at or near full extension and independent near full flexion. An ideal prosthesis would produce these characteristics (Figure 3-1), but other factors make it necessary to consider something simpler. One important factor

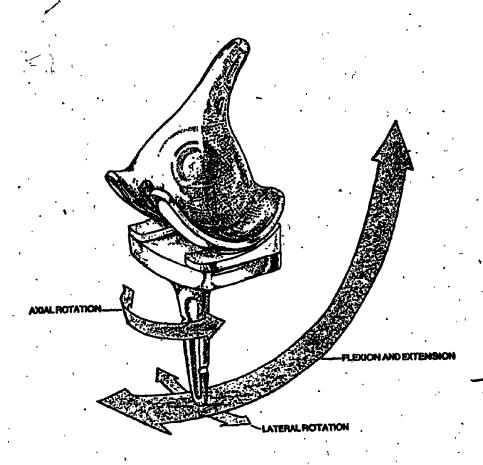


Figure 3-1 Range of movement of the spherocentric knee prosthesis (from Reference 6).

other joints which restrict and distort their patterns of movement, so that even if a kinematically perfect knee prosthesis could be designed and made, it would be irrelevant to their needs, another is that in severely disorganized knees the cruciate ligaments are often unreliable, and a kinematically perfect knee could not depend on them for its correct functioning.

• A severely and multiply disabled patient will be glad to be able to get into or out of a chair unaided, to walk on the level for short distances, and to walk up and down stairs. For these activities, a range from extension to 90° of flexion is the minimum that can be considered, much more than 110° of flexion is irrelevant. Abduction and adduction and rotation seem not to be necessary in themselves, but a prosthesis which positively prevents them is more likely to loosen.

For younger and less severely disabled patients it is desirable to provide a closer approach to normal ranges of motion, but in the present knowledge it may be dangerous to allow a young and active patient to treat a prosthetic joint as if it were a healthy natural joint.

3-3 Correction of Deformities or Instabilities

The deformities and instabilities to be considered were

outlined above. The first design implication is that the prosthetic components should have shapes which allow them to be
used with simple and straightforward alignment devices during
the operation, so that surgeons other than the originator can
obtain a desired alignment as nearly automatically as possible,
starting from any likely degree of deformity or instability.
The second is that the prosthetic component, acting together
with whatever tissues are dependable, must confer stability
where it is needed.

3-4 Working Life of Prosthesis

The possible limits to the working life of the prosthesis in the patient could be considered in order, as different ways.

The patient may die during or soon after the operation.

This is not essentially an engineering matter, but short operations are presumably less risk than long ones, and therefore simplification and consequent shortening of the operative procedure must, in general, be good.

The joint may become infected, this again is not essentially an engineering matter, but the design of the prosthesis and insertion procedure can have some effect, re-entrant curves in and unfilled spaces around the prosthetic components must, in principle, increase the chances of infection, and a short

operative time gives less change, other things being equal, for the ingress of bacteria.

One or more components may become loose. To reduce the chance of this happening, one can seek both to reduce the highest stress applied to the bone-prosthesis junctions and to increase the strength of these junctions. The general level of forces on the prosthesis is outside the designer's control, but it could be refrained from adding extra forces arising from the design of the prosthesis. Thus, if hyperextension is limited by a wholly metallic stop, significant forces must be expected to be generated when that stop functions, and these forces will be transmitted through the bone-prosthesis junctions. Similarly, if the tibial and femoral components are completely constrained in every degree of freedom except flexion-extension, any torsional, adduction or abduction moment applied to the lower leg will be transmitted through the prosthetic components and their junctions with the bone.

High friction between the prosthetic components must, in principle, increase the stresses on the bone-prosthesis junctions, although it is not certain that this is a major determinant of the highest stresses, but in general low friction must be better than high friction. The bone-prosthesis junction can be strengthened by increasing its area, by suitably disposing the area (e.g. by using a cement cured in situ).

Thus, from considering the desire to prevent loosening, one can see two possible general types of prosthesis emerging, those which are completely constrained except for flexion-extension, which therefore are likely to generate significant loosening forces, and which need substantial intramedullary stems, and those which are incompletely constrained, which depend to some extent on remaining natural tissues for stability, and which are unlikely to need intramedullary stems.

One or more prosthesis component may wear out. This will be prevented or delayed by the correct choice of material and by keeping the stresses on the bearing surfaces as low as possible. On the one hand this means providing as large a bearing as possible, and on the other hand it means attending to the factors tending to increase the applied loads under the heading of loosening.

The wear products could be harmful to the patient.

Prostheses so far used at the hip have given rise to metals in solution and particles in the vicinity of the prosthesis.

It is reasonable to assume that this will be true of all prostheses using rubbing elements, whether at the hip, the knee or elsewhere. When adjacent tissues are examined, acrylic cement particles are found, if acrylic cement is used for flexion, if at least one component is of alloy, particles of alloy are found, and if one component is of polyethylene, polyethylene

particles are found. Whether any or all of these are harmful presumably depends on the rate of production, the rate of elimination and the nature of the particles. It is known that large particles of polyethylene (and of other plastics) are carcinogenic in rats and that tumours have been found in association with large polyethylene implants in man, that particles of cobalt-chromium alloy produced by laboratory testing of hip and knee prostheses are carcinogenic in rats, and that one has occurred adjacent to an all cobalt-chromium hip prosthesis which had been in a man for years.

3-5 Practicable Insertion Procedure

Any prosthesis could be inserted with the use of hand tools, measurements being made by eye or using simple instruments such as protractors and scales, and the required alignment being obtained by successive correction to the cut surface. Such a process is likely to be time consuming and is unlikely, unless followed with great skill and patience, to produce the desired alignment every time. As in every other activity involving the fitting of many examples of the same component to hosts differing in detail, it seems likely that a small number of simple measuring devices or cutting guides, designed in conjunction with the prosthetic components, will both reduce the length of the operation and give the surgeon a better chance

of achieving the desired alignment. This will be more easily achieved if the prosthetic components are so shaped as to require relatively simple shapes to be cut in the bones, and if alignment can be readily known from measurements made on prominent geometrical features of the components.

3-6 Acceptable Salvage Procedure

If for any reason the prosthesis must be removed, it is obviously desirable to offer the patient the best possible outcome, i.e. to make the failure no worth than it need be. If the prosthetic components can be replaced with others of the same type, that will clearly be good and perhaps the best outcome, but at the other end of the scale arthrodesis must be considered.

For a good arthrodesis, one needs ideally two uninterrupted uninfected areas of cancellous bone, so placed as to
give the shortening of choice, thus prosthetic components
which require the removal of no more bone than would be removed for a primary arthrodesis, which leaves large areas of
cancellous bone in the femur and tibia, and which allow all
potentially infected foreign matter to be removed, are desirable. Cemented long intramedullary stems are from this point
of view highly undesirable.

3-7 Cost

This is a factor that should not be ignored. The total cost includes the costs of making, inspecting and distributing, and costs of holding stocks in hospitals and making prostheses available as required. The former group are fairly readily ascertainable, and reflect the complexity of the components, the number of sizes and versions, and the rate of production. The latter are less readily ascertainable, but are no less real for that, if several different devices, or versions of one device, have to be made available for any one operation, the load on the hospital organization is increased, and staff of a higher grade may be needed at certain points.

The cost of most joint replacement prostheses increases over what It might be by the widespread insistence on the best attainable surface finished and dimensional accuracy of the bearing surfaces. This arises from a desire to minimize the rate of wear, coupled with a lack of knowledge of the precise dependence of this of these factors.

3-8 Possible Mechanical Arrangements

The first regularly successful results of total knee replacement were achieved in the 1950's and 1960's, using an implant of hinged type (Figure 3-2). The names of Shiers, Waldius and McKee are probably the best known among the earlier

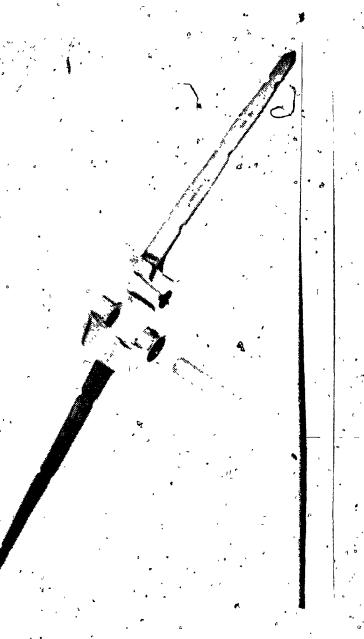




Figure 3-2 Hinge prosthesis (from Reference 23).

hinges but more recently the number of different designs has greatly increased. All knee hinges, however, have several faults. Firstly, they do not reproduce a normal flexion and extension, moving as they do around a fixed axis as opposed to the polycentric axis of the human knee joint. Secondly, they allow no movement other than flexion and extension. No rotation or lateral movement is possible and this rigidity may predispose to mechanical failure, either by breakage of implant itself or by loosening of the bond between the implant and bone. Thirdly, many of the hinge implants require removal of a considerable length of bone which may make secondary procedures difficult or impossible. The hinges have, however, an inherent stability which does not require the patient's own ligaments to be intact. (23)

been produced with the femoral and tibial components unconnected except by contact. The Freeman-Swanson (Figures 3-3, 3-4), spherocentric prosthesis (Figure 3-5), the Stabilized Gliding prosthesis (Figure 3-6) are all the examples of this type of implant. Some of them have a more normal flexion and extension movement, allow some rotation and call for removal of less bone length. However, they rely for much of their stability on the patient's intact ligaments and may be more suited to those cases where there is little initial deformity.

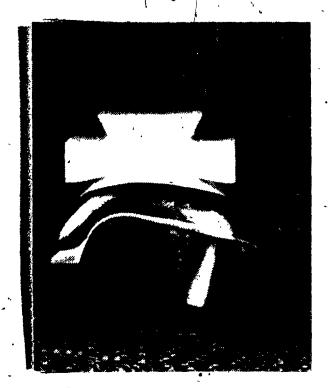


Figure 3-3 Freeman-Swanson prosthesis (from Reference 24).

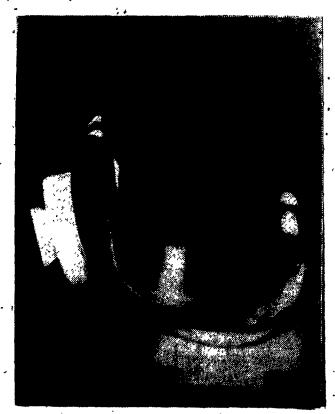


Figure 3-4 Modified Freeman-Swanson prosthesis (from Reference 24).

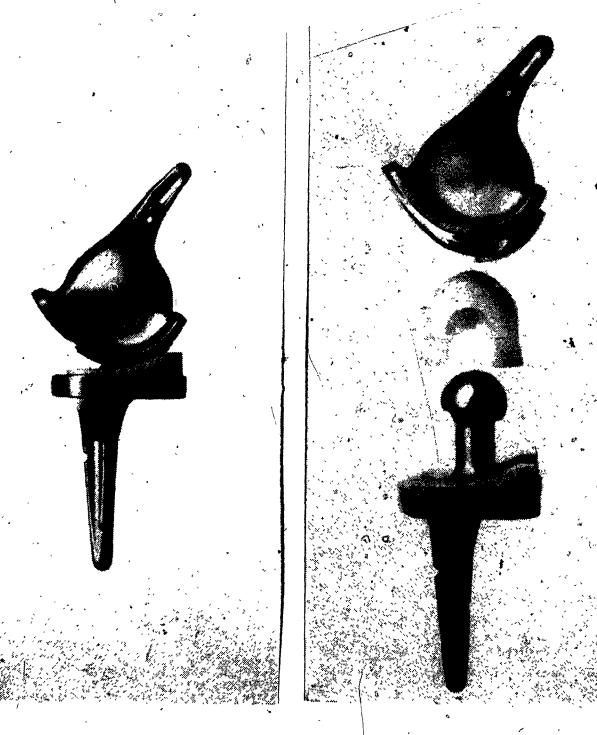


Figure 3-5 Spherocentric prosthesis (from Reference 6).





Figure 3-6

Stabilized Gliding prosthesis

- (a) In extension
- (b) In flexion
- (c) Separated components from behind

(from Reference 25)



(c)

CHAPTER 4

MATERIALS & WEAR

MATERIALS, MECHANICAL CONSIDERATION, TRIBOLOGICAL CONSIDERATION, WEAR MECHANISMS, THE NATURE OF WEAR IN ARTIFICIAL KNEE

4- Materials & Wear

The ideal implant for total knee replacements should possess certain characteristics. Flexion and extension movements should approximate to the normal knee and some rotation and lateral flexion should be possible, and in this it is implicit that full extension of the joint should be completely stable, allowing no rotation or lateral movement, but these movements should increase gradually with increasing flexion. There should be stability in both an antero-posterior and lateral direction and obviously this is of particular importance in dealing with patients who have an initial severe deformity. The insertion of the prosthesis should call for a minimal removal of bone length so that a secondary procedure, for instance an arthrodesis, can still be performed in case of failure. Probably less than one inch of bone should be removed. Therefore, the common features of an ideal design are the use of fairly thin and compact components to imitate more or less exactly the shapes of natural femoral and tibial condyles, the preservation of both the collateral and the cruciate ligaments.

4-1 Materials

The selection of suitable materials for a prosthesis must be made against the background discussed in earlier sections. A knowledge of the anatomy of the diseased and natural joint must be coupled with a clear appreciation of the design objectives, the required or desirable movement of the joint and the likely loading cycle. In addition, the environment, compatibility of the materials and their wear products with the body and fixation problem must be considered.(29)

In short prosthesis must be capable of supporting the loads experienced in everyday activities without breaking, whilst permitting the desired range of movement. Furthermore, the rate of wear should be minimal to provide adequate life of the prosthesis, whilst the materials, in both bulk and wear debris form, should be non-toxic. Finally, the method of fixation should be such that the prosthesis neither works loose in normal service nor presents an impossible task for surgeon if revision becomes necessary.

4-2 Mechanical Considerations

The knee is one of the most highly loaded and possibly the most severely stressed load bearing joint in the body. For this reason corrosion-resistance metal usually forms at least

one component of the prosthesis. The metals which have found application are stainless steel, cobalt-chromium alloys and to a lesser extent titanium. All are capable of carrying the direct, shear and bending stresses in the hinge or condylar replacement design if suitably proportioned. The mechanical properties of these materials, such as tensile and compressive strength, elastic modulus and ductility together with hardness are well known, and if the loads and their moments are specified, mechanical design of the components presents no serious difficulties.

It is, however, worth noting that if both components are made entirely of metal, as in the majority of hinge joints, exactly similar materials are employed to avoid the formation of electro-chemical corrosion cells. This requirement does not in itself present a serious design limitation from the point of view of mechanical strength, but the tribological consequences may be serious. Similar metals generally provide high frictions and wear under sliding conditions, and bearing for engineering applications generally consist of a hard material (e.g. steel) rubbing against a soft or low shear strength material (e.g. white metal). If a decision is made to make both components of a sliding pair for use in the body from metals, low friction and low wear rates can normally be provided only if hard metals are used. (30)

Ductility and resistance to impact loading and fatigue might be important in some load bearing joints, and there are some evidences that these properties might be critical for any of the metals mentioned above in knee joints, and there is a danger of fatigue failure. Figure 4-1 shows the fatigue failure in the Herbert prosthesis. The prosthesis is linked by a so-called captured ball-and-socket articulation designed to provide stability in the absence of ligaments. The articulating surfaces consist of a high-density-polyethylene socket on the femoral side and a cobalt-chromium alloy sphere on the tibial side. (32)

In recent years the merit of metal-on-plastic combinations of materials has led to the wide-scale use of one of the above metal in association with ultra-high molecular weight polyethylene (UHMWPE). This polymer has excellent tribological properties and although its mechanical properties are less favourable than those of most steels it can be used with safety if the prosthetic components are carefully designed.

Dimensional changes in the polymur might occur dusto changes in its liquid content or due to creep under load, but neither these characteristics is seen as a serious limitation on the use of UHMWPE in current forms of knee prosthesis.

Alternative materials will no doubt be considered for endo-prosthetic applications in the future, and it is worth

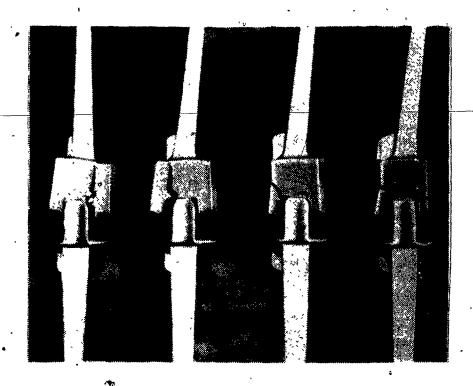


Figure 4-1 On the right are two fractures that occurred in the original model of the Herbert prosthesis introduced in the United States.

On the left are the two modified and strengthened Herbert prostheses. All fractures occurred through the medial wall.

(from Reference 32).

noting that alternative polymers, in normal and reinforced form, elastomeric materials and even ceramics have been used or proposed for other joints. However, the UHMWPE and metal in current use appear to be entirely adequate for the knee joint as far as mechanical properties are concerned. If alternative materials are introduced it is likely to be either on the grounds of improved tribological properties or enhanced compatibility with body tissues, and these factors should be thoroughly explored before other materials are used clinically.

4-3 Tribological Consideration

It has already been shown that there are few limitations on materials for the knee joint based upon strength considerations. The main considerations are therefore likely to be compatibility, friction and wear. In the field of materials in science the emphasis has, for a long time, been placed on properties related to strength, but in recent years there has been a reappraisal of the need to select material which can provide adequate life for engineering components. Although fracture of components is often sudden and usually catastrophic, wear is an indisious process and in the long run just as big a limitation on satisfactory machine performance and reliability. Furthermore, it is more difficult to combat and it is no exaggeration to say that everything that man makes wears

out. Provided that fracture of one or more components does not occur, the useful life of a total replacement knee joint is, like that of any engineering bearing, determined by the wear characteristics of the components. (33)

4-4 Wear Mechanisms

The most common and most difficult form of wear to combat is adhesive-wear. It results from the formation of miniature adhesive junctions associated with asperities on interacting surfaces. Sliding shear these junctions, and since the fracture plane does not always coincide with the original interface, a particle of material is plucked out of one of the sliding members to remain attached to the opposing surface, and ultimately to be broken off to form a wear particle. This is normally the major mode of wear between materials, but the extent to which it takes place in metal-on-plastic conjunctions is more difficult to determine.

If one of the sliding members is harder than the other, abrasive-wear may dominate the process of material removal.

The asperities on the harder material plough through the softer material leaving wear grooves and evidence of plastic flow.

The process can be likened to the action of a file and it is normally thought to dominate the wear of polymers rubbing against metals. This action is known as two-body abrasive

wear, but if hard particles are rubbed between two surfaces, scratches may be formed by a three-body abrasive wear process.

A third wear mechanism which is normally associated with hard, highly stressed machine elements like gears and rolling bearing is surface-fatigue. The process is associated with surface or sub-surface crack formation and subsequent removal of flakes of material from the surface of the formation of localized pits. (33)

Erosive and corrosive wear mechanisms can also be identified, but neither are expected to be significant in the knee joint if material selection and control is safeguarded. Corrosion which might be influenced by the presence of bacteria or other organic matter, is obviously a factor which could in principle affect the wear of joint prosthesis, but there is so far no evidence that it does so significantly in practice.

4-5 The Nature of Wear in Artificial Knee Joint

In the metal on metal prostheses a characteristic feature of the worn surfaces is the presence of fine, randomly orientated scratches.

The wear mechanism for polyethylene on steel is more subtle. It is generally thought that abrasion must play a dominant role when such a hard material as steel slides over the

This view is strengthened by the relatively soft polymer. observation that the roughness of the steel counterface directly affects the wear rate of polyethylene. However, another well known feature of the wear process for this combination of materials is the ready formation of a thin transfer-film of polyethylene on the steel. This film is patchy, initially, but then adopts a band-like appearance. The extent of the formation of a transfer-film, which can be influenced by the presence of a liquid, has an important effect upon wear rate. Once a substantial film of polymer has been formed on the counterface it seems most likely that adhesion will also contribute to the total wear rate. Tentative but important evidence of surface fatigue accompanied by the formation of cracks roughly perpendicular to the sliding direction and surface flaking with the formation of a fine wear debris. It thus appears that the wear mechanism of UHMWPE against steel is a complex process. Abrasive wear almost certainly exists, adhesive wear would seem to be unavoidable and there is now " evidence of additional wear resulting from fatigue.

CHAPTER*5

DISCUSSION AND CONCLUSIONS

5-Discussion & Conclusions

The designing of future knee prostheses must begin with an understanding of the concepts and clinical complications associated with past and present devices used in the surgical reconstruction of human knee joints. To do this in a logical fashion, one must be able to categorize by some means the subject devices. To this end, it is proposed that such classification be made based on the intrinsic stability of the device related to medial-lateral freedom, anterior-posterior freedom, and rotational freedom between femoral and tibial components.

The satisfactory design, development, manufacture, surgery and clinical evaluation associated with the artificial knee joint calls for close association of specialists with different backgrounds. Problems of communication have to be overcome, the engineer must appreciate the function of the natural joint, the disorders of the diseased joint and the problems facing the surgeon, whilst the surgeon must communicate adequately with the engineer and understand the design approach, materials selection and production techniques and the need for careful evaluation of the characteristic of individual components and the complete prosthesis in standard laboratory and simulator tests before surgery and clinical evaluation can proceed.

The replacement of the human knee joint is an active, rapidly changing field of endeavour. The great number of such replacement made in past years, primarily in patients who were elderly and chronically disabled by arthritis, have provided reduction of pain and increased function for most of the recipients. Several things can be expected to keep the state of the art advancing. They include the improvement of materials for making prosthesis, the identification of appropriate laboratory techniques for testing designs and the refinement of gait tests in the laboratory for evaluating a patient before and after an operation. (34)

According to a research that has been done with the New York Hospital-Cornell University Medical Center, considering the entire group of 178 a throplastics (29 knees with Unicondylar, Figure 5-1; 49 with Duocondylar, Figure 5-2; 50 with Geometric, Figure 5-3; 50 with Guepar, Figure 5-4; prostheses), the results were considered excellent in 47 (26%), good in 66 (37%), fair in 37 (21%), and poor in 28 (16%) (Table 1).

Thus, the majority of the results represent a significant improvement from the preoperative state, but they are far from ideal and it is apparent that none of the prostheses replacing the knee joint offer results approaching the excellence of total hip replacement in terms of either relief of pain or improvement in function, but in large part this may be

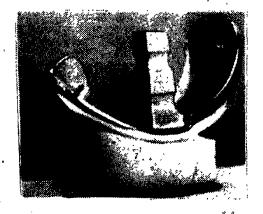


Figure 5-1 Unicondylar prostnesis (from Reference 34).

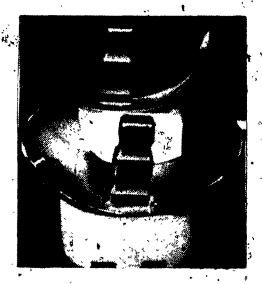


Figure 5-2 Duocondylar prosthesis (from Reference 34).

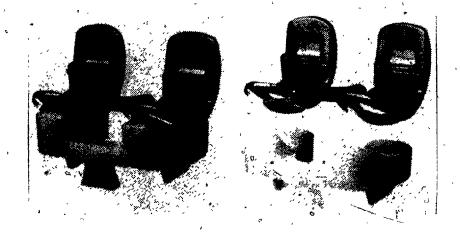


Figure 5-3 "Geometric prosthesis (from Reference 6).

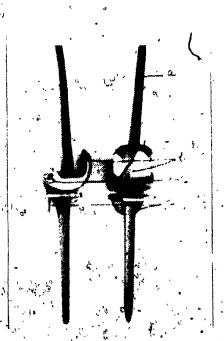


Figure 5-4 Guepar prosthesis (from Reference 36).

	No. of	Average No. of Point Score	Average nt Score	Ayerage		Results	s +	==		Pain Mod	, to	No.with Normal Re	No. Removed
Prosthesis	Knees	Knees Preop.	ď	<pre>Improvement (Per cent)</pre>	Excell.	Good	Fair	Poor.	None	None Mild Severe	ševerė	Function	
Unicondylar	23	. 64	68	54	. 2	ω	ر س	Ŋ	2	ָ דד	Š	n	'n
Duocondylar 0A	. 18	\$ 2	法	†9	ω	4	4	~	, ~	დ	m	. O	- 1
RA	42.	· 다 /	£2 ·	. 78	77	13	ο	9	18	19	Ŋ	V	m
Geometric OA	16	7.42	77	69		` A	H	N	<i>ح</i>	9	٠ س	Н	·H
RA	34	34	, 63	. 85	H٠	74	10	σ	12	17	יע	0	н
Guepar OA	02	35	. 75	7.74	Q	'	. 4	ન	, ω	დ	4	у.	н
RA.	25	31	20	126	Ŋ	בו	9	m	15	~	m	, O "	н.

i.

Table 1 (From Reference 35)

due to the inherent difficulties in arthroplasty in a joint as complex as the knee, but there is also evidence that the prosthetic design may play an important part.

Nevertheless, the primary cause of clinical failure, which is that the components of prostheses tend to work loose, must be overcome before the surgical replacement of the human knee joint can become more generally applicable. Furthermore, there are increasingly frequent introductions of new prostheses, and whereas there is no doubt a need for a range of essentially different models for specific problems of diseased joints, it must be admitted that the differences between many prostheses are small. The need for rationalization in the product range is not an uncommon problem in the engineering industry and it might well be felt in relation to the size of the market under discussion that this problem will have to be recognized sooner or later in relation to the knee joint and the hip joint.

Therefore, the functional complications experienced with current devices could be outlined as follows:

- 1-doosening of device anchorage
- 2- mechanical distortion of the device
- 3- subluxation of the bearing components
- 4- excessive wear of bearing surfaces

The key to improved design is in understanding the

causes of complications in current products and these causes could be outlined as follows:

- 1- design and material deficiencies
- 2- patient selection or implant selection error
- 3- technical installation error
- 4- misuse by the patient (trauma, overactivity)
- 5- improper post-operative management
- 6- infection
- 7- progressive tissue deterioration

Finally, it should be noted that the design, manufacture, development and evaluation of a prosthesis in the laboratory and the patient calls for patience and the utilization of the skills of various specialists. It is therefore somewhat surprising, and a matter of some concern, that new materials, new designs and new procedures can be introduced with little control and evaluation at the present time. The case for some control aimed not at a restriction of well planned programmes of work, but to safeguard the patient to the maximum extent, now calls for careful consideration. Even then patients, surgeons and engineers should not forget that the patients, surgeons and engineers should not forget that the attention ary engineering. Although it can be imitated with increasing success, it will never be duplicated. (37 & 38)

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