BIOMECHANICS AND DESIGN RATIONALE:
THE BUECHEL-PAPPAS™ ANKLE REPLACEMENT SYSTEM

by

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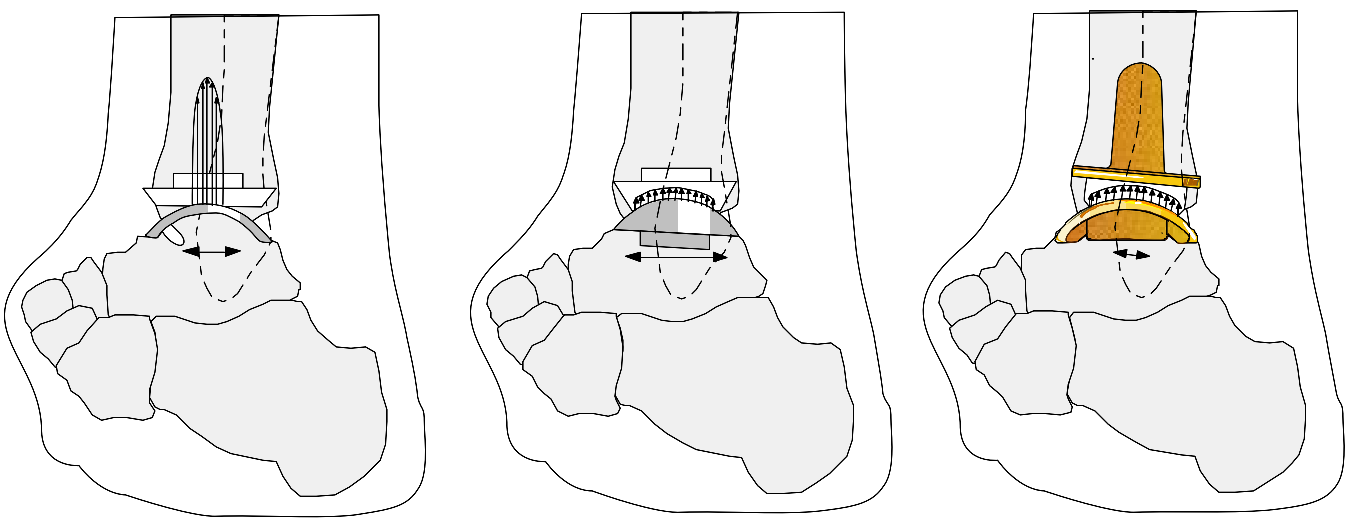
Mobility Without Congruency	Congruency Without Mobility	Mobility With Congruency*
High Contact Stress	Low Contact Stress	Low Contact Stress*



Low Constraint Forces	High Constraint Forces	Low Constraint Forces*

MOBILITY WITH CONGRUENCY

*Ideal stress and movement conditions

I BIOMECHANICS

In order to understand ankle design one must understand the underlying principles of Biomechanics.

Fig. 1 Teaching Biomechanics

The topics relating to ankle design and evaluation to be discussed here are:

1. Ankle Motion
2. Stability
3. Ankle Forces
4. Wear
5. Fixation

Once the concepts involved in these topics are reviewed, then the design rationale for the B-P ankle and its performance, in light of these concepts, will be discussed.

1. Ankle Motion

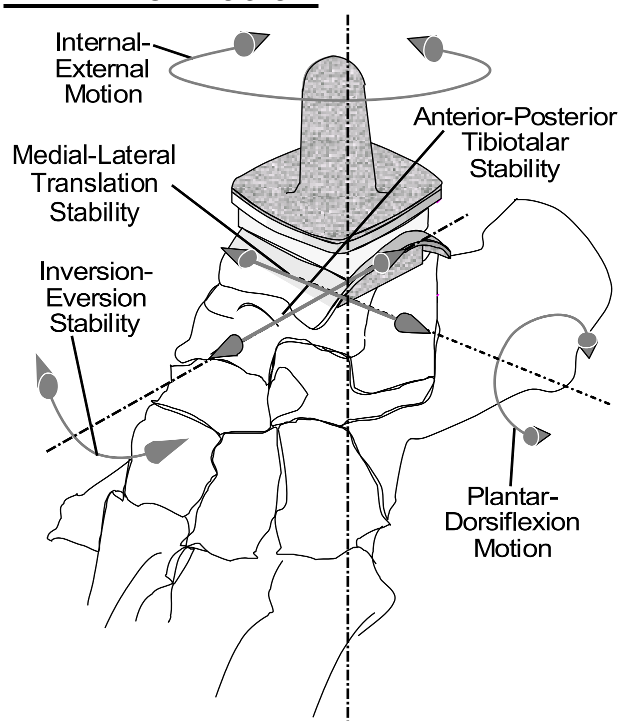


Fig. 2 Ankle Motions

The ankle has two basic degrees of motion and three degrees of stability.

Plantar-Dorsiflexion

The motions are: plantar-dorsiflexion and axial (Internal-External) rotation. In addition a small degree of inversion-eversion can occur.

The normal plantar-dorsiflexion range in level walking is typically about 25°-35° but can be in excess of 60° in other activities.[1-3]

Any restriction of this motion is undesirable as it adversely affects ankle function and can produce undesirable loading.

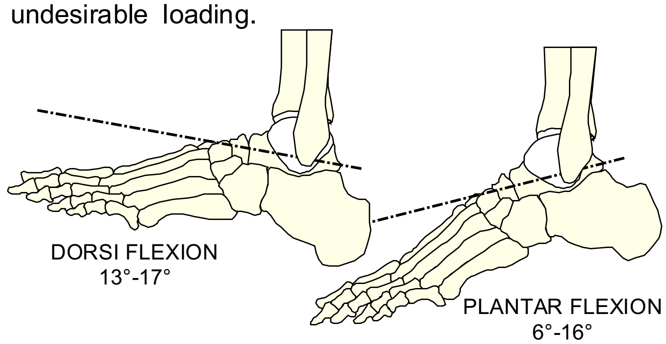


Fig. 3 Plantar and Dorsiflexion in the Normal Ankle During Walking

Axial Rotation

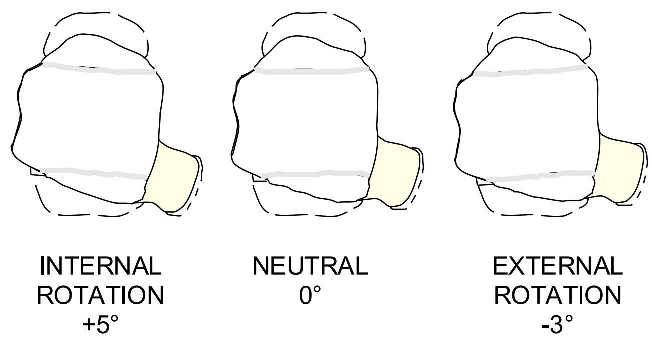


Fig. 4 Axial Rotation in the Normal Ankle During Walking

Normal axial rotation is about +5° to -3° during walking with a maximum rotation of about 16°.[1-3]

Inversion-Eversion

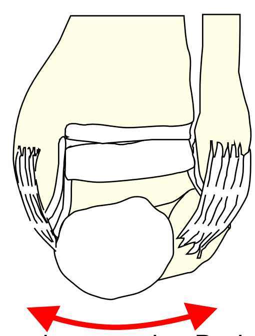


Fig. 5 Inversion-eversion During Walking

Normal inversion eversion is about +10° to -2° during walking although most of this motion is in the subtalar joint.[1-3]

2. Ankle Stability

The tibiotalar joint is stable and thus is constrained against significant anterior-posterior, medial-lateral and inversion-eversion motion.

There are two types of stability. Intrinsic stability provided by the shape of the articulating surfaces and extrinsic stability provided by soft tissues.

Anterior-Posterior

Anterior-posterior stability is primarily extrinsic and is provided by the ankle ligaments. Some intrinsic stability is also present.

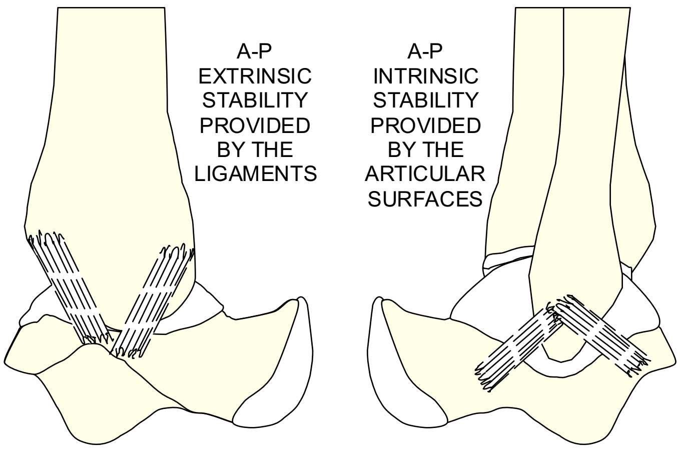


Fig. 6 A-P Stability of the Tibiotalar Joint

Medial-Lateral and Inversion-Eversion

Medial-lateral stability is almost entirely intrinsic and is provided by the ankle mortice.

Inversion-eversion stability is provided by the tibiotalar ligaments and the width of the tibiotalar articulating surface.

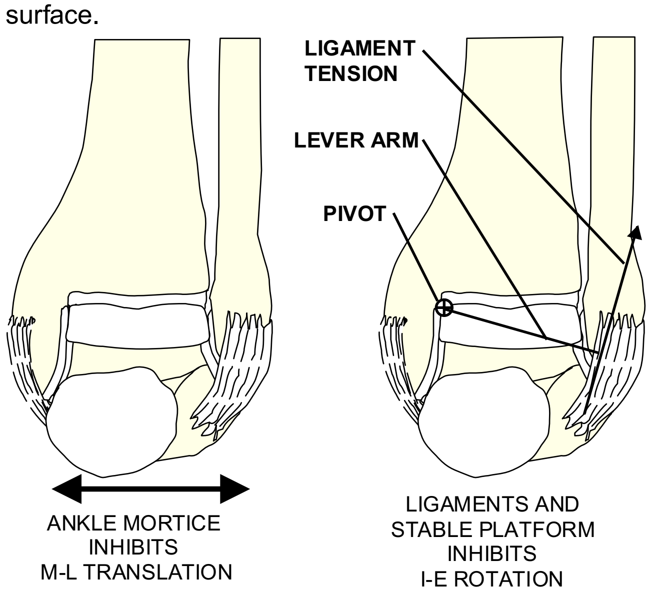


Fig. 7 M-L and I-E Stability of the Tibiotalar Joint

3. Ankle Forces

Tibiotalar compressive forces have been estimated to exceed four times body weight during normal walking. The posterior shearing forces are estimated to be about 80% of body weight.[1]

The joint compression force is carried primarily by the tibiotalar articulating surfaces and partially by the fibilotalar joint. The A-P shearing force is carried by theses surfaces and the ligaments. The M-L shearing forces are carried by the malleolar articulation and I-E torque's by the articulating surfaces and ligaments.

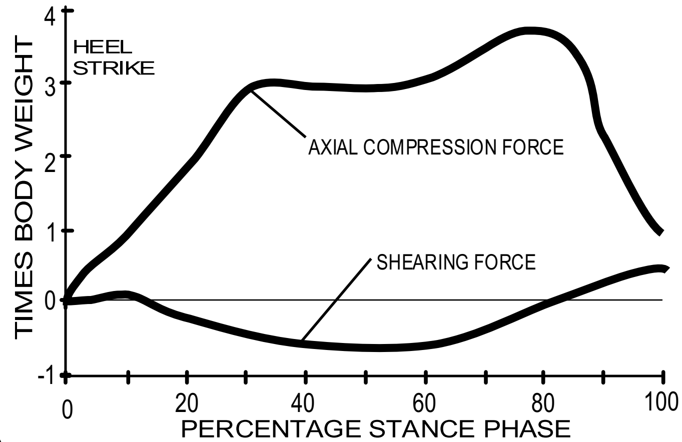


Fig. 8 Compressive Force in the Tibiotalar Joint[1]

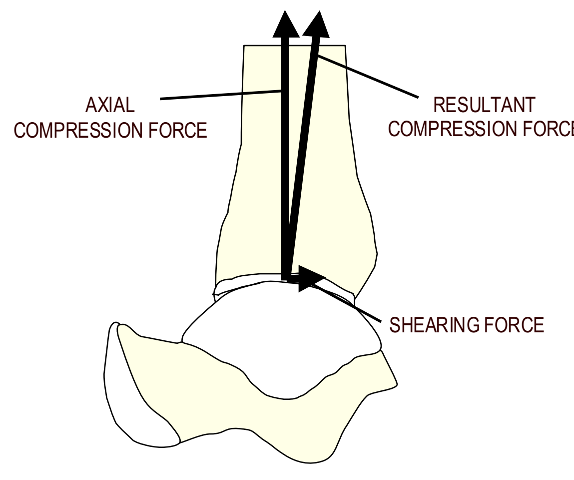


Fig. 9 Force Vectors in the Tibiotalar Joint

The combination of the axial compression and shearing forces produces a resultant force vector on the tibiotalar joint which is posteriorly inclined relative to the tibial axis.

4. Wear

To better understand the wear phenomena, and what can be done to reduce wear and its undesirable effects, one needs to examine; abrasive, adhesive, three body, and fatigue related wear; contact pressures and stresses; and the relationship between design and wear.

Abrasive Wear

Abrasive wear results from direct contact between the metal and plastic components. Even polished surfaces are microscopically rough. If the metal is allowed direct contact with the plastic the peaks (asperities) on the metal surface will slowly gouge (abrade) away the plastic as the metal surface moves over the plastic surface, much as very fine sandpaper abrades away a wooden surface.

The rate of abrasion is a function of the smoothness of the metal surface, the rate declining as the height of the asperities decline (the metal becomes smoother).[4]

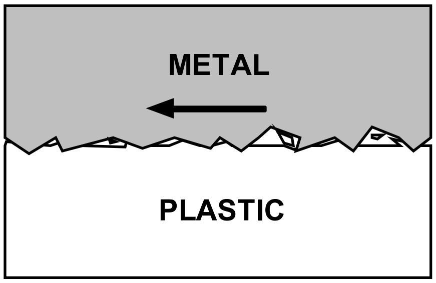


Fig. 10 Abrasive Wear

Adhesive Wear

This type of wear results from localized welding and tearing, rather than gouging, of the contacting surfaces.

When opposing asperities contact each other the very localized nature of the contact produces such high stresses that if the two materials in contact are similar they will become welded. Translation of one with respect to the other will then produce tearing or rupture of one or both of the asperities.

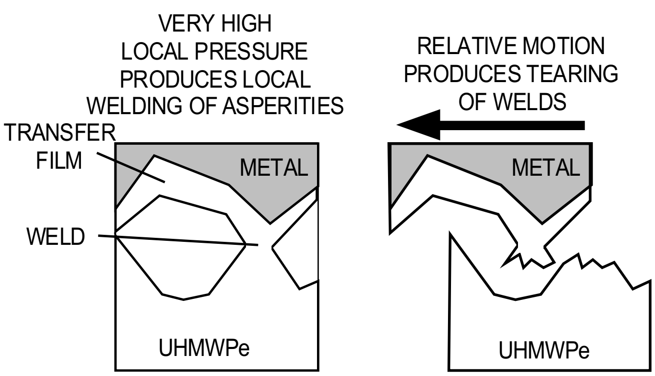


Fig. 11 Local Welding and Tearing of Asperities

This phenomena is dominant after the development of a polyethylene transfer film on the Co-Cr surface of the articulating couple. Just as the Co-Cr abrades the UHMWPe, the UHMWPe will also abrade the Co-Cr (albeit much more slowly). This roughened Co-Cr provides a base for the adherence of an UHMWPe film.

One then has similar materials in contact, and thus the proper conditions for adhesive wear. The wear rate under these adhesive conditions is much higher than that associated with smooth surface abrasive wear.

Human joint motion is characterized by a predominance of boundary and the more destructive dry lubrication.

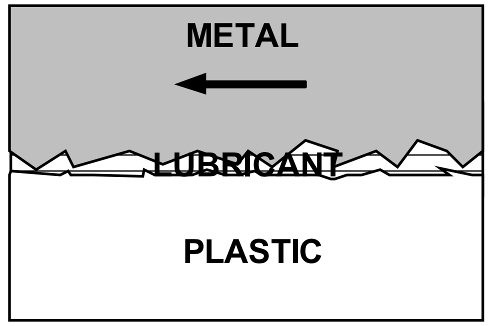


Fig. 12 Boundary lubrication

Boundary lubrication can be improved by the use of more wettable ceramic surfaces thus reducing contact

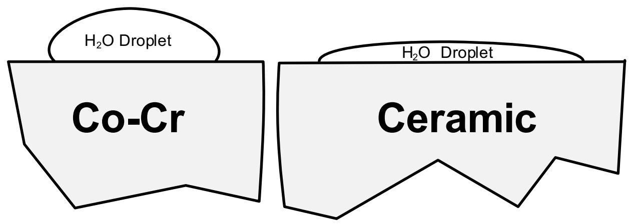


Fig. 13 Improved wettability of ceramic surfaces

Three-Body Wear

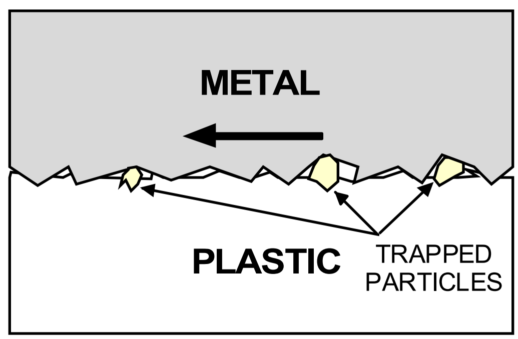


Fig. 14 Three Body Wear

The presence of contaminants such as cement, bone debris, and loose metallic beads, as well as the wear debris of the articulating couple, also contribute to wear. This contribution is called "three-body wear".

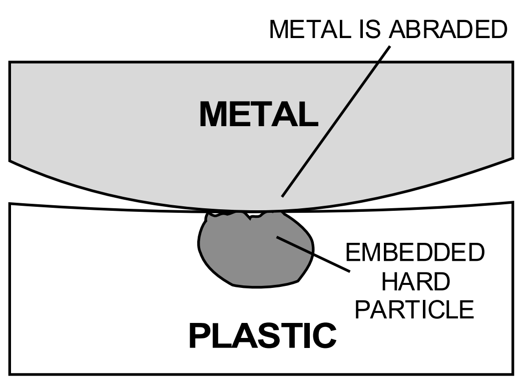


Fig. 15 Effect of an Embedded Hard Particle

Typically the harder bodies become embedded in the soft bearing. These bodies then can rapidly abrade the metal surface increasing abrasive and adhesive wear.

Surface Fatigue

The dominant wear (perhaps better called failure) mode in incongruent ankle and knee replacements is fatigue related. Incongruent bodies in contact under load will deform and produce an area of contact, or a contact patch. The highest Von-Mises, or crack initiating stress, will be about 1mm below the surface of the UHMWPe.[5]

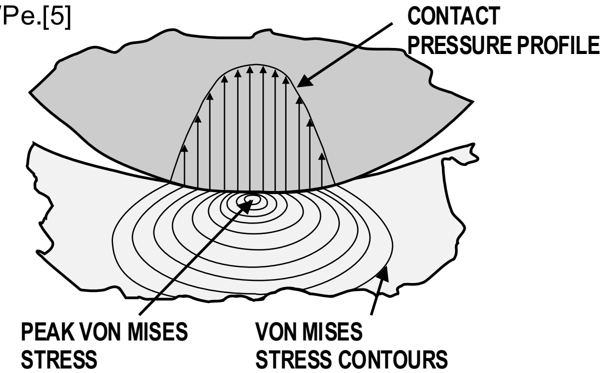


Fig. 16 Stress Contours for Incongruent Contact

As the metal component slides and rolls over the surface of the weaker plastic surface the point of peak stress will move under the surfaces of the plastic.

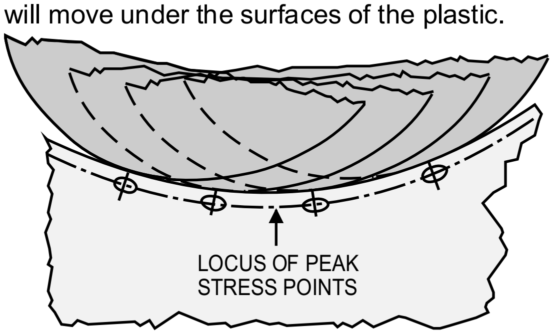


Fig. 17 Movement of Peak Von Mises Stress

If the stress is high enough, cracks will initiate below the surface. The cracks then coalesce to produce pitting, delamination, and by propagation through the part, catastrophic failure. This is a classic mode of surface failure in rolling contact.[6]

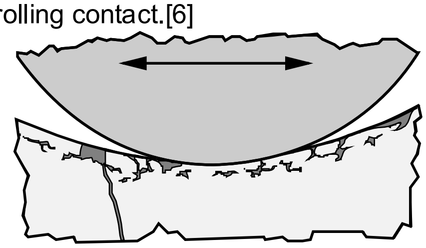


Fig. 18 Crack Propagation

Such catastrophic wear is seen below.

Fig. 19 PCA Fixed Bearing Knee.

Contact Stress

A study of contact stresses in typical knees is given in [7] and the results shown below.

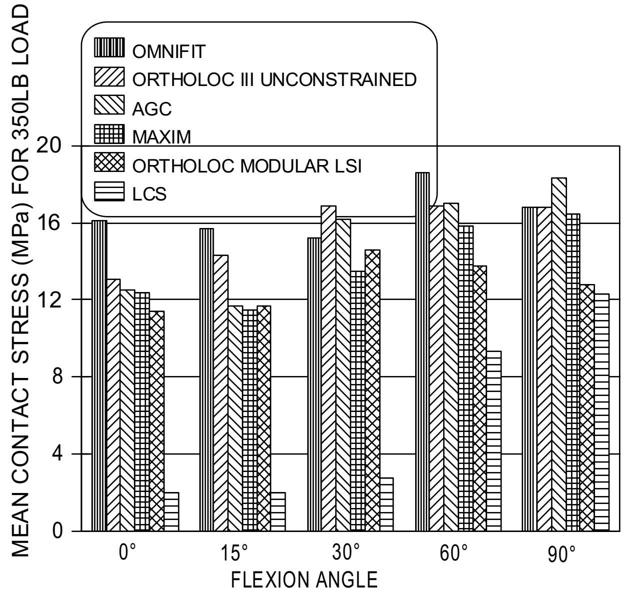


Fig. 20 Contact stresses in typical knee prostheses[7]

With the exception of the LCS knee, these figures far exceed the design stress or even the manufacturers recommended stress and thus must be considered as unsatisfactory.

Allowable Contact Stress

The allowable contact stress for applications having fluctuating compressive loading is given in [8] as 10 MPa. Using a conventional safety factor of 2 yields a design stress of 5MPa. A typical incongruent knee design where the stresses are related to the thickness of the polyethylene is shown in Fig. 21. It may be seen that this stress is excessive.

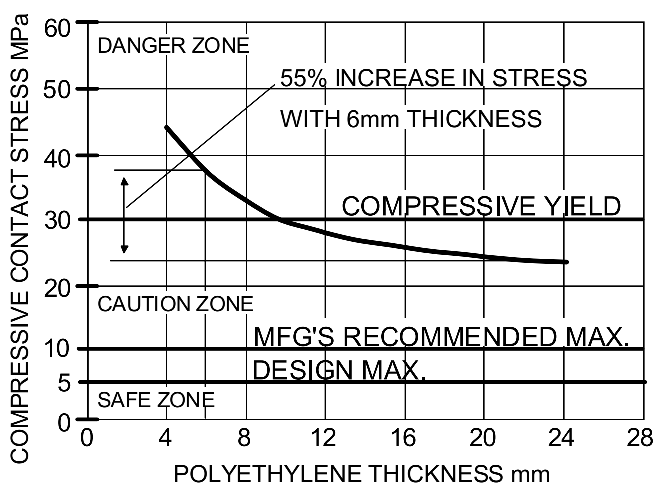


Fig. 21 Typical incongruent tibial component contact stress as a function of polyethylene thickness[9]

THE SITUATION IS AT LEAST AS SERIOUS IN ANKLE PROSTHESES SINCE THE LOADS IN THE KNEE AND ANKLE ARE COMPARABLE BUT THE ANKLE IS MUCH SMALLER IN SIZE.

II HISTORICAL BACKGROUND

Early experimentation with ankle replacement were unsuccessful leading largely to the abandonment of ankle development and use.[10-19] The primary problems with the early designs (1970-1980) included;

EXCESSIVE WEAR
EXCESSIVE CONSTRAINT
LACK OF STABILITY.

These problems produced clinical loosening, pain and loss of function leading to the failure of almost all the early designs.

1. Evolution of the B-P Ankle Replacement

The first ankle developed by our group was a cylindrical design with congruent articulating surfaces.[19] This design is shown in Fig. 22. This design was first implanted in 1974.

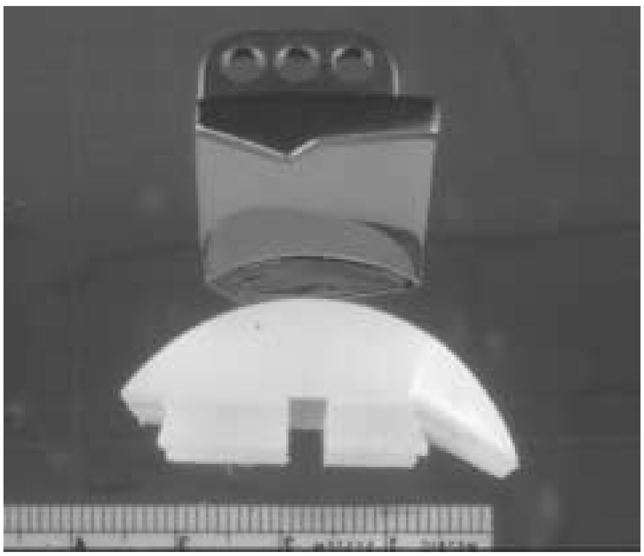


Fig. 22 Cylindrical Ankle Replacement

Fig. 23 Spherical Ankle Replacement

Shortly thereafter a design with a spherical articulating surface, as shown in Fig.23, was developed. It was implanted in 1975.

Problems [13] with these two earliest design lead to the development of an "Trunion" ankle replacement, shown in Fig. 24. This device was first implanted in 1976.

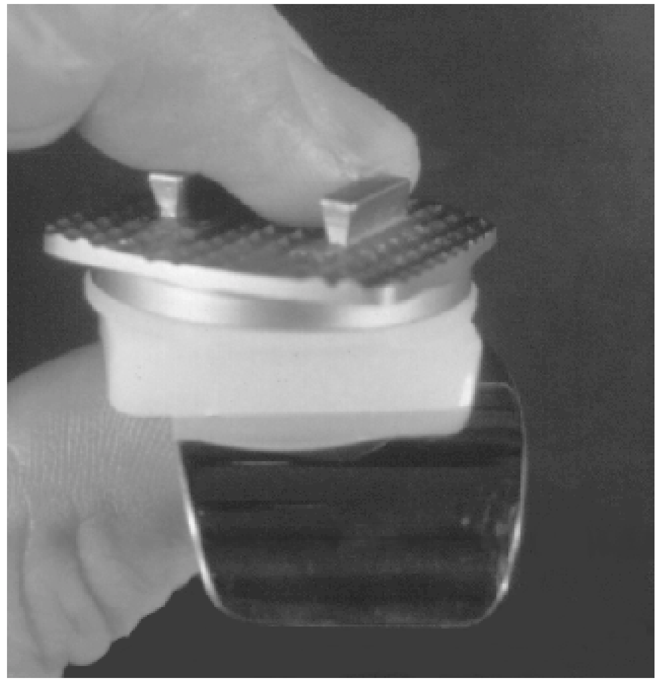


Fig. 24 The Trunion Ankle Replacement

An improved meniscal bearing device, shown in Fig. 25, was developed and first implanted in 1978.

Fig. 25 Mark I Meniscal Bearing Ankle Replacement.

The cylindrical design failed due to its failure to provide axial rotation. Although axial rotation in the ankle is small, failure to accommodate even this small motion produces excessive fixation torque leading to loosening of both the tibial and talar components.

The spherical design provides axial rotation but is inferior to the natural ankle in inversion-eversion stability since the pivot is at the center of the sphere and thus the ligament lever arm is much shorter than normal, as shown in Fig. 26. This lack of stability produces loss of function and pain leading to failure.

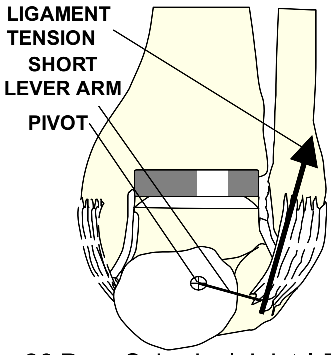


Fig. 26 Poor Spherical Joint I-E Stability

These problems and the need to have congruent articulating contact lead us to adapt the mobile bearing concept, which we first used in the shoulder in 1974, to the ankle. The rotating trunion device allowed axial rotation with congruity. It worked well clinically.

It was later determined, however, that eliminating the intrinsic A-P constraint would provide a more mobile joint without substantially compromising A-P stability. This lead to the development of the Mark I Meniscal Bearing ankle replacement.

Early results with this design were quite encouraging. A late problem, however, developed. This problem is illustrated in Fig. 27.

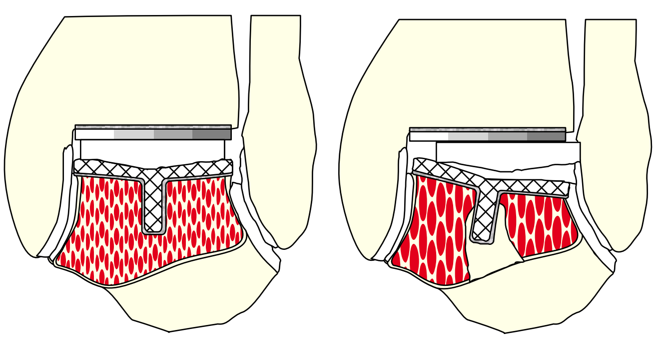


Fig. 27 Failure Mode of the Mark I

The problem was solved by using two fixation fins on the talar component rather than the single, longer, fin of the Mark I. This dual fin arrangement reduces the tendency of a fin to transfer load distally, thus reducing stress protection. Further it eliminates disruption of the talar blood supply, stopping talar necrosis. The sulcus of the Mark II is made deeper to better resist the effect of any tilting that may occur. The differences between the Mark I and II are shown in Fig. 28.

Further Finite Element analysis of the Mark I disclosed a weakness in the tibial component plate and thus the plate was made thicker on the MARK II.

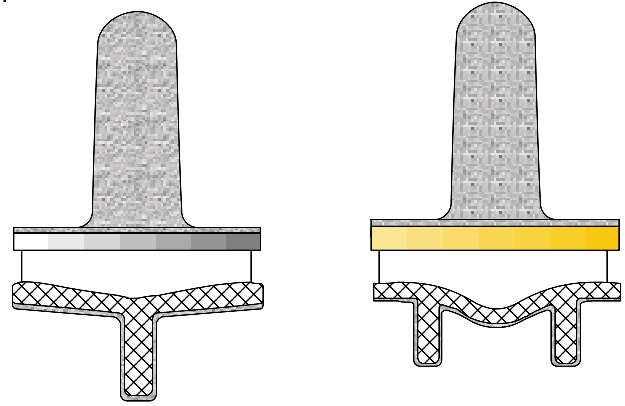


Fig. 28 Differences Between the Mark I and Mark II

The Mark II device is shown in Fig. 29.

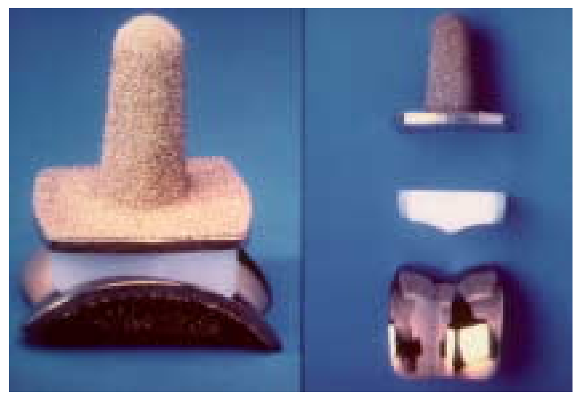


Fig. 29 The Mark II B-P Ankle Replacement

The Mark II was developed in 1989. By this time we had also developed a ceramic coating which greatly improved wear resistance and enhanced biocompatability.[20,21]

III DESIGN RATIONALE

The proper design of a prosthetic joint replacement is a complex undertaking. The important design criteria are:

- Material and wear product biocompatability
- Adequate mechanical strength
- Minimization of the joint reaction force
- Minimization of fixation interface shear
- Avoidance of fixation interface tension
- Uniformity of fixation interface compression
- Minimization of contact stress
- Duplication of anatomical function and motion
- Adequate fit for patient population
- Manufactureability
- Product and inventory costs.
- Treatment of a broad variety of pathologies
- Maximal preoperative options
- Maximal intraoperative options
- Maximal postoperative options in the event of failure
- Salvagability
- Tolerance of misalignment
- Ease of removal

The ideal implant should provide anatomical motion and function, long-term fixation and excellent wear properties.

The Mark II B-P Ankle Replacement System, designed on these principles is shown in Figs. 30 and 31. Six sizes are available.

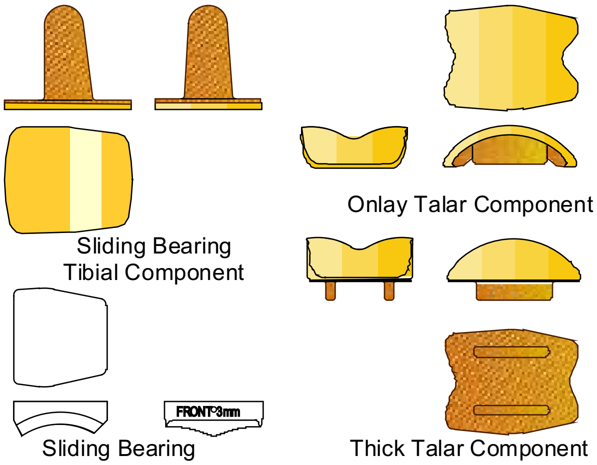


Fig. 30 Mark II B-P ankle components

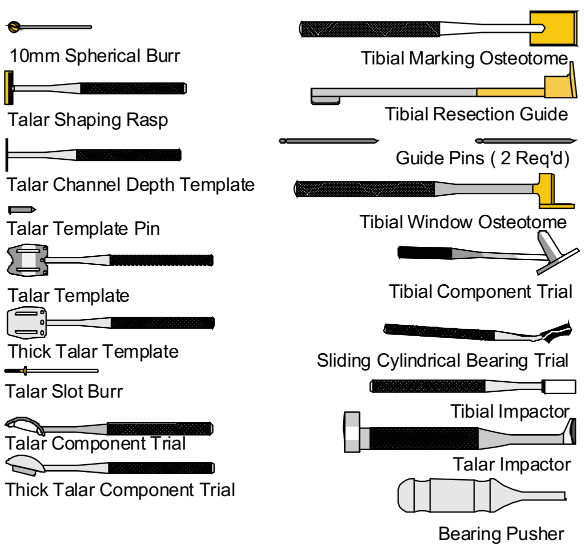


Fig. 31 The Mark II B-P ankle instruments

The primary articulation of the Mark II is generated by the use of a generating curve similar to, but smaller than, that used to generate the articular surface of the New Jersey knee.[22] In the ankle, however, since the range of motion is considerably less than the knee, a single talar radius of revolution is used rather than the multiple radii used in the knee. This single curve allows full congruity in the ankle for the entire motion range.

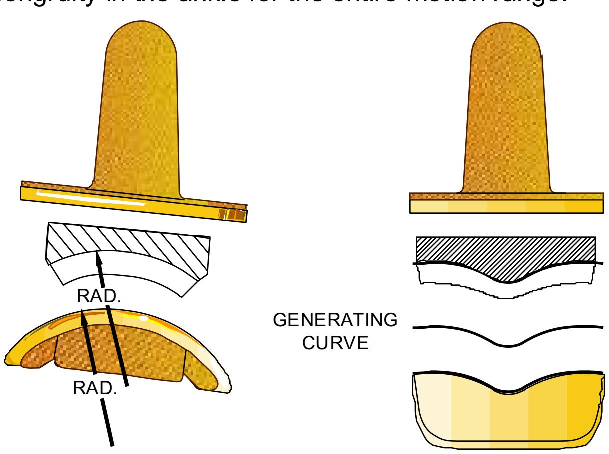


Fig. 32 The Mark II B-P articulation surfaces

1. Prosthetic Ankle Motion

The B-P ankle provides near normal plantar and dorsiflexion well beyond the motion required for walking.

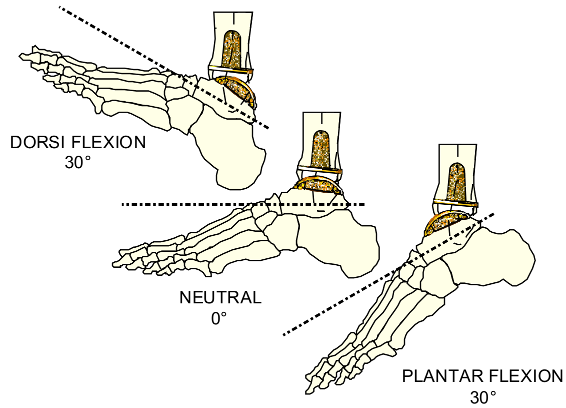


Fig. 33 B-P Ankle maximum plantar-dorsiflexion

It also provides unlimited axial rotation.

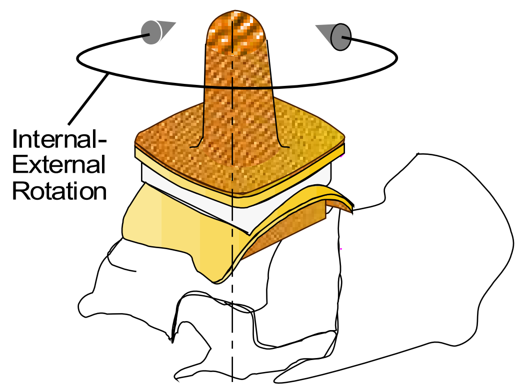


Fig. 34 Unconstrained internal-external rotation

The B-P ankle also provides limited inversion-eversion of the tibiotalar joint without loss of congruity of the contact surfaces.

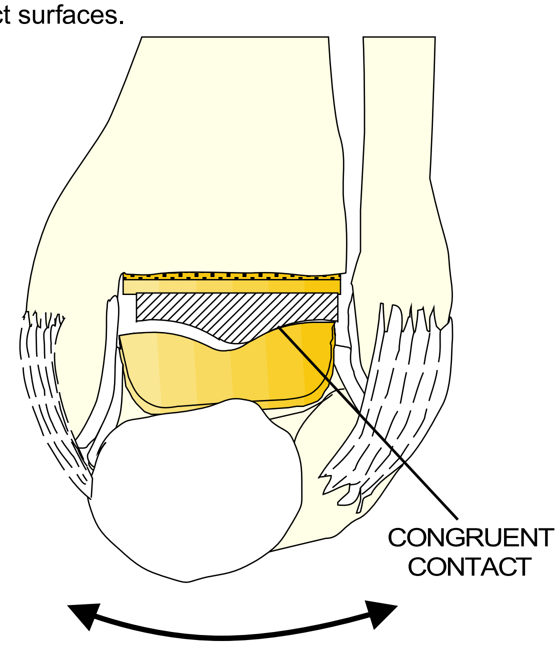


Fig. 35 Inversion-eversion of the B-P ankle prosthesis

2. Prosthetic Ankle Stability

A-P Stability

The A-P stability of the B-P ankle is primarily extrinsic, as is the natural ankle. A seven degree posterior inclination of the tibial platform provides posterior shear resistance of about 0.12 times the joint reaction force or a maximum of about 0.6 times body weight. This is most of the estimated posterior shearing force.

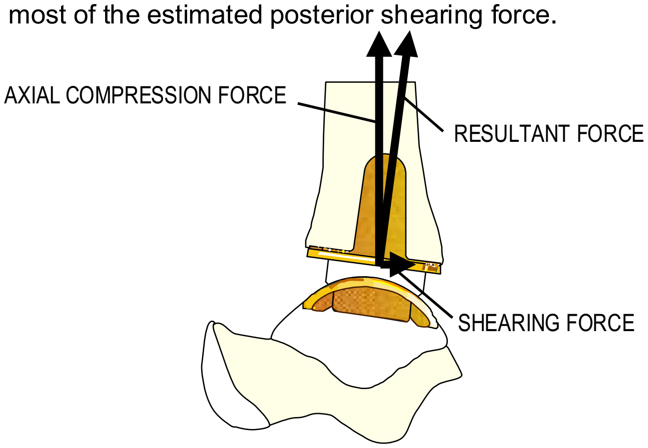


Fig. 36 Lateral view of the B-P ankle showing the posterior inclination of the tibial plate

M-L and I-E Stability

Since the B-P Ankle resurfaces the tibiotalar joint with near natural articulating surfaces it is similar in these stability modes to the normal ankle.

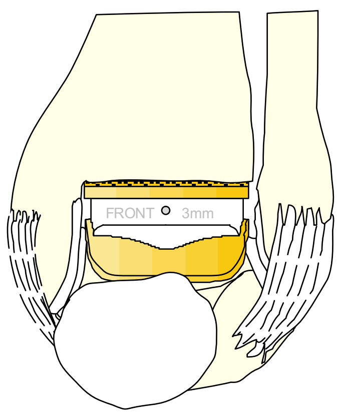


Fig. 37 Normal M-L and I-E stability of the B-P ankle

3. Prosthetic Force Resistance

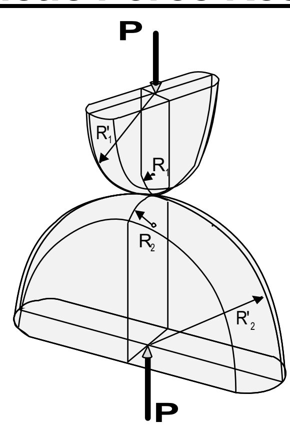


Fig. 38 Two bodies in contact

Equations, sufficient for use in knee and ankle prostheses, for the computation of the contact stress of two bodies in contact were developed in the 1930's.[6] These have been applied to the evaluation of knee prostheses.[5,22]

Since the B-P mobile ankle bearing allows Congruency and Mobility just as does the NJ knee bearing, the calculation of the contact stress in the B-P ankle articulation predicts low contact stress. This value computed at the maximum load given in [1] is appended to the results of the knee studies of Refs. [5,22] and is shown in Fig. 39.

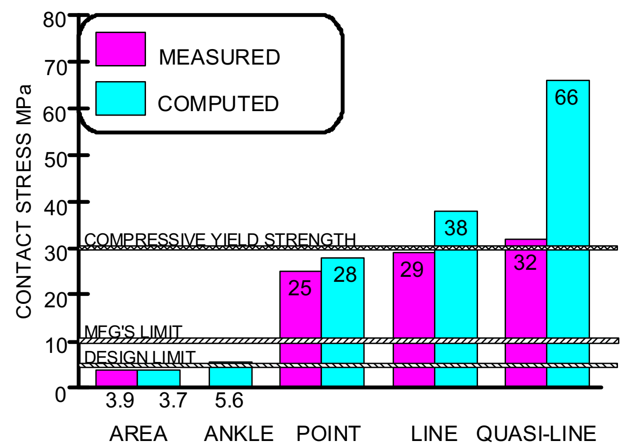


Fig. 39 Surface contact stresses for the B-P ankle and typical knee prostheses

4. Prosthetic Ankle Wear

The low contact stress associated with the B-P ankle will produce less wear than the typical fixed bearing ankles that have performed so badly.[10-12] Still the estimated contact stress in the B-P ankle is significantly higher than in the NJ knee.

It is desirable, therefore, to provide superior bearing surfaces for prosthetic ankle articulation. We have been developing a ceramic coated articulating surface since 1988. The first implantation's occurred in 1989. A ceramic TiN coating is produced as shown in Fig. 40.

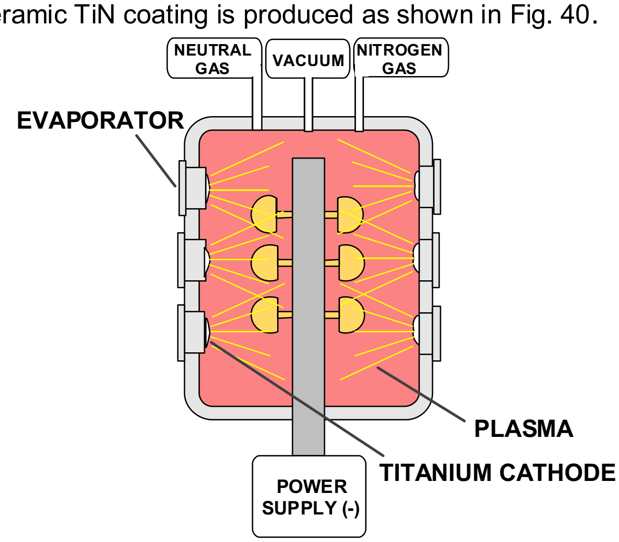


Fig. 40 Physical vapor deposition (PVD) process for TiN

When properly applied onto a titanium alloy substrate this coating becomes ionically bonded through a transition layer and cannot delaminate. This bond is far superior to adhesive bonds typically found in coated implants.

The coating has almost diamondlike hardness and thus it is much more resistant to degeneration than Co-Cr. Further it is more wettable and thus helps induce boundary lubrication thereby reducing wear.

The surface is finished to a 0.05 micron finish which contributes to its excellent wear properties.

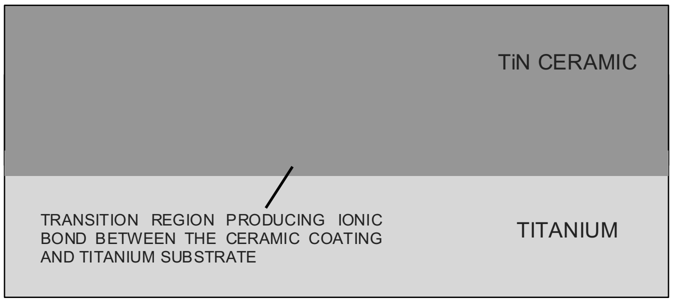


Fig. 41 TiN ceramic coating with ionic bonding

Currently all the metal implants we use are ceramic coated titanium alloy. Some of these are shown in Fig. 42.

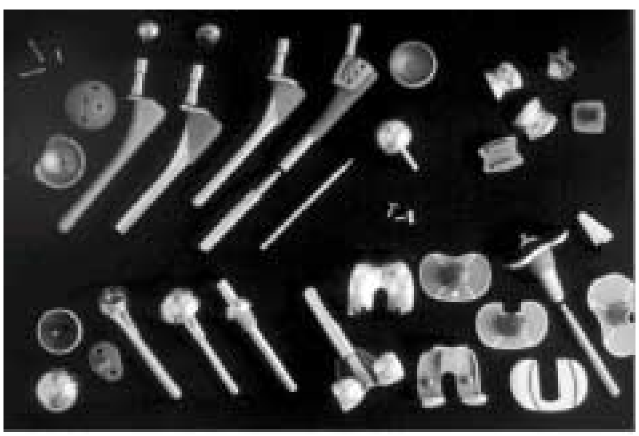


Fig. 42 Typical ceramic coated implants

This ceramic "nitride coating" is quite different than nitrided titanium. This latter coating is produced by impregnating the surface of the titanium with nitrogen ions. This layer, usually about one micron thick, is harder than the base titanium but it does not begin to approach the hardness of the ceramic.

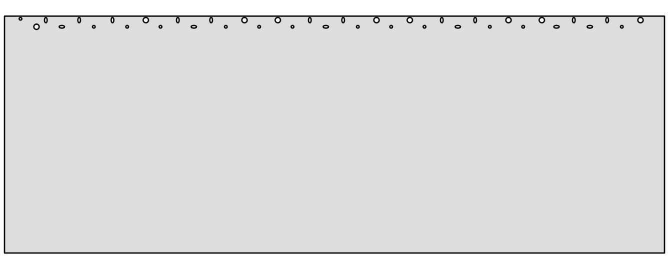


Fig. 43 Nitrided titanium

Testing

The ceramic coating produced by the UltraCoat® process has been thoroughly tested. The first test comparing the TiN ceramic to Co-Cr was performed in 1988 using the four station hip simulator shown in Figs. 44 and 45.[24]

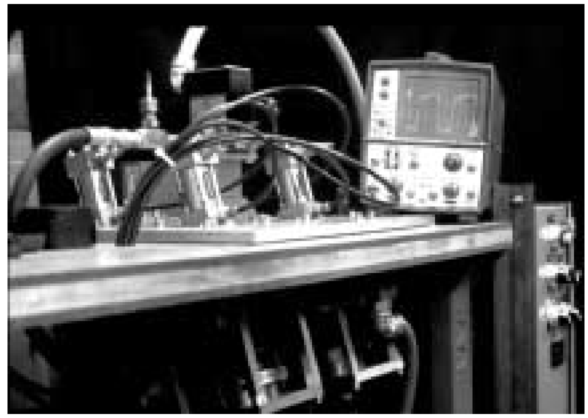


Fig. 44 Four station hip simulator

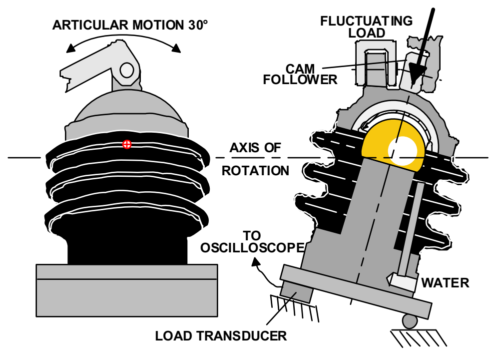


Fig. 45 Hip simulator test station

More recently a 48 million cycle test was performed, using the same equipment, testing procedure and conditions, to further evaluate the improvement in wear and to evaluate the durability of the ceramic coating in long-term use.[25]

The result of these tests are shown in Fig. 46.

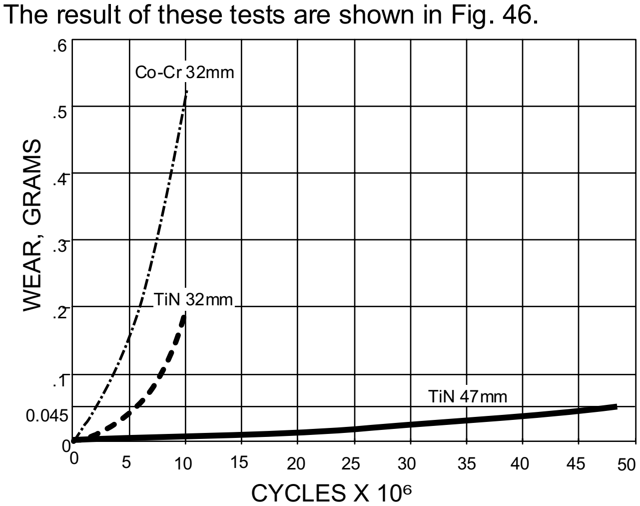


Fig. 46 Wear in hip simulator tests

The exceptional wear properties of the UltraCoat surface on the B-P Ankle prosthesis provides excellent wear properties for this device. No wear problems have been observed clinically.

5. Prosthetic Fixation

The fixation of the Mark II B-P Ankle is illustrated in Fig.47.

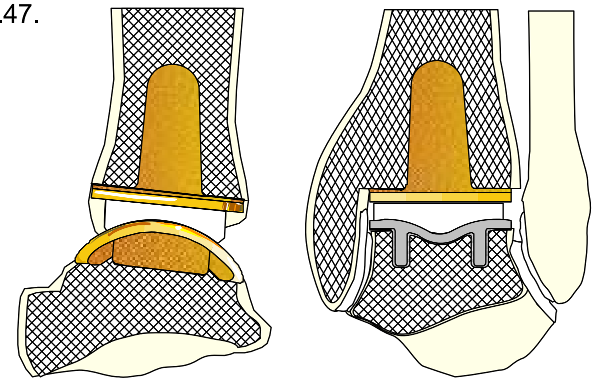


Fig. 47 Mark II B-P ankle fixation geometry

The dual fin fixation of the talar component is for the purpose of obtaining fixation on both sides of the talus so as to eliminate the resorption, and associated talar component tilt, encountered in the earlier single fin design as well as to avoid disruption of the talar blood supply produced by the single, central fin. The primary blood supply of the talus is inferior and central to the talus[27]. The single, central fin appears to substantially disrupt this source of blood supply causing talar necrosis, whereas the short, off-center fins do not.

The short fixation peg of the tibial component is designed to help resist tilting forces on the talus resulting from off-center loads. Early designs with a dual fin fixation were originally used and worked well in the relatively few cases of trunion ankles implanted. During 1977, our analysis of meniscal bearing and rotating platform knee component indicated that the short stem provided superior fixation to fin fixation. Therefore, this concept was adapted to the ankle tibial fixation in 1978, abandoning the dual fin design. Our long term, 20 year, experience with tibial knee components verifies the analysis of 1977. The fins of the bicruciate retaining tibial component normally show radiographic lucencies around the fins. These lucencies are rare with the posterior cruciate retaining tibial platform where off center loading of the tibial component is greater than in the bicruciate platform. Although loosening is not a significant problem with either knee design, radiological loosening is more apparent in the finned design.

The same situation therefore is likely to exist with the tibial ankle component. Fractures of early designed tibial plate corners indicate substantial off center loads in the ankle. Although the dual fins design should provide acceptable results, the short stem seems to be superior. In a study comparing a comparable single fin talar, dual fin tibial mobile bearing ankle with the B-P dual finned talar, stemed tibia, loosening was more apparent in the single fin talar, dual finned tibia design [28].

The fixation surfaces are three-layer BioCoat® commercially pure titanium sintered bead porous coating on a titanium alloy substrate. The mean pore size is about 325 microns. The porous coating is itself covered with a coating of TiN ceramic.

More than 10 years of clinical experience with the Mark II design has demonstrated that the talar dome collapse problem of the Mark I has been solved. The tibial peg fixation has been successful for more than twenty years in both the Mark I and II designs. Thus the fixation configuration has been found to be effective.

Biocompatability

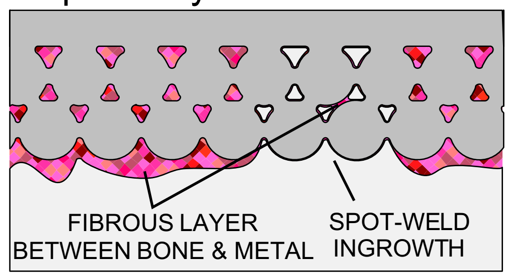


Fig. 48 Co-Cr ingrowth characteristics

Co-Cr porous coating is characterized by a lack of full bone ingrowth. As shown in Fig. 48 a fibrous layer is always present between the bone and the metal. Further, the ingrowth is limited in its coverage of the porous coating. It is characterized by a "spot weld" type ingrowth pattern.

Titanium porous coating, on the otherhand, is characterized by direct bone apposition onto the titanium[26]. Our observation of retrieved titanium implants has shown a much greater ingrowth coverage of the porous coating than we have observed onto Co-Cr implants. These characteristics are illustrated in Fig. 49.

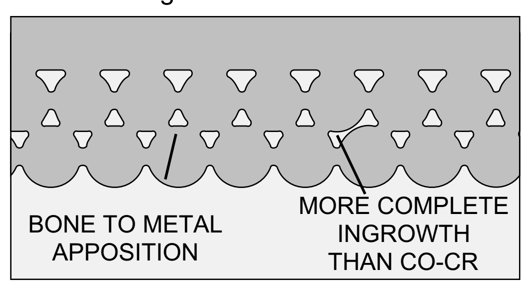


Fig. 49 Titanium ingrowth characteristics

Thus titanium, due to its better biocompatability, is superior to Co-Cr as a biological fixation surface. TiN ceramic is also biologically neutral[20] and thus one sees the same ingrowth characteristics onto the ceramic as one sees on titanium.

IV CONCLUSION

The mobile bearing Mark II B-P Ankle is the culmination of almost twenty five years of development. It fully exploits the mobile bearing concept by maintaining complete congruity for all phases of motion. Further it provides normal ankle motion and stability along with this congruity. The low wear ceramic coating of superior biocompatability, along with its porous coated ingrowth fixation geometry provide a realistic expectation for a long life and perhaps a lifetime joint replacement.

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