FINSBURY ORTHOPAEDICS

BULLETIN

14th January 2004

Medial Rotation Knee Technical Dossier

The attached document is now readily available to support your sales and marketing activities. The dossier plots the development history from the early seventies with the Freeman Swanson knee through to the late seventies with the Imperial College London Hospital (ICLH) design and then onto the Freeman Samuelson knee and eventually the Medial Rotation Knee™ which was first implanted in 1994.

The dossier provides a wealth of information regarding the clinical history and evolution of the design over the years. I hope you find this document useful, and if you would like further copies, please contact the Finsbury marketing team.

Derek R Cooper
Director of Sales & Marketing

Please contact Finsbury for a copy of the dossier.

Finsbury Orthopaedics Ltd. 13 Mole Business Park Randalls Road Leatherhead Surrey KT22 7BA United Kingdom
Web: www.finsbury.org Tel: +44 (0) 1372 360830 Email: info@finsbury.org

FINSBURY ORTHOPAEDICS

TECHNICAL DOSSIER

DEVELOPMENT OF THE MEDIAL ROTATION KNEE™

Introduction

Since 1994 the Medial Rotation Knee™ (MRK) has been in clinical use with follow up analysis by computer data base at the Royal London Hospital.

The implant is a development from the Freeman-Samuelson FS Modular and FS Integral designs - marketed by Centerpulse for primary and revision total knee replacement. The changes are part of the continuing improvement to the system as experience and technology has evolved. The Knee is designed to further improve the already outstanding resistance to polyethylene wear and to address the benefits of a more natural knee function and a more stable articulation. Particular advantage is made by the design incorporating an anterior "stabilised knee" mechanism. Hence greater flexion laxity may be accommodated without undue subluxation of the conforming surfaces. Further detailed enhancements include a larger range of sizes and improved instrumentation.

Development History

The Freeman-Samuelson Knee prosthesis has continually evolved since 1968. Three related prostheses were developed at the London Hospital. The three generations of the knee design and technique are listed below.

Group I: 1970 - 1976 Freeman-Swanson (F-S)
Group II: 1977 - 1979 Imperial College London Hospital (ICLH)
Group III: 1980 onward Freeman-Samuelson (F/S)
Group IV: 1994 onward (MRK)

Group 1: Freeman-Swanson (F-S)

Biomedical and laboratory work was conducted at Imperial College and knee arthroplasty began at London Hospital in 1968. The Knee was released to the market in 1970. The design consisted of a roller-in-trough tibio-femoral articulation. The femoral component was made of cobalt chrome with a flat medial and lateral surface (without a patella groove). The tibial design was all polyethylene with a very short and wide "stem". Both the femoral and tibial components were cemented. The edges of the components were rounded. The patella was not resurfaced. One small size was available and was used for all patients. The **F-S was the first ever metal/polyethylene condylar total Knee to be implanted.**

Four defects were later identified with this design:

1. Loosening and sinkage of the tibial component (caused by the small component size).
2. Anterior knee pain (due to not resurfacing the patella).
3. UHMWPE wear (cement particles embedded in polyethylene surface).
4. Malalignment and instability (caused by technique of balancing soft tissues).

F-S results:

1. 29% survival at 9-10 years.
2. 16% revision rate was unacceptable and led to the introduction of the ICLH prosthesis.

Group II: ICLH

The device was first used in knee arthroplasty in 1977. The features of this design included cementless fixation and patello-femoral changes. The femoral component was made of cobalt chrome and the anterior surface (medial/lateral) was still flat. The tibial implant was all polyethylene with a very short and wide "stem". The patella component was all polyethylene, flat medial/lateral and concave proximal/distal. This saddled shaped design maximized contact area and minimized medial/lateral constraint. The patella was either cemented or cementless.

Initially the femoral and tibial components were cemented. As cement failed to satisfactorily fill tibial bone defects, bone grafts were used and the tibia then underwent cementless implantation. Cementless tibial fixation gave favourable short term results and the technique was adopted for the femoral component.

An all polymeric Knee was also used in very limited numbers and the latest generation of this device is used today for nickel sensitive patients.

ICLH results:

1. 2.7% revision (uncemented tibial).
2. 19% revision (cemented tibial).
3. 16% patella lateral-subluxation - this led to a patella groove in the femoral component for the Freeman-Samuelson implant.
4. 95% patella replacement had no anterior pain.
5. 90° maximum flexion - due to patella tracking and the posterior lip of the tibial trough was too high and too anterior.

Group 111: Freeman-Samuelson (F/S):

The F/S was first used in 1980. The modifications from the ICLH to the F/S were:

1. Femoral patella groove.
2. Patella track made more posterior.
3. The posterior lip of tibial component was reduced.
4. The tibial articular surface moved posterior.
5. Adding a midline eminence on tibial plateau to fit the femoral groove.

The component materials were: Cobalt Chrome femur, all polyethylene tibia with medial/lateral fixation pegs, metal-backed tibia with central stem, and all polyethylene (saddle shaped) patella. All components were uncemented.

The Tibia stem and both Femur and Tibia pegs were supplied as modular componets initially then as integral components.

The system was marketed by Protek (then Sulzer 1996) and Biomet in the USA.

F/S results (1986):

1. > 90° flexion in 93% of patients.
2. 91% pain free.
3. Anterior knee pain not present.
4. 3 fractured patella.
5. Revision rate 1.6%.

F/S results (1995):

Survivorship: Use of the F/S started in 1980. Prior to that the fixation system was different but the articulation remained the same.

277 Knees (cemented metal-backed, stemmed tibial component).
0-11 year follow up.

Tibia: Three revised for facture of stems due to weld quality in one production batch. There were no tibial loosenings.
Ten year survival rate of 98%.

Femur: Three loosenings.
Ten year survival rate of 98.5%.

Patella: One revised when the suture line separated early post-op.
Ten year survival rate of 99.4%.

Range of movement: *80% had greater than 90° ROM.*

Group IV: Medial Rotation Knee™ (MRK):

The MRK was first used in October 1994. (Named the FS1000 until the full product launch in 2001). The modifications from the F/S to the MRK were:

1. A congruent spherical medial femoral-tibial articulation.
2. A high anterior polyethylene lip medially.
3. A lateral compartment which rotates about the medial component (the same geometry of the Freeman-Samuelson design).
4. The patella track is straight and laterally biased.
5. A textured fixation surface is added to both femur and tibia metal components.

MRK Design Rationale

The MR Knee system is the result of over twenty-five years of laboratory research and clinical experience with total knee replacement.

The MRK system:

1. Proven materials and technology.
2. Maximum congruity for
   a) Tibio-femoral articulation.
   b) Patello-femoral articulation.
3. Minimization of wear debris.
4. Stability.
5. A "concept" overview.
6. Implant design features.

1. Proven materials and technology:

The cemented MRK femoral component offers a wear resistant cobalt chrome articular surface with a stippled interior surface for good cement interdigitation. The femoral component is available with a stem or two integral finned pegs.

The tibial design is a metal backed UHMWPE assembly. The tray is cobalt chrome with a 50mm or 80mm stem. Cobalt chrome fixation pegs are located medial and lateral on the distal surface of the tray. The distal surface of the tray is stippled for enhanced cement fixation. This surface has also been used on other devices such as the Freeman Hip. The metal configuration is otherwise the same as the original F/S implant. The enhanced interference fit of the UHMWPE tibia to the metal back addresses any potential for backside wear or interprosthetic dislocation.

The polyethylene is CNC machined from compression moulded block and then, vacuum packaged with backfilled argon gas before sterilisation to limit oxidation and prevent delamination wear. The patella remains a saddle-shaped, all polyethylene component. Because of the unique finned fixation peg it can be either cemented or press-fit. The saddle-shaped patella design articulates with high area contact against the femoral component. **This design has been highly clinically successful since 1980.**

2. Maximum congruity:

a) **The tibio-femoral articulation** of the F/S Knee has twenty years of laboratory and clinical experience. The femoral and tibial articulation provides a flat medial-lateral translation and a curved anterior-posterior surface. The component is inherently constrained since the tibial surface has a raised intercondylar eminence which constrains it in the coronal plane. The femoral-tibial fit in the anterior-posterior direction has a one-to-one radiused fit. The MRK retains this configuration on its lateral side and has been adapted to a spherical fully mating configuration on the medial side. **This increases the full normal ROM contact area from 510mm^2 to approximately 1000mm^2.**

Complete interchangeability is achieved between the femoral and tibial components. This design feature provides excellent patient fit while maintaining maximum congruity between the components.

b) **The F-S patello-femoral articulation** has shown excellent long-term results. The saddle-shaped design articulates well within the femoral intercondylar notch because its shape is matched to the constant geometry of the trochlear groove. The finned peg allows good fixation yet provides initial rotational flexibility for correct alignment. Patella components are interchangeable with all femoral components for excellent patient fit and articulation. The enlarged medial spherical femoral condyle accommodates lateralisational of the tibial eminence and the lateral femoral condyle. **This uniquely allows the Knee to provide consistant lateralisation tracking of the patella. The MRK is the first and only Knee to provide this normal patella motion.**

3. Minimization of wear debris:

Wear debris has been documented to cause loosening and osteolysis in total joint arthroplasty. The F-S Knee was designed to minimize as much subluxation and wear as possible.

The combination of implant design, material selection and articulating congruency are intended to decrease wear debris in the MRK system. Rotation of the lateral femoral condyle maintains line contact with the tibia as compared to part contact with the F-S. **Medially where the highest loads are seen, full area contact is always maintained.**

4. Stability:

The MRK design affords a higher degree of inbuilt stability as compared with the F-S. This is realised anterior-medially, however the torsional subluxion possibility of the knee remains the same as the F-S in other modes. The difference being that the knee is more resistant to anterior subluxion of the femur on the tibia. **This stabilising effect is continually present unlike coventional posterior stabilisers that come into play after flexion has progressed towards 90°.**

5. The F-S "concept" overview:

Fixation Concept:

- Cemented - using conservative cement techniques.

Implant Concept:

- Using knowledge based on the world's longest experience of condylar knee replacement.
- Fixation system, sizes and shapes adapted to the individual anatomy of the femur, tibia and patella through reduced contact stresses.

- Maximum congruency between femur, tibia and patella to minimize polyethylene wear.
- Implant shape contributes to stability throughout the full range of motion.
- All of the femoral components are compatible with all the tibial components.

Surgical Concept:

- Minimal bone resection, consistent with the pathological condition.
- High quality, simple, state-of-the-art instrumentation. Accuracy ensures optimal fit at bone implant interface.
- Retention or sacrifice of posterior cruciate. (Sacrifice has proven to be clinically acceptable and improves exposure).

6. Implant Design Features:

Femoral:

- Enhanced area contact (1000mm^2).
- Stippled interlok surface for bone cement fixation.
- Complete interchangeability.
- Six sizes, anatomic right and left.
- Two peg or stem fixation.
- Constrained.
- Deep constant cross-section with fully lateralised patella throughout full ROM.
- Area contact
  - Tibio-femoral area contact maintained through full ROM.
  - Patello-femoral area contact maximised from 15 to 85 degrees flexion.
- Cobalt chrome.

Tibial:

- Enhanced contact area of approximately 1000mm^2 with a lateral subluxion range of 10° and screw home mechanism in full extension.
- Stippled interlok surface for bone cement fixation.
- Complete interchangeability.
- 50mm or 80mm round stem.
- Medial and lateral pegs.
- Five sizes.
- Four thicknesses (10.5, 13, 15.5, 18mm). (8mm available on request outside the USA).
- Cobalt chrome and UHMWPE with optimised locking mechanism.

Patella:

- All polyethylene with finned fixation peg.
- Saddle-shaped design for optimum contact area.
- Three diameters 20, 25 and 30mm.
- Complete interchangeability with femoral components.
- Extensive clinical history of cementless fixation.

Instrumentation options:

The MRK instrumentation offers intramedullary alignment with simple "Magic Spacer" control or a balancer system for full soft tissue tensioning. The instruments are easy to use and provide accurate cuts.

MEDIAL ROTATION KNEE™ TIBIO-FEMORAL GEOMETRY

General

The MRK tibio-femoral articular geometry is designed to address the following issues.

UHMWPE Wear and Damage.
Stability.
Range of Motion.
Patella Tracking.

Most tibio-femoral articulations have been designed to be "unconstrained", i.e. the tibial component is flat or of a much larger radius than the femoral component. This results in relatively small areas of contact and freedom for the femur to slide antero-posteriorly and in rotation relative to the tibia. It has been said that such sliding is desirable since backwards sliding of the femur during flexion (so called "roll-back") is thought to be a feature of the normal knee. The lack of resistance to tibio-femoral rotation should help to prevent tibial loosening and will permit "normal" tibial rotation in flexion.
Unfortunately the combination of low contact area and uncontrolled skidding over the tibia provides cyclical sliding at high stresses. This is precisely the environment which is most likely to damage UHMWPE and allows anterior subluxion of the femur on the tibia in flexion.

Finsbury believe that the tibio-femoral surfaces should be designed to provide much greater contact area to reduce wear and increase stability. It would be unthinkable to use a hip prosthesis with a 28mm diameter femoral head and a 32mm diameter acetabular socket: the consequences for the UHMWPE from the high stresses and uncontrolled skidding and overall stability would be disastrous!

Full area contact has been achieved in the MRK by making the medial tibial and femoral surfaces spherical. This ensures complete congruency from full extension to 100° flexion. The lateral surface is formed as a cone, centred on the medial sphere. This results in full congruency when the femur is in full extension. The medial tibial articular area has a high anterior lip to provide complete ROM posterior stability.

UHMWPE "Wear" and "Damage"

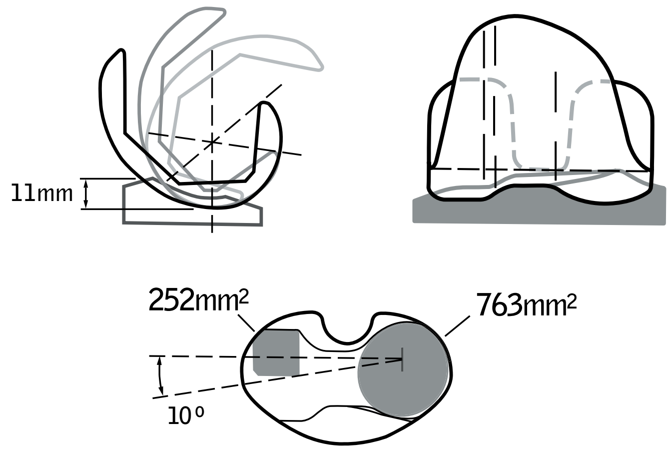
Finsbury distinguish between "wear" of the articular area and "damage" occurring elsewhere in the prosthesis. For example, the changes which may occur in the lip of an acetabular component if it impinges against the femoral neck, we would regard as damage, but the changes occurring as a consequence of the reciprocating action of the head on the articular surface we would regard as wear.

In this section we deal with wear. The next section deals with damage.

Polyethylene wear in the knee has been a clinical problem as a result of using non-congruent surfaces through part or all of the range of movement. The F-S (not the MRK) implant used a congruent cylindrical articulation for over 20 years. This has demonstrated to yield very low wear rates in the articular area in of the order of 0.025mm/year. ***(Plante-Bordeneuve P, Freeman MAR: Tibial High-Density Polyethylene Wear in Conforming Tibio-Femoral Prostheses. JBJS; 75B: 630-636 1993).***

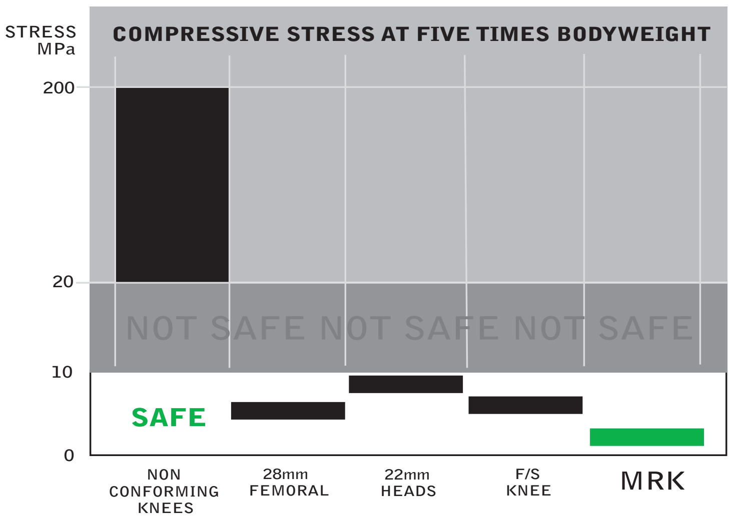
The MRK surface stresses have been reduced (with the object of further reducing wear) by making the medial tibio-femoral surfaces conforming spheres and by displacing the inter-condylar eminence laterally, thus increasing the medio-lateral extent of the sphere. As a result, an articular contact area of 763mm² is achieved medially (Fig. 1). Expansion of the medial contact area (and reduction of medial contact stresses) is of particular importance since the medial side of the knee is believed to be more heavily loaded than the lateral, ie the resultant force acts somewhat medially.

Fig 1



The lateral side of the femur makes area contact with the tibia in neutral rotation. From 0° to 10° of exterior rotation there is line contact (as against point contact in the F-S).

The raw material manufacturers of UHMWPE quote a maximum stress for compressive sliding wear of 10 MPa. At an applied load of 5 x bodyweight (350 kilograms) typical condylar knee designs have nominal stresses in the range 20-200 MPa. The F-S nominal contact stress is 6.8 MPa and the MRK contact stress is 3.4 MPa throughout the range of flexion in neutral exterior rotation or 4.5 MPa if only the medial contact area is considered. The latter is the result of over 1000mm².



It is clear from various studies that the wear rate for UHMWPE will also vary by material quality, sterilisation methods and manufacturing processes etc. These variables apply equally to acetabular components although acetabular components are congruent with femoral heads, for example at 5 x bodyweight, 22mm and 28mm femoral heads result in stresses of 8.7 and 5.3 MPa respectively. (See graph above).

Stability

Posterior Stability

The soft tissues in the human knee prevent posterior tibial subluxation. In contrast, if the tibia is replaced with ACL resection and the component has a relatively flat surface, antero-posterior subluxation is possible even if the PCL is retained. This is the result of imprecise control of the flexion gap and the PCL not being correctly tensioned. ***(Moilenen T et al: The Case for Resection of the Posterior Cruciate Ligament. J Arthroplasty 10; 564-568 1995).*** When ascending stairs, knees replaced in this way display forward subluxation of the femur on the tibia during flexion, in contrast to the normal situation in which the femur remains in position or "rolls back". ***(Stiehl JB et al/: Fluroscopic Analysis of Kinetics after Posterior-Cruciate-Retaining Knee Arthroplasty. JBJS 77B 884-889 1995).***

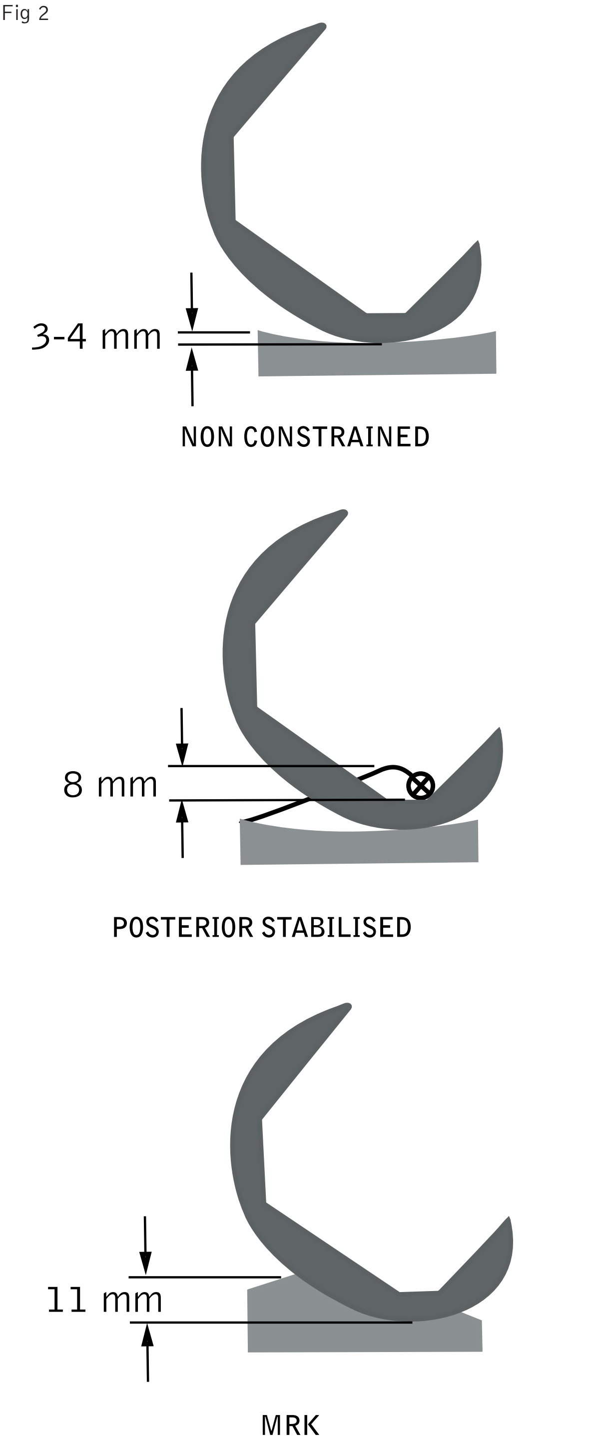
Studies have shown little, if any, roll-back occurs medially (as in the MRK) and that lateral roll-back is mainly due to tibial rotation ***(Moilanen et al: The Case for Resection of the Posterior Cruciate Ligament. J Arthroplasty 10; 564-568 1995).*** This situation is replicated in the MRK system.

A posterior stabilised knee combined with femoral bar and excision of both cruciate ligaments may be used to overcome instability (eg the Insall/Burstein). Such mechanisms control errors of the flexion gap up to about 8mm. This mechanism has disadvantages; i) it can still dislocate in deep flexion; ii) high contact stresses are induced in the peg; iii) strong intercondylar femoral bone must be resected to accommodate the femoral box; iv) the components can be difficult to implant; v) most importantly, the femoral 'box' needed for the femoral bar, interrupts the floor of the patella groove of the femoralcomponent from about 60° onwards raising the risk of patella mal-tracking or clunking.

The Freeman series of Knee implants have been posteriorly stabilised by the anterior lip on the tibia in conjunction with precise adjustment of the flexion gap.

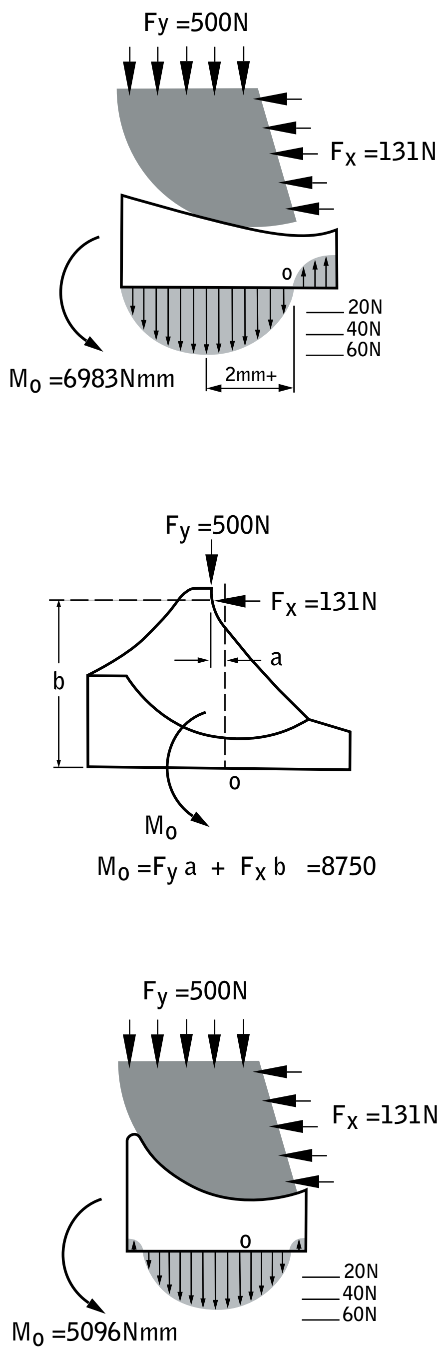
The MRK is posteriorly stabilised by the position of the anterior lip on the medial tibial articular surface which conforms with the spherical femoral surface to a depth of 11mm (Fig.2). The theoretical and clinical result is a knee which has high AP stability in flexion.

Fig 2



All posterior stabilising mechanisms tend to rotate the tibial component downwards anteriorly. The following illustrate "turning moments" for three configurations. 1) The F-S after 2mm of forward femoral subluxation. 2) A posterior stabilised implant of the F-S geometry with femoral bar. 3) The MRK as shown in Figure 3. It is clear from this illustration the MRK is the most stable and causes the least rotational dislocating force.

Fig 3



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Rotational Stability

The human knee with intact cruciate ligaments allows internal/external rotation of the tibia in flexion around a controlled axis situated roughly through the femoral attachment of the PCL. In the absence of the ACL, and with relatively flat prosthetic articular surfaces, this axis cannot be controlled within the replaced knee. Put another way, such implants are rotationally unstable.

Control of the axis (but not limitation of the range) is provided in the MRK by the ball and socket medial compartment to make the Knee rotationally stable about the centre of the medial sphere.

It has been said that rotational constraint between the tibio-femoral surfaces will result in tibial component loosening: hence the use of unconstrained or meniscal bearings. However, it has been found that: (1) using RSA, no evidence for rotational migration of semi-constrained tibial components as compared with unconstrained components has been found, (2) there is no evidence from a review of the literature that tibial components in condylar knees do in fact loosen rotationally and (3) these findings follow that the torque which can be transmitted from the femur to the tibia in a semi-constrained condylar knee (eg the MRK) during everyday activities of a replaced knee are much lower than the torques required to loosen any reasonably well fixed tibial component.

Because of the spherical shape of the medial compartment of the MRK (vs the cylinder-in-trough shape of the F-S) rotational movement will not damage the antero-medial UHMWPE.

Full Extension

In full extension the human knee locks in tibial internal rotation. Similar "locking" is achieved in the MRK by virtue of the conforming geometry and antero-lateral tibio-femoral contact.

Range of Motion

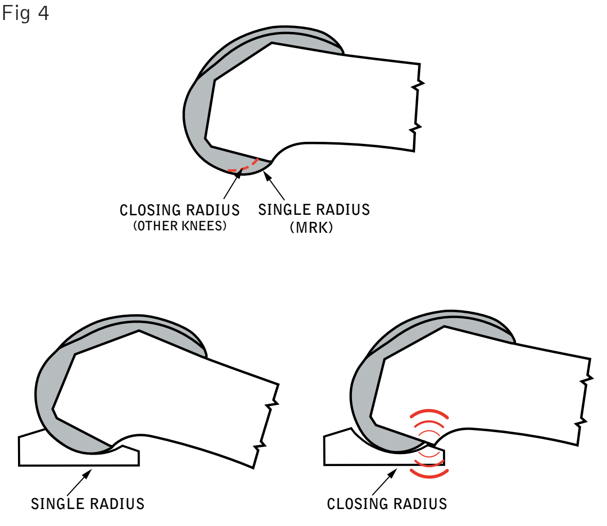
1.1 Flexion/Extension

The femoral and tibial surfaces of the MR Knee are in full contact from 0 to 100°. Beyond 100°, flexion is not limited but the posterior femoral condyle reduces its contact with the tibia whilst maintaining congruency. (Fig 4).

The congruence in the medial tibio-femoral compartment and the posterior position of the contact area within the tibial surface (Fig 2) means the axis of flexion is restricted to the posterior third of the tibia throughout the range of motion. This maintains a long quadriceps lever arm throughout the range and avoids posterior impingement in full flexion.

Because the posterior femoral articular surface is a single radius (to provide conformity and to mimic the human knee), it is longer than would be the case if the radius were of the conventional closing type. As a consequence, the chance of contact between the proximal extremity of the resected posterior femoral condyle and the tibial component in full flexion is reduced (Fig 4).

Fig 4



1.2 Rotation

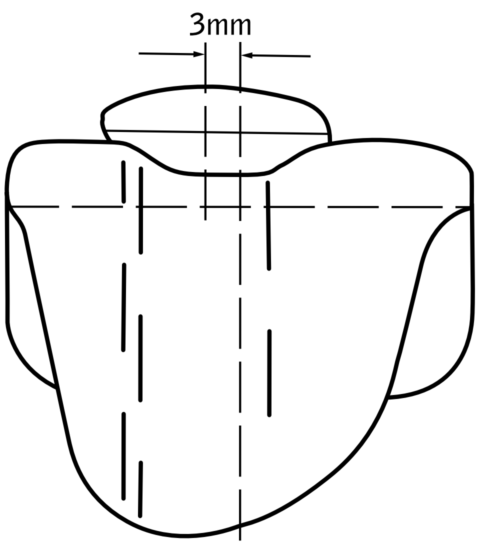
Rotation in flexion occurs in the human knee and is required in many activities. Post-operatively, rotation (even if the implant is unconstrained) is limited by tension in the capsule resulting from "twisting" of the soft tissues as the tibia rotates.

The MRK is designed to allow 10° of rotation, how much of this range is obtained post-operatively depends on the tension in the capsule in flexion.

1.3 Patella Tracking

The patella groove is displaced laterally by about 3mm relative to the midline of the femoral component. This (1) allows the patella to track laterally throughout knee motion (Fig. 5) i.e. the Q angle is reduced particularly in flexion as compared with other implants and (2) permits an increase in the spherical medial contact area. The first reduces the magnitude of the laterally directed forces on the patella and thus reduces the chance of patella subluxation. To assist in this, the lateral aspect of the patella groove is maintained as a distinct track from 0° to full flexion. Unlike other types of knee replacement the MRK provides good contact with the patella in the region of the posterior inter-condylar notch.

Fig 5



Conclusion

The MRK provides an improved geometry over conventional condylar knee replacement based on long term clinical success with the F-S Knee without compromising the materials, fixation or knee function.

The F/S vs the MRK

1) The principle difference between the F/S and the MRK is in the medial tibio-femoral compartment.

2) Viewed from the side the medial femoral condyle of the MRK has a single radius as has the F/S. It has the same radius (ie it is spherical) as viewed from the front (unlike the F/S which is flat).

The tibial surface is also spherical and conforms with the femur anteriorly for a vertical distance of 11mm. The F/S tibia is in the shape of a trough 1mm in depth, with an anterior non-conforming lip having a total depth of 7mm.

As a consequence: (1) the contact area medially in the MRK is 763mm^2 verses 255mm^2 in the F/S; (2) full contact is maintained when the femur rotates on the tibia whereas the F/S subluxes; and (3) the MRK has greater posterior tibial stability in flexion.

3) The lateral tibio-femoral joint is essentially the same as the F/S but: (1) the anterior tibial flat is circular in the A/P direction, the circle being centred on the spherical medial surface; and (2) the width of the femoral surface is 14mm vs 17mm in the F/S. As a consequence: the lateral femoral condyle has an area contact of 252mm^2 and makes line contact if the tibia rotates (vs. Point contact in the F/S).

4) The Patella groove is 3mm more lateral in the MRK at 90° of flexion and its medial shoulder is 12mm lower. As a consequence the Q angle and anterior bulk of the femoral component are reduced.

FINSBURY
ORTHOPAEDICS

Finsbury Orthopaedics Limited
13 Mole Business Park
Randalls Road
Leatherhead
Surrey KT22 0BA
United Kingdom
Tel: +44(0)1372 360830
Fax: +44(0)1372 360779
Email: mail@finsbury.org
Web: www.finsbury.org