

# GAAK SPHERE

MEDIALY STABILIZED KNEE

REDISCOVER THE ANATOMICAL WAY



## Design Rationale

Joint

Spine

Sports Med



## INDEX

1. THE CLINICAL CHALLENGE	4
2. THE ORIGINS OF A STABLE CONCEPT	6
3. GMK SPHERE: STABILITY FOR LIFE	8
4. HOW THE KNEE MOVES	9
5. STABILITY IN TKA IMPROVES PATIENT SATISFACTION	10
6. STABILITY	11
6.1 Stability - in vitro analysis	13
6.2 Stability - in vivo analysis	14
7. NATURAL PATELLAR TRACKING	15
8. ANATOMICAL FIT	16
9. PATIENT-SPECIFIC KINEMATICS	17
10. MAXIMIZED CONTACT AREA AND MINIMIZED WEAR RATE	18

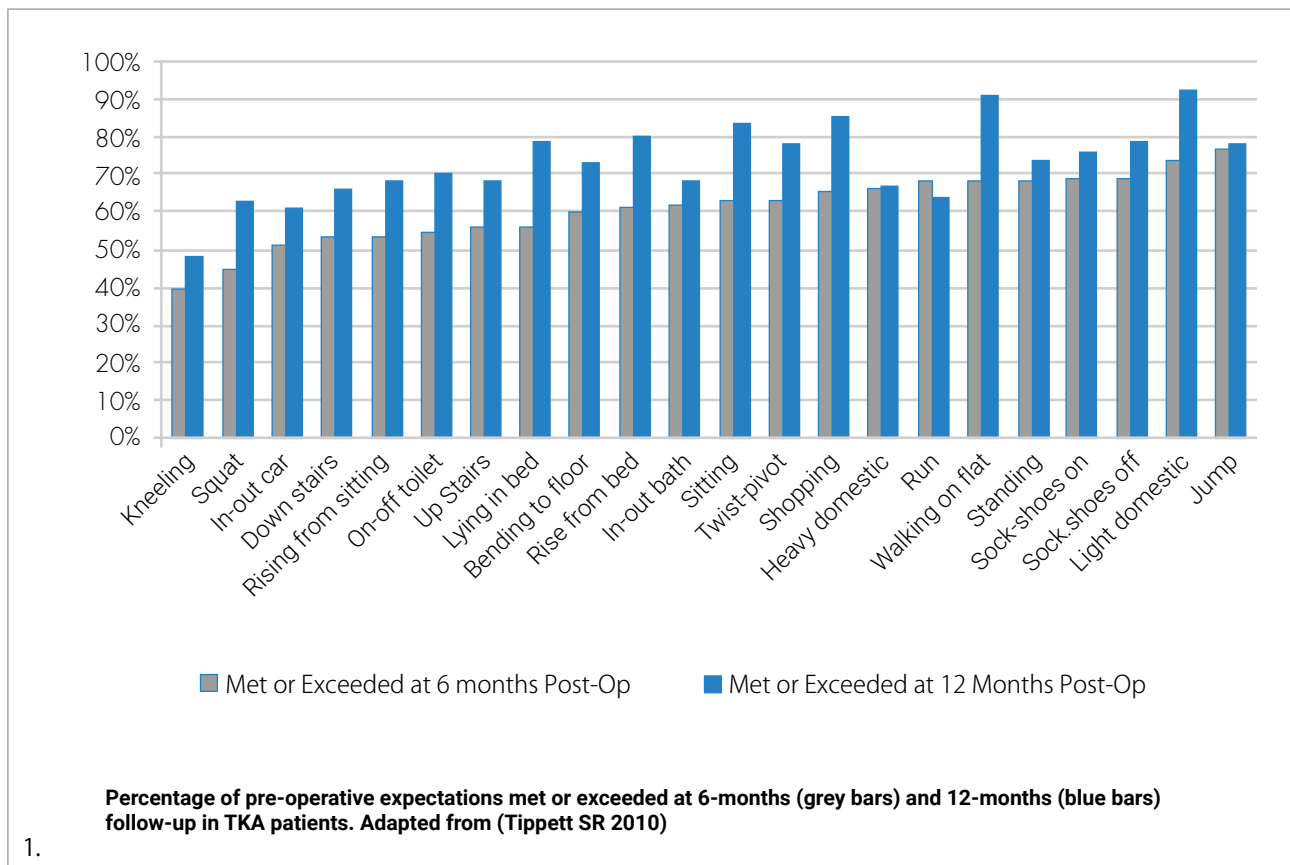
## 1. THE CLINICAL CHALLENGE

Is Total Knee Arthroplasty a successful procedure? Are patients satisfied after Total Knee Arthroplasty? Can they perform all the activities that they were able to perform before starting to have knee pain and disease? How can we define a successful procedure? Can your TKA patients go dancing, golfing or simply ascend and descend stairs in a confident way? In other words have they forgotten their artificial joint?

Even if knee replacement is considered a successful treatment, TKA patients are not completely satisfied with this procedure and there is still room for improvement. Bullens et al. identified a poor correlation between the traditional objective scores (Knee Society Score and Radiologic assessment) and a subjective patient-assessed satisfaction score (Visual Analogue Scale score) (Bullens PHJ 2001). A UK study evaluated the patient satisfaction using the Oxford knee score on a cohort of 10,000 patients more than one year following total knee replacement: almost 20% were not satisfied after their TKA (Baker PN 2007).

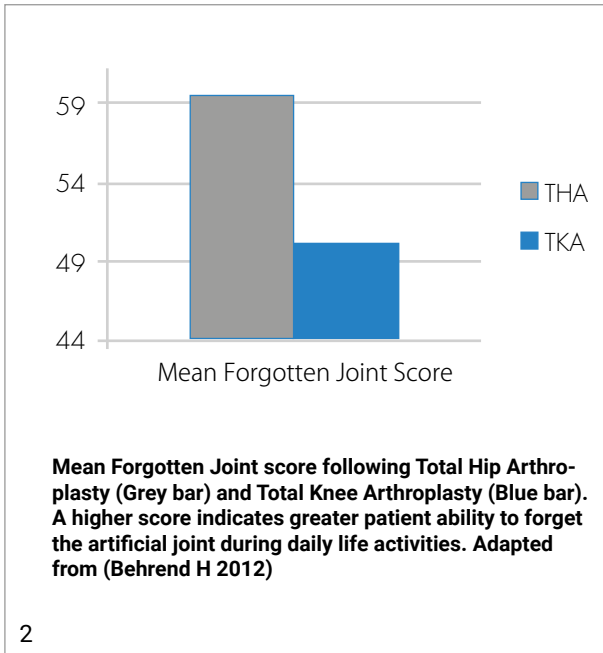
Recent studies show that patients' pre-operative expectations are higher than their post-operative ability (Nilsson AK 2009). 98% of TKA patients expected to have major improvement in pain; at 12 months 93% reported less pain but this percentage decreased to 63% at the 5-years follow-up. 96% of TKA patients expected improvements in function during activities of daily living, but 90% and 61% of patients experienced improvements at 12-months and 5-years respectively. Also, expectations regarding leisure activities are higher than the outcomes: at 1-year only 24% of patients are able to go dancing and golfing although 41% had this expectation pre-operatively (Nilsson AK 2009).

Tippett et al. have performed a comparison between pre-operative expectations and post-operative satisfaction in 2010 (Tippett SR 2010). Patients' expectations are not always realized after TKA, and many patients' still report difficulties during normal daily living activities such as ascending and descending stairs.



Patients' satisfaction following THA is higher if compared to TKA and a forgotten Hip is much more common than a forgotten Knee. In the study published by Bourne et al. 89% of THA patients and only 81% of TKA patients expressed greater overall satisfaction: in particular THA patients expressed higher satisfaction in the ability to perform daily activities compared to TKA patients (Bourne RB 2010).

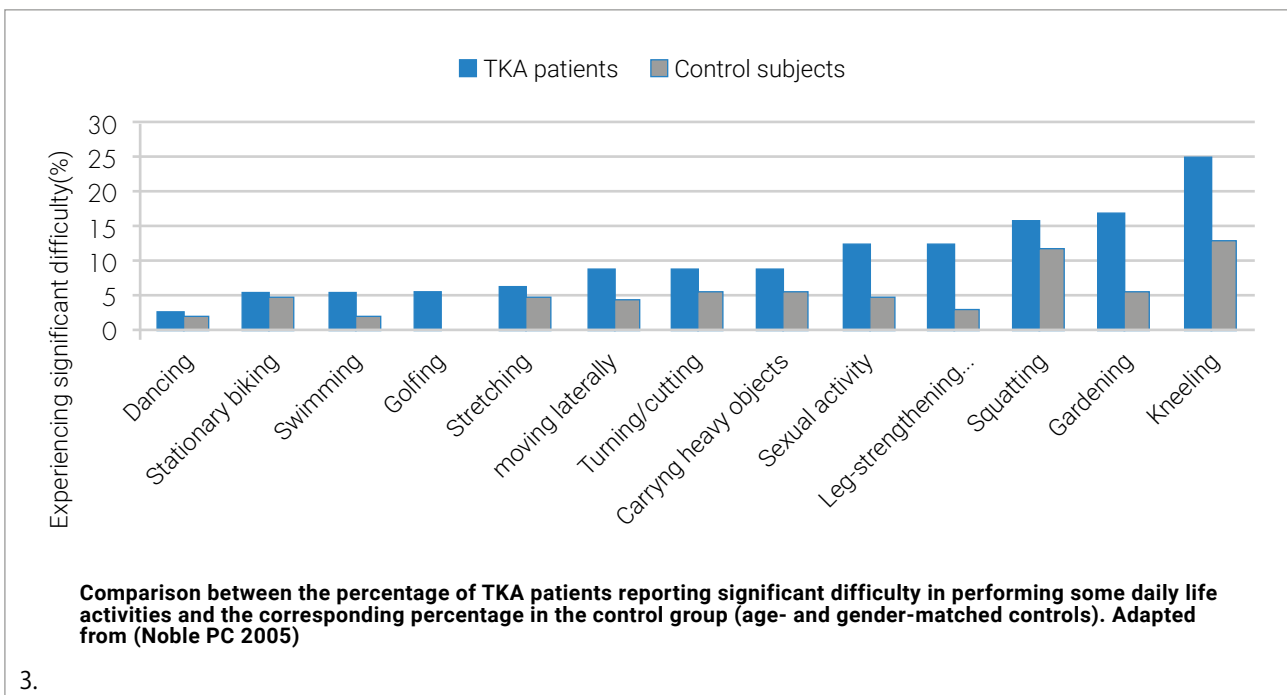
Following hip replacement patient expectations are more frequently met (78% vs 70%) compared to knee replacement and patients are more willing to undergo another surgery (Bourne RB 2010). Moreover, the patient's ability to forget the artificial joint in everyday life is greater following hip arthroplasty compared to TKA (Behrend H 2012).



While Total Hip Arthroplasty and Total Knee Arthroplasty are considered different procedures having the same goal, the improvements provided by the two replacements are not always comparable. Bachmeier et al. compared the outcomes following hip joint surgery and knee joint surgery and they found that the improvement in pain and physical function was significantly greater in THA patients (Bachmeier CJ 2001). Higher functional ability, especially in managing stairs, and less pain was reported after hip replacement compared with total knee replacement. Improvements occur more rapidly following THA (Wylde V 2009).

Noble et al. wondered if TKA can restore normal knee function: patients who received a total knee implant still experience significant difficulties during activities in daily life when compared to their age- and gender-matched peers (Noble PC 2005).

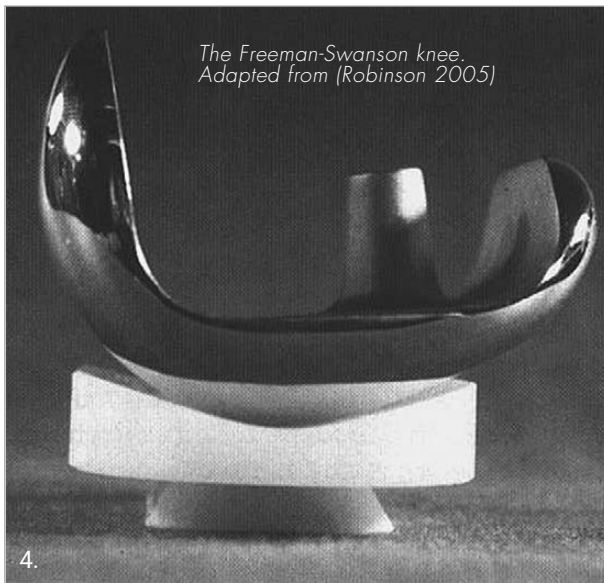
Published data shows that Total Knee Arthroplasty requires significant improvements in the procedure and prosthesis design in order to increase patient satisfaction and meet their expectations, to help them to forget the artificial limb and to restore normal knee function and stability.



## 2. THE ORIGINS OF A STABLE CONCEPT

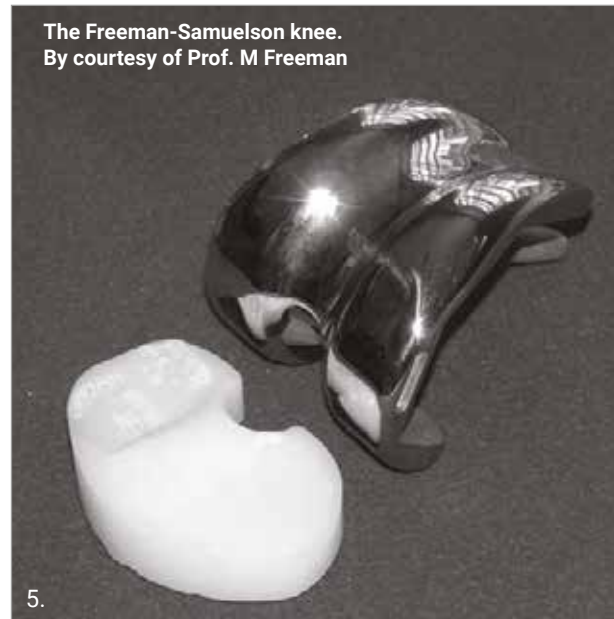
Prof. Michael Freeman started working on knee replacement in the 1960's when he founded, together with Prof. Alan Swanson, a Biomechanics Unit in the Department of Mechanical Engineering at the Imperial College in London. At that time, knee prostheses were mainly full cobalt chrome hinges that allowed flexion-extension only. Prof. Freeman and Prof. Swanson started working on the first condylar replacement and developed the first ever condylar metal/polyethylene total knee for implantation, the Freeman-Swanson knee.

At the time, it was believed that the femur rolled backwards on the tibia during flexion and this movement was generated by the action of the 4-bar link in the knee. In order to avoid roll-back, the knee was designed as a roller in a trough with a cylindrical femoral component and a polyethylene baseplate with same radius as the femoral radius. This first modern knee prostheses was manufactured by Howmedica and available in just one size.



*The Freeman-Swanson knee.  
Adapted from (Robinson 2005)*

In the late 1970's, learning from the experience gained with these knee designs, Prof. Freeman and Kent Samuelson MD designed the Freeman-Samuelson knee, manufactured by Protek in Bern. The design added a midline gap between the two femoral condyles to better remove cement from the posterior side and a defined trochlea groove, which enhanced patellar stability. The Swedish Knee Arthroplasty register reported a 10-year rate of survival (aseptic loosening) of 96.6% for the cemented Freeman-Samuelson knee (2,695 prosthesis) (Robertsson O 2000).



**The Freeman-Samuelson knee.  
By courtesy of Prof. M Freeman**

The designers started realizing that the two sides of the knee behave in a different way and believed it was necessary to allow longitudinal rotation in the prosthetic design. In the late 80's the MRK (Medial Rotation Knee) was designed as a modification of the Freeman Samuelson knee and was characterized by a congruent and spherical roller-in-trough articulation (remaining unchanged from the Freeman-Samuelson knee). Finsbury Orthopedics Limited began the commercialization of the MRK knee in 2001. This was the first introduction of an asymmetric knee prosthesis, which aimed to reproduce the medial stability inherent in the native knee while allowing for rotation around a medial axis.

The MRK was successful and was the knee implant with the lowest revision rate in the 2012 UK National Joint Register for the third consecutive year (National Joint Registry for England and Wales 2012). However, some criticism of the design suggested that the sagittal congruency of the lateral compartment inhibited rotation and limited flexion. The anterior flange of the prosthesis was also longer and more bulky than other successful contemporary knee designs.



In the late 1990's, Prof. Freeman began collaboration with Prof. Vera Pinskerova (University of Prague, Czech Republic) and a group of Japanese surgeons to study and better understand knee joint anatomy and movements. They published a number of papers on these two subjects by studying MRI of cadaveric and living knees and a collection of these studies is published in "The Anatomy and Movements of the Tibio-Femoral Joint" published by Prof. Freeman and Prof. Pinskerova in April 2014.

The results showed that the medial condyle experiences minimal antero-posterior translation at least until 120°, while the lateral condyle tends to exhibit considerable anterior-posterior motion during flexion-extension. The

medial stability characterizes every type of movement, while the anterior-posterior movement in the lateral compartment is not constant, but does occur in certain activities (Freeman MA 2005).

These new observations were used for a further design refinement of the knee prosthesis by removing constraint on the lateral side and allowing the knee to move in a way sympathetic to the kinematics of each individual patient. This was felt to be preferable to imposing "guided motion" based on an average of the translation and rotation observed in a healthy knee.

In 2010, Prof. Michael Freeman was introduced to Medacta by Prof. Richard Field (Elective Orthopaedic Centre, Epsom, UK) establishing a productive collaboration that resulted in an innovative project that reflected the mission of Medacta of providing safe and effective solutions to improve patient well-being. Together, they embarked upon development of a new prosthetic design intended to provide maximum functional stability throughout the range of motion resulting in increased patient satisfaction and less anterior knee pain: GMK Sphere.

### 3. GMK SPHERE: STABILITY FOR LIFE

Based on the knee anatomy and kinematic studies performed by Prof. Michael Freeman and Prof. Vera Pinskerova, the GMK Sphere is an innovative total knee implant designed to deliver maximum functional stability with the goal of increasing TKA patient satisfaction during activities of daily living and decreasing post-operative knee pain.

The GMK Sphere is characterized by four key features:

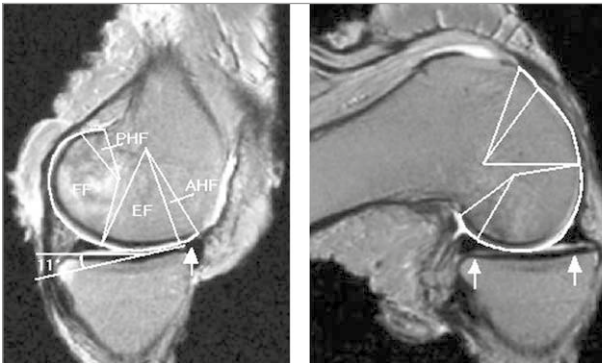
- **STABILITY**  
A stable, fully conforming medial compartment providing AP stability in mid-flexion and throughout the range of motion.
- **NATURAL PATELLAR TRACKING**  
An innovative patellar tracking design conceived to reduce the patellofemoral joint pressure and address anterior knee pain.
- **PATIENT-SPECIFIC KINEMATICS**  
A design that accommodates the best pattern of kinematic motion for each patient rather than imposing some assumed «norm».
- **ANATOMICAL FIT**  
A design resulting from an extensive anthropometric research from a global database.





## 4. HOW THE KNEE MOVES

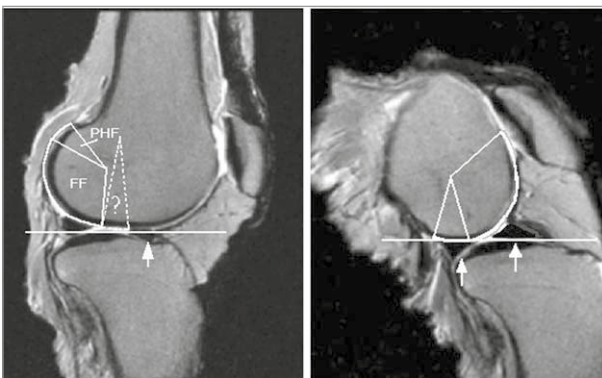
From 1997 onwards Prof. Michael Freeman and Prof. Vera Pinskerova have studied anatomy and kinematics of the knee joint. Additional scientific contributions were provided by Parm Johal (Johal P 2005) and a group of Japanese surgeons (Nakagawa S 2000). The major findings of these studies are described here below.



8. **MRI of the medial compartment of a knee.**  
Adapted from (Freeman MA 2005)

The medial compartment of the knee shows the following features:

- Concave tibial condyle (spherical dish);
- Fixed medial meniscus;
- The femoral condyle does not move antero-posteriorly with flexion to 120° (no femoral “roll-back”);
- The collateral ligament is broad and on average no more than 3 mm lax.



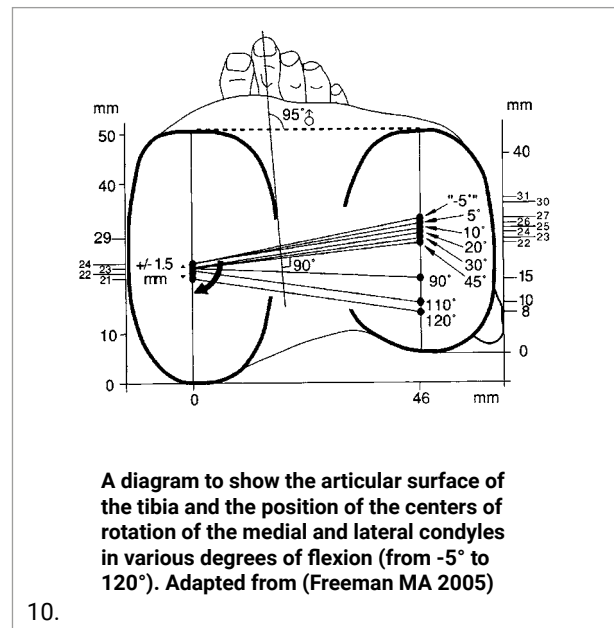
9. **MRI of the lateral compartment of a knee.**  
Adapted from (Freeman MA 2005)

The lateral compartment of the knee shows the following features:

- Flat tibial condyle;
- The meniscus moves A-P with the femur;
- The femur tends to roll backwards with flexion;
- The collateral ligament is narrow and lax at 90° of flexion.

In summary, the medial femoral condyle rotates into flexion around a center and articulates with the tibial plateau translating no more than 1.5 mm anteroposteriorly, weight bearing and non-weight-bearing.

The lateral femoral condyle also rotates around its center but in contrast to the medial side, during certain activities, it tends to translate posteriorly about 15 mm by a mixture of rolling and sliding. As a consequence between 10° and 120° the femur tends to rotate externally (tibia internally) about 30° around a medial axis.



## 5. STABILITY IN TKA IMPROVES PATIENT SATISFACTION

Patients who receive a total knee replacement prefer a feeling of «stability.» In a study in which bilateral patients had a conventional knee designs CR or PS in one knee and a more stable knee prostheses (designs with a medial “ball in socket”) in the other, 76% of patients preferred the knee with the medial “ball in socket” (Pritchett 2004) (Pritchett 2011).

These patients gave the following reasons for their preference:

- It feels more like a normal knee;
- It is stronger when ascending/descending stairs;
- It has superior single-leg weight bearing;
- It feels more stable during flexion and overall;
- There are fewer clunks, pops and clicks.

Patient preference regarding their knee arthroplasty (Patients were asked: Which is your better knee overall?)

Type of Implant	n	Prefer Knee 1	Prefer Knee 2	Cannot Tell	P*
MS vs PS	42	32 (76.2%)	4 (9.5%)	6 (14.3%)	<.001
MS vs CR	50	38 (76.0%)	6 (12.0%)	6 (12.0%)	<.001
MS vs MB	83	51 (61.4%)	25 (30.1%)	7 (8.4%)	.003

\*Likelihood ratio test for equal percentage of preferred procedures

MS = Medially stabilized knee (with a medial “ball in socket”)

PS = Posterior stabilized knee

CR = Posterior cruciate retaining knee

MB = Mobile bearing knee

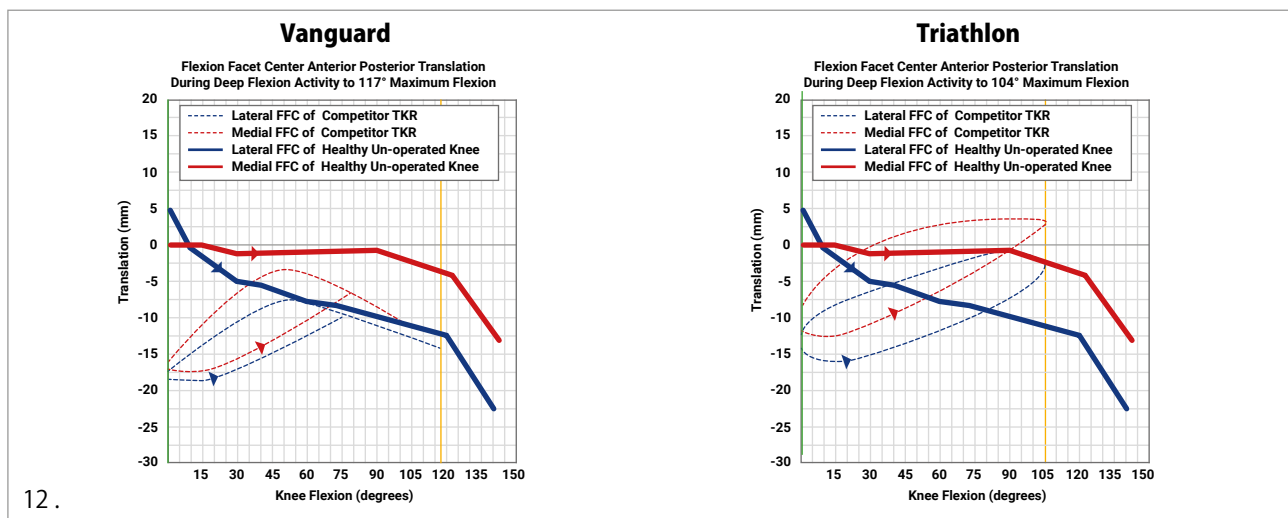


11.

## 6. STABILITY

Conventional knee designs, both cruciate retaining and posterior-stabilized, can show paradoxical motion, which is the unnatural anterior translation of the femur during flexion. The paradoxical motion may make knee patients feel insecure, especially when raising from a low seat, ascending/descending stairs or walking on uneven surfaces. Moreover, patients may be obliged to stabilize the knee through positioning or changes in muscle contraction (e.g. quadriceps avoidance gait).

Even posterior stabilized designs fail to fully restrain paradoxical motion. The PS cam-post mechanism engages only between 70° and 100° of flexion and in early flexion the femur is free to translate anteriorly showing paradoxical anterior motion. When the PS cam-post mechanism engages, both condyles show substantial rollback, even if in the unreplaced knee the medial rollback is minimal (Blaah 2004) (Morra EA 2008).



12.

Adapted from (Morra EA 2008)



13.

The GMK Sphere is designed with a spherical and fully congruent medial compartment which provides anterior-posterior stability in mid-flexion and during the range of motion. This mechanism is also named "ball-in-socket mechanism" (Hossain F 2011).

In vivo and in vitro studies show that the GMK Sphere fully congruent medial compartment provides:

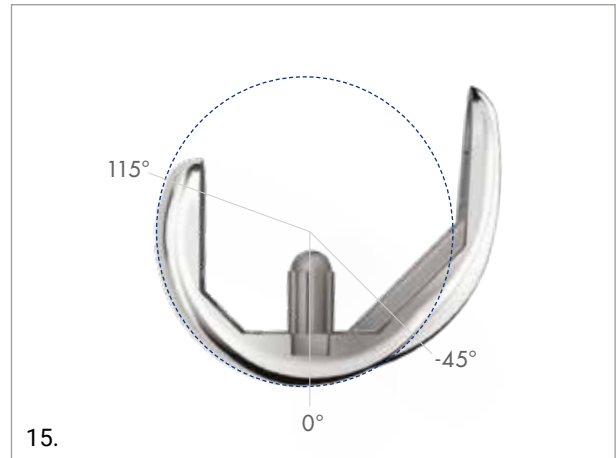
- High stability throughout the range of motion (Morra and Greenwald 2013) (Imam M 2014)
- No paradoxical motion between femur and tibia (Morra and Greenwald 2013) (Imam M 2014)
- No implant-related "mid-flexion" instability (Morra and Greenwald 2013) (Imam M 2014)

The fully conforming design of the GMK Sphere medial compartment could reduce also noise (i.e. pops, clicks, and clunks) that may be generated by the replaced knee (Sharkey PF 2011).

The GMK Sphere medial ball-in socket mechanism can replicate the function and the stability provided by the ACL and PCL and the medial meniscus.



Constant femoral radius between - 45° and 115° degrees of flexion in the medial compartment. Same radius in the medial and lateral sagittal profile.



The posterior medial condyle is wider than the lateral one to increase medial stability throughout the range of motion, to maximize the contact area and to better accommodate natural anatomy.



### 6.1 STABILITY - IN VITRO ANALYSIS

The Orthopaedic Research Laboratories (Ohio, USA) used a computational kinematic model to compare the motion of the GMK Sphere design with in vivo kinematic data of the healthy, un-operated knee (Morra and Greenwald 2013).

The protocol required the identification of two reference points called the Flexion Facet Centers (FFC) for both the medial and lateral femoral condyles that correspond to the centers of rotation. The model measured the position of these points in respect to the tibia showing the anterior-posterior motion for each condyle as flexion progresses during a stand to squat activity. The position of the medial and lateral FFC are compared with FFC motion reported in the in vivo kinematic study of weight bearing, healthy intact knees.

The GMK Sphere kinematic pathway compares very favorably with in vivo kinematic data of the healthy, un-operated knee. The position of the lateral FFC begins 2 millimeters anterior of the midline of the tibial insert at full extension and progresses in a manner similar to the intact healthy knee's lateral FFC as flexion progresses.

The position of the medial FFC begins 5 millimeters posterior to the midline of the tibial insert, but closely follows the same trend as the intact medial FFC, remaining in the same position for most of the high flexion activity.

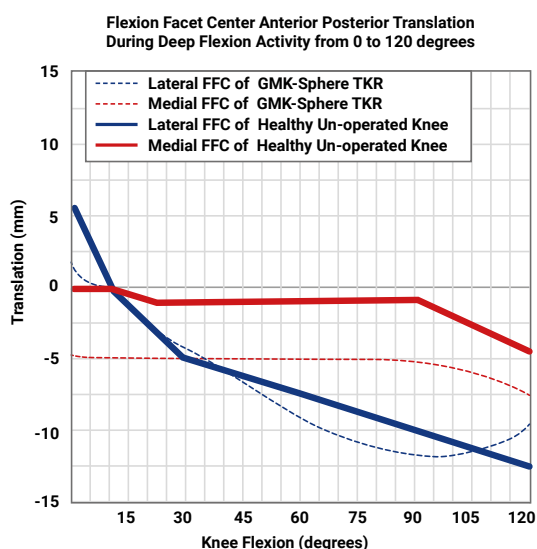
The 5 mm posterior offset is much shorter than the offset observed in other conventional knee designs and is meant to facilitate knee flexion.

To summarize, the GMK Sphere design offers stability in the anterior-posterior direction while still offering a natural posterior translation of the lateral femoral condyle, both hallmarks of the healthy, un-operated knee during high flexion activities.



The GMK Sphere Flexion Facet Centers (medial FFC in red and lateral FFC in blue)

17.



The GMK Sphere anterior-posterior translation of FFC points closely match intact healthy knee FFC anterior-posterior translation Adapted from (Morra EA 2008)

18.

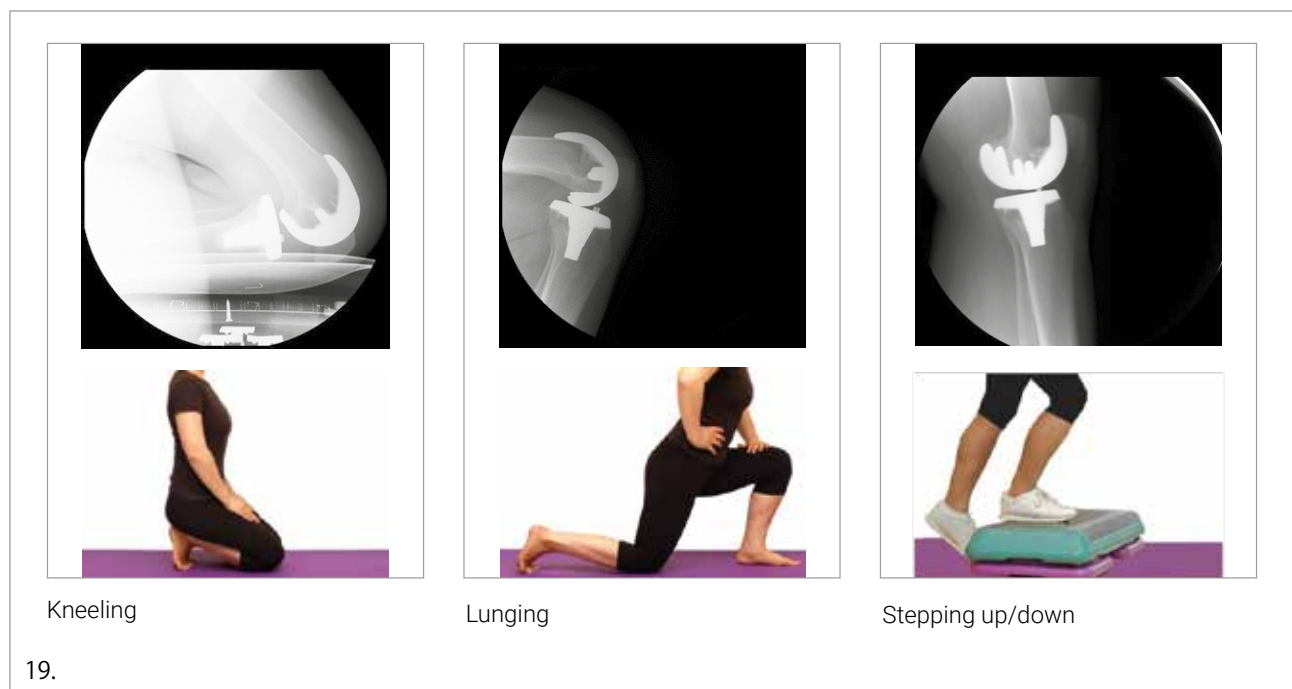
**6.2 STABILITY - IN VIVO ANALYSIS**

Prof. Scott Banks (University of Florida, USA) conducted an in vivo fluoroscopic study to quantify motions in knees with the GMK Sphere implant to address two questions (Imam M 2014):

- Does the medially conforming GMK Sphere design provide an AP-stable articulation that provides for tibiofemoral translations that are comparable to, but not larger than, translations measured in natural knees?
- Does the medially conforming GMK Sphere design provide sufficient rotatory laxity to allow tibiofemoral rotations comparable to, but not larger than, rotations measured in natural knees?

The study was conducted on 16 knees (15 subjects) that received a GMK Sphere implant at least 6 months before the examination. The patients were asked to perform different activities in front of a fluoroscope: kneeling, lunging, stepping up/down.

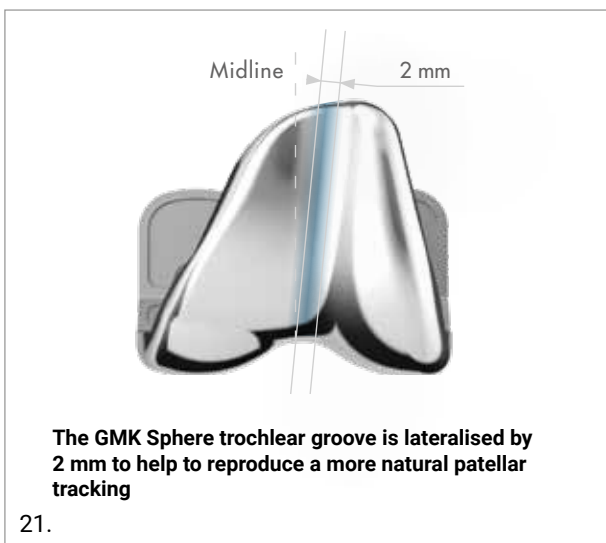
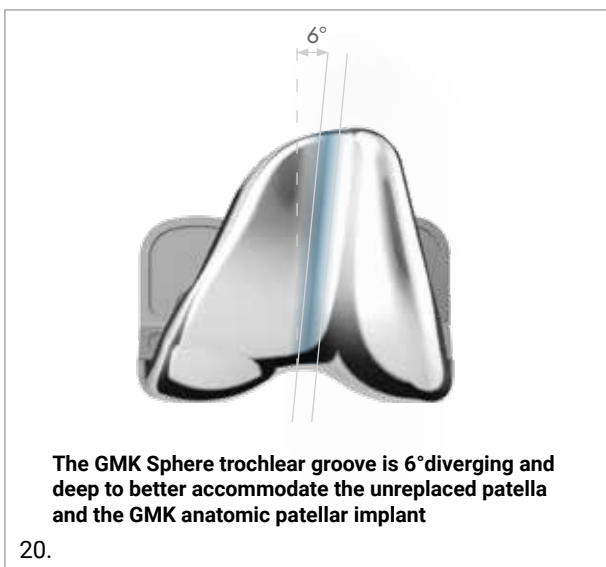
Fluoroscopic observation of these knees showed a stable medial articulation with little translation, and a lateral articulation translating in direct relation to tibial rotation. Tibial rotation during kneeling (8° average) was approximately twice that observed in knees with an earlier medially conforming TKA design (Moonot P 2009) and similar to that observed in natural knees (Hamai S 2009). At 6 months follow-up, knees with the GMK Sphere arthroplasty show functional kinematics that are AP stable and have more natural tibial rotation, consistent with the implant design intent.



## 7. NATURAL PATELLAR TRACKING

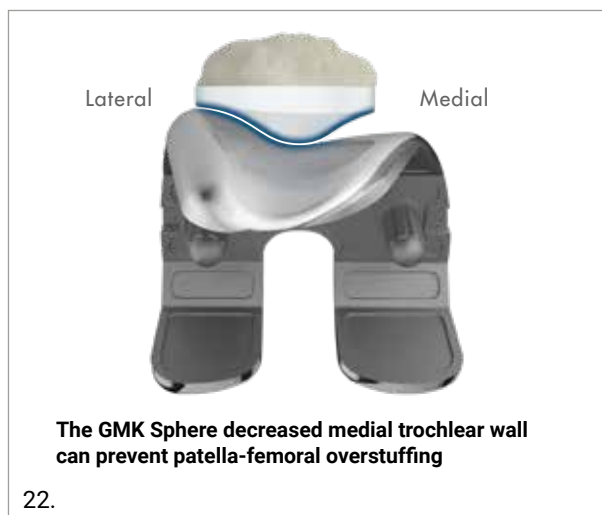
Following TKA the patello-femoral joint is often medialised when compared to the un-replaced knee (Meijerink HJ 2007). An abnormal patellar tracking could result in an abnormal tensioning of the soft tissues, patellar instability, pain, wear and failure (Armstrong AD 2003). Abnormality of the patella-femoral joint could increase the risk of anterior knee pain (D'Lima DD 2003).

The GMK Sphere trochlea groove has been designed asymmetric ( $6^\circ$  diverging), deep (7 mm) and lateralized by 2 mm in comparison to the midline of the femoral component. This design allows for a more natural medial-lateral translation of the patella during flexion-extension and can reduce the stress on either the natural patella or the patellar implant, also reducing the risk of subluxation.



The asymmetric and anatomic anterior flange is designed to restore the lateral patellar tracking decreasing the risk of anterior overstuffing of the knee. Conventional TKA sometimes introduces a high medial wall that could overstress the soft tissues in that portion of the joint and

does not contribute to the patellar tracking, as the mediolateral forces during flexion act from the medial to the lateral compartment (Belvedere C 2007) (Yamada Y 2007). The GMK Sphere is designed with a flattened medial trochlear wall, which prevents patella-femoral overstuffing minimizing retinacular tension.



In order to increase the region of contact between the patella and the femoral component at high values of flexion, the trochlea surface is extended posteriorly up to high flexion. This design could decrease the risk of "patellar clunk" found in certain knee designs (Kulkarni SK 2000).

The combination of the patello-femoral joint design and the facility to reproduce natural posterior translation of the lateral condyle is intended to reduce retropatellar pressure and consequently decrease the risk of anterior knee pain. In conventional knee designs, the anterior translation of the femoral component could increase patello-femoral joint pressure during flexion. By contrast, the GMK Sphere provides a stable medial compartment, which does not translate anterior-posteriorly.

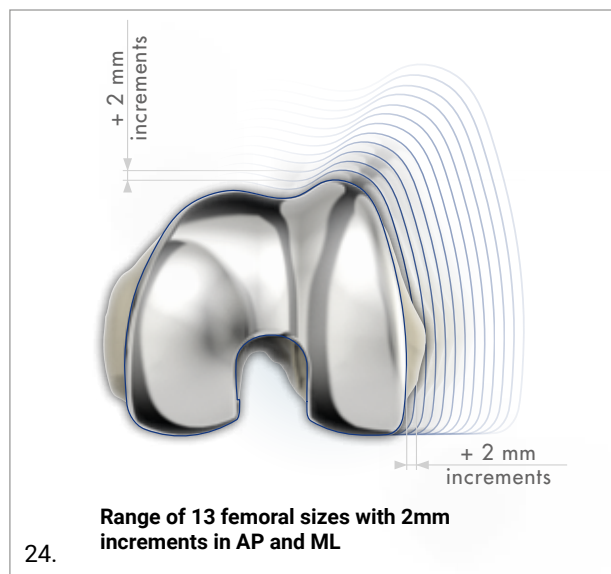


Finally, anatomic patellar implant with medialised dome is designed to maximize bony coverage with potentially less risk of patella tilt, improved stability and contact area.

## 8. ANATOMICAL FIT

A global database containing more than 15,000 CT and MRI scans of knees was analyzed to validate the GMK Sphere design. Medacta developed an algorithm that automatically measures some anthropometric dimensions and performs a statistic analysis (Data on file: Medacta).

The GMK Sphere provides a range of 13 femoral sizes with 2 mm increments that best fit a broad spectrum of anatomic profiles.



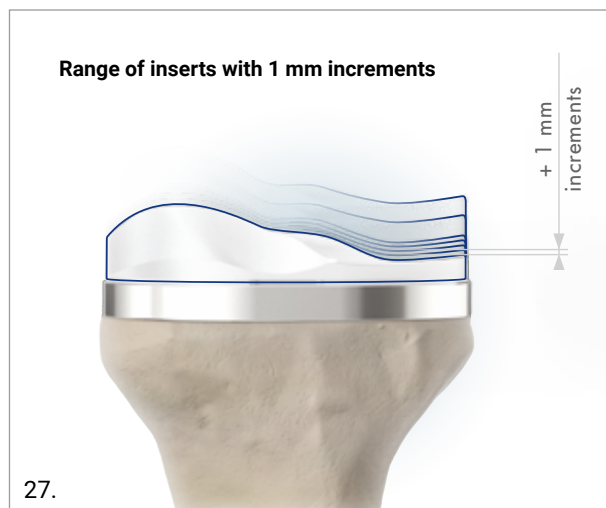
The anatomically shaped tibial baseplate fits the asymmetrical profile of the tibia. The tibial baseplate maximizes the coverage of the proximal tibia, transferring loads to the cortical rim, thus increasing stability and reducing the risk of subsidence and avoiding painful conflicts with posterior soft tissues (Westrich GH 1995). The shape also can simplify implant positioning.



The GMK tibial baseplate features also a mirror polished surface finishing. Mirror polished surface finishing of the baseplate can minimize the magnitude of backside wear in case some micromotion still exists. Mirror polishing is considered as one of the most effective solutions to counter wear phenomena (Engh 2001).



GMK Sphere offers a range of inserts with 1 mm increments bringing up to 7 the range of available insert's thickness.



The combination of 13 femoral sizes and inserts with 1 mm increments allows the surgeon to «fine tune» ligament balance and improve stability throughout the range of motion.



## 9. PATIENT-SPECIFIC KINEMATICS

The aim of a total knee replacement is the restoration of the normal functions of the leg in relation to the daily activities of the patient. Comparing to the conventional knee designs, the GMK Sphere knee is designed to guarantee a more natural kinematics of the knee joint, allowing stability in the medial compartment throughout flexion and freedom of translation in the lateral compartment.

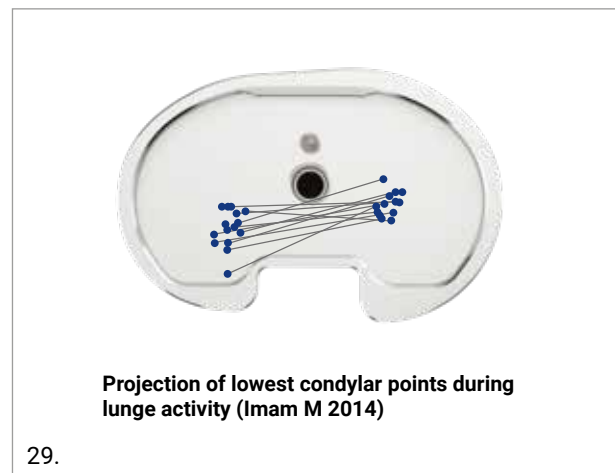
GMK Sphere accommodates the best pattern of kinematic motion for each patient rather than imposing some assumed «norm» (Imam M 2014). This is achieved by:

- «Ball in socket» stability throughout the range of motion in the medial compartment
- Freedom of movement in the lateral compartment

GMK Sphere features an unconstrained lateral compartment, which allows for a more natural rotation around the medial side with a more physiologic posterior translation of the lateral femoral condyle, which varies according to the patient and the activity (Imam M 2014).

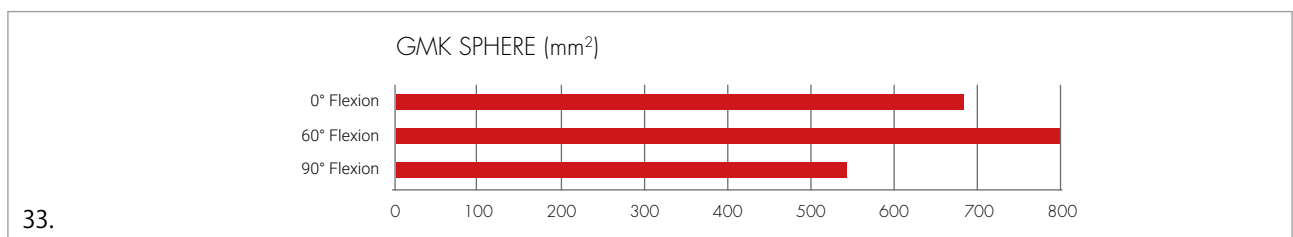
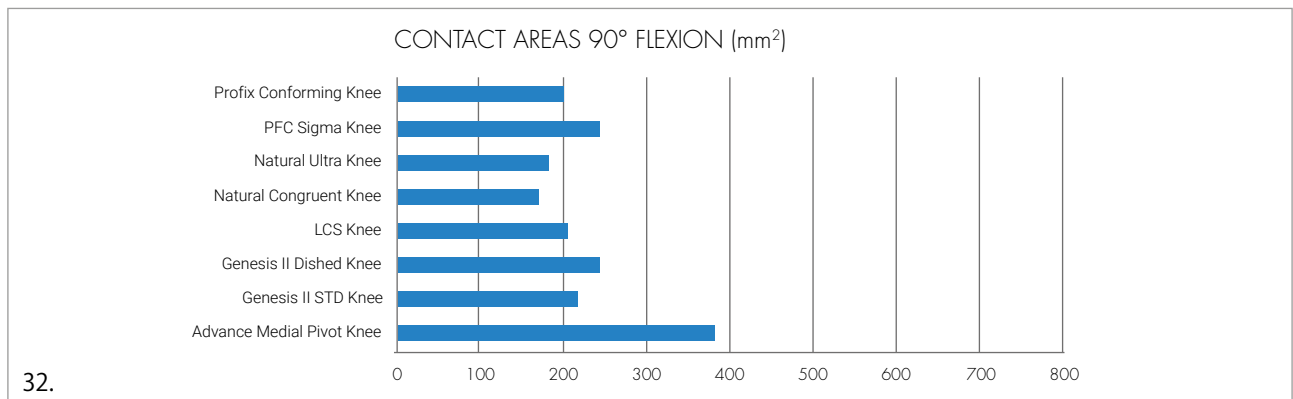
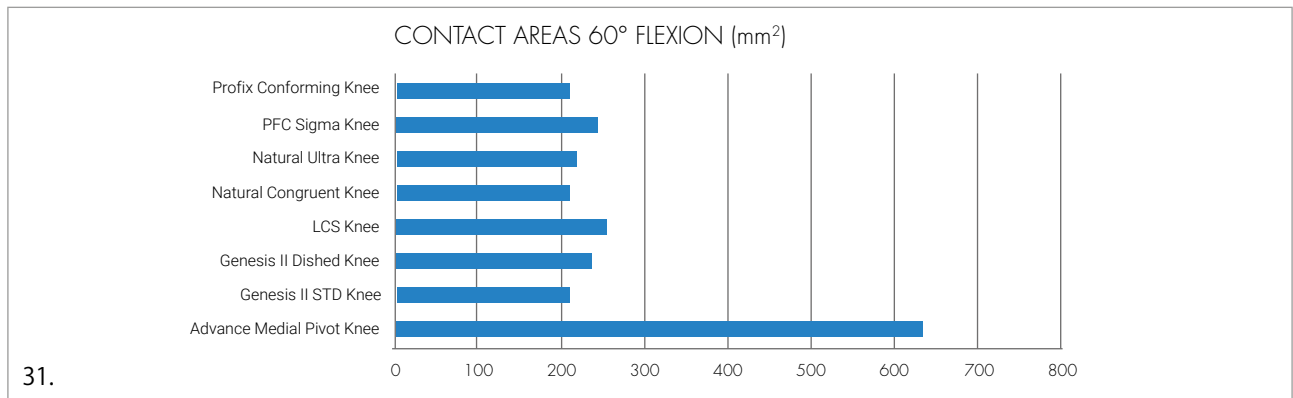
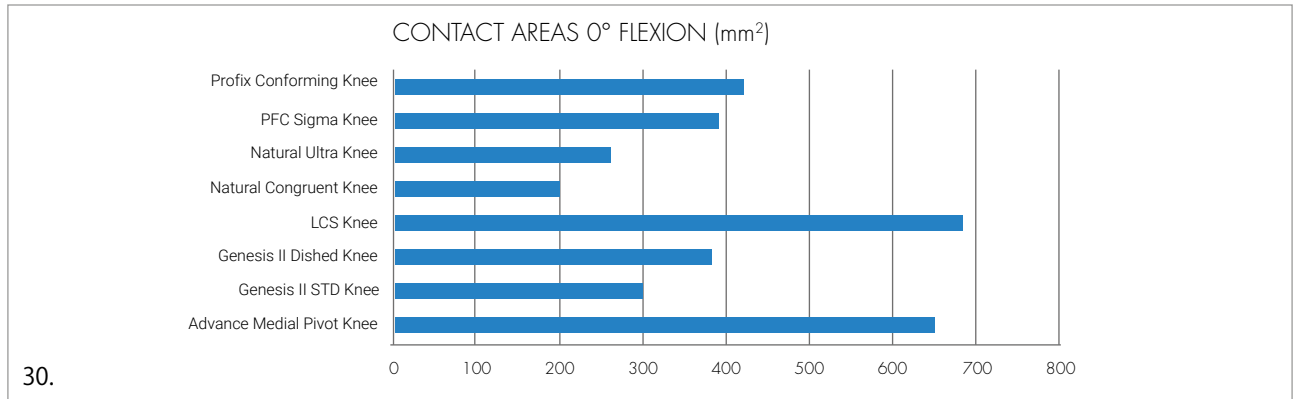


The in vivo fluoroscopic study performed by Prof. Scott Banks (University of Florida, USA) proved that the GMK Sphere kinematics, for a given activity, differs in the different subjects and is therefore highly individual (Imam M 2014).



10. MAXIMIZED CONTACT AREA AND MINIMIZED WEAR RATE

A laboratory evaluation has demonstrated that GMK Sphere design provides for maximal contact area in the medial compartment throughout the range of loaded motion. Considering that, generally, the majority of load is applied through the medial compartment, an extensive spherical contact in the medial femoro-tibial joint is desirable. Although the lateral femoro-tibial compartment is not congruent on the sagittal plane, it is congruent in the coronal plane, further reducing contact stress levels



Contact areas were measured using a 3D Software imposing contact between femur and insert at three different flexion angles, 0°, 60° and 90°, according to the protocol used by the Orthopaedic Research Laboratory. The results show that with GMK Sphere the contact areas at 0°, 60° and 90° of flexion are higher than the contact areas for other knee designs. This could generate better load distribution with lower risk of PE delamination, lower contact stresses and higher stability.

Studies already demonstrated that the principles of the GMK Sphere design allow for less wear compared to the wear found with other designs (Minoda, et al. 2003) (Minoda Y 2009). In 2009, a Japanese study showed that

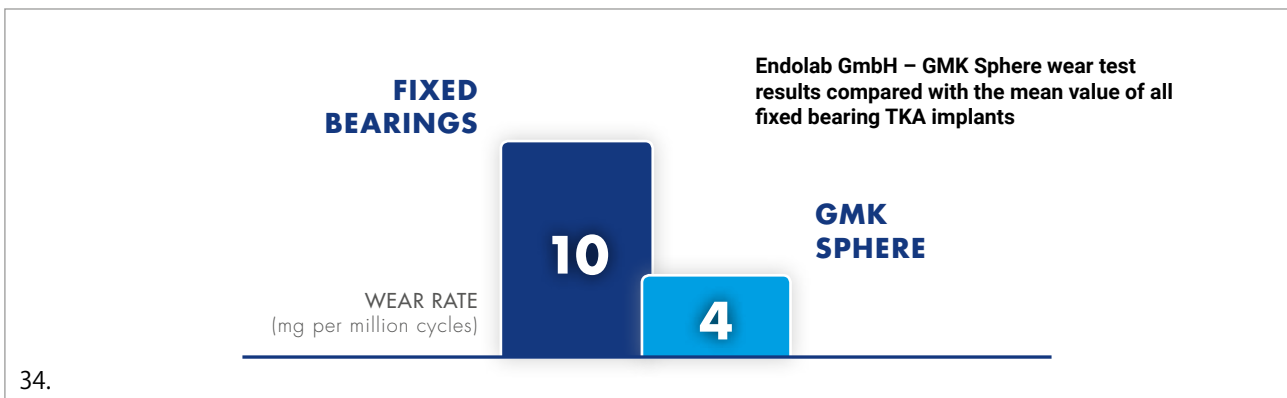
mobile bearing and PS knees show significantly more wear than a medially stabilized knee (Minoda Y 2009).

Endolab GmbH laboratory (Germany) performed a wear test evaluating the GMK Sphere wear rate. The load and constraints were applied by means of a knee simulator that is able to reproduce the normal gait cycles in terms of forces and moments. The test was performed at a frequency of 1 Hz ± 0.1 Hz for 5 million of cycles.

Results show that the GMK sphere wear rate is about 4 mg per million cycles and the wear rate is less than half the average wear rate found for all the fixed bearing knee implants tested by the same laboratory (Data on file: Medacta) (Haider and Kaddick 2012).

Prosthesis Type	Total Number of Particles
Posterior stabilized	1160 x 105
Mobile-bearing	1750 x 105
Medially stabilized	570 x 105

In vivo analysis of PE wear particles after TKA (52 knees, 1y post-op) (Minoda Y 2009)



## BIBLIOGRAPHY

1. Armstrong AD, Brien HJ, Dunning CE, King GJ, Johnson JA, Chess DG. «Patellar position after total knee arthroplasty: influence of femoral component malposition.» *J Arthroplasty*, 2003; 18(4):458.
2. Bachmeier CJ, March LM, Cross MJ, Lapsley HM, Tribe KL, Courtenay BG, Brooks PM. «A comparison of outcomes in osteoarthritis patients undergoing total hip and knee replacement surgery.» *Osteoarthritis Cartilage*, 2001; 9(2):137-46.
3. Baker PN, van der Meulen JH, Lewsey J, Gregg PJ. «The role of pain and function in determining patient satisfaction after total knee replacement.» *J Bone Joint Surg Br.*, 2007; 89(7):893-900.
4. Behrend H, Giesinger K, Giesinger JM, Kuster MS. «The «forgotten joint» as the ultimate goal in joint arthroplasty: validation of a new patient-reported outcome measure.» *J Arthroplasty*, 2012; 27(3):430-436.
5. Belvedere C, Catani F, Ensini A, Moctezuma de la Barrera JL, Leardini A. «Patellar tracking during total knee arthroplasty: an in vitro feasibility study.» *Knee Surg Sports Traumatol Arthrosc*, 2007; 15(8):985-93.
6. Blaha. «The rationale for a total knee implant that confers anteroposterior stability throughout range of motion.» *J Arthroplasty*, 2004; 19(4 Suppl 1):22-6.
7. Bourne RB, Chesworth B, Davis A, Mahomed N, Charron K. «Comparing patient outcomes after THA and TKA: is there a difference? .» *Clin Orthop Relat Res*, 2010; 468(2):542-6.
8. Bullens PHJ, van Loon CJM, de Waal Malefijt MC, Laan R, Veth R. «Patient Satisfaction After Total Knee Arthroplasty A Comparison Between Subjective and Objective Outcome Assessments.» *J Arthroplasty*, 2001; 16(6):740-7. «Data on file: Medacta.» n.d.
9. Data on file Medacta.
10. D'Lima DD, Chen PC, Kester MA, Colwell CW Jr. «Impact of patellofemoral design on patellofemoral forces and polyethylene stresses.» *J Bone Joint Surg Am*, 2003; 85-A Suppl 4:85-93.
11. Engh A. Gerard, Lounici Smain, Rao R. Anandand, Collier B. Matthew. In vivo deterioration of tibial baseplate locking mechanisms in contemporary modular total knee components. *The Journal of bone and joint surgery*, 2001.
12. Freeman MA, Pinskerova V. «The movement of the normal tibio-femoral joint.» *J Biomech*, 2005; 38(2):197-208.
13. Hamai, Moro-oka TA, Miura H, Shimoto T, Higaki H, Fregly BJ, Iwamoto Y, Banks. Knee kinematics in medial osteoarthritis during in vivo weight-bearing activities. *J Orthop Res*. 2009 Dec.
14. Hossain F, Patel S, Rhee SJ, Haddad FS. «Knee arthroplasty with a medially conforming ball-and-socket tibiofemoral articulation provides better function.» *Clin Orthop Relat Res*, 2011; 469(1):55-63.
15. Johal P, Williams A, Wragg P, Hunt D, Gedroyc W. «Tibio-femoral movement in the living knee. A study of weight bearing and non-weight bearing knee kinematics using 'interventional' MRI .» *J Biomech*, 2005; 38(2):269-76.
16. Kulkarni SK, Freeman MA, Poal-Manresa JC, Asencio JI, Rodriguez JJ. «The patellofemoral joint in total knee arthroplasty: is the design of the trochlea the critical factor?» *J Arthroplasty*, 2000; 15(4):424-9.
17. Meijerink HJ, Barink M, van Loon CJ, Schwering PJ, Donk RD, Verdonschot N, de Waal Malefijt MC. «The trochlea is medialized by total knee arthroplasty: an intraoperative assessment in 61 patients.» *Acta Orthop*, 2007; 78(1):123-7.

18. Minoda Y, Kobayashi A, Iwaki H, Iwakiri K, Inori F, Sugama R, Ikebuchi M, Kadoya Y, Takaoka K. «In vivo analysis of polyethylene wear particles after total knee arthroplasty: the influence of improved materials and designs.» *J Bone Joint Surg Am*, 2009; 91 Suppl 6:67-73.
19. Minoda Yukihide, Kobayashi Akio, Iwaki Hiroyoshi, Miyaguchi Masatsugu, Kadoya Yoshinori, Ohashi Hirotsugu, Yamano Yoshiki and Takaoka Kunio. Polyethylene Wear Particles in Synovial Fluid After Total Knee Arthroplasty. *CLINICAL ORTHOPAEDICS AND RELATED RESEARCH* Number 410, pp. 165–172 © 2003 Lippincott Williams & Wilkins, Inc.
20. Morra EA, Rosca M, Greenwald JF, Greenwald AS. «The influence of contemporary knee design on high flexion: a kinematic comparison with the normal knee.» *J Bone Joint Surg Am*, 2008; 90 Suppl 4:195-201.
21. Morra, EA, and S Greenwald. «Simulated kinematic performance of the GMK Sphere total knee design during a stand to squat activity.» Study report, Orthopaedic Research Laboratories Cleveland, OH USA, 2013.
22. Moonot P, S. Mu, G. T. Railton, R. E. Field, S. A. Banks. Tibiofemoral kinematic analysis of knee flexion for a medial pivot knee *Knee Surg Sports Traumatol Arthrosc* (2009).
23. Nakagawa S, Kadoya Y, Todo S, Kobayashi A, Sakamoto H, Freeman MA, Yamano Y. «Tibiofemoral movement 3: full flexion in the living knee studied by MRI.» *J Bone Joint Surg Br*, 2000; 82(8):1199-200.
24. «National Joint Registry for England and Wales.» 9th Annual Report, 2012.
25. Nilsson AK, Toksvig-Larsen S, Roos EM. «Knee arthroplasty: are patients' expectations fulfilled? A prospective study of pain and function in 102 patients with 5-year follow-up.» *Acta Orthopaedica*, 2009; 80 (1): 55–61.
26. Noble PC, Gordon MJ, Weiss JM, Reddix RN, Conditt MA, Mathis KB. «Does total knee replacement restore normal knee function?» *Clin Orthop Relat Res*, 2005; (431):157-65.
27. Pritchett. «Patient preferences in knee prostheses.» *J Bone Joint Surg Br*, 2004; 86(7):979-82. Pritchett. «Patients prefer a bicruciate-retaining or the medial pivot total knee prosthesis.» *J Arthroplasty*, 2011; 26(2):224-8.
28. Robertsson O, Scott G, Freeman MA. «Ten-year survival of the cemented Freeman-Samuelson primary knee arthroplasty. Data from the Swedish Knee Arthroplasty Register and the Royal London Hospital.» *J Bone Joint Surg Br*, 2000; 82(4):506-7.
29. Robinson. «The early innovators of today's resurfacing condylar knees.» *J Arthroplasty*, 2005; 20(1 Suppl 1):2-26.
30. Sharkey PF, Miller AJ. «Noise, numbness, and kneeling difficulties after total knee arthroplasty: is the outcome affected?» *J Arthroplasty*, 2011; 26(8):1427-31.
31. Tippet SR, Mang J, Dwyer KA, Lesko J, O'Dell T. «Collecting Data with Palm Technology: Comparing Preoperative Expectations and Postoperative Satisfaction in Patients Undergoing Total Knee Arthroplasty.» *J Bone Joint Surg Am*, 2010; 92 Suppl 2:59-67.
32. Westrich H, Geoffrey, Haas B, Steven, Insall N, John and Frachie Alessandro. Resection specimen analysis of proximal tibial anatomy based on 100 total knee arthroplasty specimens. *The Journal of Arthroplasty* Vol 10 No.1 1995.
33. Wylde V, Blom AW, Whitehouse SL, Taylor AH, Pattison GT, Bannister GC. «Patient-reported outcomes after total hip and knee arthroplasty: comparison of midterm results.» *Arthroplasty*, 2009; 24(2):210-6.
34. Yamada Y, Toritsuka Y, Horibe S, Sugamoto K, Yoshikawa H, Shino K. «In vivo movement analysis of the patella using a three-dimensional computer model.» *J Bone Joint Surg Br*, 2007; 89(6):752-60.

NOTES

Lined area for notes with horizontal ruling lines.





---

**REDEFINING BETTER  
IN ORTHOPAEDICS  
AND SPINE SURGERY**

---

MEDACTA.COM



**Medacta International SA**  
Strada Regina - 6874 Castel San Pietro - Switzerland  
Phone +41 91 696 60 60 - Fax +41 91 696 60 66  
info@medacta.ch

Find your local dealer at: [medacta.com/locations](https://www.medacta.com/locations)

All trademarks and registered trademarks are the property of their respective owners.  
Please verify approval of the devices described in this document with your local Medacta representative.

GMK Sphere  
Design Rationale

ref: 99.26sphere.11DR  
rev. 03

Last update: September 2019