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GMK SPHERE PUBLICATION REVIEW

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Introduction

Total knee arthroplasty (TKA) has been performed for more than four decades. The procedure has been successful in relieving patients' pain but both orthopaedic surgeons and patients continue to seek better functional results: a forgotten knee after TKA is unusual, whereas a forgotten hip after total hip replacement is commonplace.

Conventional designs of knee replacements, i.e. the posterior cruciate ligament (PCL) retaining and PCL substituting knee replacements, failed to reproduce normal knee kinematics. Anterior cruciate ligament deficiency after TKA causes forward femoral motion during knee flexion, the so called "paradoxical motion". However, excessive joint laxity is associated with persistent pain and poor long-term outcomes due to instability.

The stability and the kinematics of the knee depend on the musculature, the surrounding ligaments and the geometry of the articular surfaces. Recent works on natural knee kinematics show that the posterior femoral condyles are spherical in shape. The medial sphere is located in a conforming socket, created anteriorly by the upward sloping tibial condyle and posteriorly by the firmly attached posterior horn of the medial meniscus. Laterally, the tibial surface is flat. The collateral ligaments differ from each other in that the medial collateral ligament (MCL) remains tight during flexion, whereas the lateral collateral ligament (LCL) becomes loose. As a result, the medial femoral condyle does not move antero-posteriorly between full extension and 120 degrees of flexion, whereas the lateral one translates posteriorly. This combination equates to tibial internal rotation around a medial axis. From 120 degrees to full flexion both femoral condyles roll back.

Partly in order to provide antero-posterior stability, a single-radius tibio-femoral prosthesis was designed. The first implant of this type was the Freeman/Swanson prosthesis implanted in the late 60s, followed by the ICLH and the Freeman/Samuelson prostheses. All these implants had a single radius femur articulating with a single radius trough in the tibial component on both the medial and the lateral side. The disadvantage of this design was that longitudinal rotation was possible only through the subluxation of fully conforming articular surfaces. Hence the challenge has been to design a knee prosthesis which provides antero-posterior stability and simultaneously allows longitudinal rotation, i.e. could reproduce the pattern of movement as reported in the natural knee.

The first TKA with a medially spherical design was the Medial Rotation Knee (Finsbury Instruments), but this retained a conventional lateral compartment with a roller-in-a-trough geometry. The goal was then to reproduce not only the medial anatomy but also the shapes of articulating surfaces in the lateral compartment. The concept of the GMK Sphere TKA is based on medial antero-posterior stability combined with lateral freedom of motion, resulting in a medial centre of longitudinal rotation as exhibited by the normal knee. Antero-posterior stability is achieved through its fully congruent medial compartment. The medial femoral condyle has a single radius in both the sagittal and the frontal planes and corresponds in shape to the medial concavity of the tibial insert. This "ball-in-socket" mechanism improves stability through the complete arc of active flexion. The increased contact area reduces contact stresses and possibly polyethylene wear. The prosthesis must be implanted so that the MCL is under sufficient tension to prevent the femur lifting away from the tibia by more than 2mm as in the natural knee. This combination of a medial ball-in-socket and a correctly tensioned MCL represents the fundamental characteristic of this prosthesis and is similar in principle to that of the natural knee. The lateral compartment has an anteroposteriorly flat condylar tibial surface articulating with a circular femoral component. The circle has the same sagittal radius as the medial condyle has.

When the prosthesis flexes, the lateral femoral condyle tends to roll backwards which equates to femoral external rotation (tibial internal rotation). This movement is possible because the LCL is loose in flexion. The combination of a fully congruent medial compartment and an unconstrained lateral tibial surface together with tight MCL and loose LCL enables flexion accompanied by femoral external rotation around the stable medial condyle.

The GMK Sphere has been designed with two goals: to provide antero-posterior stability throughout the active range of flexion and to restore the natural knee kinematics. The design Team believes that providing stable and consistent knee kinematics is an essential requirement for good long-term clinical results.

The GMK Sphere was first implanted in 2011. Medacta then carefully evaluated its performances for more than 3 years post marketing surveillance in a selected number of hospitals on more than 3,000 patients in order to responsively launch GMK Sphere implant worldwide. This booklet is a collection of the scientific and clinical evidence collected so far on GMK Sphere proving that it kept the promise: GMK SPHERE, stability for life!

Prof. Vera Pinskerova



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Patient preferences in TKA

The role of pain and function in determining patient satisfaction after total knee replacement. Data from the National Joint Registry for England and Wales.

BAKER P.N., VAN DER MEULEN J.H., LEWSEY J., GREGG P.J. - *J Bone Joint Surg Br.* 2007 Jul; 89(7):893-900

A postal questionnaire was sent to 10,000 patients more than one year after their total knee replacement (TKR). They were assessed using the Oxford knee score and were asked whether they were satisfied, unsure or unsatisfied with their TKR. The response rate was 87.4% (8231 of 9417 eligible questionnaires) and a total of 81.8% (6625 of 8095) of patients were satisfied. Multivariable regression modelling showed that patients with higher scores relating to the pain and function elements of the Oxford knee score had a lower level of satisfaction ($p < 0.001$), and that ongoing pain was a

stronger predictor of this. Female gender and a primary diagnosis of osteoarthritis were found to be predictors of lower levels of patient satisfaction. Differences in the rate of satisfaction were also observed in relation to age, the American Society of Anesthesiologists grade and the type of prosthesis. This study has provided data on the Oxford knee score and the expected levels of satisfaction at one year after TKR. The results should act as a benchmark of practice in the United Kingdom and provide a baseline for peer comparison between institutions.

Comparing patient outcomes after THA and TKA: is there a difference?

BOURNE RB, CHESWORTH B, DAVIS A, MAHOMED N, CHARRON K - *Clin Orthop Relat Res.* 2010 Feb;468(2):542-6

Both primary total hip (THA) and knee (TKA) arthroplasty relieve pain, restore function, and increase mobility. Despite these successes, there is controversy as to whether THA or TKA provides greater or similar improvement. We therefore compared primary THA and TKA patient results in terms of (1) willingness to have surgery again; (2) WOMAC change score; (3) whether expectations were met; and (4) satisfaction. Patients undergoing primary THA were more willing to undergo their surgery again (THA 96%, TKA 89%), demonstrated greater WOMAC change scores,

more frequently reported their expectations were met (THA 78%, TKA 70%), and expressed greater overall satisfaction (THA 89%, TKA 81%). In addition, patients undergoing THA expressed higher satisfaction with pain reduction while performing activities (ie, walking, stairs, and sitting/lying) and their ability to perform daily activities (ie, stairs, transportation, getting up, lying in bed, and light domestic duties) when compared with patients undergoing TKA. Our data suggest primary THA offers superior short-term outcomes when compared with primary TKA.

Patients prefer a bicruciate-retaining or the medial pivot total knee prosthesis.

PRITCHETT J.W. - *J Arthroplasty.* 2011 Feb;26(2):224-8

Four-hundred forty patients underwent staged bilateral total knee arthroplasty using a different prosthesis on each side. Prostheses used were anterior-posterior cruciate-retaining (ACL-PCL), posterior cruciate-retaining (PCL), Medial Pivot (MP), posterior cruciate-substituting (PS), and mobile bearing (MB). At the 2-year evaluation, we asked "Which is your better knee overall?" Responses were as follows: 89.1% preferred the ACL-PCL to the PS and 76.2% preferred the MP to the PS. The ACL-PCL and the MP were preferred equally.

The MP was preferred over the PCL by 76.0%, and 61.4% preferred the MP over the MB. The PS and PCL were preferred equally. Range of motion, pain relief, alignment, and stability did not vary significantly by prosthesis used. Patients with bilateral total knee arthroplasties preferred retention of both cruciates with use of the ACL-PCL prosthesis or substituting with an MP prosthesis.

Key Features - Stability

Simulated kinematic performance of the GMK Sphere total knee design during a stand to squat activity

MORRA E. A., GREENWALD A. S. - Study report, Orthopaedic Research Laboratories Cleveland, OH USA, 2013

INTRODUCTION

A total knee arthroplasty (TKA) that closely approximates the feel and function of a healthy un-operated knee is increasingly identified by both patients and clinicians as an objective of knee replacement surgery. Although TKA surgery enjoys 90% of outcomes with good to excellent results, some patients have difficulty adjusting their gait to accommodate the new articulations inherent in contemporary implant designs. Paradoxical motions inclusive of anterior sliding and lateral pivot are examples of aberrant TKA kinematics. The GMK-Sphere Total Knee is a contemporary design which has a conforming “ball-in-socket” medial femoral tibial articulation intended to confer anterior-posterior stability while the lateral femoral tibial articulation is sagittally unconstrained to allow the rollback observed in the natural human knee. These design features may reduce paradoxical motion and provide more natural kinematics. This paper compares the motion of the GMK-Sphere TKA design with in vivo kinematic data of the healthy, un-operated knee during a deep flexion activity by employing a computational kinematic model of the design which facilitates comparison.

COMPUTATIONAL KINEMATICS

KneeSIM software (LifeModeler, San Clemente, California) provides a dynamic, physics-based, musculoskeletal modeling environment of the left leg of a nominal sized, male, virtual patient.

GMK-Sphere component geometries were derived from the measured articular surfaces of implantable quality components employing a three dimensional laser scanner, rather than relying on idealized computer aided design (CAD) models. The benefit from this reverse-engineering procedure is a determination of actual component fit which directly relates to the accuracy of the manufacturing process. Activities of daily living, such as deep knee bend, are propelled by flexor and extensor muscle groups and restrained by the capsular and ligamentous structures surrounding the knee. A generalized contact algorithm allows the TKA components to articulate in a natural manner during a full activity cycle. Animations of component motions and quantitative data plots are generated to characterize

the resulting kinematics, allowing comparison to those of the healthy intact knee.

Reference markers called Flexion Facet Centers (FFCs) are determined for both the medial and lateral femoral condyles for ten male subjects in the in vivo kinematic study. The markers are located at the geometric center of each condyle. They help quantify the motion of the patient’s femur with respect to the tibia, showing the anterior-posterior motion for each condyle as flexion progresses during a stand to squat activity. The computational kinematic model also uses FFC markers to quantify the progressive path of motion of the GMK-Sphere femoral component. An arbitrary ending flexion angle of 120 degrees was selected for the simulated stand to squat activity. The resulting synchronized animations of component motions and FFC data plots characterize the GMK-Sphere. The anterior-posterior translation of medial and lateral FFCs are compared in the data plot with FFC motion reported in the in vivo kinematic study of weight bearing, healthy intact knees.

DISCUSSION

In general, the GMK-Sphere kinematic pathway compares very favorably with in vivo kinematic data of the healthy, un-operated knee. 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 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.

CONCLUSION

The medially stabilized design of the GMK-Sphere 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.

Femorotibial kinematics and load patterns after total knee arthroplasty: an in vitro comparison of posterior-stabilized versus medial-stabilized design

STEINBRÜCK A., SCHRÖDER C., WOICZINSKI M., FOTTNER A., PINSKEROVA V., MÜLLER P. E., JANSSON V. - *Clin Biomech (Bristol, Avon)*. 2016 Mar;33:42-8

BACKGROUND

Femorotibial kinematics and contact patterns vary greatly with different total knee arthroplasty (TKA) designs. Therefore, guided motion knee systems were developed to restore natural knee kinematics and make them more predictable. The medial stabilized TKA design is supposed to replicate physiological kinematics more than the posterior-stabilized TKA system. We conducted this study to compare a newly developed medial stabilized design with a conventional posterior-stabilized design in terms of femorotibial kinematics and contact patterns in vitro.

METHODS

Twelve fresh-frozen knee specimens were tested in a weight-bearing knee rig after implantation of a posterior stabilized and medial-stabilized total knee arthroplasty under a loaded squat from 20° to 120° of flexion. Femorotibial joint contact pressures in the medial and lateral compartments were measured by pressure sensitive films and knee kinematics were recorded by an ultrasonic 3-dimensional motion analysis system.

FINDINGS

The medial stabilized design showed a reduction of medial femorotibial translation compared to posterior-stabilized design (mean 3.5mm compared to 15.7mm, $P<0.01$). In the lateral compartment, both designs showed a posterior translation of the femur with flexion, but less in the medial stabilized design (mean 14.7mm compared to 19.0mm, $P<0.01$).

In the medial femorotibial compartment of medial stabilized design, we observed an enlarged contact area and lower peak pressure, in contrast in the lateral compartment there was a reduced contact area and an increased peak pressure.

INTERPRETATION

While posterior-stabilized design enforces a medio-lateral posterior translation, the medial stabilized arthroplasty system enables a combination of a lateral translation with a medial pivot, which restores the physiological knee kinematics better.

Can a total knee arthroplasty be both rotationally unconstrained and anteroposteriorly stabilised? A pulsed fluoroscopic investigation.

SCOTT G., IMAM M. A., EIFERT A., FREEMAN M. A. R., PINSKEROVA V., FIELD R. E., SKINNER J., BANKS S. A. - *Bone Joint Res.* 2016 Mar;5(3):80-6

OBJECTIVES

Throughout the 20th Century, it has been postulated that the knee moves on the basis of a four-bar link mechanism composed of the cruciate ligaments, the femur and the tibia. As a consequence, the femur has been thought to roll back with flexion, and total knee arthroplasty (TKA) prostheses have been designed on this basis. Recent work, however, has proposed that at a position of between 0° and 120° the medial femoral condyle does not move anteroposteriorly whereas the lateral femoral condyle tends, but is not obliged, to roll back – a combination of movements which equates to tibial internal/ femoral external rotation with flexion. The aim of this paper was to assess if the articular geometry of the GMK Sphere TKA could recreate the natural knee movements in situ/in vivo.

METHODS

The pattern of knee movement was studied in 15 patients (six male; nine female; one male with bilateral TKAs) with 16 GMK Sphere implants, at a mean age of 66 years (53 to 76) with a mean BMI of 30 kg/m² (20 to 35). The motions of all 16 knees were observed using pulsed fluoroscopy during a number of weight-bearing and non-weight-bearing static and dynamic activities.

RESULTS

During maximally flexed kneeling and lunging activities, the mean tibial internal rotation was 8° (standard deviation (sd) 6). At a mean 112° flexion (sd 16) during lunging, the medial and lateral condyles were a mean of 2 mm (sd 3) and 8 mm (sd 4) posterior to a transverse line passing through the centre of the medial tibial concavity. With a mean flexion of 117° (sd 14) during kneeling, the medial and lateral condyles were a mean of 1 mm (sd 4) anterior and 6 mm (sd 4) posterior to the same line. During dynamic stair and pivoting activities, there was a mean anteroposterior translation of 0 mm to 2 mm of the medial femoral condyle. Backward lateral condylar translation occurred and was linearly related to tibial rotation.

CONCLUSION

The GMK Sphere TKA in our study group shows movements similar in pattern, although reduced in magnitude, to those in recent reports relating to normal knees during several activities. Specifically, little or no translation of the medial femoral condyle was observed during flexion, but there was posterior roll-back of the lateral femoral condyle, equating to tibiofemoral rotation. We conclude that the GMK Sphere is anteroposteriorly stable medially and permits rotation about the medial compartment.

Changes in anteroposterior stability and proprioception after different types of knee arthroplasty

WAUTIER D., THIENPONT E. - *Knee Surg Sports Traumatol Arthrosc.* 2016 Feb 11

PURPOSE

To compare different types of knee arthroplasty, in selected patients with a knee score above 80 points, for their post-operative changes in anteroposterior (AP) laxity and proprioception.

METHODS

Four groups of each ten patients were tested for AP translation after different types of arthroplasty with a KT-1000 device at 30°, 60° and 90° of flexion. Proprioception of the joint was evaluated by joint position sense with three different tests. Clinical outcome of stability and proprioceptive testing was analysed by comparing the results of three (KSS, KOOS and FJS-12) patient-reported outcome measurement scores (PROMS) for each of the different implant types.

RESULTS

Anteroposterior laxity was observed at 30° and 90° of flexion for the two PS TKA designs included in this study, but not for the UKA or the medial pivot design. All knee designs, except UKA, had an increased laxity at 60° of flexion. Proprioceptive testing was inconclusive. PROMS were not able to identify differences in clinical outcome among different knee designs in these selected patients, despite observed differences in AP laxity.

CONCLUSION

Increased AP laxity is a result of the surgical procedure in knee arthroplasty. UKA is the only design mimicking native laxity of the knee. A medial pivot design can obtain the same result as UKA at 30° and 90° of flexion, but not at the importantly cited 60° of flexion as tested under non-load-bearing conditions. The clinical relevance of this study is that despite of an important range of AP translations among the different knee designs, good-to-excellent patient-reported outcome was observed within the findings of this study.

Prospective observational study on medial stabilized knee design

BEAL M. - Podium presentation at the 8th M.O.R.E. Symposium Lugano, 2016

INTRODUCTION

Total knee arthroplasty is a well-established procedure to treat the pain and disability associated with osteoarthritis of the knee, but many patients still experience dissatisfaction with this surgery, possibly due to some subtle instability needed for higher order activity such as stair climbing. Patient satisfaction after a total knee replacement is likely multifactorial, but instability of the components is a likely cause of postoperative pain and dissatisfaction.

MATERIAL AND METHODS

Medial stabilized knee designs offer enhanced sagittal stability through the arc of flexion. We used a custom infrared navigation system and stability assessment rig to examine the passive kinematics of femur with respect to the tibia and to obtain force displacement data in the anterior-posterior (AP), varus-valgus (VV), and internal-external (IE) rotation planes using an instrument handle with a load cell. The passive kinematics for the femur and tibia were collected using the navigation system that measured the forces applied to the lower limb as it was moved in the sagittal, frontal, and transverse planes independently. Knee stability data were collected before and after arthroplasty when the knee was flexed at 0°, 20°, 60°, and 90° in 18 cadaveric specimens. Before the components were cemented in the knee, the orientation of the bone cuts was recorded using the navigation system. Paired t-tests were used to test for differences in maximum anterior displacement during passive kinematics and in ranges of motion during knee stability tests before and after TKA. The data was quality-checked for normality, and non-normal data was either transformed or tested using a non-parametric Mann-Whitney test.

RESULTS AND DISCUSSION

During passive kinematics, maximum anterior displacement after TKA ($\mu = 12.61$ mm) was significantly greater than maximum anterior displacement before TKA ($\mu = 6.90$ mm) ($p < 0.001$), and the knee were in deeper flexion when this maximum occurred ($p < 0.001$) likely related to the increased translation of the lateral compartment of the knee. We found no statistical difference in AP translation between the preoperative state with both cruciate ligaments intact and the medial stabilized total knee replacement. In addition, increased IE rotation of the tibia with respect to the femur was found in the post reconstruction knee. Our findings show a tendency for increased sagittal stability of a medial stabilized knee design with increased rotation of the tibia with respect to the femur in the post reconstruction state.

Simulation Analysis of Design and Alignment Variables in Knee Arthroplasty

GREENWALD A. S., MORRA E. A., PHIL(OXON) D. - Podium presentation at the 8th M.O.R.E. Symposium Lugano, 2016

INTRODUCTION

Although Total Knee Arthroplasty (TKA) surgery enjoys 90% of outcomes with good to excellent results, some patients have difficulty adjusting their gait to accommodate the new articulations inherent in contemporary implant designs. This study employs a computational kinematic simulator to compare TKA component motions for a medial pivot and cruciate retaining design during walking gait. The effect of two different surgical alignment methods are also investigated, mechanical alignment and kinematic alignment.

METHODS

KneeSIM software provides a dynamic, physics-based, musculoskeletal modeling environment of a nominal sized, male, Caucasian virtual patient. Activities of daily living, such as level walking gait, are propelled by flexor and extensor muscle groups and restrained by the capsular and ligamentous structures surrounding the knee. A generalized contact algorithm allows the TKA components to articulate in a natural manner during a full activity cycle.

Three-dimensional solid models of the femoral, patellar and tibial insert components were obtained for each total knee design investigated. The modeled components were “implanted” in the virtual joint space per each manufacturer’s mechanical alignment surgical procedure. A standardized ISO level walking gait activity was conducted for both designs. The tibial and femoral components for each design were then rotated 3 degrees valgus to represent a kinematic surgical alignment and the experiment repeated.

RESULTS

Synchronized animations of component motions for both TKA designs were compared side by side from a top down view, with the tibial insert fixed and the relative motion of the femoral component visualized. The femoral motions for mechanical alignment and kinematic alignment scenarios were visually compared.

DISCUSSION AND CONCLUSION

When comparing the effect of surgical alignment on component motions, the motion results varied little for both designs regardless if they were mechanically or kinematically aligned. Both TKA designs are functionally insensitive to surgical alignment during the highly loaded stance portion of walking gait, although some variation was apparent during the less loaded swing phase.

Differences were apparent when comparing the motions of the medial pivot design to the cruciate retaining design. The medial pivot design appeared stable in comparison to the cruciate retaining design, eliminating the paradoxical motions of anterior sliding and lateral pivot displayed by the cruciate retaining design that allowed contact regions to traverse a large distance during an activity cycle.

GMK Sphere: intra-operative observations using navigation

RINCIARI E. - Podium presentation at the 8th M.O.R.E. Symposium Lugano, 2016

INTRODUCTION

The kinematics of the native healthy knee shows a rollback of the lateral femoral condyle concomitant with tibial internal rotation during flexion. The medial femoral condyle however hardly moves anteroposteriorly from full extension to 120° of flexion. From 120° to full flexion, both condyles roll back onto the posterior horn of the medial meniscus.

Mimicking the natural knee kinematics in an artificial prosthesis is thought to be important in improving patient outcomes and may also determine the long-term survival. The type and the design of the prosthesis along with the surgical procedure can affect the final kinematics of the knee, which can eventually influence outcome.

The GMK Sphere Total Knee System is an innovative design which has a highly conforming medial “ball-in-socket” femoro-tibial articulation intended to deliver anterior-posterior stability. On the contrary the lateral femoro-tibial articulation is unconstrained to accommodate the rollback observed in the natural human knee. These design features may reduce paradoxical motion and provide more natural kinematics.

MATERIAL AND METHODS

The purpose of this study is to evaluate GMK Sphere kinematics in vivo and, using a computer, measure medial AP stability, rotation and lateral shift during active flexion and extension movements. An infrared-based navigation system (iMNS, Medacta International, Castel San Pietro, Switzerland) has been used to measure the translation of the medial and lateral compartments of the knee. 50 patients undergoing GMK Sphere total knee arthroplasty will be enrolled in the study.

The translation of the medial and lateral compartments is calculated from the Femoral Flexion Facets (FFCs) translations projected, with the aid of dedicated software, perpendicular to the tibia cut plane, as previously checked and validated. Anterior/posterior translation (mm) of the projection of the medial and lateral FFCs on the tibial cut plane will be plotted in relation to leg flexion. The acquisition of the kinematic diagram is performed through a flexion/extension movement. Antero-posterior behaviour through the entire ROM of the medial and lateral FFCs will be graphically represented in terms of linear displacement (mm), starting from the initial position up to maximum

flexion. In this study a sensitive, non-motor spinal block anesthesia was used, with active, non-weight-bearing motion recorded.

RESULTS AND DISCUSSION

15 patients have been enrolled for this preliminary analysis. The only quantitative outcome that we can draw today is that the overall range between the initial position and 90° is significantly different between the medial and lateral compartments. In particular, the lateral compartment shifts much more than the medial (8.133 Vs 2.000), and overall both translate posteriorly. These findings seem to prove the expected AP stability of the medial ball-in-socket design especially in the arc of mid-flexion, but this finding should be verified on a wider sample.

This study has some limitations: the patient is not under load, motor block anaesthesia could influence the physiological joint movement during passive flexion-extension of the leg, the physiological lengthening of thigh muscles can be affected by the use of tourniquet with possible changes of the joint movement.

Key Features - Natural patella tracking

Kinematics and contact patterns before and after TKA: an in vitro comparison of Medial Stabilized vs. Posterior Stabilized design

STEINBRÜCK A., SCHRÖDER C., WOICZINSKI M., TATJANA M., FOTTNER A., PINSKEROVA V., MÜLLER P., JANSSON V. - Podium presentation at the International Society for Technology in Arthroplasty, Vienna, Austria, September 2015

INTRODUCTION

Despite consequent advancement in Total Knee Arthroplasty (TKA) up to 20% of patients are not satisfied after having been operated. Beside correct implantation, the design of the TKA-system is supposed to be a key factor of a successful TKA. Consequently it has been tried to restore natural kinematics by the design of the prosthesis. A medially stabilized design therefore is supposed to allow a lateral translation with a medial pivot.

OBJECTIVES

Our study compared posterior stabilized (PS) with medially stabilized (MS) TKA-design in terms of kinematics, femorotibial and patellofemoral contact patterns in vitro.

METHODS

Twelve fresh frozen human knee specimen (8 male, 4 female, Ø 63,9 y) were tested in a knee rig under natural condition and after TKA with the two different types of TKA systems (GMK PS; GMK MS Sphere; Medacta International, Switzerland). The knee rig simulated a loaded squat from approximately 20°-120° of flexion with a ground reaction force of 50 N. An ultrasound 3D-motion analysis system (Zebris, CMS 10, Germany) measured complete knee kinematics and pressure sensitive foils (Tekscan Inc. US) analysed the femorotibial and patellofemoral contact patterns. By having the same bone cuts for the PS and MS knee system the direct comparison within every single knee specimen could be performed. For statistics mixed effects models were applied by utilizing random intercept per specimen to compare PS and MS during the whole squat. $P < 0.05$ represented statistical differences.

RESULTS

Femorotibial kinematics of MS design showed a significant reduction of medial femorotibial translation compared to PS design. At 120° of flexion the PS design displayed a mean posterior translation of the femur related to the tibia of 15.62 mm, while the MS design translated medially only an average of 3.45 mm in the same direction. In the lateral compartment both designs showed a posterior translation of the femur in relation to the tibia. At 120° of flexion the femur of the PS design translated 19.00 mm posteriorly compared to the MS design with 14.73 mm ($p < 0.01$). In the medial femorotibial compartment of MS design we observed an enlarged contact area (+175.6 mm²) and lower peak pressure (4.83 MPa), in contrast in the lateral compartment there was a reduced contact area (-19.68 mm²) and increased peak pressure (+0.63 MPa) compared to PS design ($p < 0.01$). The retropatellar peak pressure increased significantly after TKA, while the contact area decreased significantly compared to natural conditions. The contact area at 120° flexion showed no difference between GMK Sphere and the natural knees. The PS had a lower contact area. Retropatellar mean pressure increased for the PS compared to MS and natural knee (Figure 9). There was no significant difference of the retropatellar peak pressure between MS and PS.

CONCLUSION

Neither of the two designs seems to replicate completely the physiological movement of the knee. However, the MS TKA system provided a lateral translation with a medial stable compartment, which is supposed to provide a-p stability and restore the physiological knee kinematics in the active arc of flexion. In terms of retropatellar contact patterns MS restored natural conditions better than PS.

Medially stabilized design: the patella-femoral joint kinematics

MANNING D. - Podium presentation at the 8th M.O.R.E. Symposium Lugano, 2016

INTRODUCTION

The patella-femoral joint can be the bell weather of a well functioning knee. Optimal functioning of the patella-femoral joint requires proper femoral and tibial implant positioning in all planes (sagittal, coronal, and axial), proper femoral-tibial balance in the coronal and sagittal plane and kinematics that provide femoral roll back with progressive knee flexion. Unfortunately, most TKA designs are by definition, sagittally unstable as they lack bi-cruciate function and patients may complain of anterior knee pain with weight bearing in flexion activities, a sense of instability and recurrent effusions with increased activity. This may be the reason several investigators have identified less than optimal satisfaction following TKA and the least satisfaction being with weight bearing in flexion activities. The medially stabilized TKA provides enhanced sagittal stability and the patella-femoral joint is the benefactor.

MATERIAL AND METHODS

Our impression of medially stabilized TKA patella-femoral kinematics is formed by 2 recent studies we performed at Northwestern and Ohio State Universities. The first study examined 18 cadaveric normal knees that underwent Sphere TKA with a custom infrared guidance system to assess passive kinematics and specific force translation relationships at 0, 20, 60 and 90 degrees of flexion. The second study is a randomized, prospective single blinded study of PS vs. Sphere TKA. 51 patients were successfully randomized to receive GMK PS vs. Sphere TKA and have 1-2 year follow-up. Outcomes included clinical scores (knee society score, VR12, forgotten knee score, Oxford knee score) as well as KT 1000 sagittal plane stability testing and a battery of custom questions. The custom battery of questions (scored on a likert 1-10 scale) was split equally between 2 groups (6 questions each). 1 group focused on patient satisfaction with weight-bearing-in-flexion activities and the other on non-flexion activities. Each question was compared between PS and Sphere groups and total score for weight-bearing-in-flexion and non-flexion activities (max 60 points each) were compared between PS and Sphere groups.

RESULTS

In the cadaveric study, the normal knee and the post reconstruction Sphere TKA were identical in varus-valgus stability at each range of flexion tested at up to 10 N. ($p=0.57-0.25$). Anterior-posterior (sagittal plane) stability was also statistically identical to the native state in mid flexion (20 and 60 degrees flexion) at up to 100N ($p=0.29 - 0.37$). Internal-External motion throughout the arc of flexion was also statistically identical to native state ($p=0.11$).

In the clinical study, to no surprise, we found no difference in clinical scores with the small number of patients studied. These blunt instruments have routinely been unable to identify differences in clinical outcome between prosthesis due to almost universally good outcomes. However, sagittal plane stability was significantly enhanced in the Sphere group in mid flexion. KT1000 readings for the PS group averaged 10.3 mm at 30 degrees knee flexion at 30Lb force while the Sphere knees averaged 5.7mm ($p<0.0001$). The custom battery of questions (Weight-bearing-in-flexion group: satisfaction with kneel, squat, descend stairs, ascend stairs, out of chair, and off toilet; Non-flexion group: satisfaction with sitting, light housework, walking, standing, bending, and lying) showed a clear preference for Sphere TKA during flexion activities. Sphere total weight-bearing-in-flexion score was significantly higher than that for PS ($p=0.04$) while no difference was identified in non-flexion activities between the groups.

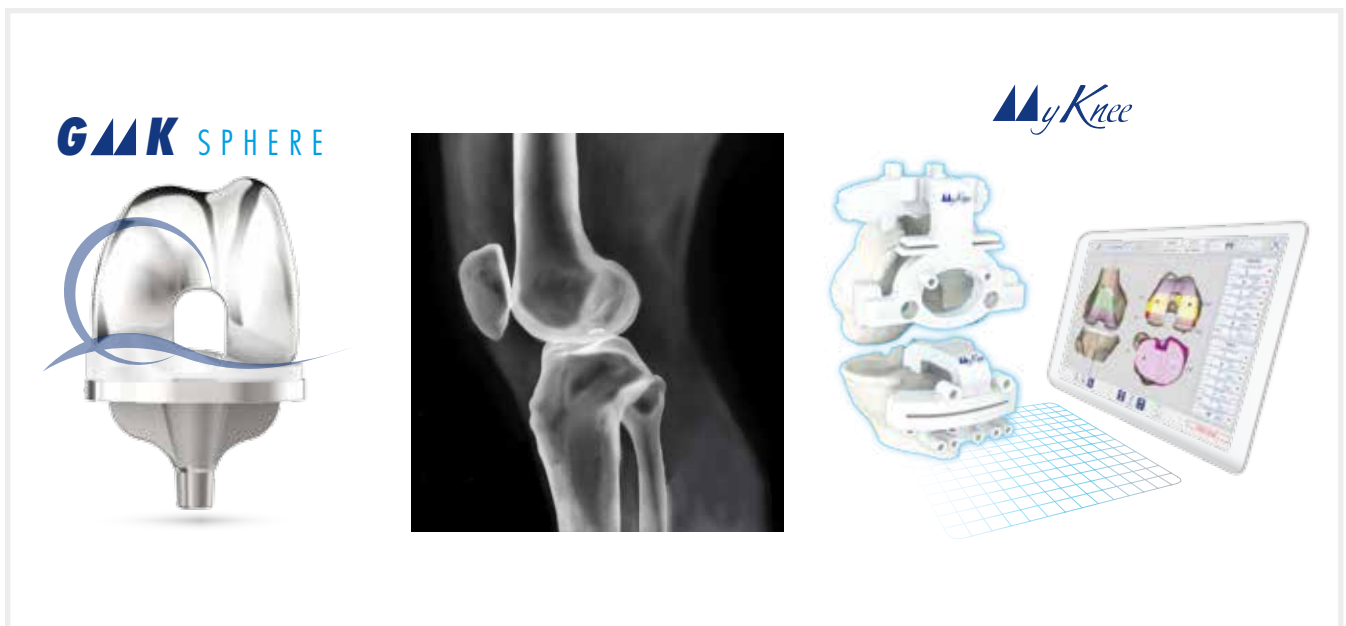
CONCLUSION

In conclusion the medially stabilized TKA design affords sagittal plane stability akin to the native knee in mid flexion allowing patients to excel during weight bearing in flexion. This relationship is favorable to the patella femoral joint, improves quadriceps power and efficiency and decreases anterior knee pain when femoral and tibial implants are appropriately placed.

Key Features - Anatomic fit

The GMK Sphere AP/ML aspect ratio was validated by an extensive anthropometric research on the MyKnee Patient Matched Technology database, containing at the time of the study more than 15,000 CT and MRI scans of knees from all over the world.

This analysis led to an unparalleled range of 13 AP femoral profiles in 2 mm increment, as well as to 6 anatomic, left and right, tibia sizes.



Key Features - Patient specific kinematics

In vivo kinematics of a medially conforming & rotationally unconstrained TKA design introduction

IMAM M., EIFERT A., FIELD R., BANKS S. - Podium presentation at the International Society for Technology in Arthroplasty, Kyoto, Japan, September 2014

Total knee arthroplasty (TKA) designs evolve as evidence accumulates on natural and prosthetic knee function. TKA designs based upon a medially conforming tibiofemoral articulation seek to reproduce essential aspects of normal knee stability and have enjoyed good clinical success and high patient satisfaction for over two decades. Fluoroscopic kinematic studies on several medially conforming knee designs show extremely stable knee function, but very small ranges of tibial axial rotation compared to healthy knees. The GMK Sphere TKA is a recent evolution in medially-conforming TKA designs that adopts a sagittally unconstrained lateral tibiofemoral articulation to allow more natural tibial rotation. This study was conducted to quantify motions in knees with this prosthesis to address two questions:

1. 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?
2. 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?

MATERIALS AND METHODS

Fifteen patients (9 females), mean age 65 years and mean BMI of 30 ± 3 , consented to participate. Sixteen knees received the GMK Sphere TKA. Mean Oxford Knee Score (OKS) improved significantly from 19 ± 7 to 40 ± 3 six months post-surgery ($P < 0.0001$). On the day of the study, the mean OKS, Knee Society Score, EQ5D and Heath status scores were 40, 87, 0.83 and 85 respectively. Mean ROM from active maximum extension till maximum supine flexion was $108^\circ \pm 8^\circ$.

Motions in 16 knees were observed using pulsed-fluoroscopy during a range of activities. Subjects were observed in maximum flexion kneeling and lunging positions, and in stepping up/down on a 22cm step. Model-image registration methods were used to quantify three-dimensional knee motions from digitized fluoroscopic images.

RESULTS

Tibial internal rotation averaged 8° during lunge and kneeling activities. During lunging, the medial and lateral condyles were an average of 2mm and 8mm posterior to the tibial sulcus, respectively, and 2mm and 9mm posterior to the tibial sulcus during kneeling. During the stair-stepping activity, the medial condyle did not translate significantly, while the lateral condyle moved 5mm posteriorly with flexion, accompanying 5° tibial internal rotation.

DISCUSSION

The GMK Sphere TKA was designed to provide intrinsic stability through a medially conforming articulation, and provide for more natural tibial rotation with an unconstrained lateral articulation. Fluoroscopic observation of these knees during lunge, kneel and stair-stepping activities 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 et al., *Knee Surg Sports Traumatol Arthrosc*, 2009) and similar to that observed in natural knees with medial osteoarthritis (Hamai et al., *J Orthop Res*, 2009). At only six 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.

Patient satisfaction

GMK Sphere. International, multi-centre, prospective, observational study

FIELD R., SKINNER J., SCOTT G., VAN OVERSCHELDE P. - Podium presentation at the 8th M.O.R.E. Symposium Lugano, 2016

INTRODUCTION

The research department at the South West London Elective Orthopaedic Centre (SWLEOC) co-ordinates UK and international, multi-surgeon, multi-centre surveillance studies of hip and knee implants to provide medium and long-term outcome data on implant performance and survival. Studies are designed to comply with the UK Orthopaedic Data Evaluation Panel (ODEP) recommendations. Data obtained from these ODEP surveillance studies can be benchmarked against data our institution's database containing outcome information from over 35'000 hip and knee replacement patients.

MATERIAL AND METHODS

The GMK Sphere ODEP study started in October 2012. To date, 283 operations have been entered into the study. The study group comprises 172 female and 111 male subjects. At surgery, the average Age and BMI of the study subjects was 67.4 years (range 31-88 yr) and 30.33 (range 19.04 – 43.58) respectively. The operations were undertaken by eight surgeons, at four centres - the Royal National Orthopaedic Hospital, Stanmore; the Royal London Hospital, London; The South west London Elective Orthopaedic Centre, Epsom and AZ Maria Middelaers, Ghent, Belgium.

To date, 4 study subjects have withdrawn, three have died and two knees have been revised. Euroqol (EQ5D), and Oxford Knee Scores, and Knee Society scores have been collected. Radiographic analysis has been undertaken. By the middle of March 2016, 6 month, 1, 2 and 3 year data had been obtained for 236, 171, 81 and 20 study subjects, respectively.

RESULTS

The average EQ5D, Health State Scores, Oxford Knee Scores, IKSS Knee score & IKSS Function scores are shown below:

	Pre-op	6 Months	1 Year	2 Years	3 Years
EQ5D	0.446 (SD 0.271)	0.709 (SD 0.239)	0.766 (SD 0.230)	0.732 (SD 0.283)	0.789 (SD 0.230)
Health State	64 (SD 19.78)	73 (SD 16.66)	77 (SD 19.04)	76 (SD 20.96)	77 (SD 19.76)
Oxford	19.31 (SD 8.04)	34.96 (SD 8.46)	37.50 (SD 9.41)	36.55 (SD 10.50)	39.75 (SD 7.98)
IKSS Knee Score	41.0 (SD 16.05)	73.9 (SD 14.28)	N/A	N/A	84.6 (SD 9.21)
IKSS Function Score	48 (SD 18.35)	80 (SD 20.48)	N/A	N/A	85 (SD 21.29)

CONCLUSION

One of the analyses that we undertake in our early evaluation of implants is to examine the patient reported pre-operative to post-operative improvements in each of the twelve domains of the Oxford knee score. Our early data-set shows that GMK Sphere patients enjoy a greater increase in several domains when compared to other designs of knee replacement. Patient matching and evaluation of more cases, at more time points will identify whether this early observation is confirmed by rigorous statistical analysis.

Greater Medial Compartment Forces During Total Knee Arthroplasty Associated With Improved Patient Satisfaction and Ability to Navigate Stairs

JACOBS C. A., CHRISTENSEN C. P., KARTHIKEYAN T. - *J Arthroplasty*. 2016 Sep;31(9 Suppl):87-90

BACKGROUND

The purpose of this study was to determine if postoperative patient satisfaction, subjective outcomes, and functional force testing differed between those with symmetric or asymmetric intraoperative mediolateral (ML) compressive forces. We hypothesized that the threshold would be similar to the previously reported valued of 15 lbf and that a significantly greater proportion of those with more symmetrical medial and lateral compressive forces would be satisfied with their total knee arthroplasty.

METHODS

A commercially available instrumented trial tibial liner was used to measure ML compressive force differences with the knee at 0°, 20°, and 90°. Patient satisfaction and Knee Society Scores were compared between patients with ML asymmetries above and below the calculated optimal threshold.

RESULTS

Surprisingly, lower ML asymmetries in extension were associated with a greater risk of being dissatisfied. Of the 50 total knee arthroplasties, 6 of 23 (26%) with ML force asymmetries <10 lbf were dissatisfied compared with 0 of 27 with ML asymmetries >10 lbf ($P = .01$). Greater asymmetry was associated with significantly greater gains in EQ-5D scores ($P = .05$) and pain scores ($P = .03$) and greater pain relief ($P = .006$) and reduced impact forces when navigating stairs ($P = .05$).

CONCLUSION

Contrary to our hypotheses, the results of this study support the concept that recreating greater forces in the medial compartment much like that of the native knee may yield improved patient reported outcomes and increased patient satisfaction. The current results further suggest that recreating greater medial compartment forces may have the greatest affect on more demanding activities such as navigating stairs.



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HEADQUARTERS

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

REPRESENTATIVE

Switzerland - Frauenfeld

Gewerbestrasse 3 - 8500 Frauenfeld
Phone +41 (0) 848 423 423 - Fax +41 (0) 848 423 424 - info@medacta-swiss.ch

SUBSIDIARIES

Australia - Medacta Australia PTY.LTD

Unit A1, 16 Mars Road - Lane Cove - NSW 2066
Phone +61 (2) 94202944 - Fax +61 (2) 94202578 - info@medacta.com.au

Belgium - Medacta Belgium B.V.B.A./S.P.R.L.

5a Rue de la Maîtrise - 1400 Nivelles
Phone +32 (0) 67 555 482 - Fax +32 (0) 67 555 483 - info@medacta.be

Canada - Medacta Canada Inc.

31 McBrine Drive, Unit 11- N2R 1J1 - Kitchener, Ontario
Phone +1 519 279 1934 - Fax +1 519 279 1938 - info@medacta.ca

China - Medacta China

Room 610, Building 1, No. 363 Changping Road - Shanghai, China
info@medacta.cn

France - Medacta France SAS

6 Rue du Commandant d'Estienne d'Orves - Parc des Chanteraines - 92390 Villeneuve - La Garenne
Phone +33 147 39 07 22 - Fax +33 147 39 73 17 - info@medacta.fr

Germany - Medacta Ortho GmbH

Jahnstrasse 86 - D - 73037 Göppingen
Phone +49 (0) 7161 50 44 30 - Fax +49 (0) 7161 50 44 320 - info@medacta.com

Italy - Medacta Italia Srl

Via G. Stephenson, 94 - 20157 Milano
Phone +39 02 390 181 - Fax +39 02 390 00 704 - mail@medacta.it

Japan - Medacta Japan CO. LTD

Chichibuya Bldgs. 2F 3-7-4 Kojimachi, Chiyoda-ku, Tokyo 102-0083
Phone +81 (0) 3 6272 8797 - Fax +81 (0) 3 6272 8798 - info@medacta.co.jp

Spain - Medacta España SLU

Avda de las Jacarandas - 2 - Edificio CREA Oficina 631- 46100 - Burjassot
Phone +34 (0) 963 484 688 - Fax +34 (0) 963 484 688 - info@medacta.es

UK - Medacta UK Limited

16 Greenfields Business Park - Wheatfield Way - Hinckley - Leicestershire - LE10 1BB
Phone +44 (0) 1455 613026 - Fax +44 (0) 1455 611446 - info@medacta.co.uk

USA - Medacta USA, Inc.

1556 West Carroll Avenue - Chicago - IL 60607
Phone +1 312 878 2381 - Fax +1 312 546 6881 - info@medacta.us.com

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