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The ACL-PCL Substituting Knee

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# Clinical Summaries

 **MicroPort**  
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# Clinical Summaries

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# Clinical Summaries

## Medial-Pivot Kinematics

### Barnes, 2011

#### **Kneeling Is Safe for Patients Implanted With Medial-Pivot Total Knee Arthroplasty Designs.**

*Barnes CL et al.*

*JOA. 26(4): 549-554.*

- ▶ Nine ADVANCE Medial-Pivot (MP) and 9 ADVANCE Double-High (DH) TKA's were analyzed under radiographic surveillance at standing, mid kneeling, and full kneeling.
- ▶ In vivo tibiofemoral contact positions were obtained using the 3- to 2-dimensional image registration technique.
- ▶ This study indicates that kneeling is safe in MP total knee arthroplasties even in the absence of a cam-post or posterior cruciate ligament.
- ▶ The patients performed the activity without any discomfort and the femorotibial AP articulation remained within the confines of the design geometry.

### Miyazaki, 2011

#### **Analysis of the Kinematics of Total Knee Prostheses With a Medial Pivot Design.**

*Miyazaki Y et al.*

*JOA. 26(7): 1038-1044.*

- ▶ Analysis of the kinematics of the ADVANCE knee revealed that the medial condyle is fixed and the lateral condyle shows anterior movement in the early stage, changing thereafter to posterior movement.
- ▶ The amount of movement of the medial condyle was almost fixed. On the other hand, after showing initial anterior movement in the early stage of flexion, the lateral condyle began to show posterior movement in many patients.

### Freeman/Pinskerova, 2005

#### **The movement of the normal tibio-femoral joint.**

*Freeman MR and Pinskerova V.*

*Journal of Biomechanics. 2005; 38(2): 197-208.*

- ▶ Using fluoroscopy, MRI, CT, or RSA, this review found that medially the condyle hardly moves antero-posteriorly from 0° to 120° but the contact area moves backward in flexion, not the condyle.
- ▶ Laterally the femoral condyle and the contact area move posteriorly but to a variable extent in the mid-range causing tibial internal rotation to occur with flexion around a medial axis.

### Komistek, 2003

#### **In vivo fluoroscopic analysis of the normal human knee.**

*Komistek RD, Dennis DA, Mahfouz M.*

*Clin Orthop Relat Res. 2003; 410:69-81.*

- ▶ The objective of the current study was to use fluoroscopy and CT to accurately determine the three-dimensional, in vivo, weight-bearing kinematics of five normal knees in five activities.
- ▶ During all five activities, the lateral condyle experienced significantly more anteroposterior translation, leading to axial rotation of the tibia relative to the femur.

# Clinical Summaries

## Medial-Pivot Kinematics

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### Schmidt, 2003

#### Fluoroscopic analyses of cruciate-retaining and medial pivot knee implants.

Schmidt R, et al.

*Clinical Orthopaedics and related research.*

2003; 410:139-47.

- ▶ Study compared the gait kinematics of the Sigma CR, the Advance CR, and the Advance CS using fluoroscopic analysis.
- ▶ Data suggested that the Advance MP TKA shows a MP motion during the stance phase of gait with a lower frequency of condylar lift-off than conventional CR designs.

### Blaha, 2003

#### Kinematics of the human knee using an open chain cadaver model.

Blaha JD et al.

*Clin Orthop Relat Res.* 2003 May;(410):25-34.

- ▶ This study used seven knees from cadavers moved by pulling on the quadriceps tendon in an open chain fashion using video motion analysis to determine the instantaneous helical axis of movement.
- ▶ The results of this study show that the medial side of the knee stays stable in spinning kinematics whereas the lateral side has a rolling motion in full flexion progressing to a spinning motion in midflexion and counter-translation near full extension.

### Freeman/Pinskerova, 2000

#### Tibiofemoral movement 1: the shapes and relative movements of the femur and tibia in the unloaded cadaver knee.

H Iwaki, V Pinskerova, MAR Freeman.

*JBS Br, 82-B:8 (2000): 1189-1195.*

- ▶ The purpose of this study was to determine the shapes and movements of the articular surfaces in six unloaded cadaveric knees.
- ▶ The medial femoral condyle does not move in the AP direction until flexion of 110° is obtained.
- ▶ Both medial and lateral femoral condyles found to be circular.

### Hill, 2000

#### Tibiofemoral movement 2: the loaded and unloaded living knee studied by MRI.

P Hill, H Iwaki, V Pinskerova, MAR Freeman.

*JBS Br, 82-B:8 (2000): 1196-1198.*

- ▶ This study sought to determine if living knees behaved similarly in terms of motion to the above mentioned findings from cadaver knees.
- ▶ Images taken of 13 normal knees in all phases of flexion.
- ▶ Medial AP position did not change from -5° to 110°.
- ▶ Lateral side rolled forward from flexion to extension.

# Clinical Summaries

## Medial-Pivot Kinematics

### Nakagawa, 2000

#### Tibiofemoral movement 3: full flexion in the living knee studied by MRI.

S Nakagawa, MAR Freeman et al.  
*JBJS Br*, 82-B:8 (2000): 1199-1200.

- ▶ This study examined the active flexion from 90° to 133° and passive flexion to 162° using MRI in 20 unloaded knees in Japanese.
- ▶ Flexion past that arc was accompanied by backward movement of the medial femoral condyle 4.0 mm and by backward movement laterally of 15 mm, i.e., by internal rotation of the tibia.
- ▶ At 162° the lateral femoral condyle lies posterior to the tibia.

## Survivorship

### Fitch/Sedacki, 2014

#### Mid- to long-term outcomes of a medial-pivot system for primary total knee replacement – A systematic review and meta-analysis.

DA Fitch, PhD, K Sedacki, MS, Y Yang, MA, MS, Biostatistician  
*Bone Joint Res*. 2014 Oct; 3(10): 297-304.

- ▶ Included 8 studies with a total of 1146 TKR's performed in 6 countries.
- ▶ The pooled component survivorship estimates were **99.2% and 97.6% at 5 and 8 years**, respectively.
- ▶ Additionally, the weighted mean post-operative KSS was 87.9, in the excellent range.

#### ▶ OPEN ACCESS ARTICLE

### Chinzei, 2014

#### Satisfactory results at 8 years mean follow-up after Advance MP TKA.

Chinzei N, et al.  
*Knee*. 2014; 21(2):387-390.

- ▶ This study aimed to investigate the clinical and radiological results and complications of 76 TKA's using the Advance MP, at mid-term follow-up.
- ▶ Survivorship analysis indicated a success rate of **98.3%**.
- ▶ Patients achieved excellent clinical and radiographic results without any implant-related failures at mid-term follow-up.

### Schmidt, 2014

#### Midterm clinical and radiographic results of the medial pivot total knee system.

Schmidt R, Ogden S, Blaha JD, Alexander A, Fitch DA, Barnes CL.  
*International Orthopaedics*. 2014.

- ▶ Study found component survivorship (Advance MP), excluding revisions for infection or trauma, was **96.6% at five years in 365 TKA's**.
- ▶ The average Knee Society score was 95.5 at final follow-up, with 358 (98%) having excellent or good results.

# Clinical Summaries

## Survivorship

### Vecchini, 2012

**Clinical and radiologic outcomes of total knee arthroplasty using the ADVANCE Medial Pivot Prosthesis. A mean 7-years follow-up.**

*Vecchini E, et al.*

*The Knee. 2012; 19: 851-855.*

- ▶ The purpose of this study was to evaluate clinical and radiologic results of the 172 Advance Medial Pivot Total Knee Arthroplasties, at a mean follow-up of 7 years.
- ▶ The Kaplan–Meier survivorship analysis showed a cumulative success rate of **98.6%**.

### Karachalios, 2009

**A mid-term clinical outcome study of the Advance Medial Pivot knee arthroplasty.**

*Karachalios T, et al.*

*The Knee. 2009. 16(6):484-8.*

- ▶ Prospective clinical outcome study of 284 arthroplasties in 225 consecutive patients with a mean follow-up of 6.7 years (range 4 to 9 years).
- ▶ Survival analysis showed a cumulative success rate of **99.1%** at 5 years.
- ▶ This study demonstrates satisfactory mid-term clinical results for this knee design.

### Yuom, 2014

**Total Knee Arthroplasty Using a Posterior Cruciate Ligament Sacrificing Medial Pivot Knee: Minimum 5-year Follow-up Results.**

*Yuom Y-S, et al.*

*Knee Surg Relat Res. 2014. 26(3):135-140.*

- ▶ The purpose of this study was to evaluate minimum 5-year follow-up clinical and radiological results of TKA using a posterior cruciate ligament sacrificing (PS), non-substituting Advance Medial Pivot Knee.
- ▶ 120 knees were examined in the study.
- ▶ KS knee and function scores, as well as WOMAC scores were significantly improved after surgery.
- ▶ **The seven-year survival rate was 98.1% in the Kaplan-Meier survival analysis.**

### Brinkman, 2014

**Midterm results using a medial pivot total knee replacement compared with the Australian National Joint Replacement Registry data.**

*Brinkman, Justus-Martijn, et al.*

*ANZ journal of surgery 84.3 (2014): 172-176.*

- ▶ 50 consecutive knee replacements using a medial pivot-type knee replacement were compared with the results in the Australian Orthopaedic Association National Joint Replacement Registry.
- ▶ There was no statistically significant difference in revision rate compared with the registry results.
- ▶ The medial pivot knee-type implant in this series provided pain relief, functional improvement and a revision rate, similar to what is reported in the literature.

# Clinical Summaries

## Survivorship

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### Bae, 2012

#### Clinical Outcome of Total Knee Arthroplasty With Medial Pivot Prosthesis: A Comparative Study Between the Cruciate Retaining and Sacrificing

*Bae DK et al.*

*JOA. 26(5): 693-698*

- ▶ The purpose of this study is to evaluate results after total knee arthroplasty using a medial pivot prosthesis with the posterior cruciate ligament (PCL)-retaining and PCL-sacrificing techniques.
- ▶ 67 CR knees and 70 CS knees were included in the study.
- ▶ The clinical results of total knee arthroplasty with a medial pivot prosthesis were satisfactory, whether the PCL was retained or sacrificed.

### Fan, 2010

#### Primitive results after medial-pivot knee arthroplasties: a minimum 5-year follow-up study.

*Fan, Cheng-Yu, et al.*

*JOA.25.3 (2010): 492-496.*

- ▶ 58 medial-pivot TKA were enrolled with a minimum 5-year follow-up.
- ▶ The Knee Society score improved from 30.5 to 91.1 in objective and from 36.7 to 82.3 in functional scale.
- ▶ The medial-pivot TKA provided significant improvement in the postoperative range of motion, objective Knee Society score, pain scale, and functional score ( $P < .05$ ) statistically.

### Anderson, 2010

#### Medium-Term Results of Total Knee Arthroplasty Using a Medially Pivoting Implant: A Multicenter Study

*MJ Anderson, et al.*

*J of Surg Orthop Adv, 19:4 (2010) p. 191-195.*

- ▶ This study evaluated the performance of the ADVANCE® Medial-Pivot (MP) TKA after a mean follow-up of 5.4 years.
- ▶ Multicenter, prospective clinical study of 276 patients who underwent primary TKA with ADVANCE® Medial-Pivot TKAs.
- ▶ **Survivorship was 97.4% with revision or loosening as the endpoint.**

# Clinical Summaries

## Minimized Contact Stresses

### Clem, 2013

#### Long-term wear analysis of retrieved medially-pivoting TKA patients.

Clem WC, Sambu SN, Bible S, Spurgeon GW, Moseley JP.  
Data on file with MicroPort Orthopedics.

- ▶ Study measured the in- vivo linear wear rate of medially- pivoting tibial inserts using a novel laser scanning technique.
- ▶ The average wear rates of the retrieved MP inserts were 0.052 & 0.030 mm/year on the medial & lateral compartments respectively.
- ▶ The in-vivo wear rates as reported by different manufacturers in the literature ranged from 0.02-0.67 mm/year. The MP inserts exhibited lower wear than the reported values.

### Minoda, 2003

#### Polyethylene wear particles in synovial fluid after TKA.

Minoda Y, et al.  
*Clin Orthop Relat Res.* 2003. 410:165-172.

- ▶ The aim of this current study was to examine polyethylene particles in synovial fluid at an early stage, and to compare the aMP™ Knee System with established PS knees.
- ▶ Synovial fluid was obtained 1 year after knee arthroplasty from 17 patients with well-functioning prostheses (22 knees, 11 posterior-stabilized prostheses and 11 medial pivot prostheses).
- ▶ There was a statistically significant number of fewer particles found in the Medial-Pivot knees compared with the PS knees.

### Schmidt, 2011

#### In Vitro Assessment of a Cruciate Retaining and Cruciate Sacrificing Medially Pivoting Knee Replacement.

Schmidt R, et al.  
Poster No. 1150; ORS 2011 Annual Meeting.

- ▶ The objective of this study was to determine the wear rates of the new eMP™ Total Knee Replacement (TKR) System with conventional polyethylene using an in-vitro wear simulator and compare these results with other knee systems.
- ▶ See below for the wear rates of the different systems.
- ▶ The results for the EVOLUTION® CS illustrate how modern designs with advanced manufacturing techniques can successfully reduce the wear rate of knee replacements without sacrificing fatigue strength in exchange for low wear.

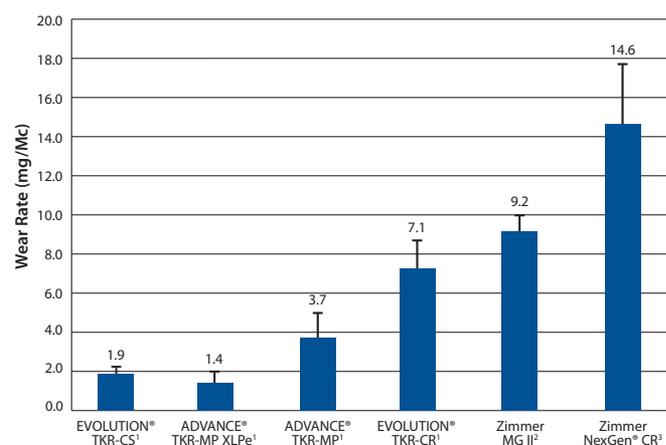


Figure 1: Wear rates for EVOLUTION® and ADVANCE® compared to published wear rates for two Zimmer® systems

1. Data on file at MicroPort Orthopedics Inc.
2. Schwenke T. Difference in wear between load and displacement control tested total knee replacements. *Wear*; 2009, 267: 757-62.
3. Haider et al. "Comparison Between Force-Controlled and Displacement-Controlled in vitro Wear Testing On A Widely Used TKR Implant." *Transactions of the Orthopedic Research Society* 2002, Dallas TX, Vol. 27:1007

# Clinical Summaries

## Enhanced Quad Efficiency

### LaMontaigne, 2014

#### Quadriceps and Hamstring Muscle Activation and Function Following Medial Pivot and Posterior Stabilized TKA: Pilot Study.

LaMontagne M, et al. 2014.

- ▶ This study used electromyography (EMG) analysis to examine knee biomechanical function of total knee patients with a Medial Pivot knee during various slopes and surfaces and sit-to stand tasks.
- ▶ Specifically, the aim was to investigate the muscle function of the quadriceps and hamstring muscles during certain movements and tasks.
- ▶ NexGen PS knee patients were used to compare against the Medial Pivot patients.
- ▶ One of the more important findings was that the Medial Pivot patients showed **less quad activation in various movements, indicating more efficiency.**

### Blaha, 2012

#### Assessment of a Medial Pivot Total Knee Arthroplasty Design in a Cadaveric Knee Extension Test Model.

Blaha JD et al.

JOA. 2012; 27(8): 1460-1468.

- ▶ This study compared in vivo testing with open-kinematic chain behaviors in cadaver knees implanted with a Medial-Pivot prosthesis.
- ▶ Specimen's limbs were computed tomography scanned, and infrared arrays on tibia and femur were registered to bone markers. Motion of the joint and quadriceps force were reported from 90° flexion to full extension.
- ▶ The prosthesis tested exhibits kinematic behavior similar to that in their normal state, **with no difference in quadriceps force required for extension.**

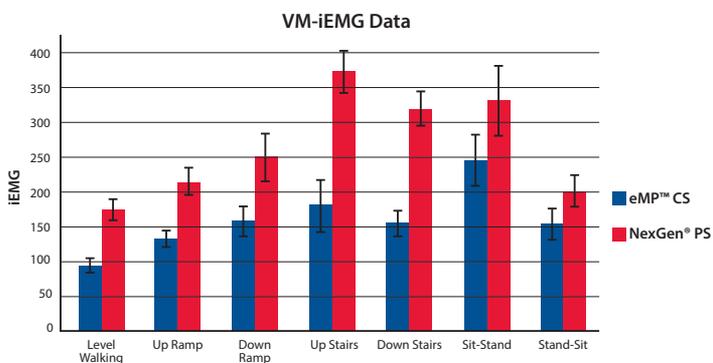
### Mahoney, 2002

#### The effect of total knee arthroplasty design on extensor mechanism function.

Mahoney OM et al.

J Arthroplasty. 2002;17:416.

- ▶ This study compared single- and multi- radius knees and the effect they have the extensor mechanism.
- ▶ 83 knees had a multi-radius knee and 101 had a single-radius knee.
- ▶ They found that the patients with a single-radius implant gained flexion more rapidly, were able to rise from a seated position quicker without using their arms, and had significantly less anterior knee pain.



# Clinical Summaries

## Patient Satisfaction

### Pritchett, 2011

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

Pritchett J.

JOA. 2011; 26 (2): 224-8

- ▶ Total of 440 patients underwent bilateral TKR using a different prosthesis on each side.
- ▶ 5 knee prostheses were used: ACL-PCL retaining, CR, medial or lateral pivot, mobile-bearing, and PS. **Patients preferred retention of both their cruciate ligaments or substitution with a medial or lateral pivot prosthesis over all others.**
- ▶ Author concluded the reasons may have been from increased stability, proprioception and quadriceps efficiency.

### Yuom, 2014

#### Total Knee Arthroplasty Using a Posterior Cruciate Ligament Sacrificing Medial Pivot Knee: Minimum 5-year Follow-up Results.

Yuom Y-S, et al.

Knee Surg Relat Res. 2014. 26(3):135-140.

- ▶ The purpose of this study was to evaluate minimum 5-year follow-up clinical and radiological results of TKA using a posterior cruciate ligament sacrificing (PS), non-substituting Advance Medial Pivot Knee.
- ▶ 120 knees were examined in the study.
- ▶ KS knee and function scores, as well as WOMAC scores were significantly improved after surgery.
- ▶ **The seven-year survival rate was 98.1% in the Kaplan-Meier survival analysis.**

### Schmidt, 2014

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- ▶ Study found component survivorship (Advance MP), excluding revisions for infection or trauma, was **96.6% at five years in 365 TKA's.**
- ▶ **The average Knee Society score was 95.5 at final follow-up**, with 358 (98%) having excellent or good results.

## Noise Generation

### Pritchett, 2013

#### A Comparison of the Noise Generated from Different Types of Knee Prostheses

Pritchett, James W.

Journal of Knee Surgery 26.02 (2013): 101-104.

- ▶ This prospective study was conducted with 465 (930 knees) patients to evaluate noise after bilateral TKA. A different randomly selected prosthesis was used on each side.
- ▶ The prostheses used were medial pivot (MP), anterior and posterior cruciate ligament retaining (ACL-PCL), posterior cruciate ligament retaining (PCL), posterior cruciate-substituting (PS), or mobile bearing (MB).
- ▶ Noise-related symptoms were reported by **12% of the patients with MP prostheses, 4% of patients with ACL-PCL, 31% of patients with PCL, 33% of patients with PS, and 42% of patients with MB.**
- ▶ Occasionally, patients were concerned or dissatisfied with this phenomenon. Noise was less common with TKAs that used MP and ACL-PCL knee prostheses than with TKAs that used other prostheses.

# Clinical Summaries

## Highly Crosslinked Polyethylene (HXLPE) vs. Conventional Polyethylene (CPE)

### Hinarejos, 2013

**Highly Crosslinked Polyethylene does not reduce the Wear in Total Knee Arthroplasty In Vivo Study of Particles in Synovial Fluid.**

*Hinarejos P et al.*

*The Knee. 2013; 28: 1333-1337*

- ▶ The aim of the study was to put to the test in vitro findings among studies suggesting lower wear with highly crosslinked polyethylene.
- ▶ 12 months after surgery, a joint aspiration was performed and the synovial fluid of 34 patients (17 with X3® and 17 with CPE) was studied analyzing the number, size and shape of the polyethylene particles between groups.
- ▶ In all cases, a cemented PS Triathlon was used with either their X3® or conventional polyethylene.
- ▶ No significant difference in the concentration, size, or morphology of polyethylene particles was found in vivo between the two groups.

### Paxton, 2015

**Is there a difference in TKA risk of revision in highly crosslinked versus conventional polyethylene?**

*Paxton E, et al.*

*Clin Orthop Relat Res. 2015.*

- ▶ This study aimed to examine if there were differences among HXLPE and CPE in Nex-Gen and PFC knees.
- ▶ **A total of 60,841 (79%) had CoCr-CPE bearing, 11,048 (14%) had CoCr-HXLPE bearings, and 5195 (7%) were unknown.**
- ▶ At 5 years follow-up, cumulative incidence of revision for CoCr-CPE and CoCr-HXLPE were 2.7% and 3.1%, respectively. Similar results were found in all comparisons. **No differences were found.**

### Inacio, 2013

**Alternative bearings in total knee arthroplasty: risk of early revision compared to traditional bearings. An analysis of 62,177 primary cases.**

*Inacio MC, et al.*

*Acta Orthopaedica. 2013; 84 (2): 145-152.*

- ▶ This study performed an analysis on 62,177 primary cases to compare the short-term revision risk in alternative surface bearing knees.
- ▶ Oxidized Zirconium (OZ) femoral implants with CPE, CoCr w/ HXLPE, and CoCr w/ CPE were all evaluated for their risk of revision.
- ▶ After a median follow-up of 2.8 years, it was determined that neither the OZ-CPE or CoCr-HXLPE demonstrated a statistically significantly higher risk of revision.

### Minoda, 2009

**Comparison between highly cross-linked and conventional polyethylene in total knee arthroplasty.**

*Minoda Y, et al.*

*The Knee. 2009; 16(5): 348-351.*

- ▶ The aim of this study was to compare radiographic and clinical results of CPE and HXLPE in 202 NexGen®, CR TKR's.
- ▶ 113 CPE knees and 89 HXLPE knees were evaluated.
- ▶ Study found no differences in ROM or KSS. There were no revisions or clinical failures between groups.



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