ATTUNE GRADIUS™ Curve- Designed to Reduce Mid Flexion Instability: Summary of the In-Vitro and In-Vivo Science

Mark A. Heldreth, Sr. Engineering Fellow, DePuy Synthes Inc., Warsaw, IN

A summary of work previously published by U. Denver, U. Kansas, & ETH Zurich

1. Introduction

- Mid flexion instability, resulting in "paradoxical" anterior motion of the femur with respect to the tibial, has been previously reported in the literature for various CR knee designs(1)
- A unique, patented, femoral design was developed using a gradually reducing radius (ATTUNE GRADIUS™ Curve) with the goal of reducing mid-flexion instability
- Pre-clinical in-vitro studies at the U. of Kansas and the U. of Denver evaluated the potential for these modifications to reduce mid-flexion instability(2)
- A subsequent in-vivo fluoroscopy study at the ETH in Zurich evaluated mid-flexion stability of ATTUNE® CR FB Knee vs traditional design(3)

ATTUNE GRADIUS™ Curve – gradually changing radius & center of femoral rotation

2. Methods

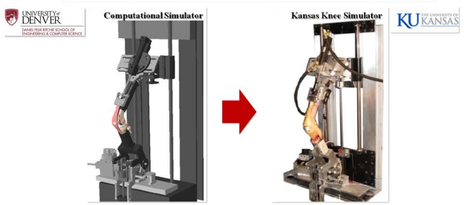
Pre-clinical Computational Design & Experimental Testing

Pre-clinical In-vitro Kinematics

- Combined computational (U. Denver) and experimental (U. Kansas) lower limb kinematics analysis simulating activities of daily living (ADL)

In-vivo Fluoroscopy Kinematics

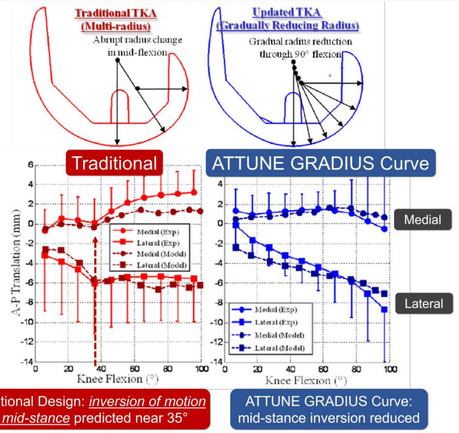
- IRB approved in-vivo study – 15 ATTUNE CR Knee pts, 15 traditional CR pts
- Mobile fluoroscope combined with registration of 3D implant model to 2D images
- Medial and lateral low points of femoral component tracked across tibial surface during ADL



In-vivo Fluoroscopic Kinematics

3. Results – Pre-Clinical

- Computational and experimental tibiofemoral kinematics – *AP translation of femoral condyle wrt tibia*(3)
  - Top Curve - Medial
  - Bottom Curve – Lateral
- The ATTUNE GRADIUS Curve "attenuated the anterior slide of the medial femoral condyle and led to a gradual posterior translation of the lateral condyle with knee flexion"(4)



Traditional Design: *inversion of motion in mid-stance* predicted near 35°

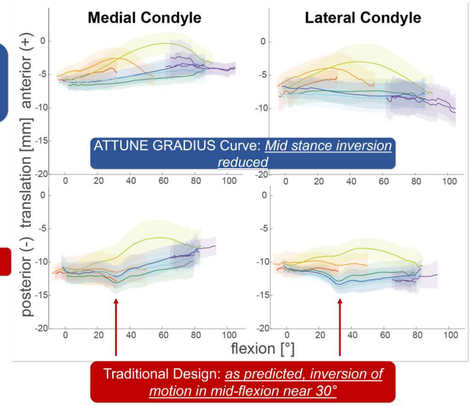
ATTUNE GRADIUS Curve: mid-stance inversion reduced

3. Results – In-Vivo Fluoroscopy

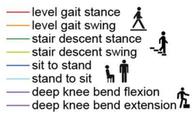
- In-vivo fluoroscopy – *AP translation of femur wrt tibia*(4)
- Multiple activities of daily living
- *ATTUNE GRADIUS Curve Design* – for the patients studied, more stable AP motion in mid-flexion vs. Traditional Design

ATTUNE GRADIUS Curve

Traditional



Traditional Design: *as predicted, inversion of motion in mid-flexion near 30°*



4. Discussion

- Extensive pre-clinical computational and cadaveric weight bearing biomechanics studies were utilized to understand the cause of mid-flexion changes in femoral-tibial AP motion, otherwise known as "paradoxical motion"(1).
- In a traditional femoral design, the sudden transitions between femoral condyle radii during flexion, and the resulting change in femoral center of rotation, were identified as being related to sudden mid-flexion changes in femoral-tibial AP motion
- The development of a novel, patented, gradually reducing femoral radius (ATTUNE GRADIUS Curve) was developed to eliminate these sudden mid-flexion changes.
- Subsequent weight bearing in-vivo fluoroscopy confirmed that the gradually reducing femoral radius (ATTUNE GRADIUS Curve) design *reduced the occurrence of sudden mid-flexion changes in femoral-tibial AP motion,* when compared to traditional femoral design

5. Conclusion

- **Clinical Significance**:
  - Previous intra-operative studies have identified that mid-flexion instability can be a distinct form of laxity that exists even when the knee is well balanced in extension and deeper flexion(4).
  - When compared to a traditional femoral design, the unique ATTUNE GRADIUS Curve femoral design has been shown to reduce mid-flexion instability in patients during weight bearing activities.

- **References**:

1) Dennis, et al – In-vivo fluoroscopic analysis of fixed-bearing total knee replacements, CORR, 2003:114-130
2) Clary, et al – Improving Dynamic Mid-Stance Stability: An Experimental and Finite Element Study, ORS 2012 Annual Meeting, Poster No. 1044, San Francisco, CA
3) List, et al – Influence of Gradually Reducing Femoral Radii in Total Knee Arthroplasty on in Vivo Tibiofemoral Kinematics During Daily Activities: A Videofluoroscopy Study, ISTA 2018 Annual Meeting, Presentation #5731, London, UK
4) Minoda, et al – Intraoperative Assessment of Mid Flexion Laxity in Total Knee Prosthesis, The Knee, 2014, 21:810-814

169675-210308 GLBL

All products may not be available and/or approved or cleared by all global regulatory authorities. Please contact your sales representative for questions regarding regional product availability and indications.
Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson&Johnson

ATTUNE GRADIUS™ Curve & SOFCAM™ Contact– Designing Smooth Cam-Post Contact: The In-Vitro and In-Vivo Science

Mark A. Heldreth, Sr. Engineering Fellow, DePuy Synthes Inc., Warsaw, IN

A summary of work previously published by U. Denver, U. Kansas, & U. Tennessee

1. Introduction

- Posterior stabilized (PS) knees may help reduce “paradoxical” tibiofemoral anterior-posterior kinematics(1)
- Some PS designs have demonstrated high forces being transferred to the poly post, resulting in damage to the posterior surface(2)
- New, patented, femoral design uses a gradually reducing radius (ATTUNE GRADIUS™ Curve) with the goal of reducing mid-flexion instability
- Pre-clinical studies @ U. of Kansas and U. of Denver evaluated the potential to reduce mid-flexion instability and PS cam/post contact forces(3)(4)
- Subsequent in-vivo fluoroscopy study at the U. of Tennessee evaluated the resulting knee kinematics in Attune PS FB knee patients(5)

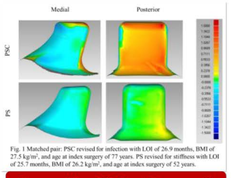


Fig. 3 Matched pair: PSC revised for infection with LOI of 26.9 months, BMI of 27.5 kg/m², and age at index surgery of 77 years. PS revised for stiffness with LOI of 25.7 months, BMI of 26.2 kg/m², and age at index surgery of 52 years.

Competitive PS Post Damage(2)

ATTUNE GRADIUS™ Curve – gradually changing radius & center of femoral rotation

2. Methods

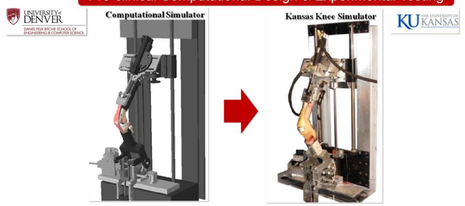
Pre-clinical In-vitro Kinematics(3)(4)

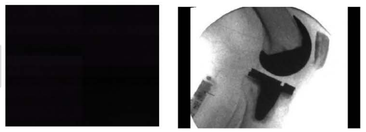
- Combined computational (U. Denver) and experimental (U. Kansas) lower limb kinematics analysis simulating activities of daily living (ADL)

In-vivo Fluoroscopy Kinematics(5)

- IRB approved in-vivo study – 32 ATTUNE® PS FB Knee patients
- Mobile fluoroscope combined with registration of 3D implant model to 2D images
- Medial and lateral low points of femoral component tracked across tibial surface during ADL

Pre-clinical Computational Design & Experimental Testing



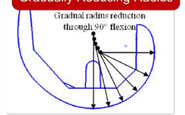


In-Vivo Fluoroscopic Kinematics

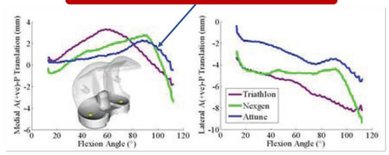
3. Results: Pre-Clinical

- ATTUNE GRADIUS Curve maintains medial stability and lateral rollback during deep knee bend(3)
- SOFCAM™ Contact designed to avoid abrupt transition to cam/post kinematics
- In computational models, ATTUNE PS Knee was found to reduce post forces during transition to cam/post kinematics(4)

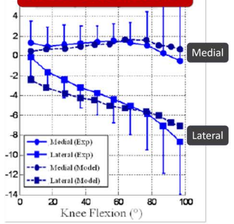
ATTUNE GRADIUS™ Curve Gradually Reducing Radius

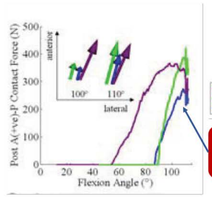


Gradual Transition to SOFCAM™ (4) Contact



Simulated Deep Knee Bend(3)





Reduced Cam/Post Forces With ATTUNE Knee(4)

3. Results: In-Vivo Fluoroscopy

- n = 32 ATTUNE PS FB Knee patients
- “Subjects experienced low overall mid flexion paradoxical anterior sliding” during deep knee bend(5)
- ATTUNE GRADIUS Curve + SOFCAM Contact demonstrated “…consistent posterior femoral rollback and external axial rotation of the femur with respect to the

Gradual Transition to SOFCAM™ Contact

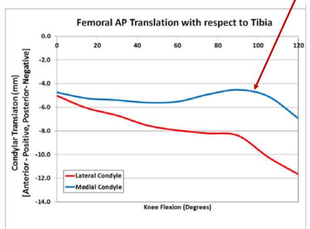


Figure1: Lateral and Medial Condylar translation during DKB [Anterior (Positive)/Posterior (Negative)].

4. Discussion

- Extensive pre-clinical computational and cadaveric weight bearing biomechanics studies were utilized to develop a design with reduced mid-flexion instability and smooth transition to cam/post kinematics(3)(4).
- The gradually reducing femoral radius (ATTUNE GRADIUS Curve) “attenuated the anterior slide of the medial femoral condyle and led to a gradual posterior translation of the lateral condyle with knee flexion” during weight bearing cadaveric testing(3)
- Combining ATTUNE GRADIUS Curve with careful positioning and shape of the PS cam/post engagement (SOFCAM Contact) was shown to have potential for reducing forces on the post when compared to two leading competitors(4).
- During weight bearing in-vivo fluoroscopy, the ATTUNE GRADIUS Curve and SOFCAM Contact together resulted in ATTUNE PS Knee kinematics demonstrating “consistent posterior femoral rollback and external axial rotation of the femur with respect to the tibia.”(5)

5. Conclusion

- **Clinical Significance**:
  - Some PS TKR designs have demonstrated high forces being transferred to the poly post, resulting in damage to the posterior surface(2)
  - Through proper control of mid flexion stability (ATTUNE GRADIUS Curve) and appropriate positioning and shape of the cam/post geometry (SOFCAM Contact), smooth transition to cam/post kinematics and reduced post forces can be realized(3)(4)(5) .

- **References**:

1) Dennis, et al – In-vivo Fluoroscopic Analysis of Fixed-Bearing Total Knee Replacements, CORR, 2003:114-130
2) Weitzler, et al – The Effect of Constraint on Post Damage in Total Knee Arthroplasty: Posterior Stabilized vs. Posterior Stabilized Constrained Inserts, ORS 2018 Annual Meeting, Poster No. 1879, New Orleans, LA
3) Clary, et al – Improving Dynamic Mid-Stance Stability: An Experimental and Finite Element Study, ORS 2012 Annual Meeting, Poster No. 1044, San Francisco, CA
4) Fitzpatrick, et al – Post-Cam Engagement During Dynamic Activity With Current Posterior-Stabilized TKR, 18th Congress of the European Society of Biomechanics (2012), Presentation 1700, Lisbon, PT
5) Sharma, et al – In Vivo Kinematic Performance of Gradually Variable Radius PS Primary TKA, ORS 2019 Annual Meeting, Poster No. 0895, Austin, TX

169668-210308 GLBL

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson&Johnson