Clinica Ortopedica e
Traumatologica
Università degli Studi di Pavia

Fondazione IRCCS Policlinico
San Matteo

Chairman: Prof. F.M. Benazzo

Session: Gap balancing in TKA

Do the new designs play a role?

F.M. Benazzo

Key points

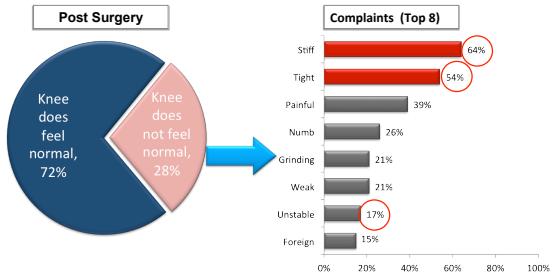
- New designs: the needs (unsatisfied patients)
- Undersizing, oversizing: mistakes or compromises?
- The registries
- Halfway conclusion
- VBK
- New designs on the market
- Conclusions

New designs

Usually a new prosthesis is born on previous TKA designs with the aim to improve the results, matching the unmet needs of the patients

- Registries analysis
- PROMs
- Engineering studies

State of art



Inappropriately Sized Implants: Undersized Components

- Instability often develops early after a total knee arthroplasty in which the femoral component is undersized in the antero-posterior dimension

  Pagnano et al, 1998

- Instability after total knee arthroplasty is a cause of failure and a reason for 10% to 22% of revisions

  Yercan, 2005

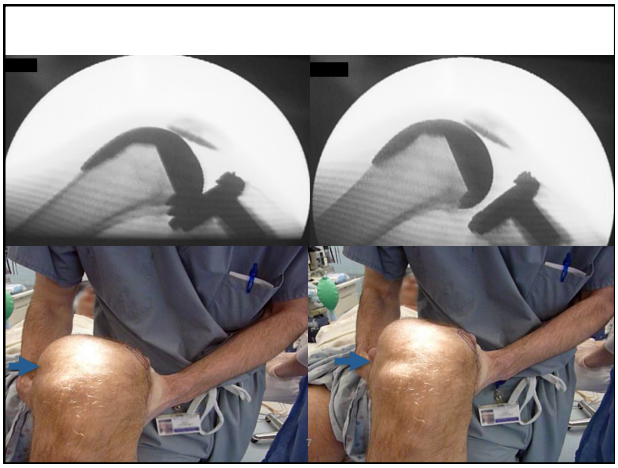
Inappropriately Sized Implants: Undersized Components

- Symptomatic flexion instability-common reason for revision TKA within five years after the index

  Fehring, 2001

- Radiographic evidence of instability following primary TKA
  - excessive posterior condylar resection
  - inadequate distal femoral resection
  - non-weight bearing gapping
  - bearing surface eccentricity

  Firestone, 2006



Inappropriately Sized Implants: Oversized Components

Inappropriately Sized Implants: Oversized Components

After 180 navigated TKA cases, several knees received oversized femurs that resulted in early revisions and painful knees at 1.5 years postoperatively

"we noticed several times the femoral components were oversized"
"Since the prosthesis overhangs in width…there is impingement on the soft tissues"
"we had to perform revision surgery…due to the excessive size"

David et al, 2008

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Inappropriately Sized Implants: Oversized Components

Overhang of femoral component was highly prevalent, occurring more often and with greater severity in women…doubles the odds of clinically important knee pain two years after TKA

Overhang 40% men; 68% women (overhang 3mm or greater)

Mahoney et al, 2010

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Inappropriately Sized Implants: Oversized Components

Inappropriately Sized Implants: Oversized Components

In the 109 TKA knees observed, 50% of medial condylar offset were significantly increased and 80% of lateral condylar offset were found to have significantly greater posterior condylar offset compared with the preoperative measurement

Ishii, 2010

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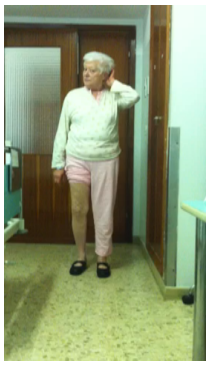
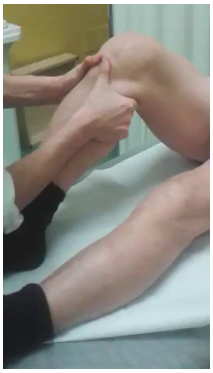
Gap balancing: failure pattern



Gap balancing: gold-standard



How we can reach the best situation?

- Implant design (</> 50% of importance?)
- Surgeon ability (</> 50% of importance?)

State of the art of the registries

The analysis of all the available TKA registries gives following key information:

- CR TKAs have better survivorship than PS TKAs
- Fixed TKAs have better survivorship than mobile TKAs
- Cemented TKAs have better survivorship than uncemented TKAs. Hybrid fixation is not differentiable with cemented fixation.

State of the art of the registries

The analysis of all the available TKA registries gives following key information:

- High-flexion TKAs demonstrate a trend to have a lower survivorship than “normal” TKAs
- Not all the implants have the same learning curve

Registries evidence: CR vs PS

England, Wales and Northern Ireland (Kaplan-Meier)

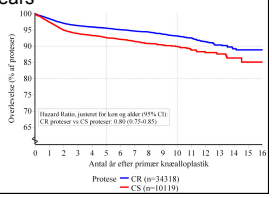
- Cemented, unconstrained, fixed 2.90% at 9 years
- Cemented, posterior-stabilised, fixed 3.32% at 9 years

Australia (cumulative percent revision of primary total knee replacement by stability):

- Minimally stabilised 6.2% at 12 years
- Posterior stabilised 7.6% at 12 years

Denmark

- the risk of revision using CR total prosthesis is statistically significantly less (0.83 times) than using PS prosthesis.”



Conclusions so far

- Not all patients are satisfied
- Anatomy is not matched by the available sizes and shapes: compromises
- Need of highly performing implants: more demanding surgical technique, worse results
- PS knees perform not at the same level of CR knees

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Virtual Biomechanics Knee (VBK)

- **VBK** – validated numerical simulation of individual knee specimens
- Each numerical model calibrated using robotic experiments (KUKA)
- TKA function can be assessed virtually in terms of joint stability, envelope of motion and functional activities

Virtual Biomechanics Knee (VBK) VBK

- **TKAs (LPS / CR) implanted into human specimens (N=7)**
- **Robotic testing of intact knee and with TKA**
- **Resection study for model calibration**

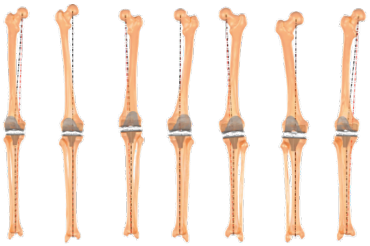
Implantation

- **Specimen specific VBK model of each knee**
- **Virtual surgery using same placement as in real surgery**
- **Virtual testing of knee with TKA**
  - **VV stability (±10 Nm)**
  - **AP stability (±100 N)**
  - **IE laxity (±6 Nm)**

Digitization of implant position

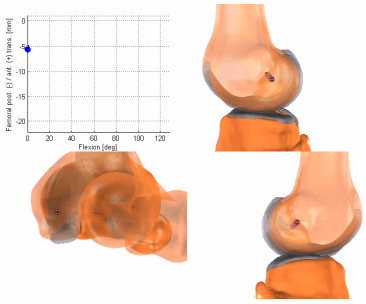
Siggelkow et. al, ORS 2011
Validation Study with Prof. F. Benazzo

Post-Op Alignment



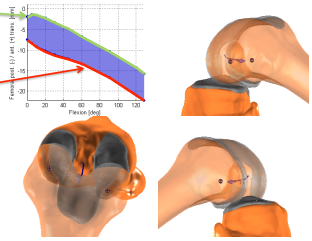
- Average: 1.6° varus
- Range 4° varus to 3° valgus

Intact Knee



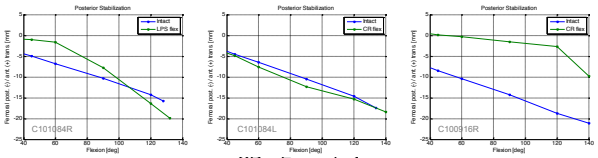
Intact Knee

- Posterior stabilization (by PCL)
- Anterior stabilization (by ACL)



Example Results of TKAs

Drawer test with 100N in posterior direction on tibia with compressive load of 44N



LPS
- Cam-post engages at approx. 70°
- Consistent pattern between knees

CR – Example 1
- PCL was still strong after robotic testing
- TKA curve followed curve of intact knee closely in higher flexion.

CR – Example 2
- PCL was weak after robotic testing (partially torn out)
- Femur more anterior in higher flexion.

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New goals of the implant designer

- Cover the complexity of morphotypes and kinematics
- Anatomic-friendly design (avoid overstuffing, etc.)
- Address different populations, worldwide
- Reproducible ligament balancing
- Personalized care for individual patients
- Less or no surgical compromises

- Persona (Zimmer)
- Attune (DePuy Snthes)

The future of TKA

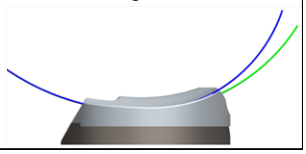
- Address different populations
- Cover the complexity of morphotypes and kinematics

The future of TKA

- Reproducible ligament balancing
- Anatomic-friendly design (avoid overstuffing, overhanging)
- Advanced solutions (coatings)

New design: Persona (PS)

- Tibiofemoral kinematic design that more accurately reflects kinematics in patient's knee
- Left and right articular surface designed to accommodate asymmetric kinematics of knee
- Articular surface with differential conformity
  - Medial sagittal radius similar to LPS flex
  - Lateral sagittal radius is increased to encourage differential rollback

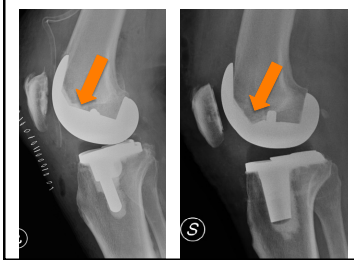


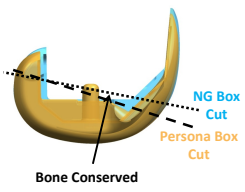
New design: Persona (PS)

- Anatomic sagittal radius (J-Curve) – natural knee radii
  - Helps maintain ligamentous balance and stability through ROM
- Multi-radius cam
  - Proprietary design – consistently drives posterior rollback
  - Maintains point of spine engagement throughout ROM

New design: Persona

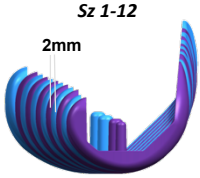
- Bone preservation
  - No trochlea bone resection
  - No additional resection posterior condyles
  - Increased bone conservation – 25% more bone



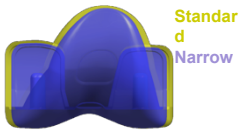


New design: Persona

12 A/P Sizes
Sz 1-12



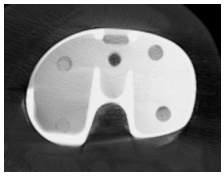
2 M/L Widths
Standard/Narrow



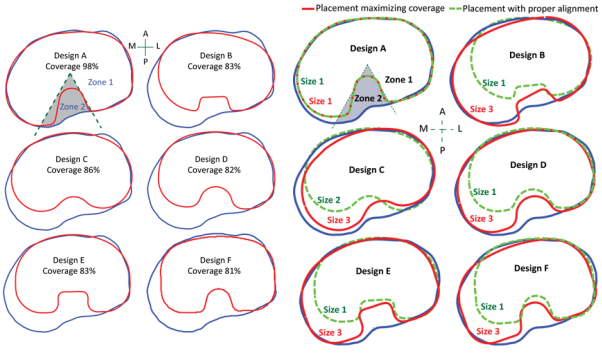
- 21 distinct femoral profiles – narrow and standard
  - Avoid M/L overhang and potential downsizing and ↓ flexion
  - Maximize bone coverage for improved fixation
  - Narrow femur: steeper 10^0 Q-angle and thinner anterior flange

Persona Tibia Plate

- Asymmetric plate, medialized keel addressing:
- coverage, rotation,
- alignment with the canal



Tibia Coverage, Malalignment and Malrotation



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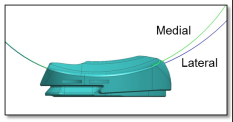
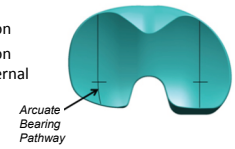
Persona Articular Surfaces

- *Enhanced Thickness Offerings (1mm)*
- *Asymmetric Profile and Articulation*
- *Soft Tissue Friendly Perimeter*
- *Robust Locking Mechanism*

Persona CR Features - Liner

- Continues with asymmetric femoral condyles principle ("Big Wheel/Little Wheel")
- Differential conformity in CR articular surfaces
  - Medial – decreased sagittal radius
  - Lateral – increased sagittal radius
  - Increased contact area in deep flexion
  - Curved "Arcuate Bearing Pathway" on lateral surface – accommodates external femoral rotation in high flexion





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New design: Attune Sagittal Radius of Curvature

Multi-Radius of Curvature

Single Radius of Curvature

ATTUNE GRADIUS™ Curve

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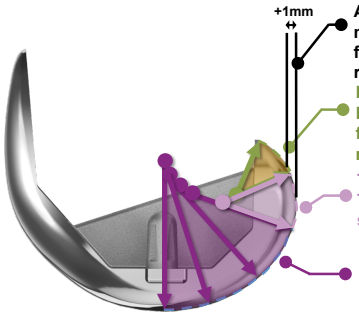
New design: Attune (PS)



Additional mm of metal to help balance flexion gap after PCL resection

High Flexion Radii: Reduced radii allow freedom to rotate in maximum flexion

Transition Radius: Transitions to cam / spine engagement

ATTUNE GRADIUS™: Gradually reducing radius from 5° to 70° flexion

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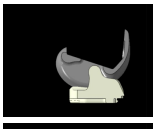
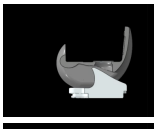
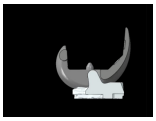
Attune: PS Cam/Spine Engagement

ATTUNE™ PS FB System



SIGMA® PS FB System





NexGen® PS FB System

Triathlon® PS FB System

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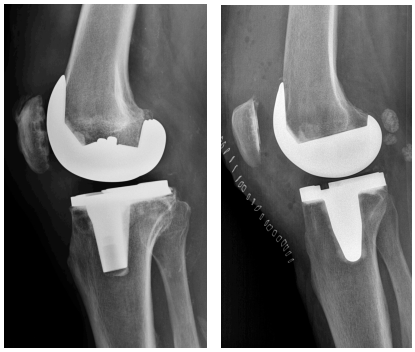
New designs: Persona vs Attune

New designs: Persona vs Attune

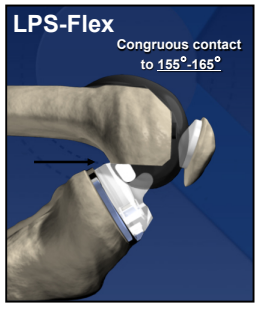


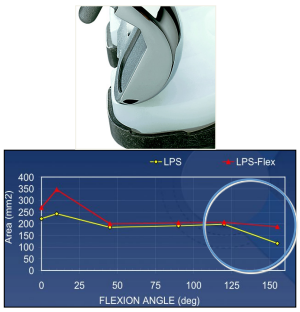
Intelligent Instrumentation

Conclusions

- New designs are backed up by intensive research
- Research driven by the unmet needs
- Anatomy-matched design to decraese the compromises
- Kinematics reproduced as much as possible
- Balancing still in the hand of the surgeon

Extended Condyles continued with less bone resection

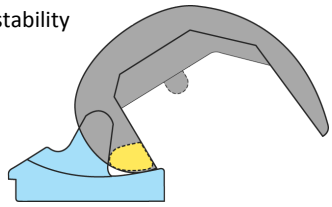




Need graph of Persona contact area in high flexion

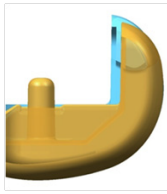
Spine/Cam Mechanism

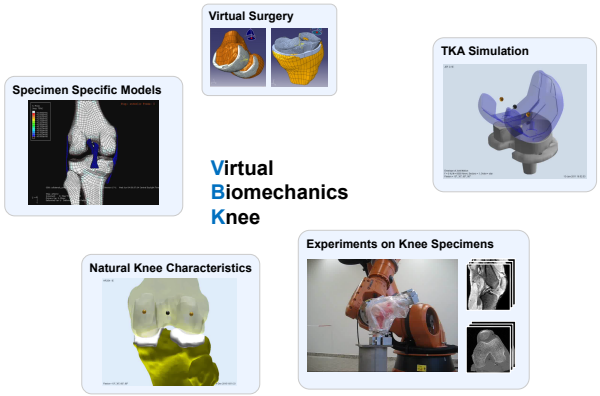
- Similar spine cam mechanism as LPS
  - Lower contact point
  - Increased jump height
  - Improved flexion stability



Persona™ PS Knee

- Maintain safe 155° flexion
- Perserve 25% more native bone
- Maintain contact area in high flexion





Literature evidence: PS high flex

THE JOURNAL OF BONE & JOINT SURGERY

High incidence of loosening of the femoral component in legacy posterior stabilised-flex total knee replacement

H. S. Han,
S.-B. Kang,
K. S. Yoon

2007

- NexGen LPS-flex (Zimmer), high- flexion fixed TKR
- at a mean of 32 months (30 to 48) after operation, progressive complete radiolucent lines were found around the femoral components on the radiographs of 27 (38%) TKRs
- Radiolucent lines were observed beneath the anterior flanges of the femoral components on the lateral radiographs

Literature evidence: PS high flex

Clin Orthop Relat Res
DOI 10.1007/s11999-012-2628-5_2012

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

SYMPOSIUM: SPECIAL CONSIDERATIONS FOR TKA IN ASIAN PATIENTS

Brief Followup Report

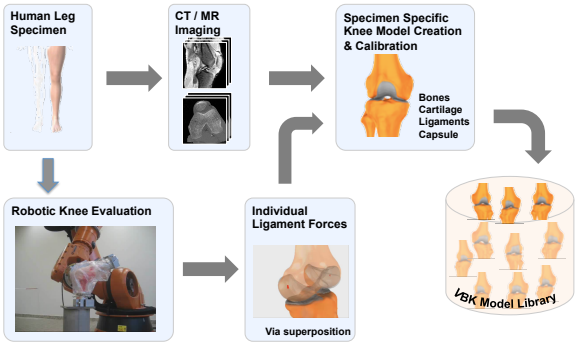
Does High-flexion Total Knee Arthroplasty Allow Deep Flexion Safely in Asian Patients?

Hyuk-Soo Han MD, PhD, Seung-Baik Kang MD, PhD

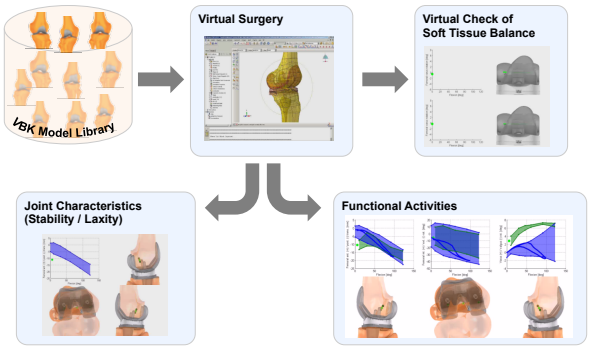
- 72 Nexgen LPS-flex fixed TKAs in 47 patients
- The probability of revision-free survival for aseptic loosening was 67% and 52% at 5 and 8 years, respectively
- Radiolucent lines were most frequently noted (69%) in Zone 1 of femoral components
- Midterm high-flexion TKA survival in Asian cohort was lower than that of conventional and other high-flexion designs.

Virtual Biomechanics Knee (VBK)

Specimen Specific VBK Model Creation

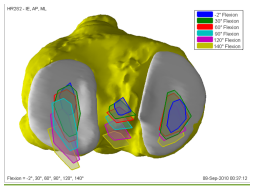


Virtual Biomechanics Knee (VBK) VBK
Application



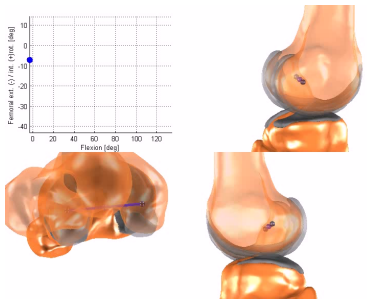
Virtual Biomechanics Knee (VBK)
Summary Findings

- Suitable to analyze the effect of prosthesis design *and* placement
- Drove smaller sizing increments (Tibia / Femur)
  - Resulted in substantially smaller changes in laxity in tests
  - Allows for a better fine-tuning of ligament balance

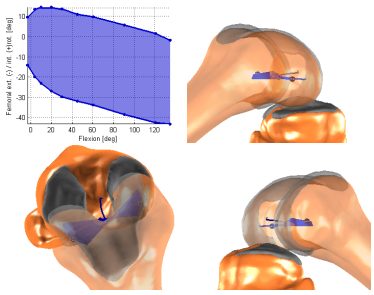


- Active motion will be within envelope
- Envelope guides motion to a certain degree
- Envelope = basis to understand knee function

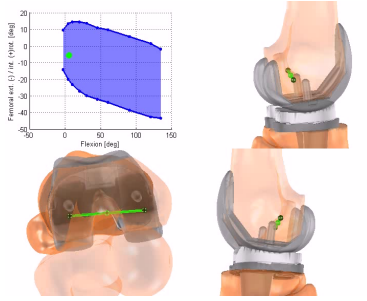
Example: Intact Knee



Example: Intact Knee



Example: TKA



Example: TKA