Clinica Ortopedica e Traumatologica
Università degli Studi di Pavia

Fondazione IRCCS
Policlinico S. Matteo

Chairman: Prof. F. Benazzo

EFORT
Implant & Patient
Safety Initiative

Where do we have problems in arthroplasty?

Need for innovation – where and why?

when and how?

F.Benazzo

Disclosures

- Designer of Modulus hip system (2001, Limacorporate)
- Designer of Nex Gen Modular Mini keel for MIS (2005, Zimmer)
- Designer of Ceramic knee (Multigen) (2007, Limacorporate)
- Designer of Persona primary knee (2009-2012, Zimmer)
- Designer of Persona revision (PCCK) (2014…, ZimmerBiomet)
- Designer of Modulus R hip system (2016, Limacorporate)
- Designer of M-Vizion (Modular Revision Stem) (2018…, Medacta)
- Designer of X-Motion (Cer-Cer resurfacing) (2019…, Limacorporate)
- …

What is “innovation”? Innovation is when:

1) We can achieve the same results with less economical burden (less costs, shorter time)
2) We can achieve the same results with better reliability and reproducibility
3) We can achieve better results with no remarkable increase of costs/time
4) The benefit obtained is collective (for the community)

5) Innovation becomes revolution (“disruptive technology”) when an unsolvable issue finds a solution

1) Innovation - Where? Why? When?

- Where: → materials
  → bearing couples
  → technology implementing the quality of surgical procedures (augmented reality; AI; ML) and peri-operative protocols (ERAS, Fast Tracks, outcomes)

Femoral component

Players:

- CrCbMb (and coated)
- Oxinium
- Ceramic
- Peek

Clin Orthop Relat Res (2016) 474:2405–2413
DOI 10.1007/s11999-016-4801-8

Clinical Orthopaedics and Related Research®
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SYMPOSIUM: ADVANCES IN PEEK TECHNOLOGY

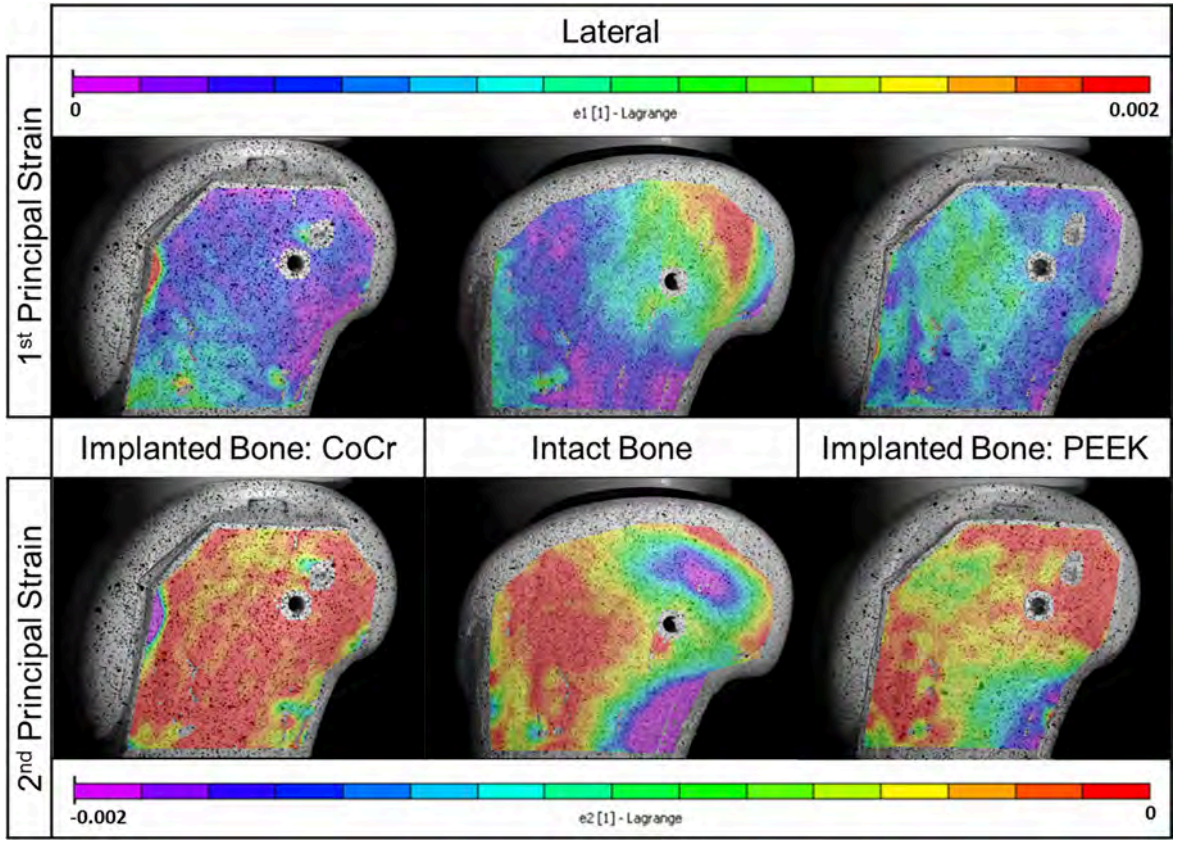
Does a PEEK Femoral TKA Implant Preserve Intact Femoral Surface Strains Compared With CoCr? A Preliminary Laboratory Study

Kathryn E. Rankin PhD, Alexander S. Dickinson PhD, Adam Briscoe PhD, Martin Browne PhD

Published online: 28 March 2016

Conclusions The strain shielding observed with the contemporary CoCr implant, consistent with clinical bone mineral density change data reported by others, may be reduced by using a PEEK implant.

Clinical Relevance This bone analog in vitro study suggests that a PEEK femoral component could transfer more physiologically normal bone strains with a potentially reduced stress shielding effect, which may improve long-term bone preservation. Additional studies including paired cadaver tests are necessary to test the hypothesis further.



Clinical Biomechanics 70 (2019) 153–157

Contents lists available at ScienceDirect

Clinical Biomechanics

journal homepage: www.elsevier.com/locate/clinbiomech

Structural stability of a polyetheretherketone femoral component—A 3D finite element simulation

Jian-ping Wang[a,b], Dong Guo[b], Shi-hua Wang[b], Yong-qiang Yang[b], Guoan Li[a,*]

[a] Orthopaedic Bioengineering Research Center, Newton-Wellesley Hospital/Harvard Medical School, Boston, MA, United States of America
[b] Henan Polytechnic University, Jiaozuo 454000, Henan Province, China

ARTICLE INFO

Keywords:
Total knee arthroplasty
Polyetheretherketone
Cobalt–chromium
Structural stiffness
Interface deformation.

ABSTRACT

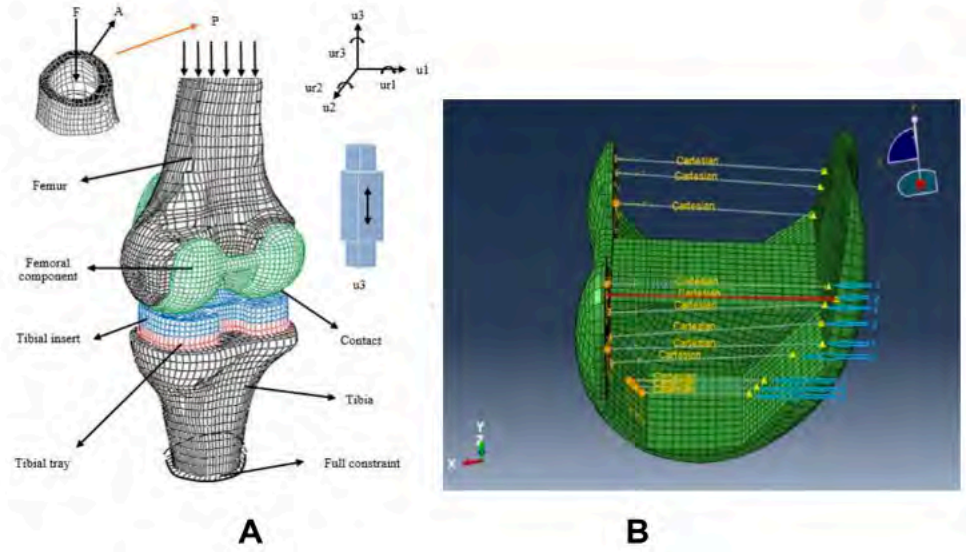
Background: Because its mechanical properties are similar to cortical bones of the knee, polyetheretherketone (PEEK) material has been used to make total knee arthroplasty (TKA) components. This study investigated the PEEK femoral component deformation of a TKA system and compared the data with that of a cobalt–chromium (CoCr) component.

Methods: A 3D finite element knee model was constructed using CT images of a normal subject. A knee prosthesis was installed on the model to simulate a TKA knee. The material properties of the bone were assumed linear and transverse isotropic. The femoral component was modeled using a PEEK or CoCr material. A compressive load was applied to the knee at full extension. Tibiofemoral contact stresses and femoral component deformations were analyzed.

Findings: Under a 3 kN load, the maximal Von-Mises stresses in the femoral component were 14.39 MPa and 30.05 MPa for the PEEK and CoCr components, respectively. At the tibial polyethylene surface, the CoCr femoral component caused higher contact stresses (> 2.2%) than the PEEK component. The deformation of the PEEK component was over 3 times larger than that of the CoCr component (0.65×10^{-3} mm vs 0.2×10^{-3} mm).

Interpretation: The PEEK femoral component could result in lower contact stresses, but larger deformations in the TKA knee compared to the CoCr component. An increased deformation of the PEEK component indicates a reduction in its structural strength. Future investigation should examine if the reduced structural strength will

Clinical Biomecha



None of 1-4 points

5. Conclusion

The results of this FE modeling study indicated that the PEEK femoral component could result in lower component-bone interface stresses and contact stresses in the TKA, but could result in larger deformations in the TKA system than the CoCr component. While the reduced stresses could be an advantage to reduce the stress shielding effect on the TKA knee, the increased femoral component deformation could imply a reduction in structural stiffness of the PEEK component. Further evaluation is necessary to evaluate if the reduced structural stiffness of the PEEK component will affect the femoral component-bone interface integration in-vivo (i.e., component loosening) and if it will affect the fatigue life of the TKA system.

Comparative analysis of current 3D printed acetabular titanium implants

Dall'Ava *et al. 3D Printing in Medicine* (2019) 5:15

Outer surface

- Surface morphology (*scanning electron microscopy*)
- Porous structure features (*x-ray micro-computed tomography)*

1) SEM showed partially molten titanium beads on all cups

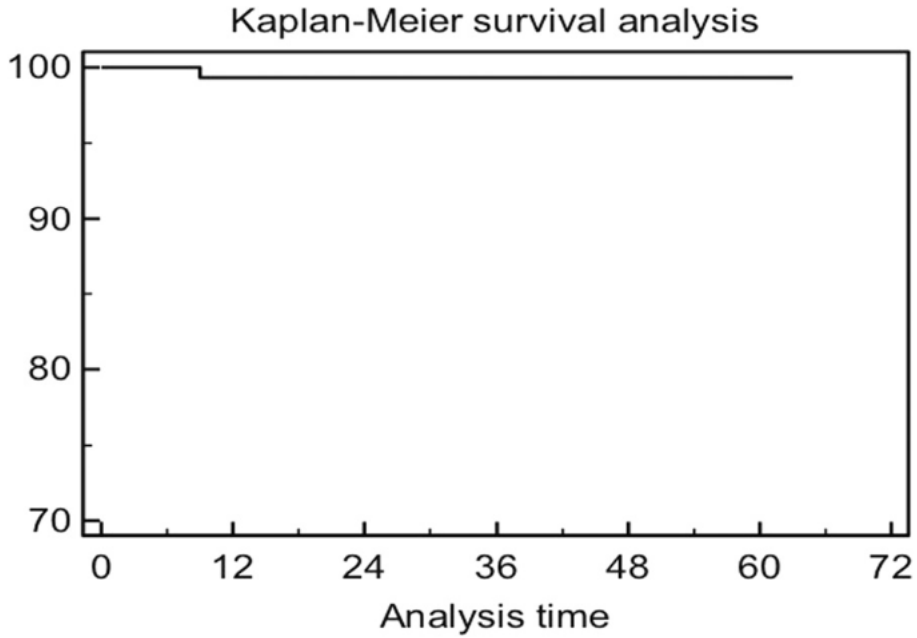
2) The existence of titanium beads on 3D printed parts is a known by-product of the manufacturing process; however, their prevalence on acetabular cups used in patients is an interesting finding, since these beads may potentially be released in the body

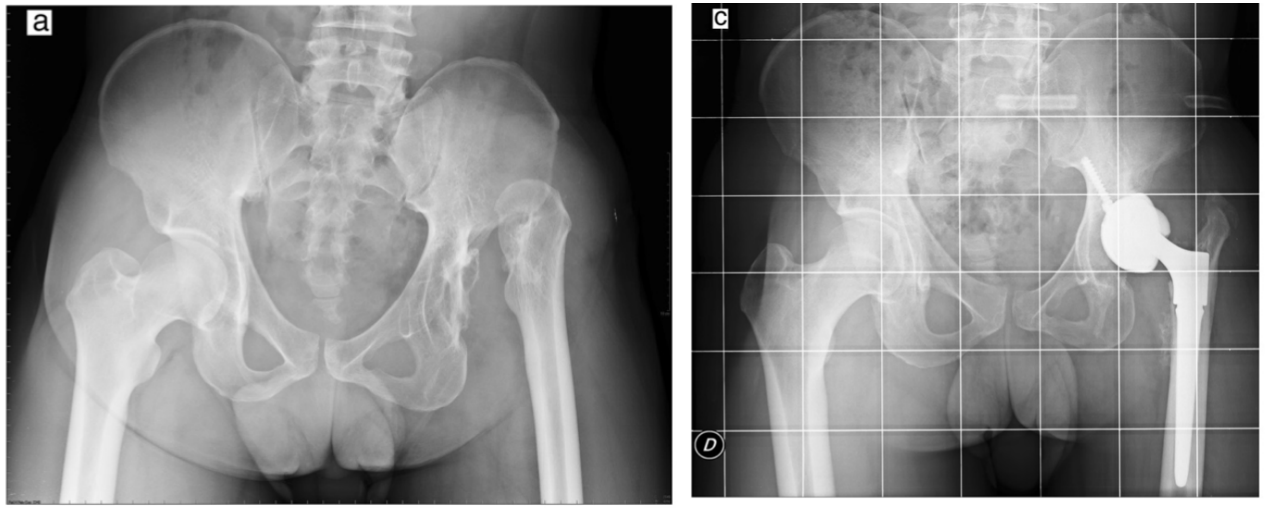
Clinical and radiographic outcomes of a trabecular titanium™ acetabular component in hip arthroplasty: results at minimum 5 years follow-up

BMC Musculoskeletal Disorders (2015) 16:375

Loris Perticarini*, Giacomo Zanon, Stefano Marco Paolo Rossi and Francesco M. Benazzo

134 total hip replacements and eight revisions were carried out using DELTA-TT primary cups

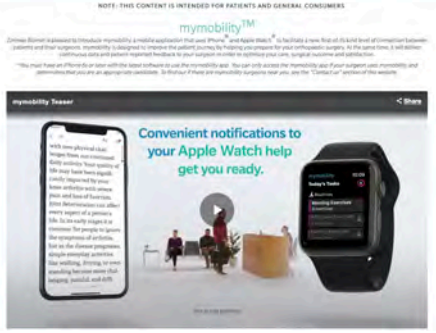


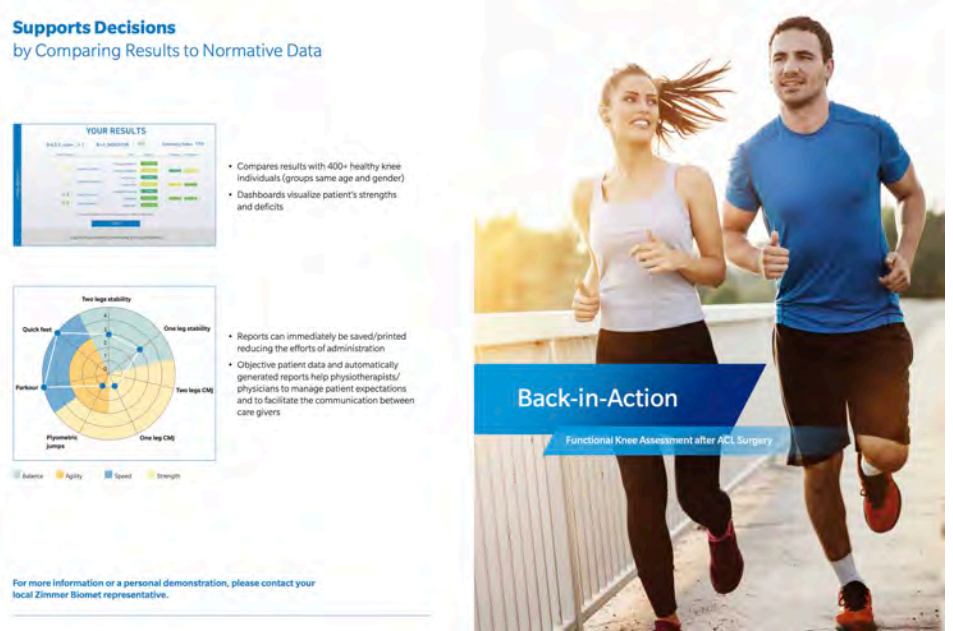


Points 2, 4 achieved

Innovation: Functional outcome

- Personalized and controlled rehabilitation programs
- Software and hardware to evaluate the recovery
- Evaluation using App and Smartwatch

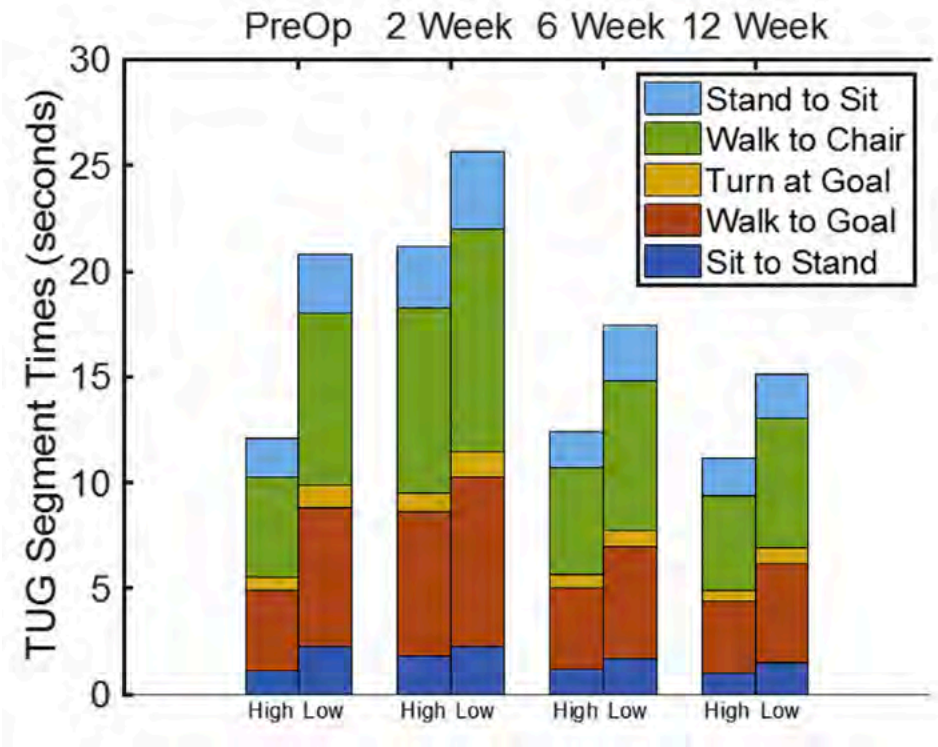




Machine Learning Groups Patients by Early Functional Improvement Likelihood Based on Wearable Sensor Instrumented Preoperative Timed-Up-and-Go Tests

The Journal of Arthroplasty

Riley A. Bloomfield et al. 2019



Conclusion: This work supports using wearable sensors to instrument functional tests during clinical visits and using machine learning to parse complex patterns to reveal clinically relevant parameters.

Points 2,3,4, achieved; 5?

2) Innovation - Where? Why? When?

Why: - first purpose → improving quality of healthcare with better products

- second purpose → Introduction of new or restyled products is a basic principle for profit companies

→ profit for the orthopaedic companies → increased market share → employment issues

- third purpose → *Nunquam invenietur, si contenti fuerimus inventis*

Seneca, Naturales Quaestiones, 6, 5, 2.

«Nothing would ever be found, if we felt satisfied with our discoveries»

2) Innovation - Where? Why? When?

- Polyethilene particles→activation of osteoclasts→osteolysis→ aseptic loosening of the implants
- Forced evolution in tribology → both technical and cultural

Gamma air sterilization → oxidation→ wear

Improved quality of the the PE: X-link, Vit.E doped

Still, we believe that reticulation is more important then sterilization technique, which is not

Nothing would ever be found, if we felt satisfied with our discoveries

Additive manufacturing

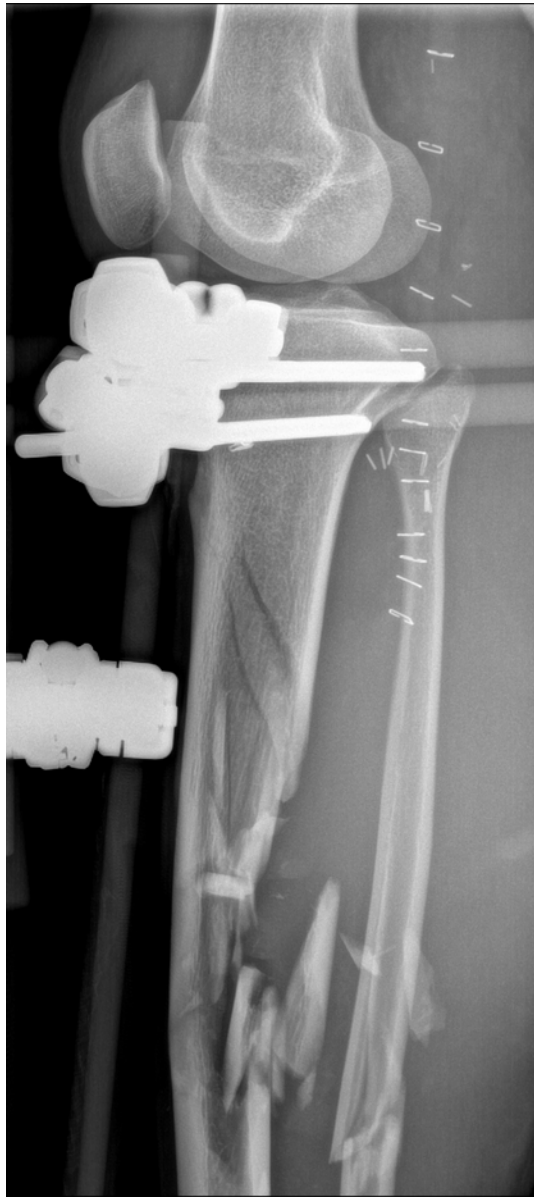
Off-the-shelf

Custom made

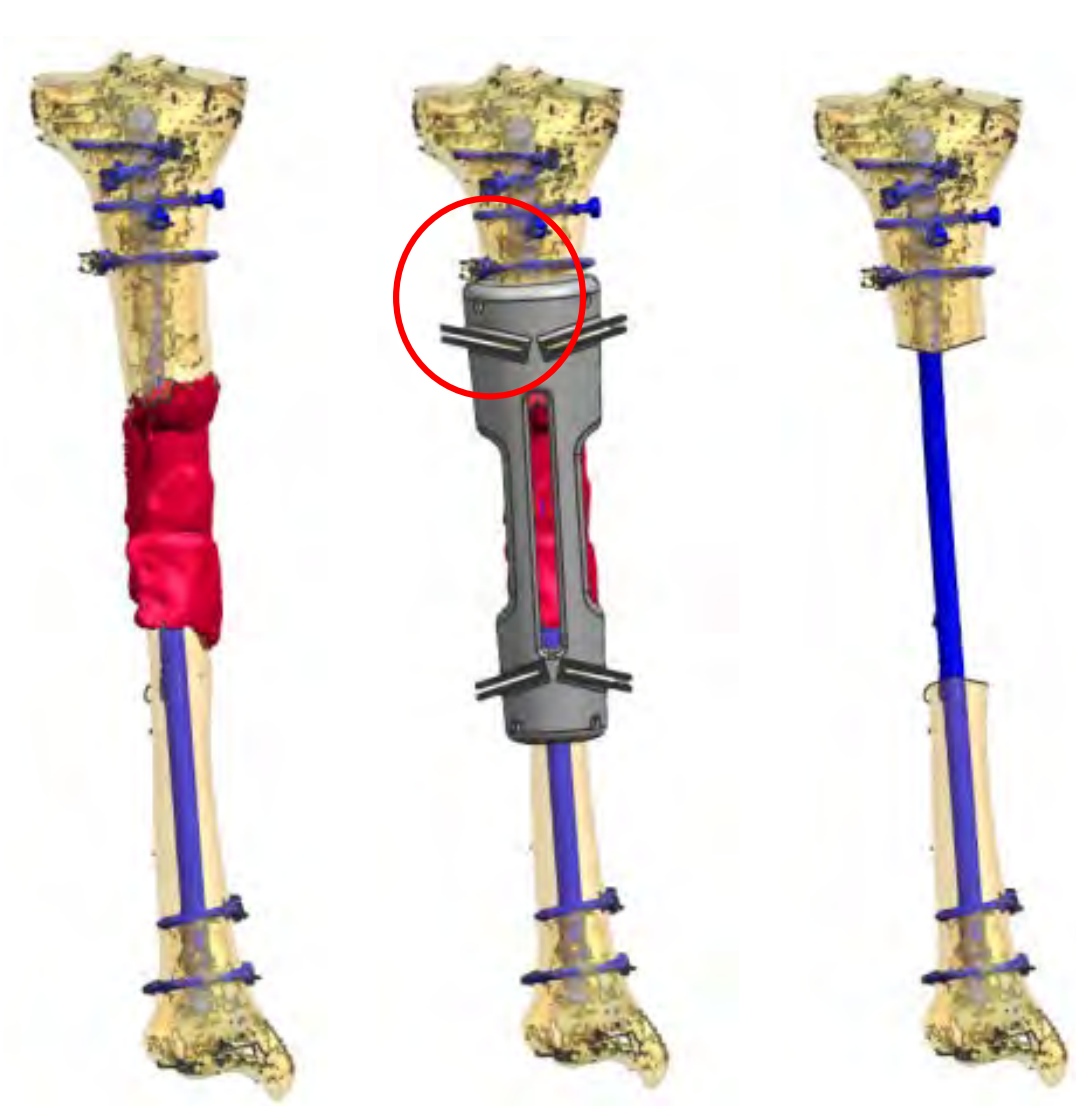
Innovation brought by
- Development/improvement of CAD
- Calculation power/algorithm
- Metallurgy of the metal powders

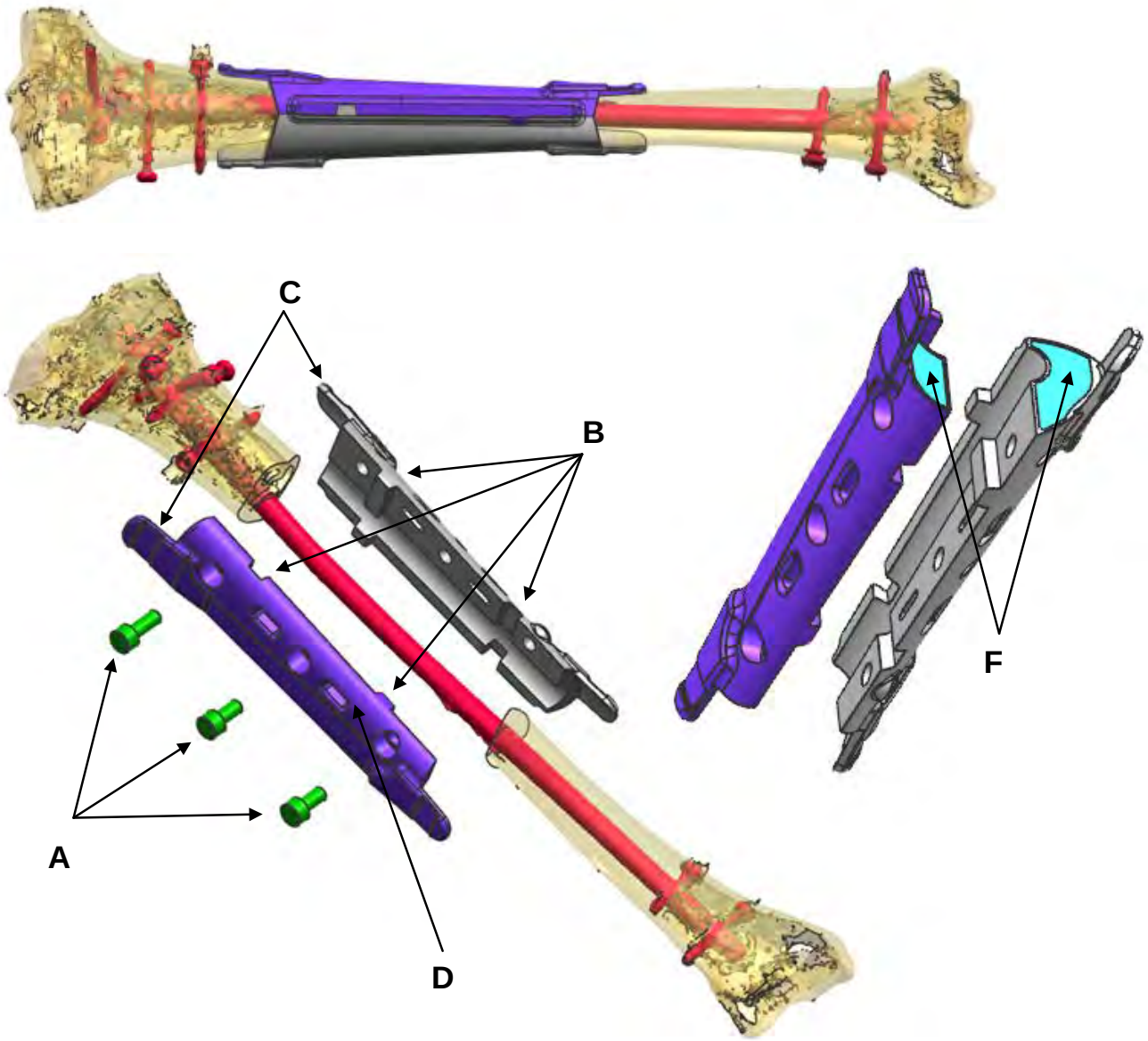
Questions:
- Real advantages for surgeons/pts? No real superiority in terms of durability compared to conventional cups
- Worth of using considering the increased costs? Are we spending more achieving the same results?
- Customs: - only for revision? → potential innovation in custom primary implants (!!)
  - advantages for selected surgeons/patients?

3D Printing: Replacement of bone defects

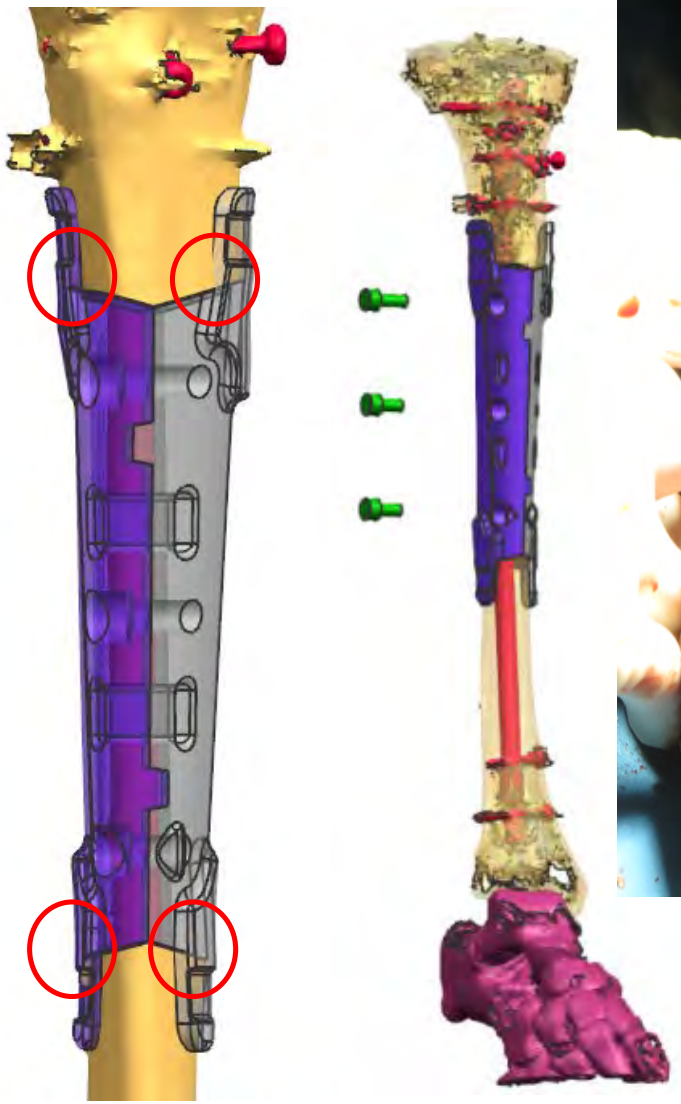


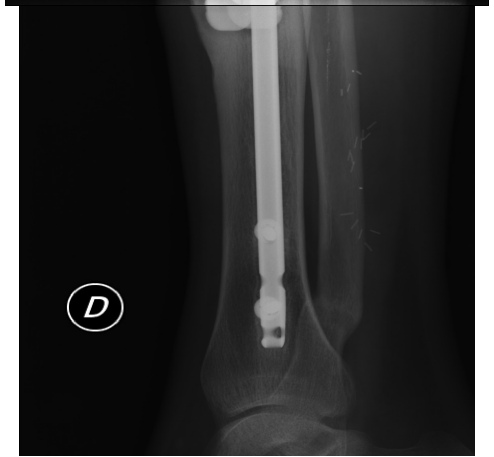
3D printing





12 m f-up





3) Innovation - Where? Why? <u>When?</u>

<u>When</u>: → from a marketing standpoint, as soon as a product shows a deflection of popularity, and/or a decreased market share, or a competitor product with some specific peculiarities (improvements?) becomes available

2018

The Journal of Arthroplasty 33 (2018) 3739–3745

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Complications - Infection

The Use of Tantalum Metaphyseal Cones for the Management of Severe Bone Defects in Septic Knee Revision

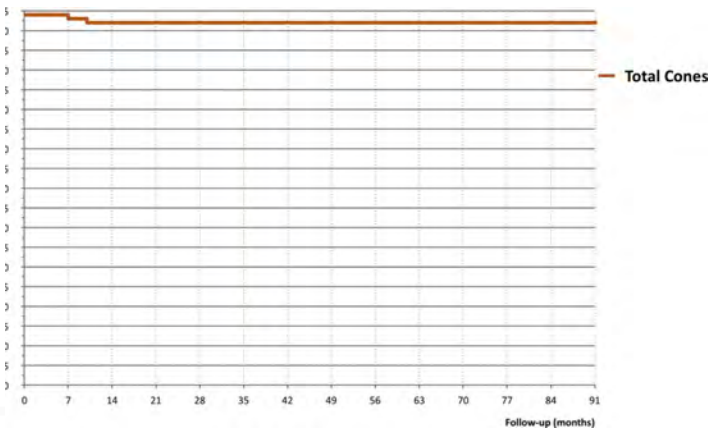
Giorgio Burastero, MD [a], Luca Cavagnaro, MD [a,*], Francesco Chiarlone, MD [b], Mattia Alessio-Mazzola, MD [b], Giuliana Carrega, MD [c], Lamberto Felli, MD [b]

[a] Orthopedic and Traumatology Unit 2, Santa Corona Hospital, Pietra Ligure, Savona, Italy
[b] Department of Surgical Sciences (DISC), Orthopaedic Clinic, Policlinico San Martino IST, Genova, Italy
[c] MIOS, Infectious Diseases and Septic Orthopaedics, S. Maria di Misericordia Hospital, Albenga, Savona, Italy

Table 1
Main Demographic and Surgical Data.

Parameter	Value
Sex	
Female	34 (56.7)
Male	26 (43.3)
Body mass index (kg/m^2)	
Female	28.9 ± 5.5
Male	26.1 ± 4.3
Age at time of surgery (y)	67.9 ± 8.8
Side of procedure	
Right	37 (61.7)
Left	23 (38.3)
Indication for revision surgery	
Second-stage reimplantation for PJI	60 (100)
Level of constraint at time of explant	
Hinged	7 (11.7)
Constrained	14 (23.3)
Posterior stabilized	35 (58.3)
Unicompartmental	4 (6.7)
Comorbidity	28 (46.7)
Diabetes	15 (25)
Rheumatoid arthritis	4 (6.7)
Cardiopathy	3 (5)
Smoking status	
Nonsmoker	42 (70)
Current	9 (15)
Former	9 (15)
Previous surgeries	3 ± 1.5

Values are given as N (%) and plus or minus values are the mean ± standard deviation.
PJI, periprosthetic joint infection.



60 patients
94 cones
FU 43.5 m
Massive bone loss – Constrained or semiconstrained knees

Excellent clinical and radiographic midterm outcomes were achieved with a low complication rate. Tantalum cones may be considered a safe and effective option in the management of massive bone defects also in septic knee revision surgery.

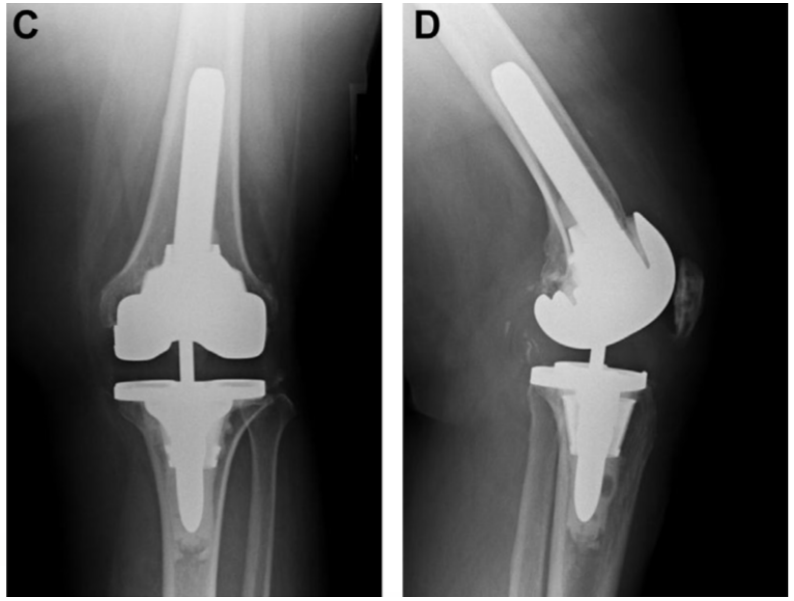
Excellent Metaphyseal Fixation Using Highly Porous Cones in Revision Total Knee Arthroplasty

Kevin M. Denehy, MD [a], Sarag Abhari, MS [b], Viktor E. Krebs, MD [c], Carlos A. Higuera-Rueda, MD [d], Linsen T. Samuel, MD, MBA [c], Assem A. Sultan, MD [c], Michael A. Mont, MD [e], Arthur L. Malkani, MD [f, *]

The Journal of Arthroplasty 2019

62 patients

Mean F-U	26.5 mo
Survival	90.2 %
Excluding infection	100 %



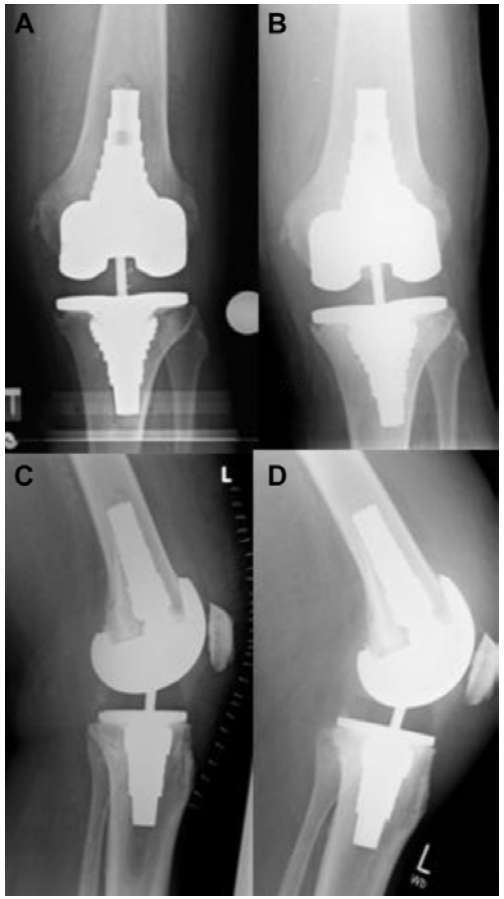
Are Stems Redundant in Times of Metaphyseal Sleeve Fixation?

Wolfgang Scior, MD [a], Debashish Chanda, MD [a, b], Heiko Graichen, MD, PhD [a, *]

[a] *Department of Arthroplasty and General Orthopaedic Surgery, Asklepios Orthopaedic Hospital Lindenlohe, Schwandorf, Germany*
[b] *Department of Orthopedics, GNH Hospital, Gurgaon, Haryana, India*

The Journal of Arthroplasty ,2019

93 patients out of 482 (stems used if insufficient fixation in zone 1
85 controlled at 3 years, mean F-U 58.2 mo (range 36-78)
10 failure→re-revised, only 1 for tibial sleeve non integration
99% survival rate

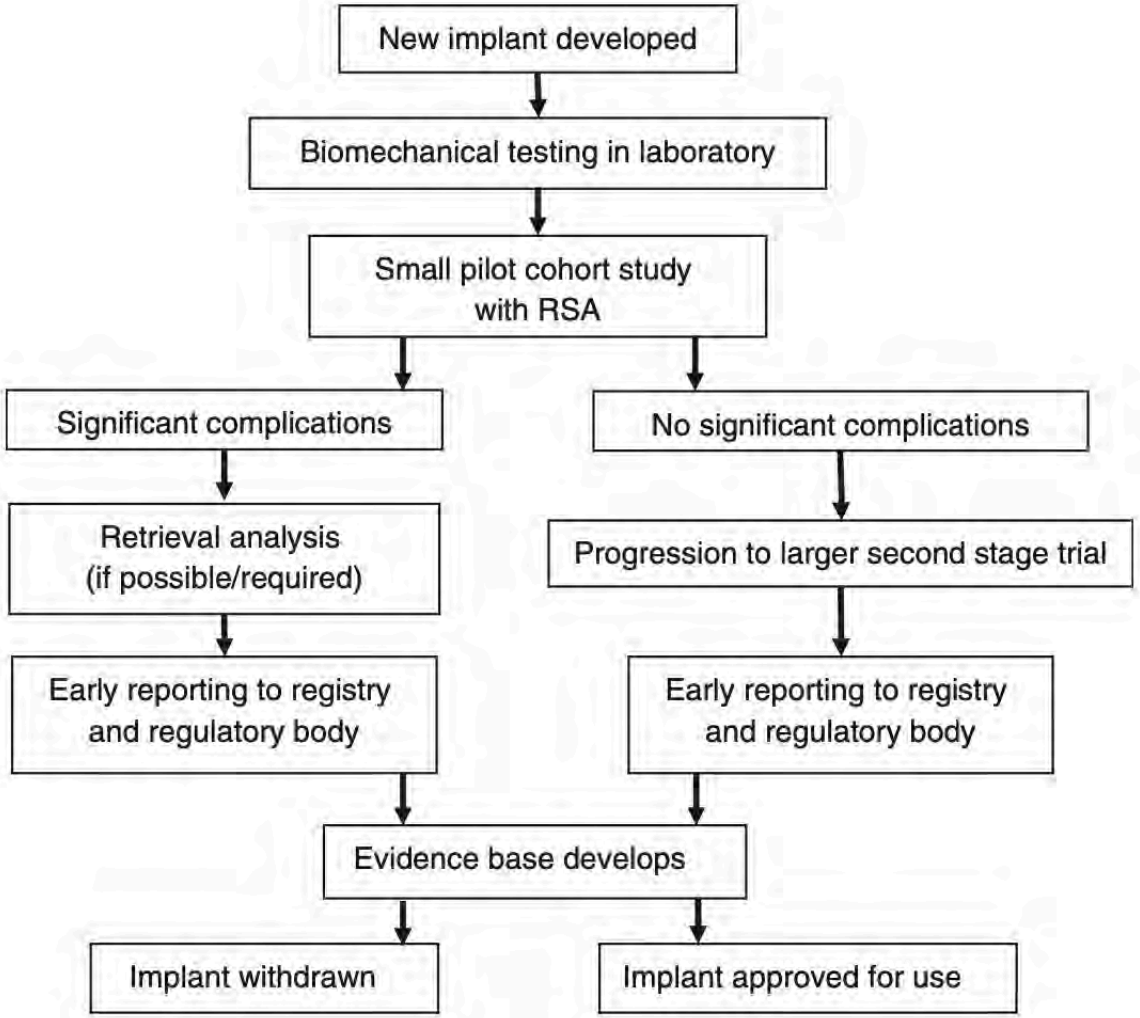


«As stems can cause specific problems like stem pain or malalignment in bowed tibia and femur, the fixation with sleeve only is tempting».

Radical change in surgical technique (stemless revisions) due to innovation in design and quality of the device for metaphyseal fixation/reconstruction

3 years FU

4) Innovation - How?



How should new orthopaedic implants be introduced: an example and recommendations for best practice

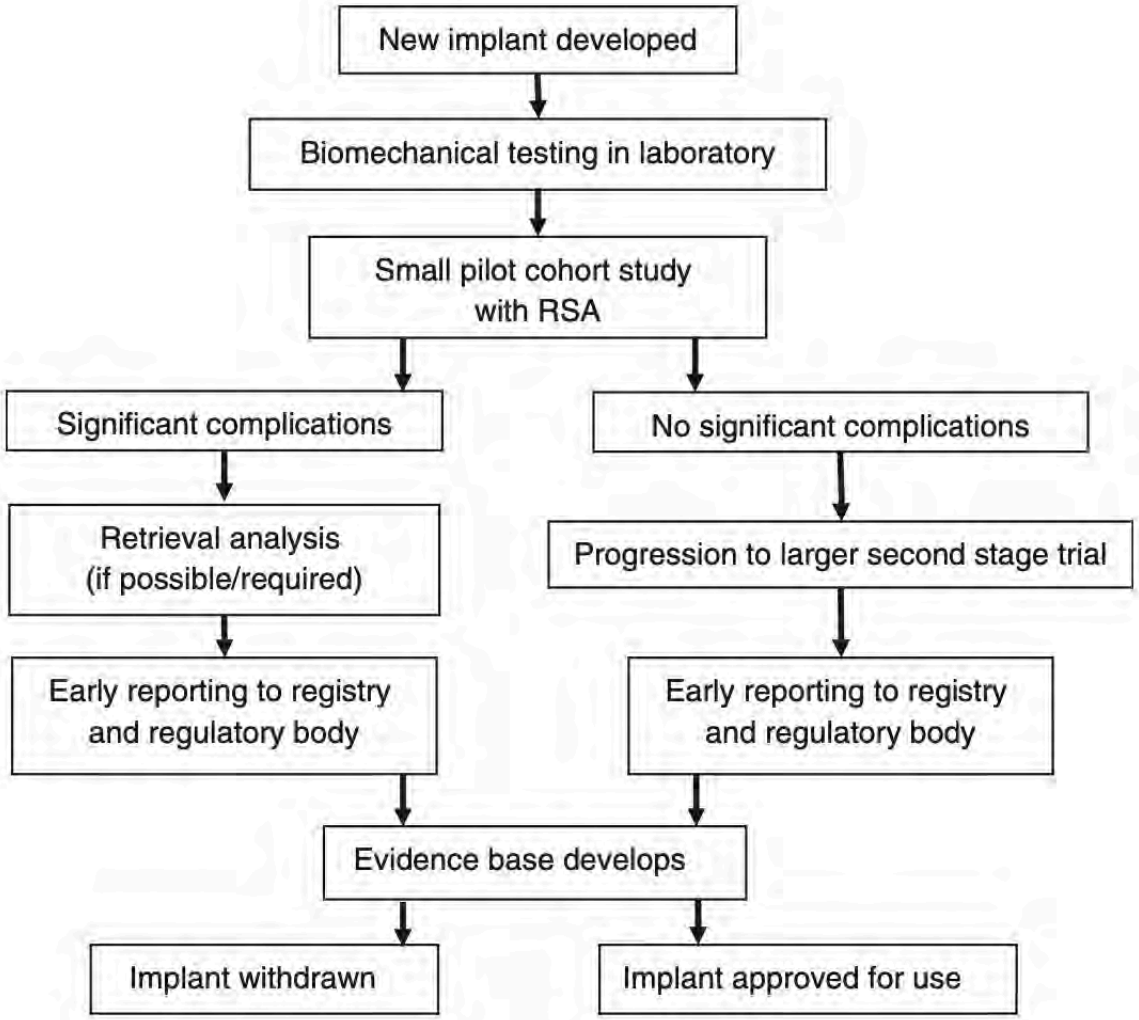
Richard Hannan,* Varun Arora,* Richard Beavert and Paul Harvie*

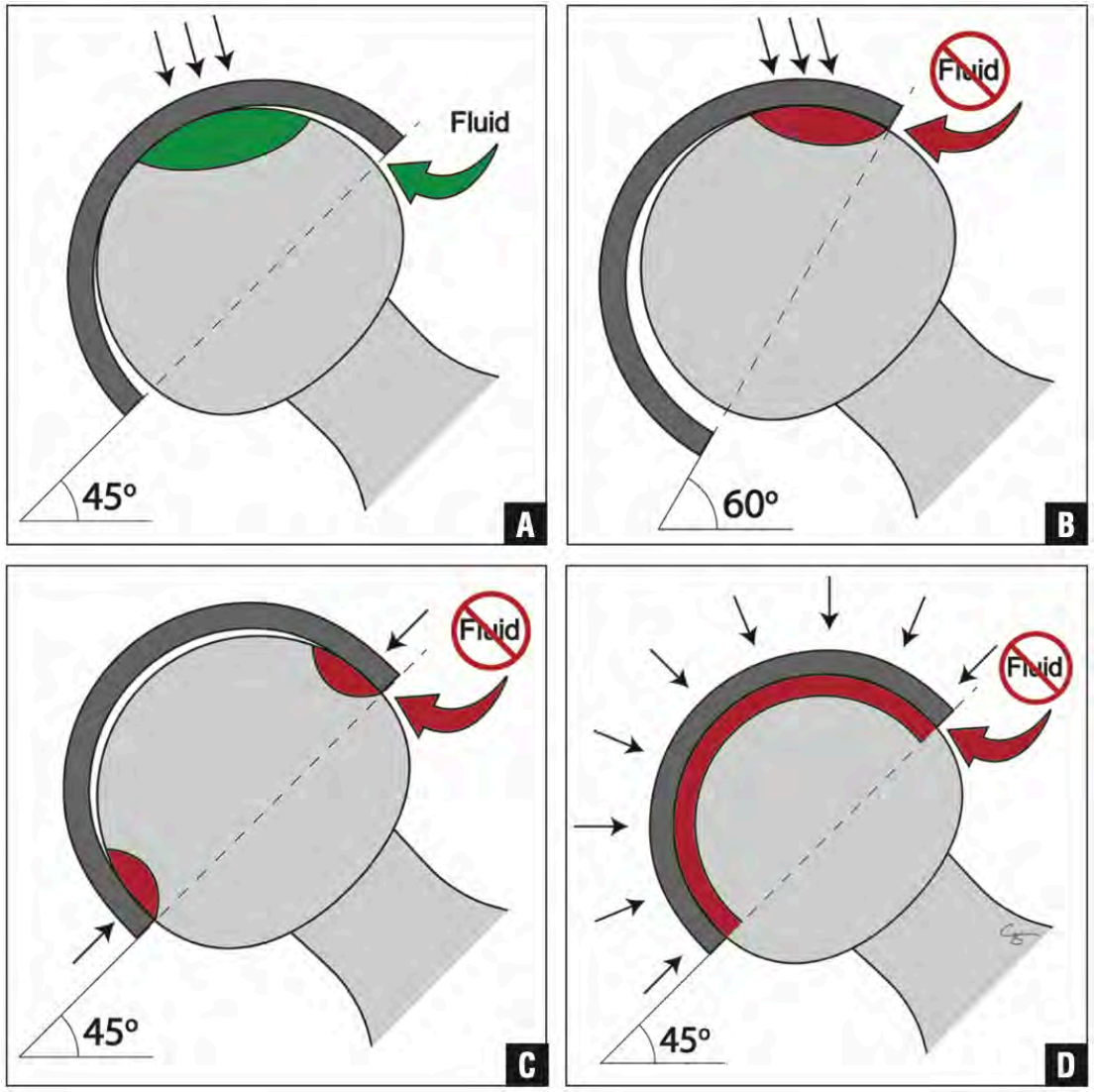
ANZ J Surg 88 (2018) 284–289

Metal in Total Hip Arthroplasty: Wear Particles, Biology, and Diagnosis

Derek F. Amanatullah, MD, PhD; Mark G. Sucher, MD; George F. Bonadurer III, BS; Gavin C. Pereira, MBBS, FRCS (Tr & Orth); Michael J. Taunton, MD

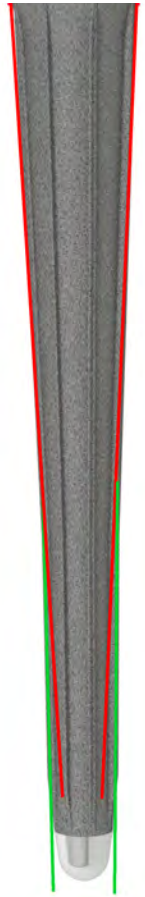
Orthopedics. 2016; 39(6):371-379.





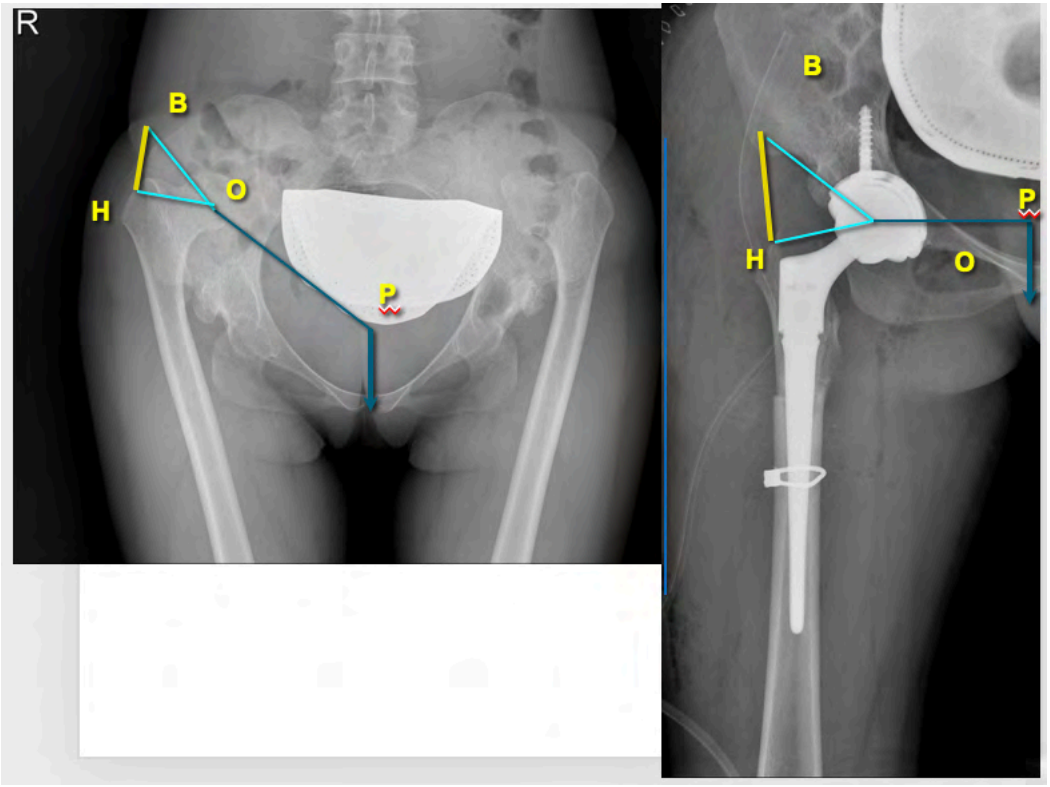
New implant design with new concept

Dual conical stem

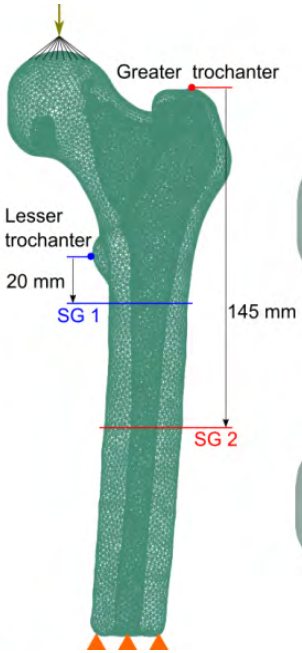


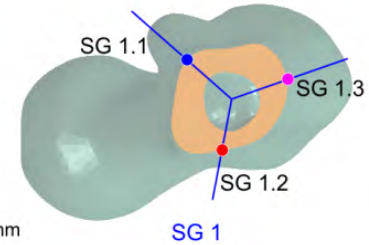
5°

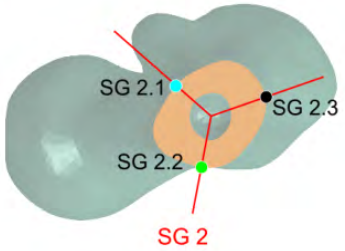
2°

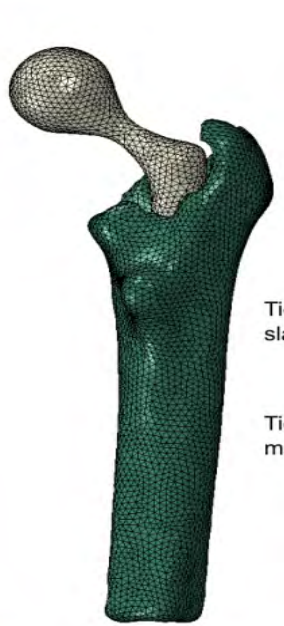


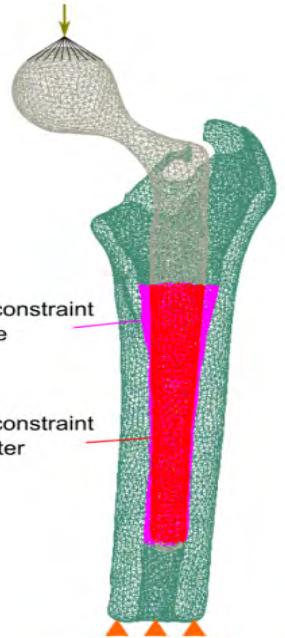
FE model pre- and post-implant

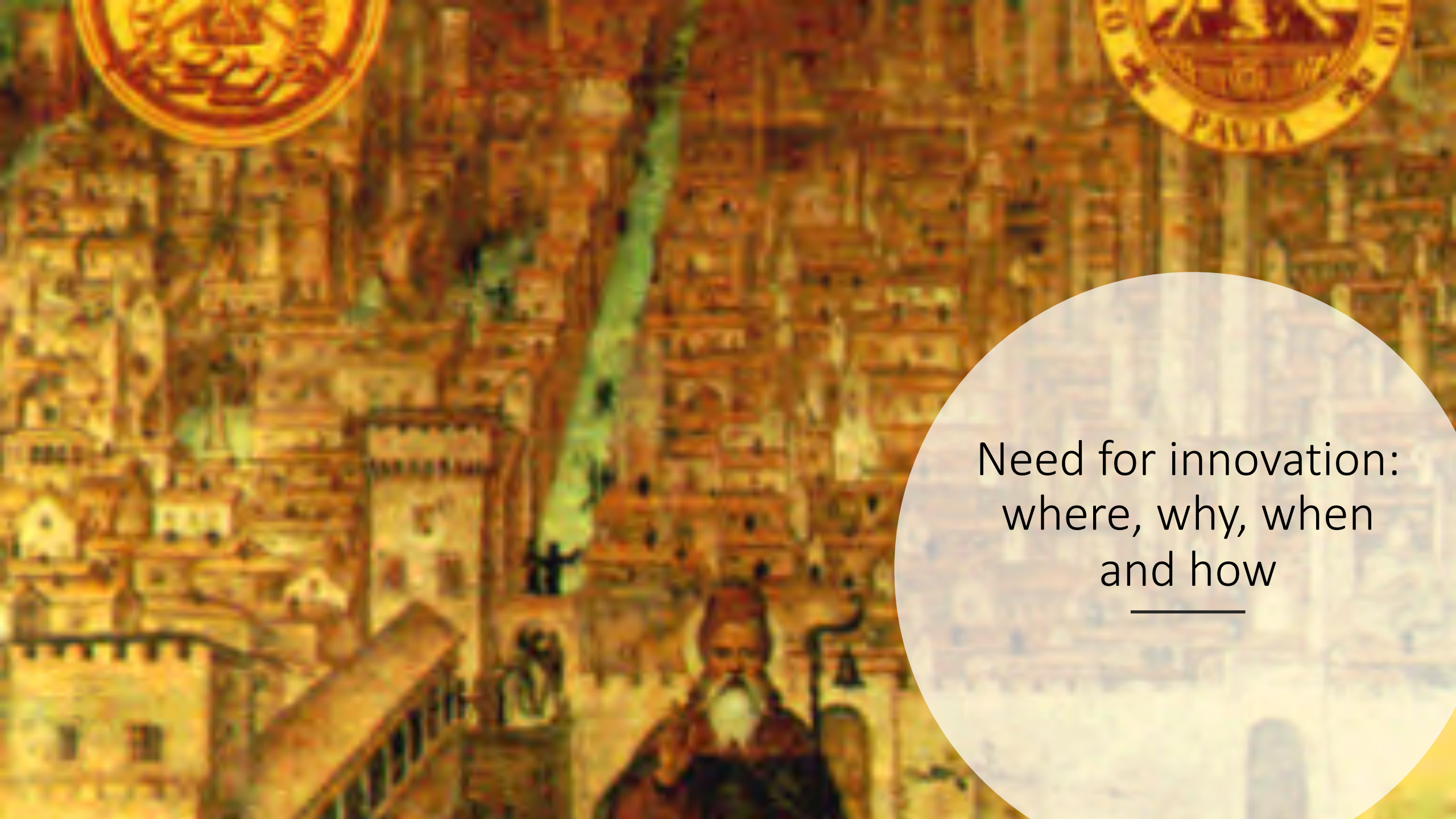












Need for innovation: where, why, when and how

Score to evaluate functional outcomes: are they enough?

- Harris Hip Score (HHS)
- Physical Component Summary (PCS)
- Mental Component Summary (MCS)
- 36-Item Short-Form Health Survey (SF-36)
- EQ-5D
- Oxford Hip Score (OHS) / Oxford Knee Score
- Forgotten Joint Score
- …

The Journal of Arthroplasty Vol. 27 No. 3 2012

The "Forgotten Joint" as the Ultimate Goal in Joint Arthroplasty

Validation of a New Patient-Reported Outcome Measure

Henrik Behrend, MD,* Karlmeinrad Giesinger, MD, MSc,*
Johannes M. Giesinger, MSc, PhD,† and Markus S. Kuster, MD, PhD*

Robotics in Hip and Knee Arthroplasty: Real Innovation or Marketing Ruse

Robert E. Booth, MD [a,*], Peter F. Sharkey, MD [b], Javad Parvizi, MD, FRCS [b]

The Journal of Arthroplasty 34 (2019) 2197–2198

We are dancing on the asymptotic apex of a concept - the replacement of arthritic joint surfaces with prosthetic materials – where any change must be substantiated by the principles of the scientific method that for centuries has served us so well. Much of today's innovation is fostered by industry rather than by academia.

Paradoxically, those high-volume surgeons who can afford it, do not need it; low-volume surgeons who need it, cannot afford it.

One cannot ignore the subjective aspects of unsophisticated patient demand, marketing allure, possible psychological patient satisfaction, and the "Dumbo's feather" effect for the inexperienced surgeon

Bringing a robot to your operating room may be much like bringing the electronic medical record to your clinic.

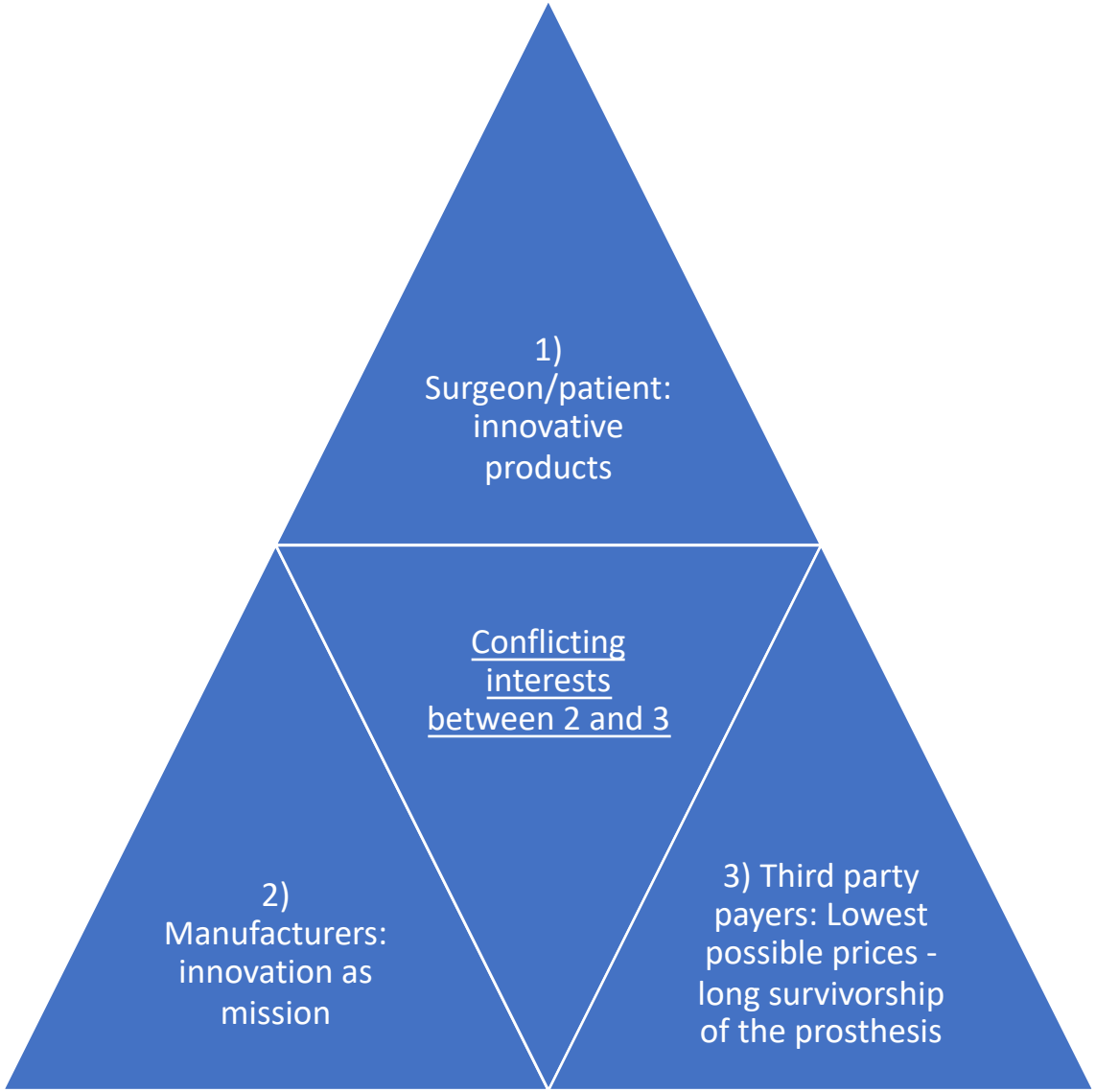
The promise of robotics remains seductive and should be pursued. Objective scientific evidence must necessarily precede its general implementation.

Are we now on the right path?

- Surgeon/Patient
- Health politic
- Manufacturer

Innovation

The antithetic triangle




PAVIA