Computational biomechanics at Zimmer Biomet

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Research Associate Director
Computational Biomechanics

ZIMMER BIOMET
Moving You Forward.™

Agenda

Few words about Zimmer Biomet and me

The environment for medical devices

Classic use of modeling in the medical device industry

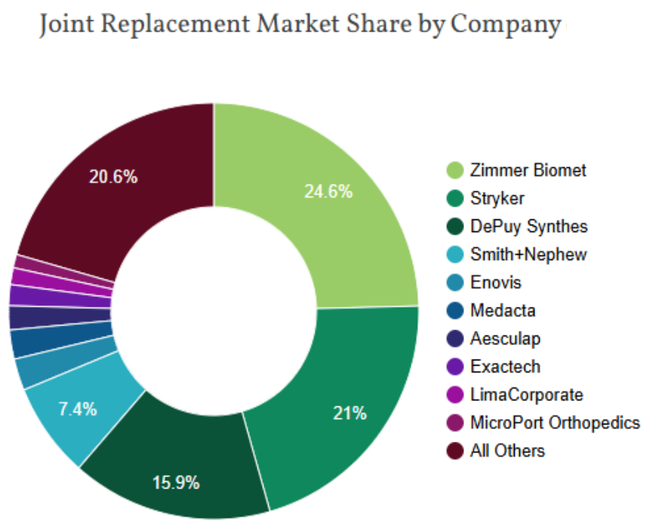
- Finite element analyses
- Anatomical analyses

Emerging applications of modeling

- In silico clinical trials

Zimmer Biomet

- 17,000 Team Members, globally
- In Switzerland: EMEA headquarter in Zug, production facility in Winterthur
- Fortune 500 company, 2024 net sales of $7.6 billion



Musculoskeletal Product and Services Portfolio

- #1 Knee Arthroplasty 
- #1 Hip Arthroplasty 
- #5 Shoulder, Elbow and Wrist Arthroplasty 
- Craniomaxillofacial 
- Thoracic 
- Smart Implants 
- Trauma 
- Foot and Ankle 
- Sports Medicine 

- Allograft service 
- Bone Healing 
- Early Intervention & Biologics 
- Surgical Products 
- Oncology & Specialized Implant Solutions 
- Bone Cements & Accessories 
- Mixed Reality 
- Robotics & Intelligent Instruments 
- Care Management & Patient Engagement 
- Predictive Analytics & Data Insights 

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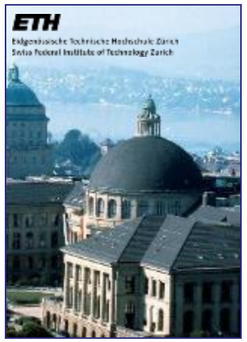
Few words about me

Mechanical engineering

Biomechanics



PhD

Group leader
Clinical Biomech

Research

Comput Biomech manager

1998 2003 2008 2011 2017 Today

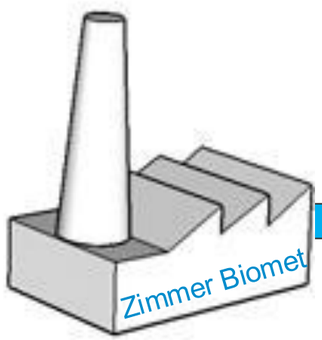
Environment in the medtech industry

Introducing a new medical device to market

Ensure safety and effectiveness of **product that will be implanted in people**

→ Important consequences if we make the wrong decisions

→ Highly regulated industry



Manufacturer

Design Dossier

Design Exam

Certification

Risk analysis

What could go wrong?

↓

Analysis
Tests
Optimization

↓

Mitigate the causes of failure

Biomechanical risks

What could go wrong?

Analysis
Tests
Optimization

Mitigate the causes of failure

Fatigue Strength

Kinematic Function

Wear Behaviour

Implant Fit/ Size Portfolio

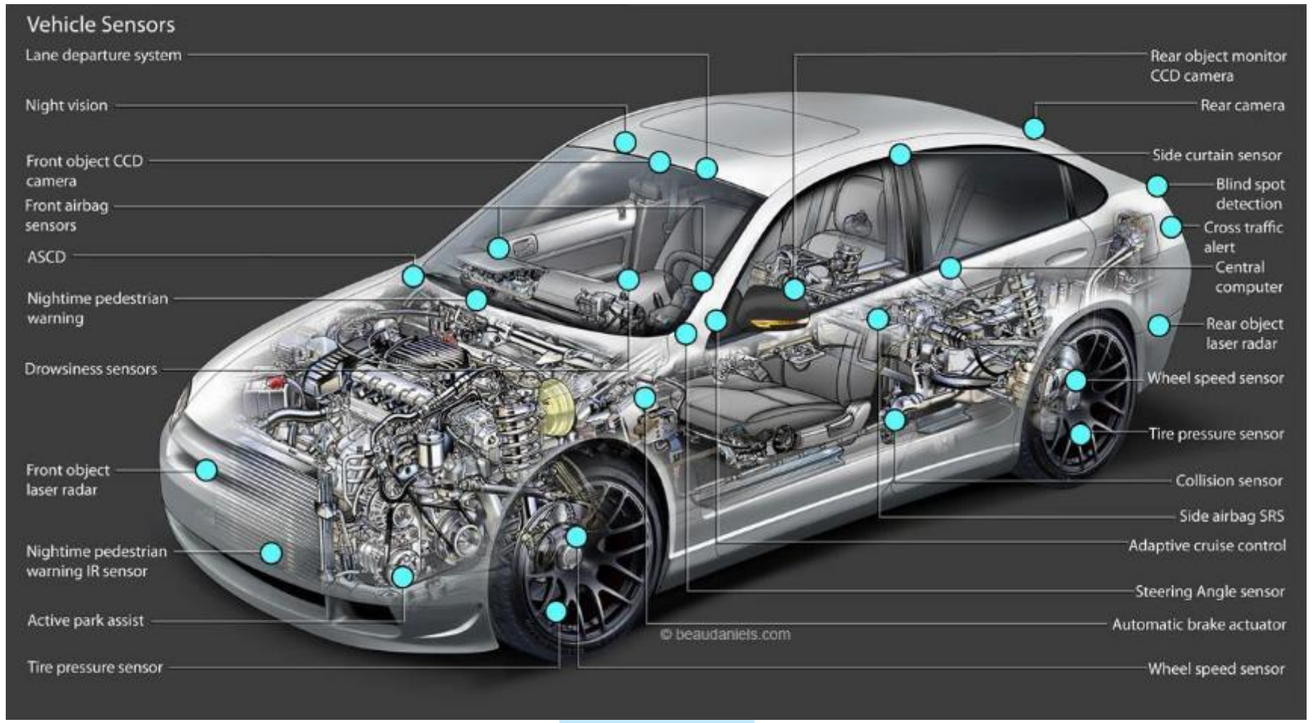
Primary Stability

Surgical Technique

Secondary Stability

many more aspects…

Model input



VS

Subject created by man, we understand the compexity

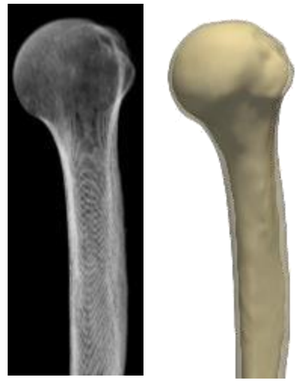
Subject created by nature, we try to understand as best we can (ethically)

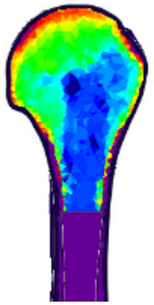
Sources of uncertainties

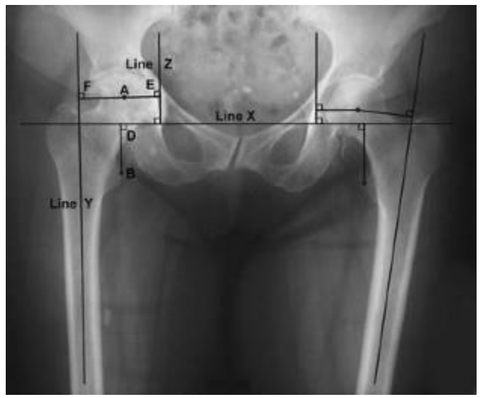
- Anatomy
- Bone quality
- In-vivo loading
- Surgery etc.

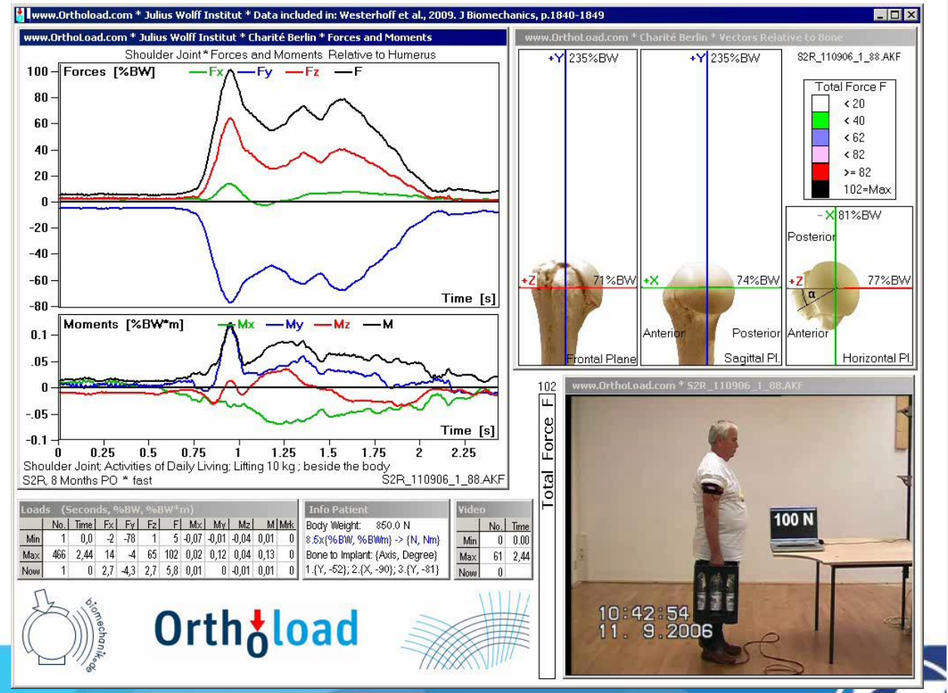
Sources of uncertainties as input

- Anatomy
- Bone quality
- In-vivo loading
- Surgery etc.









And how we deal with uncertainties

Worst case testing:

If that passes, it always will

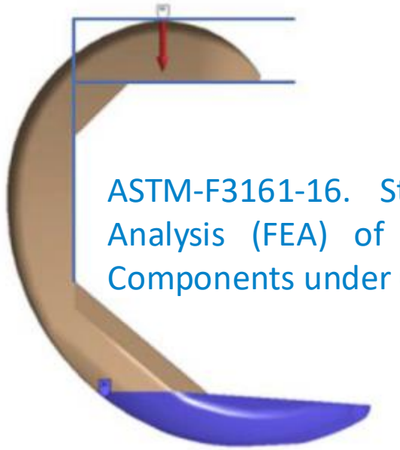
And how we deal with uncertainties

ASTM-F2996-20. Standard Practice for Finite Element Analysis (FEA) of Non-Modular Metallic Orthopaedic Hip Femoral Stems, 2020.

Worst case testing:

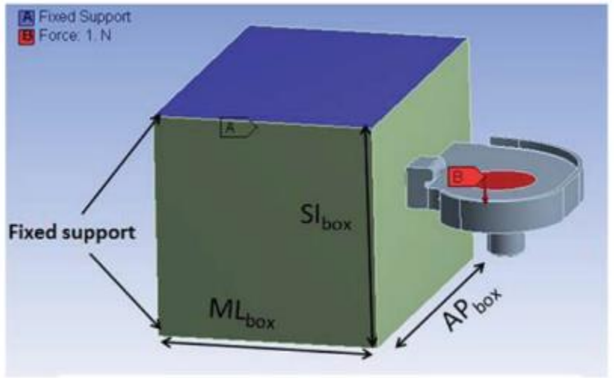
If that passes, it always will

Standards (ISO, ASTM)



ASTM-F3161-16. Standard Test Method for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Femoral Components under Closing Conditions, 2016.

ASTM-F-3334-19. Standard Practice for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Tibial Components, 2019.



And how we deal with uncertainties

Worst case testing:

If that passes, it always will

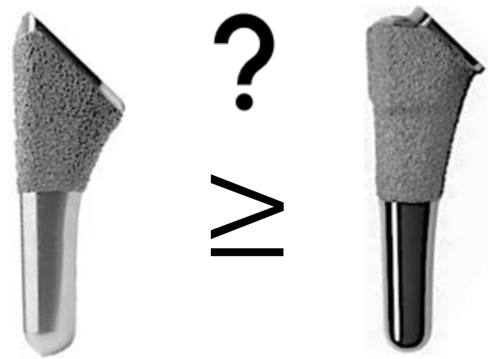
Standards (ISO, ASTM)

Compare with successful implants (equivalency to predicate)

Final assessment comes only ~10 years after implantation!

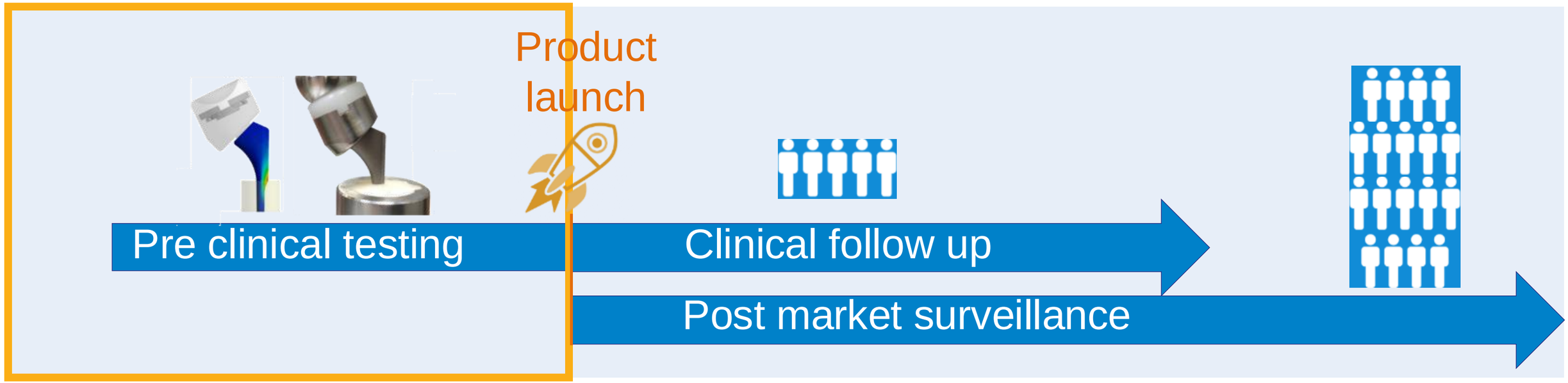
New device

Existing device with long and good clinical results



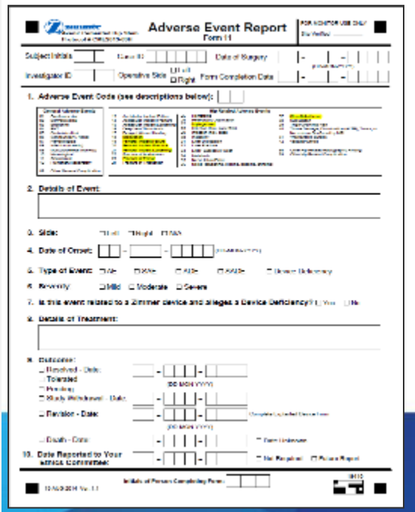
New product development support

Establish product safety and efficacy

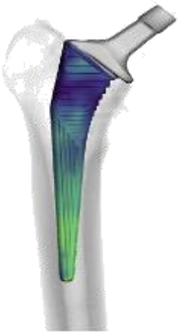


The classic use of modeling at Zimmer Biomet

Typical risks that we investigate



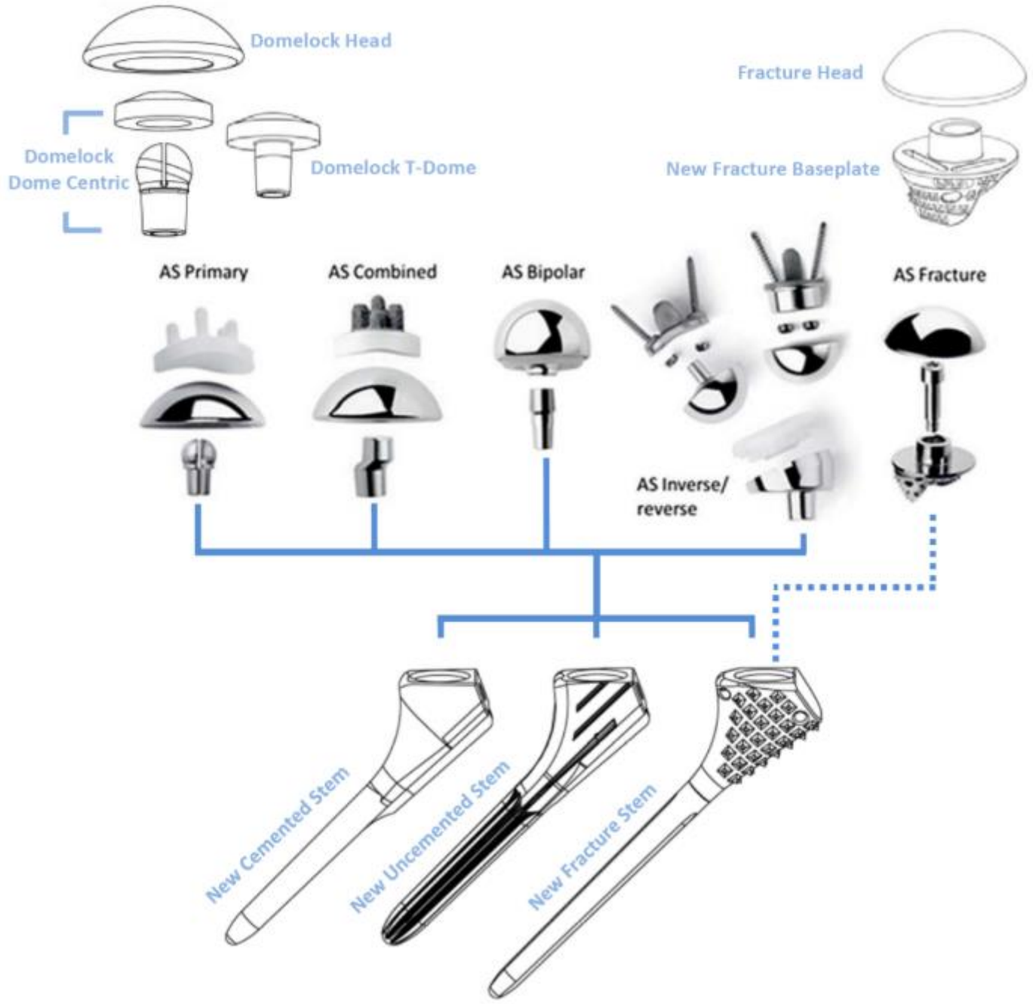
Clinical	In silico
Implant fracture	Implant fatigue stress
Aseptic loosening	Micromotion and interface strain
Implant subsidence	Permanent displacement
Bony atrophy/hypertrophy	Change in bone stress
Intra/post OP bone fracture	Bone ultimate/fatigue stress
Impingement/dislocation	Range of motion

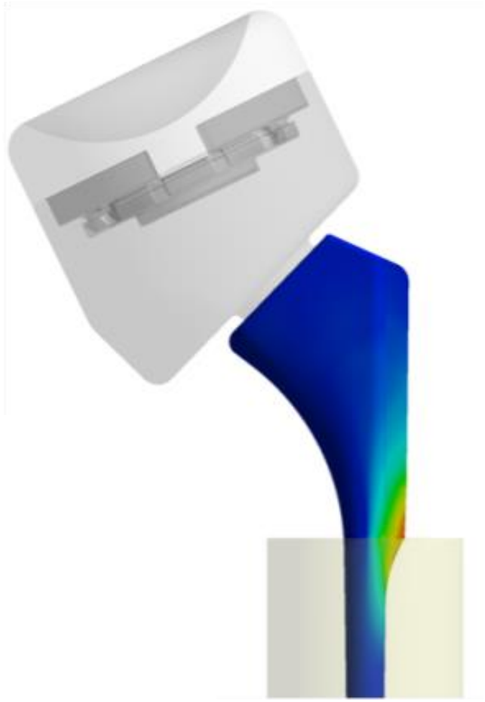


Worst-case identification

FEA - Finite element analysis

Significant time and financial gain

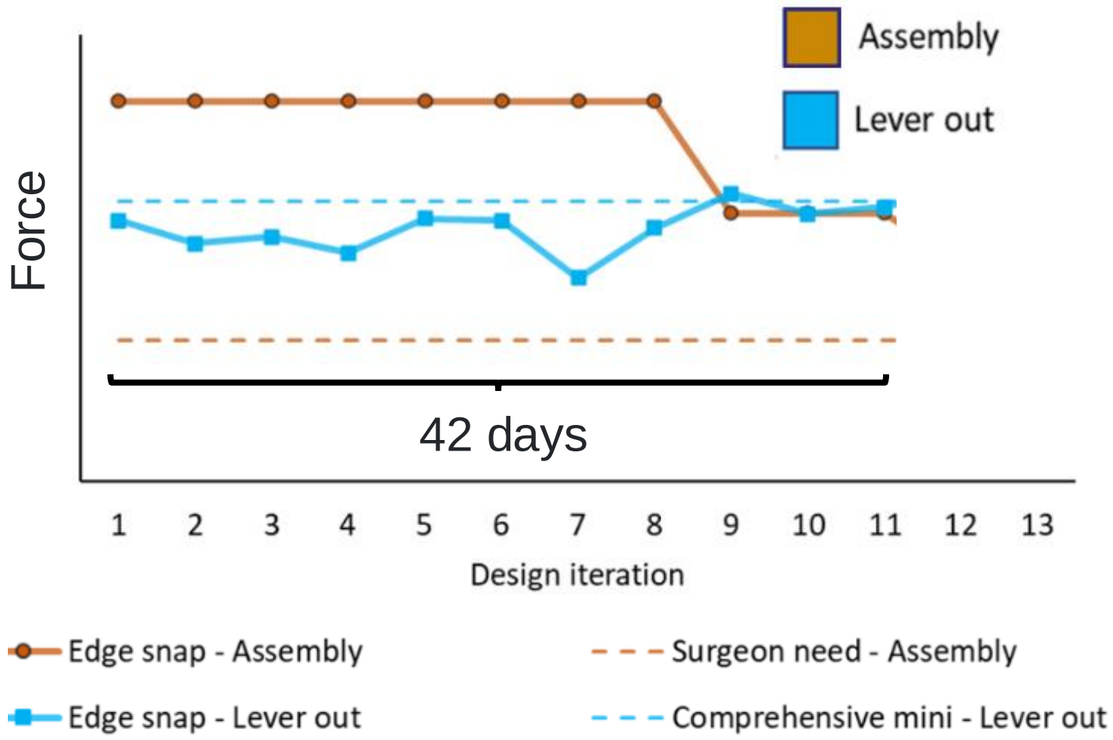


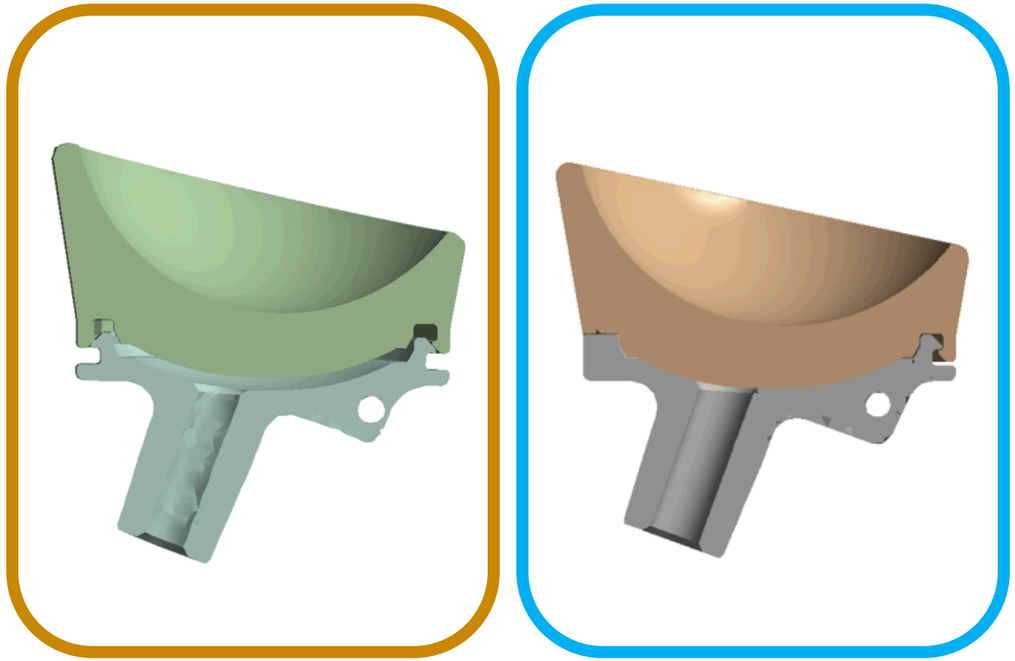


> 100 FEA simulations
of combinations

1 physical test
of worst-case

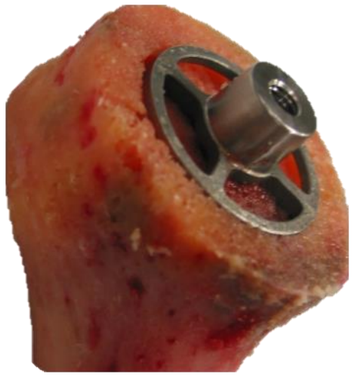
Design optimization using statistical methods

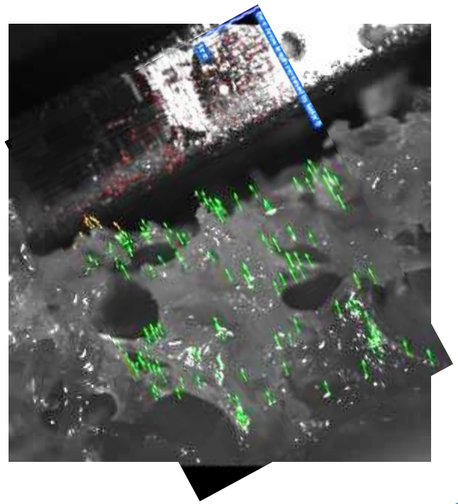


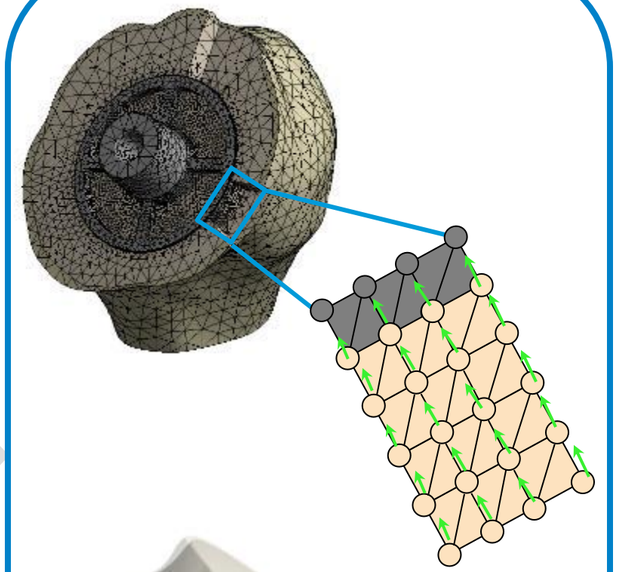


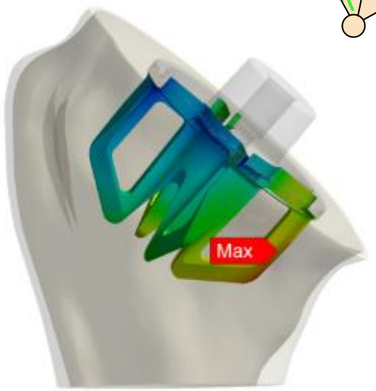
Significant time and financial gain

Enrich physical testing







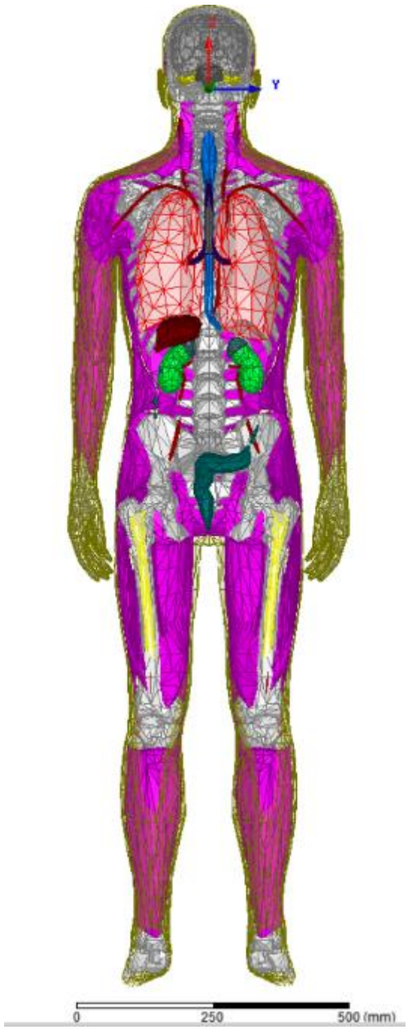


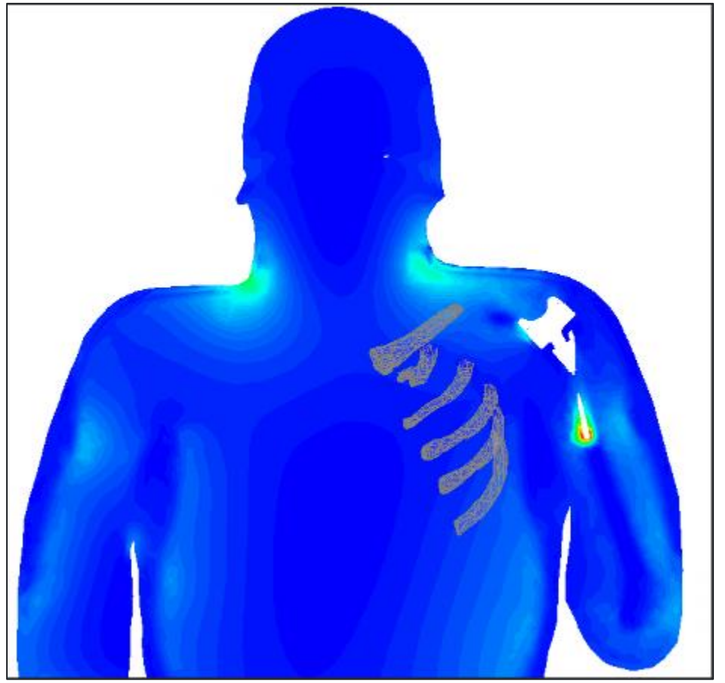
Combined approach to get a better representation of primary stability

- Full micromotion distribution
- All micromotion components
- Realistic loading conditions

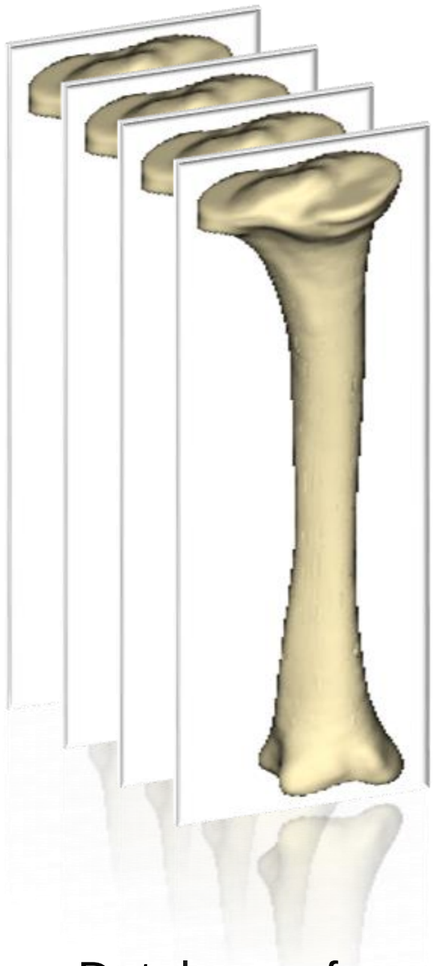
Impossible to do without modeling

MR interaction

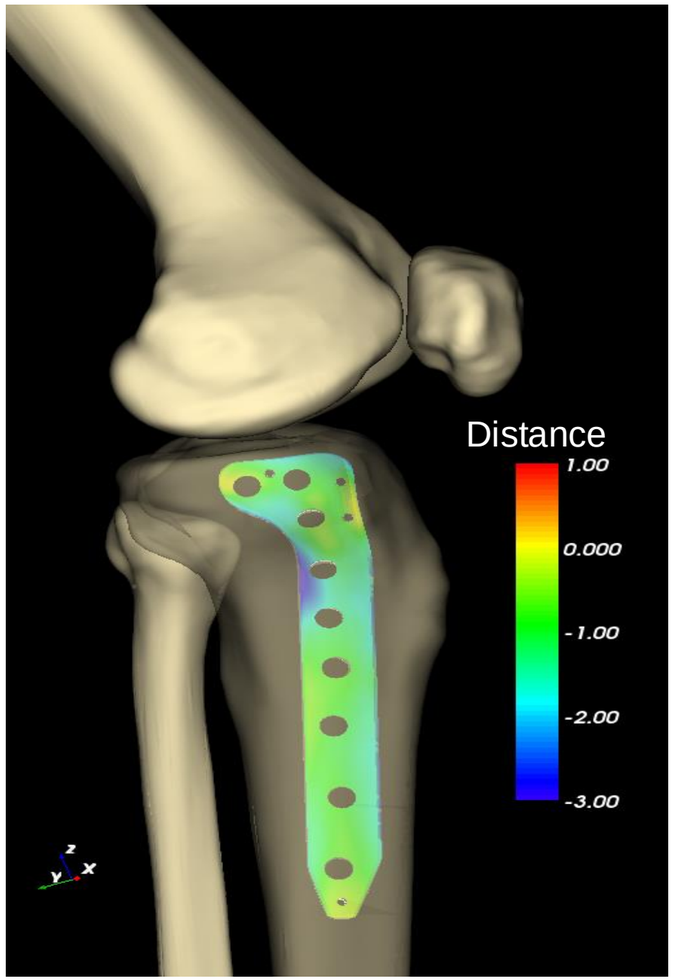


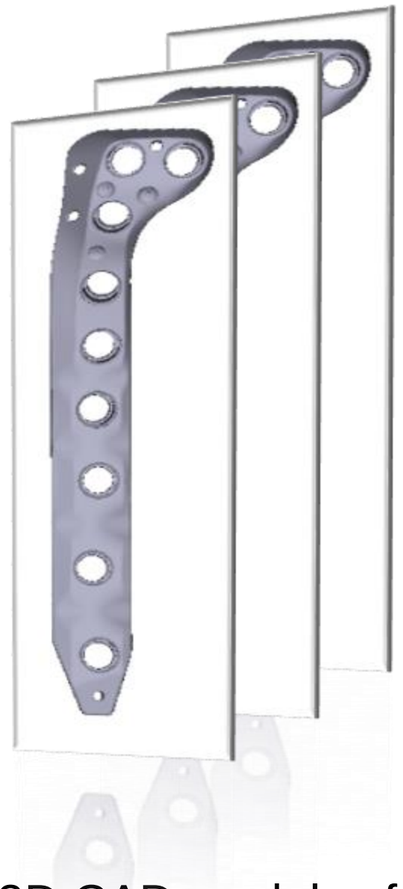


Anatomical studies - virtual surgery



Database of bone models





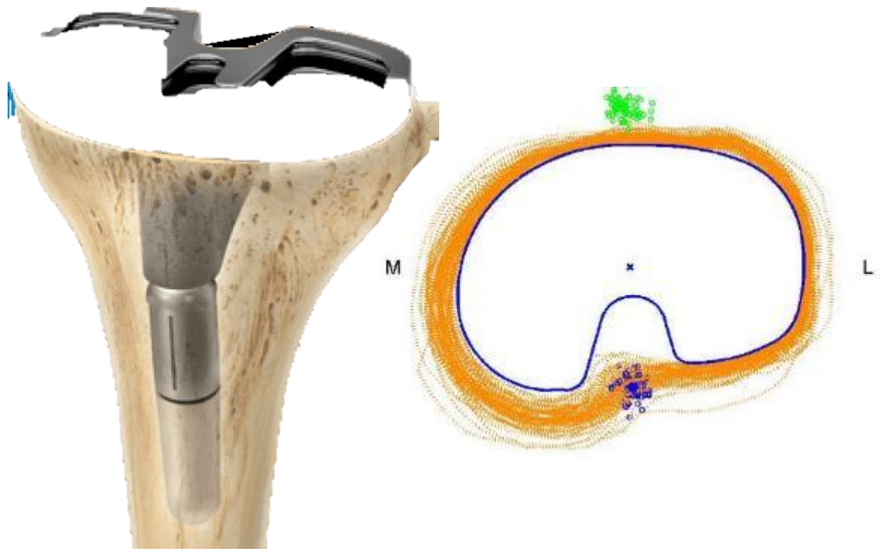
3D CAD models of implants

Support new design

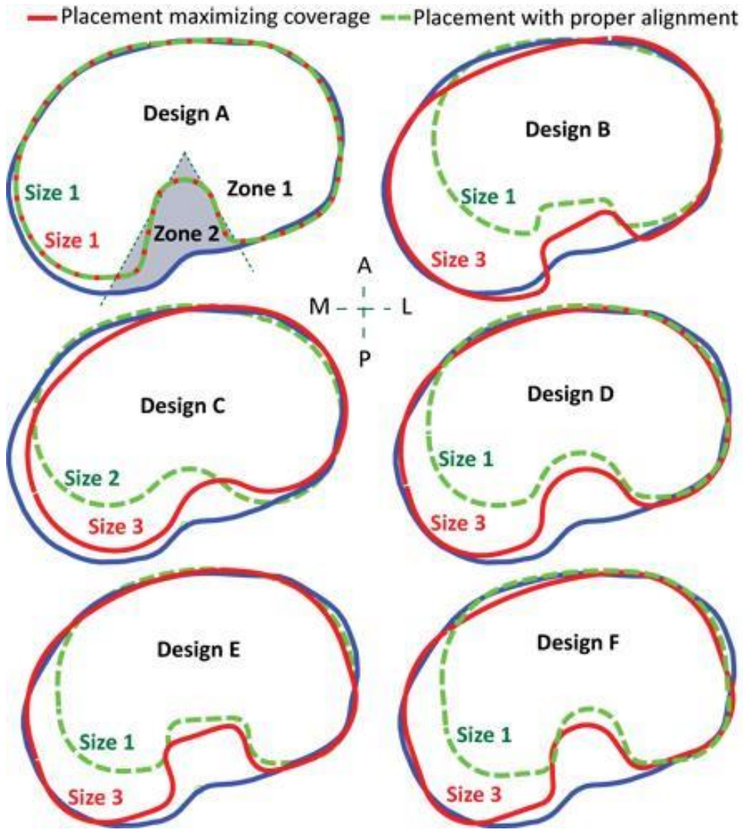
Persona tibial baseplate

Impractical to do without modeling!

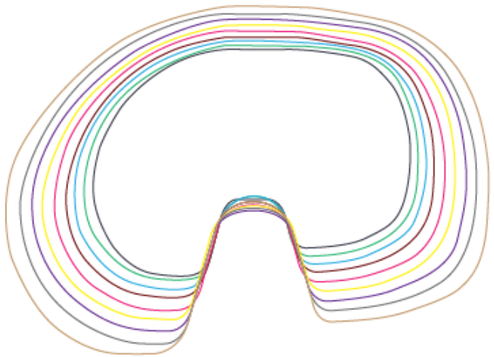
Generate design inputs



Fit quality of the designs



Support claims



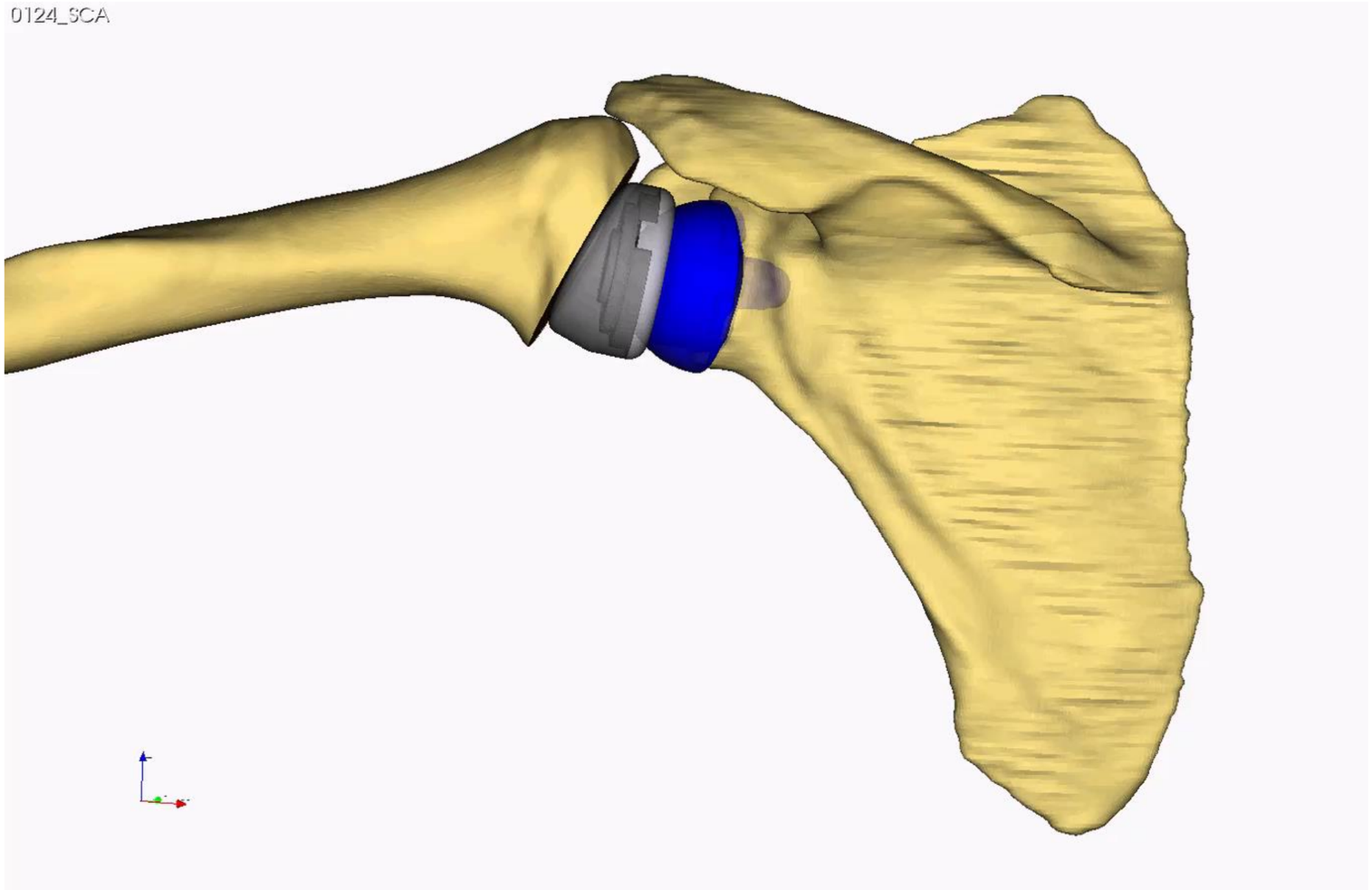
The personalized design

Tibial bone coverage
92%
with proper rotation[1]

Persona Femur is able to match
97%
each patient's native A/P dimension[2]

Ideal tibial rotation and alignment
81.4%
in vivo[3]

Range of motion analysis



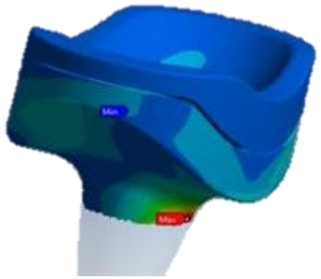
Patient-Matched Implants

Impractical to do without modeling!

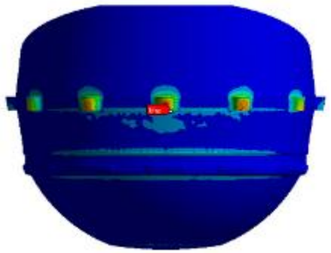
Shoulder

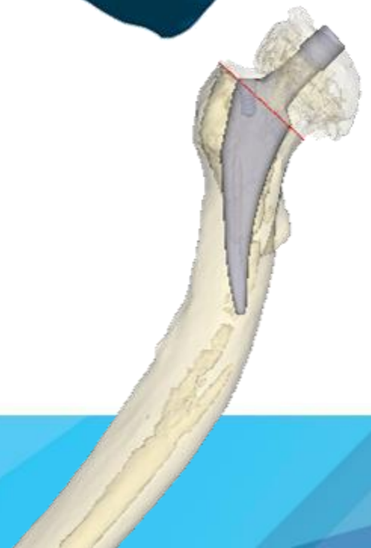
Elbow

Wrist

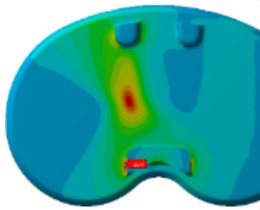


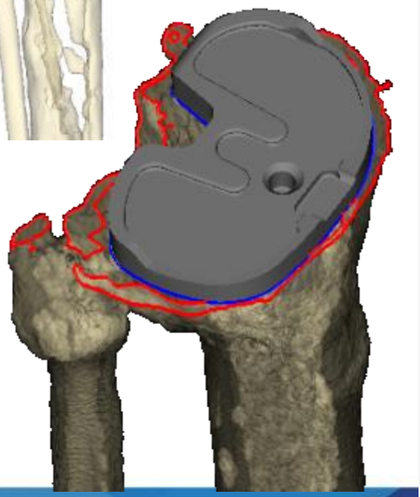
Hip



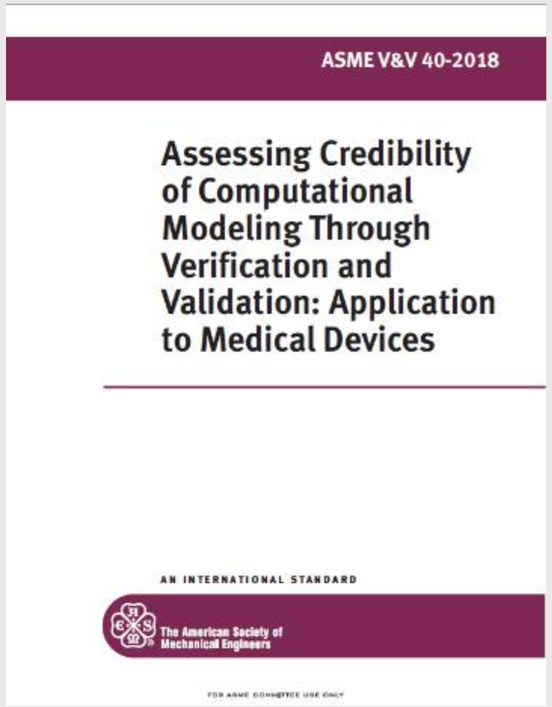


Knee

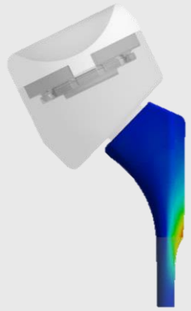




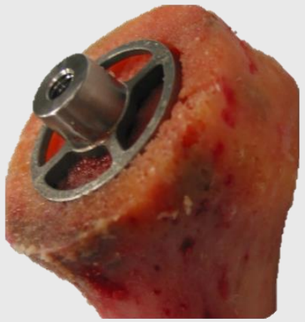
Model validation

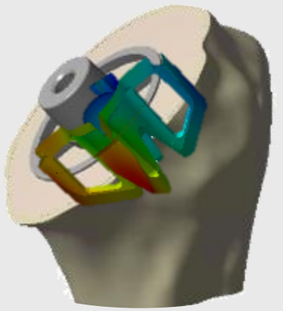


Benchtop test



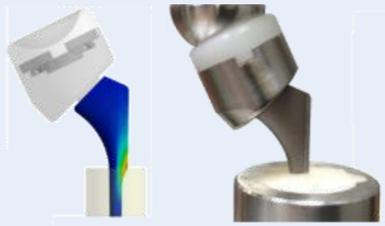
In vitro test





In silico clinical trials
ISCT

Establish product safety and efficacy



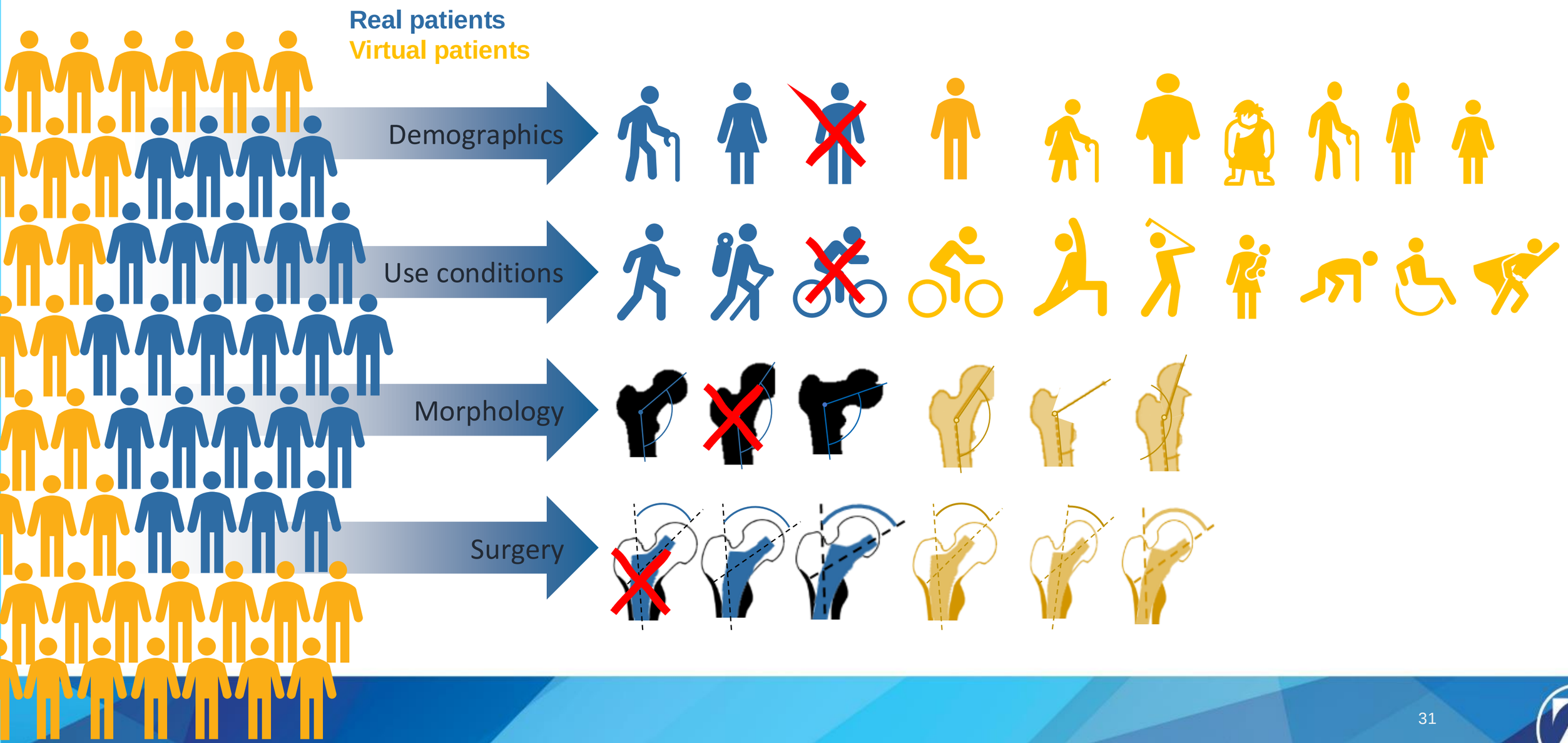
Product launch

Pre clinical testing

Clinical follow up

Post market surveillance

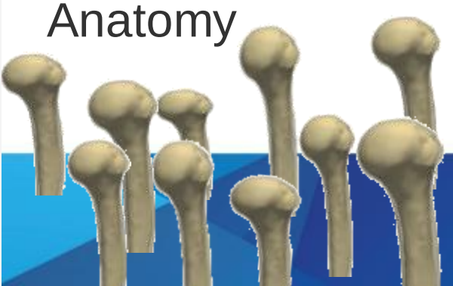
Concept of in silico clinical trials (ISCT)



Technical approach

CT | Segmentation | Virtual surgery | Meshing | Material assignment | Loading | Post processing

Patient variability
Anatomy

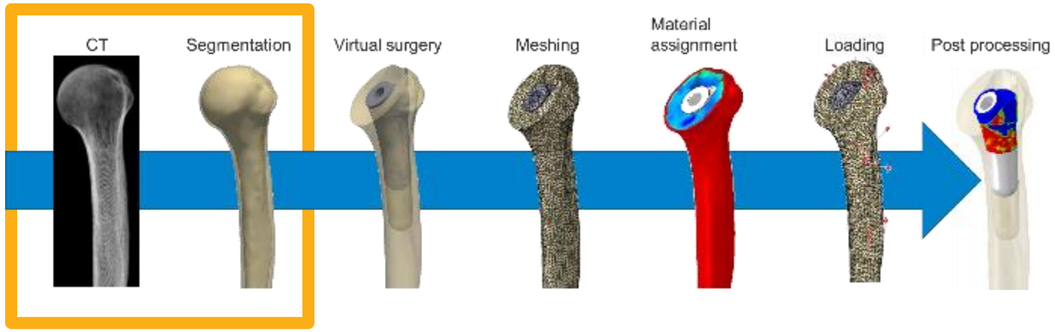


Surgical variability
- Component combinations
- Sizing
- Stem alignment

Patient variability
Bone density

Patient variability
Load

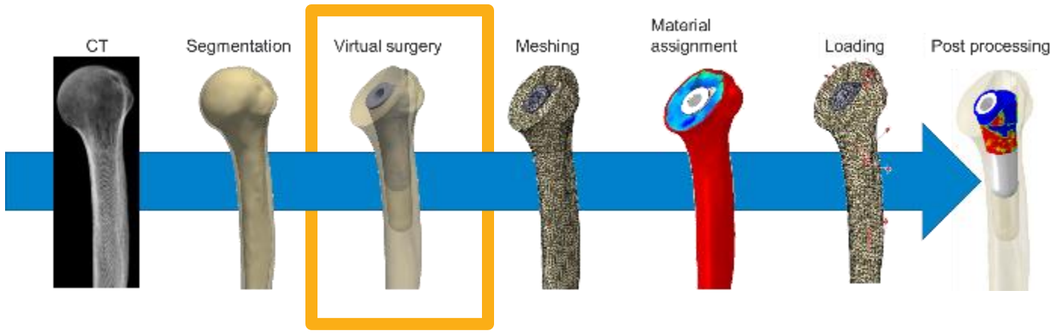
Technical approach for virtual population



45 unique anatomies

Category	Mean	SD	Min	Max
Height [m]	1.70	0.1	1.47	1.93
Weight [kg]	77.3	26.2	36.0	172.0
BMI	26.9	9.4	12.5	65.2

Technical approach for virtual population



Include surgical variability

→ Total of n=521 unique surgical interventions

45 unique anatomies

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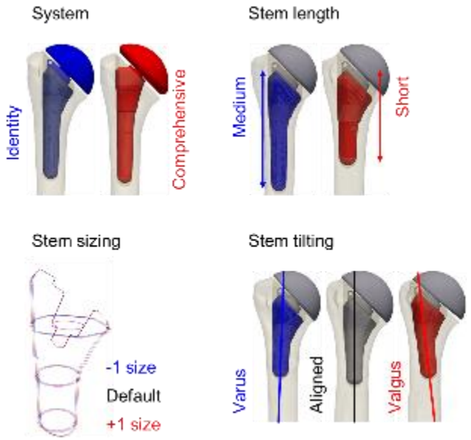
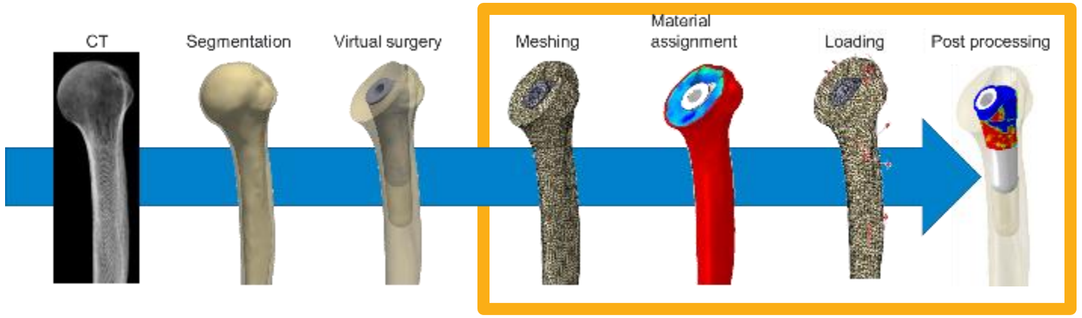
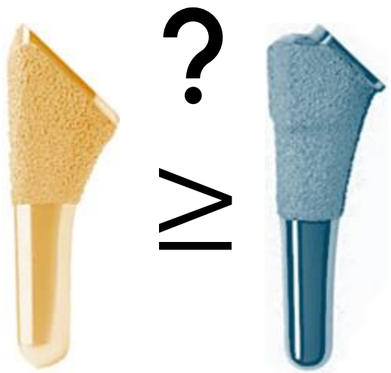


(PMCF: n=47 in TSA, n= 58 in hemi)

Technical approach for virtual population





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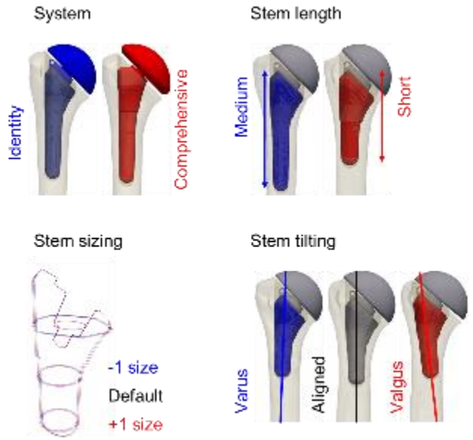
Include surgical variability
→ Total of n=521 unique surgical interventions

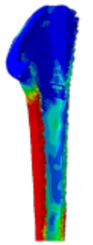


(PMCF: n=47 in TSA, n= 58 in hemi)

3000 solved models

3 load cases

Humeral loosening

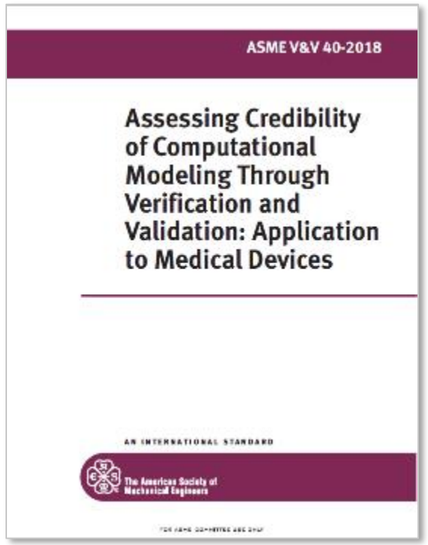


Stress shielding

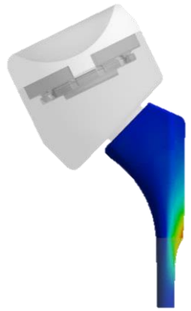
Model validation strategy

Well controlled and characterized data

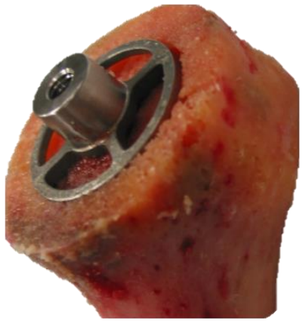
Increasing consideration of in vivo variability

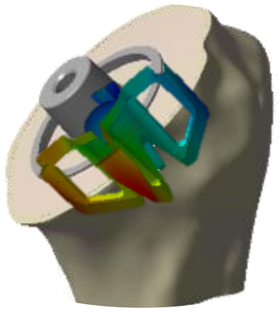


Benchtop test

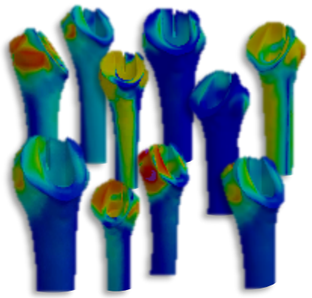


In vitro test

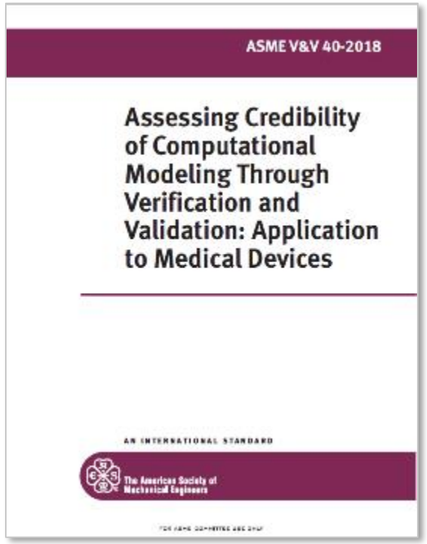




Clinical trial



ISCT model validation[1]



A risk and credibility framework for *in silico* clinical trials of medical devices

Jeffrey E. Bischoff[a,*], Mehul A. Dharia[a], Philippe Favre[b]

[a] *Zimmer Biomet, 1800 West Center Street, Warsaw, IN, 46580, USA*
[b] *Zimmer Biomet, Zählerweg 4, 6300 Zug, Switzerland*

Benchtop comparator:

- Ensure physics are modeled correctly
- Best addressed with tight control over test conditions

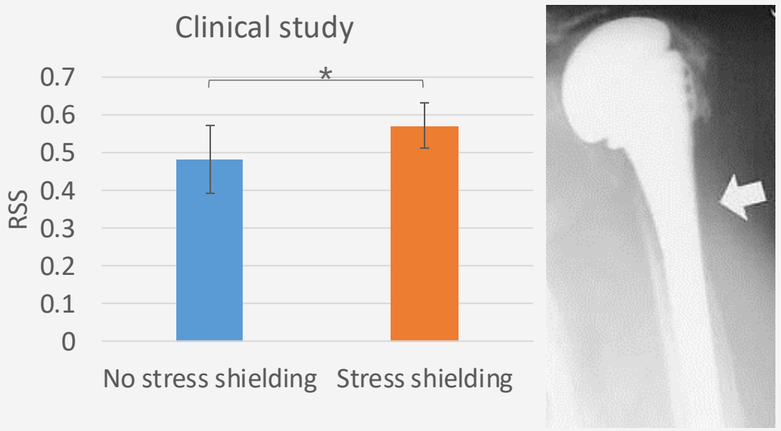
Clinical comparator:

- Ensure aspect of clinical performance, including survivorship, can be predicted appropriately
- Reproduce clinically significant differentiation in outcomes b/w different designs, variants, sizes, etc

[1] Bischoff J et al. A risk and credibility framework for in silico clinical trials of medical devices. Comput Methods Programs Biomed 2023

Clinical validation – Stress shielding

Comparator

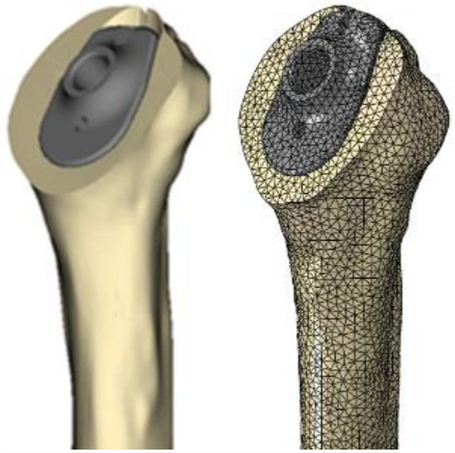


Nagels et al., JSES 2003

Statistically significant increased proximal lateral humeral cortical thinning for greater relative stem size patients (N=70, Biomodular stems)

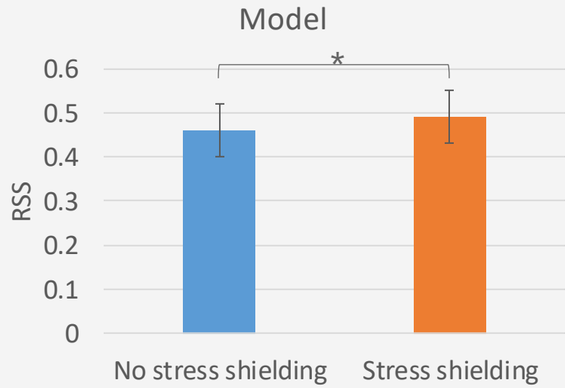
Model

N=35 bones
Biomodular stem

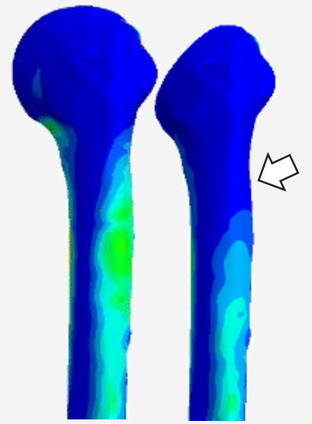


Sensitivity
Mesh size
Stem alignment
Stem size
Loading
Material properties

Comparison



N=188



Change in strain energy density
→ Bone resorption

Statistically significant increased proximal lateral humeral stress-shielding for greater relative stem size patients

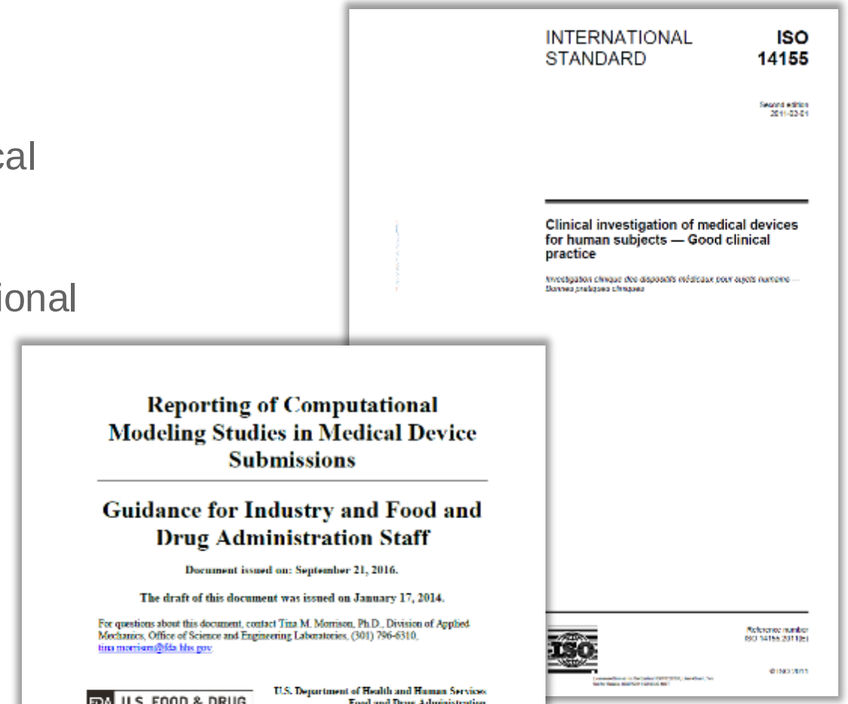
Regulatory uncertainty

Risk of rejection by the regulator reduced by:

- Following guidelines for clinical studies and computational modelling

[ISO 14155. Clinical investigation of medical devices for human subjects — Good clinical practice, 2011.]

[Guidance for Industry and Food and Drug Administration Staff. Reporting of Computational Modeling Studies in Medical Device Submissions, 2016.]



- Open and regular communication with the regulator

- Publish the approach

Conclusions

- Computer modeling is heavily leveraged at ZB (but it may not be representative of the orthopedic industry)
- Worst-case identification for physical testing is the standard, accepted use
- Allows us to have better implants, while having shorter and more efficient development and testing phases
- V&V work should not be underestimated, but model credibility is priceless
- Further standardization in emerging applications (ISCT) is greatly needed